



Participant Information Sheet: Ethics approval # 17/CEN/241

Project title:	Diabetes Community Exercise and education Programme (DCEP) and Type II Diabetes Management	
Principal investigator:	Name: Prof. Leigh Hale Department: School of Physiotherapy Position: Dean	Contact phone number: (03) 479 5425

Kia Ora/Talofa/Hello

Thank you for showing an interest in this project. Please read this information sheet carefully. Take your time and, if you wish, talk with whānau, relatives or friends, before deciding whether or not you wish to take part in this research. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

We are researchers from the University of Otago and we would like to find out how the Diabetes Community Exercise and education Programme (DCEP) (a 12 week exercise and education programme) compares to a well-researched education programme called DESMOND (a one-day, self-management education programme) for people with type II diabetes.

What is the aim of this research project?

This project would like to find out if the DCEP programme is better and more cost effective in managing type II diabetes than DESMOND.

Who is funding this project?

This project is being funded by the Health Research Council of New Zealand.

Who are we seeking to participate in the project?

Men and women who have been diagnosed with type II diabetes and are aged 35 years or over can take part in this project. Your GP will also need to agree that it is safe (in terms of your health) for you to take part in this project. We are looking for a total of 220 men or women living in Dunedin and Invercargill to take part in the project.

If you take part, what will you be asked to do?

First we will find out if you are eligible and want to take part:

If you are interested in being in this project and give us your consent, we will ask your GP to securely send information about your health to our research administrator. This will include information about your type II diabetes, other illnesses you have, medications you take, and the number of times

you visit your GP. We need this information to make sure that you are eligible to take part in this project. If you end up deciding not to take part in the project for any reason, we will safely destroy all your patient information and notify your GP that we have done this.

If you agree and are eligible to take part in this project you will be asked to sign a consent form and we will ask you to attend a pre-project testing appointment.

Following this testing appointment you will be randomly allocated to ONE of two groups: This means you will have a 50-50 chance of either being in the group that attends DCEP or in the group that attends the DESMOND programme. Please be aware that *you will not be able to choose* which group you will be in. Both groups are *free* for you to attend but unfortunately we cannot help you with transport costs to and from either the DCEP or the DESMOND groups. Whichever group you are allocated to, you will continue with your usual care for your diabetes.

If you are placed in the DESMOND group: you will attend a one-day DESMOND workshop. At the end of the project you are welcome to join the DCEP classes if you wish and if they are still running.

If you are placed in the DCEP group you will attend two 90-minute sessions per week for 12 weeks. First, the physiotherapist and the nurse will talk to you about your health and what you wish to get out of DCEP and they will ensure the exercises and education sessions are suited to you. DCEP promotes whanaungatanga or relationships where everyone (regardless of age, gender, ethnicity, deprivation status, literacy, or health) is unconditionally accepted and supported to work together towards improved health. There is a very social and supportive environment. You may bring whānau, family or friends to exercise with you. The physiotherapist and a nurse run the session to ensure you exercise safely. Each exercise session will be suited to your health and ability. During the session you will do 45 minutes of exercise, followed by 45 minutes of education on how to manage your diabetes. Exercises include warm-up, strength, fitness, and stretching exercises. The education sessions after the exercise class will have a different health professional and topic each time who will talk about managing diabetes. At the completion of the 12-week programme you are welcome to carry on taking part in an ongoing exercise-only class at the same venue run by the same staff.

Testing:

We will ask you to attend four testing appointments: (1) at the beginning of the project, (2) 3 months later, (3) 6 months later, and (4) 12 months later. Each test appointment will take no longer than one hour. You will be tested by a trained research assistant in a community-based venue. You will receive a \$20 grocery voucher for your time and travel for each test appointment. You may bring your whānau, family member, or support person with you to the testing appointments.

At each test appointment

- We will ask you questions about your health and wellbeing.
- We will also test your blood glucose control by doing a small pin-prick blood test on site. You can request Karakia before the test, and also keep the blood if you so choose. All pin-prick blood tests are otherwise safely disposed of in biohazard bags as per standard Ministry of Health protocol.
- We will measure your blood pressure, heart rate, weight, height, waist, and hip circumference.
- We will measure how far you can walk on a flat surface in 6 minutes. You walk at your own pace and you can rest if you wish to.

At the last testing appointment we may also interview you about what you thought of DCEP or DESMOND and what you think could be improved. We will use open-ended questions in this

interview so that you can talk freely. We will audio-record these interviews. The audio recording will then be transcribed word for word. You will have the opportunity to comment on your transcribed interview if you so wish to. We may ask to contact you once more after the interview to clarify some of the points you made.

As the interviews will use an open-ended technique of questioning, the precise nature of the questions which will be asked have not been determined in advance, but will depend on the way in which the interview develops. Consequently, although the Health and Disability Ethics Committee is aware of the general areas to be explored in the interview, the Committee has not been able to review the precise questions to be used. In the event that the line of questioning does develop in such a way that you feel hesitant or uncomfortable with, you are reminded of your right to decline to answer any particular question(s).

