**Chronic Omega-3 Fatty Acid Supplementation in Type 1 Diabetes**

You are being invited to take part in a research study. Before you decide 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 if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

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

The purpose of the study is to examine how the body responds when eating meals that are high in carbohydrate and fat following 6-months supplementation with omega-3 fish oils. Previous research has shown dietary omega-3 supplementation reduces risk factors for cardiovascular disease (CVD) in people with type 2 Diabetes, but it is unknown whether such improvements also occur in people with type 1 Diabetes. The findings from this study will benefit people with type 1 Diabetes by refining guidance offered to people with Type 1 diabetes

**Why have I been chosen?**

We are hoping to recruit approximately 32 adults between the ages 18 and 65 living with type 1 diabetes. You have either been approached in clinic, responded to an advertisement, or recruited by word of mouth.

**Do I have to take part?**

It is up to you to decide to take part or not. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time, without reason and with no repercussions. A decision to withdraw at any time, or a decision not to take part, will not affect the treatment you receive, your legal rights or your selection in any way.

**What will happen to me if I take part?**

If you decide to take part we will ask you to visit one of the laboratories within the School of Sport (Leeds Beckett University) on 4 separate occasions over a 9 month period. Each visit will be separated by 3 months. For each of the four visits you will be asked to arrive to the laboratory at around 08:00AM having skipped breakfast that morning and having not exercised during the previous 2-days. During the course of each visit we will measure your weight, height, and hip and waist circumference. Following this, you will be seated and a cannula (small blood taking device inserted using a needle) will be placed into a vein on the inside of your elbow. This will remain in your arm for the next eight hours and allow for blood samples to be collected when needed. Although the insertion of the cannula can cause some mild discomfort, the usually reverses quickly allowing for further blood samples to be taken in comfort. We will then conduct two non-invasive ultrasound scans (like those used to look at a baby in the womb), one on your neck and the other on your arm whilst you are lying down on your back. The one on your neck will take approximately 5-10 minutes and requires you to stay still whilst we place a pencil like probe against your neck. For the second scan, we place the ultrasound probe on your upper arm and inflate a blood pressure cuff around your lower arm for a period of 5 minutes. This is a safe procedure but will feel a little uncomfortable towards the end of the 5 minutes. This discomfort will disappear as soon as the cuff is released. You will then be provided with a breakfast-based meal consisting of pastries and fruit juice, blood samples will be collected from you (from the cannula still in place) every 30 minutes. Three hours after the breakfast meal we will conduct another ultrasound scan on your upper arm before providing you with lunch. We will then repeat the exact same blood and scanning measurements for the next four hours before removing the cannula and discharging you from the laboratory. The day is shown in figure 1 below.

During visit one only you will be asked to complete a questionnaire designed to assess your attitudes towards dietary supplements. For all four trials, each time blood is collected you will be asked to complete a questionnaire to determine how hungry or full you feel.

Figure 1. Schedule for each of the visits to the laboratory.

**What do I have to do?**

If you decide to take part you will be asked to consume approximately 4 capsules (these look like any vitamin capsule) a day by mouth whilst maintaining your normal lifestyle and diet. The only restrictions that we would wish you to follow would be to refrain from exercise 48 hours prior to each visit and arrive to the laboratory having skipped breakfast on that morning. If you should attend the hospital, for anything other than a routine appointment during the study we kindly ask that you inform a member of the research team. A member of the research team will be contactable available during your involvement throughout the study to support you.

**What are the possible disadvantages and risks of taking part?**

During the four visits, you could potentially experience low blood sugar. However, you will be continuously supervised by trained staff to reduce this risk. Although it is highly unlikely, there is a very small chance of an adverse reaction to the omega-3 supplementation. To minimise this risk if you are thought to be allergic or sensitive to fish, fish oil, or omega-3 products you will not be allowed to take part in the study or withdraw should you present with symptoms. You may experience some discomfort, such as slight pins and needles, when the blood pressure cuff is inflated around your forearm during the ultrasound scan on your arm. This discomfort will be relieved as soon as the cuff is released and cause no further discomfort. If you decide the test is too uncomfortable at any point the cuff will be deflated and the test stopped immediately. The cannula we place in your arm can sometimes result in some light, local bruising. Although this is normal to reduce the risk all cannulas will be inserted by someone who is fully qualified to do so. If you are allergic to cotton wool or plasters we will use gauze and micropore tape instead.

**What are the possible benefits of taking part?**

By taking part in this research you can learn about how your own body responds at mealtimes and determine whether or not omega-3 supplementation may be effective in improving your long-term diabetes management. You will also be contributing to research that could potentially influence strategies used to improve diabetes management in other people with type 1 diabetes. To cover any expenses you may incur due to travel or car parking, you will be offered up to £200 as way of reimbursement. Any payment made to you will be made to redeem travel expenses, not loss of earnings incurred through study participation.

**What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you may complain to the University Secretary.

**Will my taking part in the study be kept confidential?**

Yes, any information which is collected about you during this research will be kept strictly confidential. Once you decide to take part you will be given a subject number and this number will be used on all paperwork associated with the research. In this way no-one will be able to identify who the results belong to, and the master copy of names and subject numbers will be kept separately from the result sheets, in a locked cabinet accessible to only Dr Matthew Campbell, Dr Karen Birch and Miss Lauren O’Mahoney. Your name and address will not be associated with any data that is used in scientific reports or publications.

**What will happen to the results of the research study?**

When the study is completed the results will be analysed and used in the write-up of academic research publications and the PhD thesis of Miss Lauren O’Mahoney. Remember that your own results are confidential and that your name will not be associated with any information published from this study. All data will be kept for 5 years and then destroyed.

**Who is organising and funding the research?**

This research is being organised and overseen by Dr Matthew Campbell who is the Chief Investigator. The funding for this research has been made available from Leeds Beckett University and the Nutricia Research Foundation, and is supported by the University of Leeds.

**Contact for further information.**

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