Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Participant Information Sheet

Ageing well with diabetes technology: Insulin pumping in patients aged 65+ years

Sponsor: Diabetes Christchurch, Maia Foundation
Co-Lead Researchers: Dr Helen Lunt and Dr Niranjala Hewapathirana
Study Site: Diabetes Department, Christchurch Hospital Outpatients
Contact phone number: 03 3640 860
Ethics committee ref.:

You are invited to take part on a questionnaire-based study on your views on insulin pumps. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether you will participate in this study.
If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

It is up to you to decide whether you would like to take part in this study. If you sign this consent form but then decide at any point that you no longer want to be part of the study, you can withdraw your participation in the study.

WHAT IS THE PURPOSE OF THE STUDY?

Insulin pumps improve diabetes management. This study looks at how people over 65 years in New Zealand with type 1 diabetes use insulin pumps. Currently, there is not much information about how safe and practical using pumps are in this age group. More funding will soon be available for more people to use these pumps. People with diabetes are also living longer, healthier lives. This means more people in this age group might use pumps in the future. This study aims to give healthcare professionals (like yourselves) key information to provide better care for people with diabetes in this group.

HOW IS THE STUDY DESIGNED?

This study explores older patients already established on insulin pumps, with a focus on how their clinical care should be delivered. We plan to study 20 healthcare professionals who work in Diabetes Outpatients.
This is a co-designed study. The questions used in this study were developed jointly through the local diabetes society and diabetes healthcare professionals.

You will open the link on your personal computer to a software tool called 1000minds where you are presented with statements (https://www.1000minds.com/about). The link will be sent out through your work email and information will be provided about the survey at this point. This tool presents you with 2 statements at a time. Your role as a healthcare professional is to choose which statement is more important for you to discuss in a consultation with an older patient on an insulin pump. For instance, you might need to decide between: A) Individualization of glycaemic targets (such as HbA1c) or B) Ensuring nutritional goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).
It will take approximately 10 minutes for you to complete the 1000minds questions in your own time.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to take part in this study as you are a health care professional (e.g. nurse, doctor, dietitian) who works in diabetes management. We have 20 health care professionals selected for the study.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study will involve a 10-minute online survey on 1000minds. This will be accessed via a link which will be sent out to you to complete in your own time.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no identifiable risks for your participation in this study.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

There are no direct benefits to you from taking part in the study. However, taking part in the study may help to identify diabetes management areas that it would be useful for you to focus on with your patients in the future.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information from your answers to the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (such as your name, date of birth, or address). For your participation in this study, no identifiable information will be collected through the survey in 1000minds.

Information gathered from the study may go towards a publication. All responses will be reported in such a way that you will not be able to identify your own answers.

De-identified (Coded) Information

Your personal responses to the survey will be kept completely confidential. The 1000minds survey will present all recorded information from your responses to the diabetes research team as a unique code. This means that if results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your 'coded' information collected by 1000minds is stored on servers located at approved locations under contract to 1000minds (https://www.1000minds.com/privacy). Only the diabetes research team will have access to this. This information will be stored indefinitely unless deletion is requested (under the right to be forgotten). Data will only be used for the purposes described in this policy. All storage will comply with local data security guidelines.

Risks

While efforts will be made to protect your privacy, total confidentiality of your information cannot be guaranteed. Even with coded (de-identified) information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small. It may increase in the future as people find new ways of tracing information.

It is possible that this research could one day help you and other health care professionals to better manage your patients. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatize, or discriminate against your patients in this group.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the 1000minds questionnaires and the use of information, you should ask one of the researchers – Helen Heenan (research coordinator), Dr Helen Lunt (Diabetes Physician), Dr Niranjala (Nilu) Hewapathirana (Diabetes Physician), Rebecca Simpson (research assistant).

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by informing the research team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you and no further information will be collected from you after this point.

Māori Data:

This study focuses on older people who are treating their type 1 diabetes with an insulin pump. Currently, this patient population are predominantly or exclusively non-Māori. We will however continue to consult with Māori diabetes clinical staff about this study, for example regarding interpretation and dissemination of results as it relates to health service delivery.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Should you wish to withdraw from the study you can contact any of the study team mentioned in this document – Dr Helen Lunt, Dr Niranjala (Nilu) Hewapathirana, Helen Heenan or Liz Love (expert dietitian)
Should you choose to withdraw, the data already collected about you will be used. No more data will be collected about you beyond this point.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Your identity is kept confidential and so responses to the survey are anonymous. This means we cannot feedback results to individual participants. We will however be presenting study results at departmental seminars.

WHO IS FUNDING THE STUDY?

The research is being supported by registered charities the Maia Health Foundation(https://www.maiahealth.org.nz) and Diabetes Christchurch (https://www.diabeteschristchurch.co.nz/) to help with the set up costs and purchase of the 1000minds software.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The *[insert Committee name]* has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Name, position	*Dr Helen Lunt (Diabetes physician)*
Telephone number	03 3640 860
Email	*Helen.Lunt@cdhb.health.nz*

Or

Name, position	*Liz Love (Diabetes dietitian)*
Telephone number	021611584
Email	*Liz.love@cdhb.health.nz*

Or

Name, position	*Dr Niranjala Hewapathirana (Diabetes physician)*
Telephone number	03 3640 860
Email	*Niranjala.Hewapathirana@cdhb.health.nz*

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@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Māori health support please contact:

Name, position	*Debbie Rawiri (Māori diabetes nurse specialist)*
Telephone number	0272051862
Email	*Debbie.Rawiri@cdhb.health.nz*

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

Phone:	0800 4 ETHIC
Email:	hdecs@health.govt.nz

Consent:

There is no written (i.e. signed) consent needed from you for this study. This information sheet is given to you to read prior to your participation. The action of you clicking the link to complete the 1000minds survey implies consent to your participation in the study.