Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Participant Information Sheet

Ageing well with diabetes technology

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.: 2023 EXP 19329

You are invited to take part in 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, and it will not affect the care you receive. 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. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

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.

This study relates to people 65 years and over using diabetes technology such as insulin pumps with or without continuous glucose monitoring. People with type 1 diabetes will be the primary focus group referred to in the rest of the document, however acknowledging that some participants may have another type of diabetes where you are not able to make your own insulin. These participants are using PHARMAC-funded insulin pumps and so are included in our study.

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 decide not to take part, it will not affect your diabetes treatment in any way. 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 care. This study looks at how people over 65 years in New Zealand with type 1 diabetes or similar, use these pumps. Right now, we do not know much about how safe and practical these pumps are for people with type 1 diabetes over 65 years old. Soon, funding will be available for more people to use these pumps. People with diabetes are living longer, healthier lives. This means more people over the age of 65 years might use pumps in the future. This study aims to give healthcare professionals (such as doctors, nurses and dietitians) key information to provide better care for people with diabetes as they reach retirement age.

HOW IS THE STUDY DESIGNED?

This study is about older people who already use insulin pumps and focuses on how health care professionals can give better care. We are looking at around 24 patients in Christchurch who are 65 years or older and use insulin pumps. The local diabetes doctors were asked to identify patients (like you) from the insulin pump database who are 65+. This information was then passed on to the research team to contact you to be a part of the study
This study has been developed in partnership with the local diabetes society and diabetes-related health care professionals.

Here is what we need from you:

1. With a researcher you will use a software called 1000minds (https://www.1000minds.com/about). It will show you statements about what is possibly important for you to talk about during your clinic visits. You will choose which statement matters more to you. For example, you might pick between talking about: A) meeting blood sugar targets (HbA1c) or B) making sure your diet goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).

2. You will answer some questions in a private interview with a researcher. They will ask you questions about your insulin pump. This might be things like how you are using your insulin pump, and if you face any difficulties with using it now, or that you may foresee in the future (such as - if your eyesight is getting worse).

It will take about 30 minutes for you to complete both the 1000minds survey and the interview questionnaire. This will all happen in either Diabetes outpatients, the Diabetes Christchurch building (Carlyle St) or via video communication such as Zoom.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to take part in this study as you have type 1 diabetes (or another type of diabetes where you are not able to make your own insulin) and are currently on an insulin pump (for more than 3 months) and are 65 years of age or older. Based on our local pump database we have found 24 people with diabetes in this group and you are one of them.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study involves one interview. This will be at Diabetes outpatients, Diabetes Christchurch, or through video communication such as Zoom (if meeting in person is not possible). The interview should take around 30 minutes. You will spend 15 minutes with a

researcher, completing the 1000minds online survey. Then, you will have another 15 minutes to answer the interview questions.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study will explore some of your views about long-term insulin pumping. Thinking about the answers to these questions may be distressing to some people. If you want to discuss this further, you could talk to your GP or diabetes nurse. If taking part in this study makes you feel uncomfortable or distressed, then the research team may be able to help you obtain psychological support. This might be counselling through your GP or through the outpatient diabetes clinical psychologist.

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 identify diabetes management areas that may be useful for you to focus on in the future. You may wish to discuss this with your health professionals.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you and you will not be reimbursed for travel to the interview. Please talk to the research team if you require a taxi.

WHAT IF SOMETHING GOES WRONG?

There is a chance that some of the questions asked could make you uncomfortable. As mentioned above, if this occurs then the research team will be able to help you get the support you need.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information about you and your study participation. This includes the answers to the semi-structured questionnaire and the results of the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.
With your permission we will also look at your hospital records for specific health information which helps to inform the study. These include: HbA1c levels, medical history, how long you have been on an insulin pump.

<u>Identifiable Information</u>
Identifiable information is any data that could identify you (such as your name, date of birth, or address). Only diabetes researchers will have access to such information.

- Your GP will be notified of your participation in this study with your consent
- Notifying your GP is important. If study participation causes distress, then this allows proper follow-up to be arranged.

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.

<u>De-identified (Coded) Information</u>
To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the diabetes researchers. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so

that you can be identified by your coded data if needed. If results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your identifiable information is held in the Diabetes Outpatients building during the study and is only accessible to the research team involved. After the study it is kept on a hospital computer for 10 years, then destroyed. All storage will comply with local data security guidelines.

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 information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small. It may increase in the future as people find new ways of tracing information.

This research includes information about your age range, medical conditions and insulin pump experiences. It is possible that this research could one day help people in the same age group as you. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatism or discriminate against members of the same group as you.

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 interviews or 1000minds questionnaires and the use of information about you, 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:

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. Currently, older people with type 1 diabetes tend to be of European descent. This makes it unlikely that we will have anyone of Māori ethnicity included in the study. If we do identify a patient included in the study as Māori, we will make sure that their data is protected and will not be recognizable. Also, we have consulted with the local Te Whatu Ora Māori research advisor. After the study is completed, he will advise us about how best to present study findings to local Māori communities.

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 or Helen Heenan.
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?

You will be provided with a summary of the overall results of the study by May 2024 after our final participant has taken part in the study.

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 Central Health and Disability Ethics Committee 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	*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 cultural 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

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Consent Form

Ageing well with diabetes technology

Please tick to indicate you consent to the following:

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdrew may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Person signing on behalf of participant who is sight impaired Yes ☐

Name: _____ Relationship: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

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Contact phone number: 03 3640 860
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VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

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WHAT IS THE PURPOSE OF THE STUDY?

Insulin pumps improve diabetes care. This study looks at how people over 65 years in New Zealand with type 1 diabetes or similar, use these pumps. Right now, we do not know much about how safe and practical these pumps are for people with type 1 diabetes over 65 years old. Soon, funding will be available for more people to use these pumps. People with diabetes are living longer, healthier lives. This means more people over the age of 65 years might use pumps in the future. This study aims to give healthcare professionals (such as doctors, nurses and dietitians) key information to provide better care for people with diabetes as they reach retirement age.

HOW IS THE STUDY DESIGNED?

This study is about older people who already use insulin pumps and focuses on how health care professionals can give better care. We are looking at around 24 patients in Christchurch who are 65 years or older and use insulin pumps. The local diabetes doctors were asked to identify patients (like you) from the insulin pump database who are 65+. This information was then passed on to the research team to contact you to be a part of the study
This study has been developed in partnership with the local diabetes society and diabetes-related health care professionals.

Here is what we need from you:

1. With a researcher you will use a software called 1000minds (https://www.1000minds.com/about). It will show you statements about what is possibly important for you to talk about during your clinic visits. You will choose which statement matters more to you. For example, you might pick between talking about: A) meeting blood sugar targets (HbA1c) or B) making sure your diet goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).

2. You will answer some questions in a private interview with a researcher. They will ask you questions about your insulin pump. This might be things like how you are using your insulin pump, and if you face any difficulties with using it now, or that you may foresee in the future (such as - if your eyesight is getting worse).

It will take about 30 minutes for you to complete both the 1000minds survey and the interview questionnaire. This will all happen in either Diabetes outpatients, the Diabetes Christchurch building (Carlyle St) or via video communication such as Zoom.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to take part in this study as you have type 1 diabetes (or another type of diabetes where you are not able to make your own insulin) and are currently on an insulin pump (for more than 3 months) and are 65 years of age or older. Based on our local pump database we have found 24 people with diabetes in this group and you are one of them.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study involves one interview. This will be at Diabetes outpatients, Diabetes Christchurch, or through video communication such as Zoom (if meeting in person is not possible). The interview should take around 30 minutes. You will spend 15 minutes with a

researcher, completing the 1000minds online survey. Then, you will have another 15 minutes to answer the interview questions.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study will explore some of your views about long-term insulin pumping. Thinking about the answers to these questions may be distressing to some people. If you want to discuss this further, you could talk to your GP or diabetes nurse. If taking part in this study makes you feel uncomfortable or distressed, then the research team may be able to help you obtain psychological support. This might be counselling through your GP or through the outpatient diabetes clinical psychologist.

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 identify diabetes management areas that may be useful for you to focus on in the future. You may wish to discuss this with your health professionals.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you and you will not be reimbursed for travel to the interview. Please talk to the research team if you require a taxi.

WHAT IF SOMETHING GOES WRONG?

There is a chance that some of the questions asked could make you uncomfortable. As mentioned above, if this occurs then the research team will be able to help you get the support you need.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information about you and your study participation. This includes the answers to the semi-structured questionnaire and the results of the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.
With your permission we will also look at your hospital records for specific health information which helps to inform the study. These include: HbA1c levels, medical history, how long you have been on an insulin pump.

<u>Identifiable Information</u>
Identifiable information is any data that could identify you (such as your name, date of birth, or address). Only diabetes researchers will have access to such information.

- Your GP will be notified of your participation in this study with your consent
- Notifying your GP is important. If study participation causes distress, then this allows proper follow-up to be arranged.

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.

<u>De-identified (Coded) Information</u>
To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the diabetes researchers. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so

that you can be identified by your coded data if needed. If results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your identifiable information is held in the Diabetes Outpatients building during the study and is only accessible to the research team involved. After the study it is kept on a hospital computer for 10 years, then destroyed. All storage will comply with local data security guidelines.

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 information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small. It may increase in the future as people find new ways of tracing information.

This research includes information about your age range, medical conditions and insulin pump experiences. It is possible that this research could one day help people in the same age group as you. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatism or discriminate against members of the same group as you.

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 interviews or 1000minds questionnaires and the use of information about you, 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:

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. Currently, older people with type 1 diabetes tend to be of European descent. This makes it unlikely that we will have anyone of Māori ethnicity included in the study. If we do identify a patient included in the study as Māori, we will make sure that their data is protected and will not be recognizable. Also, we have consulted with the local Te Whatu Ora Māori research advisor. After the study is completed, he will advise us about how best to present study findings to local Māori communities.

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 or Helen Heenan.
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?

You will be provided with a summary of the overall results of the study by May 2024 after our final participant has taken part in the study.

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 Central Health and Disability Ethics Committee 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	*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 cultural 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

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Consent Form

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Please tick to indicate you consent to the following:

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdrew may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Person signing on behalf of participant who is sight impaired Yes ☐

Name: _____ Relationship: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

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Co-Lead Researchers: Dr Helen Lunt and Dr Niranjala Hewapathirana
Study Site: Diabetes Department, Christchurch Hospital Outpatients
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Insulin pumps improve diabetes care. This study looks at how people over 65 years in New Zealand with type 1 diabetes or similar, use these pumps. Right now, we do not know much about how safe and practical these pumps are for people with type 1 diabetes over 65 years old. Soon, funding will be available for more people to use these pumps. People with diabetes are living longer, healthier lives. This means more people over the age of 65 years might use pumps in the future. This study aims to give healthcare professionals (such as doctors, nurses and dietitians) key information to provide better care for people with diabetes as they reach retirement age.

HOW IS THE STUDY DESIGNED?

This study is about older people who already use insulin pumps and focuses on how health care professionals can give better care. We are looking at around 24 patients in Christchurch who are 65 years or older and use insulin pumps. The local diabetes doctors were asked to identify patients (like you) from the insulin pump database who are 65+. This information was then passed on to the research team to contact you to be a part of the study
This study has been developed in partnership with the local diabetes society and diabetes-related health care professionals.

Here is what we need from you:

1. With a researcher you will use a software called 1000minds (https://www.1000minds.com/about). It will show you statements about what is possibly important for you to talk about during your clinic visits. You will choose which statement matters more to you. For example, you might pick between talking about: A) meeting blood sugar targets (HbA1c) or B) making sure your diet goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).

2. You will answer some questions in a private interview with a researcher. They will ask you questions about your insulin pump. This might be things like how you are using your insulin pump, and if you face any difficulties with using it now, or that you may foresee in the future (such as - if your eyesight is getting worse).

It will take about 30 minutes for you to complete both the 1000minds survey and the interview questionnaire. This will all happen in either Diabetes outpatients, the Diabetes Christchurch building (Carlyle St) or via video communication such as Zoom.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to take part in this study as you have type 1 diabetes (or another type of diabetes where you are not able to make your own insulin) and are currently on an insulin pump (for more than 3 months) and are 65 years of age or older. Based on our local pump database we have found 24 people with diabetes in this group and you are one of them.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study involves one interview. This will be at Diabetes outpatients, Diabetes Christchurch, or through video communication such as Zoom (if meeting in person is not possible). The interview should take around 30 minutes. You will spend 15 minutes with a

researcher, completing the 1000minds online survey. Then, you will have another 15 minutes to answer the interview questions.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study will explore some of your views about long-term insulin pumping. Thinking about the answers to these questions may be distressing to some people. If you want to discuss this further, you could talk to your GP or diabetes nurse. If taking part in this study makes you feel uncomfortable or distressed, then the research team may be able to help you obtain psychological support. This might be counselling through your GP or through the outpatient diabetes clinical psychologist.

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 identify diabetes management areas that may be useful for you to focus on in the future. You may wish to discuss this with your health professionals.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you and you will not be reimbursed for travel to the interview. Please talk to the research team if you require a taxi.

WHAT IF SOMETHING GOES WRONG?

There is a chance that some of the questions asked could make you uncomfortable. As mentioned above, if this occurs then the research team will be able to help you get the support you need.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information about you and your study participation. This includes the answers to the semi-structured questionnaire and the results of the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.
With your permission we will also look at your hospital records for specific health information which helps to inform the study. These include: HbA1c levels, medical history, how long you have been on an insulin pump.