You will be involved in this project for 15 months.

Is there any risk of discomfort or harm from participation?

You may find the walking test to be a little difficult, but our trained research assistant will be beside you to ensure your safety at all times. While doing the walking test you may feel some discomfort in the form of heavier breathing (puffing), which is expected as part of the test. You will only be expected to exercise at your own comfortable pace and you should still be able to hold a conversation whilst you are doing the test. During the test, if you get tired, you are allowed to rest and we will have a chair available for you to sit on. We will monitor your blood pressure and heart rate before and after the test to ensure your safety. You may stop the walking test if you wish to.

You may also feel like there are a lot of questions at the assessments. The research assistants will ask you the questions and record your answers for you. You can choose not to answer any of the questions, or withdraw at any point, with no disadvantage to you. Let the researchers know if you are feeling tired or uncomfortable at any point.

What information will be collected and how will it be used?

We will ask you to provide details about your ethnicity, age, gender, education, income, living situation, employment, and street address. We will also collect the number of GP visits you have during the project.

We will also ask about your diabetes, health behaviours, smoking, alcohol intake, and exercise, and any current or previous medical illnesses, and what medications you are on.

Your blood glucose will be recorded, along with your blood pressure, heart rate, weight, height, waist and hip circumference, and the distance you completed during the six minute walking tests.

We will use all this information to see if your diabetes control and general health gets better, and also to make sure that you are safe during the testing and exercising (if you are in the DCEP group).

What about anonymity and confidentiality?

All information and data will be kept without your name on it in secure storage and used for research purposes only. All paper copies will be stored in the Principal Investigator's locked personal cabinet and the electronic data will be stored in the password protected university computer. At the end of the project, all paper copies of the interview or other data will be destroyed securely but the electronic data (without your name on it) will be retained for a period of 10 years for research purposes only.

The results of the project may be published in an academic journal. Your individual data will be completely anonymised so you will not be named, and all of the results will be presented in summary form only. You are more than welcome to request a copy of your results.

If you agree to participate, can you withdraw later?

You may withdraw from participation in the project at any time and without any disadvantage to yourself.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

Name: Leigh Hale Position: Principal Investigator Department: School of Physiotherapy	Contact phone number: (03) 479 5425
Name: Bonnie Scarth Position: Project Manager Department: School of Physiotherapy	Contact phone number: (03) 479 7130

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz



CONSENT FORM FOR PARTICIPANTS: Ethics approval # 17/CEN/241

Diabetes Community Exercise Programme (DCEP) and Type II Diabetes Management

Principal Investigator: Professor Leigh Hale (physio.dean@otago.ac.nz)

Following signature and return to the research team, this form will be stored in a secure place for ten years.

Name of participant:.....

1. I have read the Information Sheet concerning this project and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about taking part in this project.
3. I confirm that I meet the criteria for taking part, which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my taking part in this project is entirely voluntary.
6. I know that I am free to withdraw from the project at any time without disadvantage.
7. I know that as a participant I will be randomly allocated with a 50-50 chance into either the DCEP group or the DESMOND group.
8. I understand that I cannot choose which group of the project I will get placed in, and that the researchers have no control over which group of the project I will end up in.
9. If I am allocated to DCEP, I know that I will attend for free a 90 minute exercise and education group twice a week for 12 weeks.
10. If I am allocated to DESMOND I know that I will attend a free one-day education workshop.
11. I know that in spite of which group I end up in, I must continue to care for my diabetes as I usually do.
12. I understand that my GP has referred my patient information to the research administrator, and that my number of GP visits (but not what the visits were about) during the project will be recorded by the research team.
13. I know that as a participant I will be required to attend 4 testing appointments and I know what will happen in these appointments, as they are described in the information Sheet.
14. I understand that I can request Karakia before the blood test, and may keep the blood if I so choose, otherwise it will be safely disposed of in biohazard bags.

15. I know that the interviews will ask about my diabetes management, medications, overall health and wellbeing, and what I thought of the programme (DCEP or DESMOND), and that if I feel uncomfortable about the questions I am asked or I do not wish to answer a question, I do not have to.
16. I understand that I will be involved in the project for 15 months.
17. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.
18. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least ten years.
19. I understand that the results of the project may be published and be available in the University of Otago Library, but that any personal identifying information will remain confidential between myself and the researchers during the project, and will not appear in any spoken or written report of the project.
20. I know that I will be offered a \$20 grocery voucher to reimburse my travel costs for each testing appointment for this project.
21. I know that I will not be reimbursed for my travel cost to DCEP or DESMOND.
22. I know that no commercial use will be made of the data.

Name of participant:

Signature of participant:

Date:

Name of person taking consent

Date: