

**PARTICIPANT INFORMATION STATEMENT**

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| <b>HREC Project Number:</b> | HRE2018-0795  |
| <b>Project Title:</b>       | <i>Can self-management group education reduce fear of hypoglycaemia as a barrier to physical activity in people living with type 1 diabetes? A feasibility study.</i> |
| <b>Chief Investigator:</b>  | <i>Dr Janie Brown<br/>Senior lecturer (Curtin University), Course Coordinator (Master of Nursing Practice), Higher Degree by Research Supervisor (PhD and MPhil)</i>  |
| <b>Student researcher:</b>  | <i>Marian Brennan</i>   |
| <b>Version Number:</b>      | 3   |
| <b>Version Date:</b>        | 13/02/2019  |

**What is the Project About?**

Physical activity is often recommended to people living with Type 1 Diabetes (T1D) in an effort to reduce the risk of long-term complications associated with T1D, improve insulin requirements and improve well-being. Although beneficial, we know that as a whole, people living with T1D are less active than the general population. Research suggests these differences in physical activity may be due to specific barriers experienced by people living with T1D. We believe existing physical activity promotion initiatives for the general population do not take into account the complex factors affecting people with T1D. Currently, there are no researched programs to help people with T1D become more physically active.

This project is designed to see if a group education program, Type 1 TACTICS for Exercise helps people living with T1D overcome fear of hypoglycaemia as a barrier to physical activity. The project is based on previous exploratory work done at Curtin University and Diabetes WA in 2017. The study will involve approximately 120 adults living with T1D. If we can help people with T1D become more physically active, we may reduce the incidence of diabetes related complications and improve the lives of people living with the condition.

**Who is doing the Research?**

The project is being conducted by Curtin University and Diabetes WA. The research project is being conducted by Marian Brennan as part of her Doctor of Philosophy at Curtin University studies and is funded through the University. Diabetes WA have agreed to support the project. Marian is supervised by three experienced researchers from Curtin University, Dr Janie Brown, Prof. Gavin Leslie and Prof. Nikos Ntoumanis.

**Why am I being asked to take part and what will I have to do?**

We are looking for adults aged between 18-65 years who have lived with T1D for greater than 6 months and who did NOT participate in our research in 2017.

Participation in the project will involve being randomly allocated to either Group 1 or Group 2. This will be done by chance, like tossing a coin. Neither you nor the researcher can choose which group you go in. Each of these groups will be asked to attend an education session - part one and an education session - part two, four weeks later. Part one will run for **one to three hours** and part two for **one hour**. These group sessions will be held in north, south and central locations around Perth, Western Australia. We will make digital video recording of each group for the purposes of assessing the facilitator. A trained facilitator assessor from Diabetes WA will view the recording for assessment purposes only.

## Addressing Barriers to Physical Activity in Type 1 Diabetes

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We will ask you (regardless of the group you are allocated to) to complete a questionnaire upon arriving to group session - part one and two. A third questionnaire will be sent to you eight weeks later. You will be asked to consider questions relating to your diabetes such as how long you have had it and how it makes you feel day to day. You will also be asked questions relating to physical activity such as how much you currently do, how you feel about physical activity and what difficulties you have in participating in physical activity. The questionnaires will be completed on supplied electronic tablet devices (ipads) at part – one and part – two and will be sent to you via email or SMS link at eight weeks following part two. We are happy to provide paper questionnaires if you prefer this method. Each questionnaire will take approximately 15 minutes to complete.

Following the completion of the final questionnaire, you will be asked to return to participate in a focus group. This focus group gives you an opportunity to let us know what you thought of the sessions, what aspects were helpful and what aspects were less helpful. We would also like to know how and why these aspects were either helpful or not. Focus groups will be held north, south and central to Perth. We will make a digital audio recording so we can accurately recall conversations to identify any common themes brought up in each group. After the focus group we will make a full written copy of the recording.

### **Are there any benefits' to being in the research project?**

The results of this study will help us find acceptable and effective programs to help people living with type 1 diabetes, become more active. We believe this has great potential to improve the health and well-being of people living with type 1 diabetes across Australia. As a participant in this project, you will have the opportunity to meet and interact with other adults living with T1D who may also share some common interests and challenges. Sometimes, people appreciate the opportunity to discuss their opinions, feelings and their condition with others experiencing similar things. You will also be given the opportunity to learn about physical activity and how to participate safely. There will be no costs to you and you will be offered a Coles Myer gift card and a resistance training band in acknowledgement of your support for the study.

### **Are there any risks, side-effects, discomforts or inconveniences from being in the research project?**

Apart from giving up your time, we do not expect that there will be any risks or inconveniences associated with taking part in this study. We hope that the provided Coles Myer voucher helps compensate you for any parking costs you may incur while taking part in the study. We have been careful to make sure that the questions in the questionnaire do not cause you any distress, but if you feel anxious about any of the questions you do not need to answer them. If the questions cause any concerns or upset you, we can refer you to an appropriate professional counsellor through **Diabetes WA (1300 001 880)** or please call **Lifeline 13 11 14**.

Although we will discuss strategies to minimise these risks, undertaking physical activity which you are not accustomed to, may increase your risk of muscle soreness or injury. For people living with type 1 diabetes, physical activity can also increase the risk of hypoglycaemia. Both study groups will have access to information to help minimise these risks.

If the findings of the study suggest one form of program to be more effective than the other, those who were not in the most effective group will be given the opportunity to attend the alternate group following the completion of the project. You will be free to continue receiving your usual diabetes care during the course of the project.

### **Who will have access to my information?**

The information collected in this research will be non-identifiable (anonymous). This means that we do not need to collect individual names. We may ask you to create a unique code on your questionnaires so we can determine how your responses might have changed over time. No one, not even the research team, will be able to identify your information. The following people will have

## *Addressing Barriers to Physical Activity in Type 1 Diabetes*

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access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development.

The information we collect in this study will be kept under secure conditions at Curtin University for 25 years after the research is published and then it will be destroyed. Electronic data will be password-protected and hard copy data (including video or audio tapes) will be kept in locked storage.

The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented. Whilst all care will be taken to maintain privacy and confidentiality of any information shared at a focus group or group discussion, you should be aware that you may feel embarrassed or upset if one of the group members repeats things said in a confidential group meeting.

### **Will you tell me the results of the research?**

We will write to you at the end of the research (in about 24 months) and let you know the results of the research. Results will not be individual but based on all the information we collect and review as part of the research. Results may also be available from Diabetes WA e-newsletters, social media pages and publications.

### **Do I have to take part in the research project?**

Taking part in a research project is voluntary.

### **Can I change my mind?**

If you decide to take part and then change your mind, that is okay, you can withdraw from the project. If you choose not to take part or start and then stop the study, it will not affect your relationship with the University or Diabetes WA.

It must be noted that in an anonymous questionnaire (like we are using) you can withdraw prior to submitting your questionnaire. However, as data are anonymous we may not be able to withdraw your response once it has been submitted. We will be unable to destroy your specific information because it has been collected in an anonymous way.

### **What happens next and who can I contact about the research?**

If you decide to take part in this research we will ask you to sign the consent form. By signing it is telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.

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Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0795). Australian New Zealand Clinical Trials Registry (ANZCTR) registration number ACTRN12618001729213p. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.