<u>Identifiable Information</u>
Identifiable information is any data that could identify you (such as your name, date of birth, or address). Only diabetes researchers will have access to such information.

- Your GP will be notified of your participation in this study with your consent
- Notifying your GP is important. If study participation causes distress, then this allows proper follow-up to be arranged.

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.

<u>De-identified (Coded) Information</u>
To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the diabetes researchers. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so

that you can be identified by your coded data if needed. If results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your identifiable information is held in the Diabetes Outpatients building during the study and is only accessible to the research team involved. After the study it is kept on a hospital computer for 10 years, then destroyed. All storage will comply with local data security guidelines.

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 information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small. It may increase in the future as people find new ways of tracing information.

This research includes information about your age range, medical conditions and insulin pump experiences. It is possible that this research could one day help people in the same age group as you. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatism or discriminate against members of the same group as you.

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 interviews or 1000minds questionnaires and the use of information about you, 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:

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. Currently, older people with type 1 diabetes tend to be of European descent. This makes it unlikely that we will have anyone of Māori ethnicity included in the study. If we do identify a patient included in the study as Māori, we will make sure that their data is protected and will not be recognizable. Also, we have consulted with the local Te Whatu Ora Māori research advisor. After the study is completed, he will advise us about how best to present study findings to local Māori communities.

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 or Helen Heenan.
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?

You will be provided with a summary of the overall results of the study by May 2024 after our final participant has taken part in the study.

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 Central Health and Disability Ethics Committee 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	*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 cultural 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

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Consent Form

Ageing well with diabetes technology

Please tick to indicate you consent to the following:

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdrew may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Person signing on behalf of participant who is sight impaired Yes ☐

Name: _____ Relationship: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Participant Information Sheet

Ageing well with diabetes technology

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.: 2023 EXP 19329

You are invited to take part in 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, and it will not affect the care you receive. 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. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

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.

This study relates to people 65 years and over using diabetes technology such as insulin pumps with or without continuous glucose monitoring. People with type 1 diabetes will be the primary focus group referred to in the rest of the document, however acknowledging that some participants may have another type of diabetes where you are not able to make your own insulin. These participants are using PHARMAC-funded insulin pumps and so are included in our study.

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 decide not to take part, it will not affect your diabetes treatment in any way. 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 care. This study looks at how people over 65 years in New Zealand with type 1 diabetes or similar, use these pumps. Right now, we do not know much about how safe and practical these pumps are for people with type 1 diabetes over 65 years old. Soon, funding will be available for more people to use these pumps. People with diabetes are living longer, healthier lives. This means more people over the age of 65 years might use pumps in the future. This study aims to give healthcare professionals (such as doctors, nurses and dietitians) key information to provide better care for people with diabetes as they reach retirement age.

HOW IS THE STUDY DESIGNED?

This study is about older people who already use insulin pumps and focuses on how health care professionals can give better care. We are looking at around 24 patients in Christchurch who are 65 years or older and use insulin pumps. The local diabetes doctors were asked to identify patients (like you) from the insulin pump database who are 65+. This information was then passed on to the research team to contact you to be a part of the study
This study has been developed in partnership with the local diabetes society and diabetes-related health care professionals.

Here is what we need from you:

1. With a researcher you will use a software called 1000minds (https://www.1000minds.com/about). It will show you statements about what is possibly important for you to talk about during your clinic visits. You will choose which statement matters more to you. For example, you might pick between talking about: A) meeting blood sugar targets (HbA1c) or B) making sure your diet goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).

2. You will answer some questions in a private interview with a researcher. They will ask you questions about your insulin pump. This might be things like how you are using your insulin pump, and if you face any difficulties with using it now, or that you may foresee in the future (such as - if your eyesight is getting worse).

It will take about 30 minutes for you to complete both the 1000minds survey and the interview questionnaire. This will all happen in either Diabetes outpatients, the Diabetes Christchurch building (Carlyle St) or via video communication such as Zoom.

WHO CAN TAKE PART IN THE STUDY?

You have been chosen to take part in this study as you have type 1 diabetes (or another type of diabetes where you are not able to make your own insulin) and are currently on an insulin pump (for more than 3 months) and are 65 years of age or older. Based on our local pump database we have found 24 people with diabetes in this group and you are one of them.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study involves one interview. This will be at Diabetes outpatients, Diabetes Christchurch, or through video communication such as Zoom (if meeting in person is not possible). The interview should take around 30 minutes. You will spend 15 minutes with a

researcher, completing the 1000minds online survey. Then, you will have another 15 minutes to answer the interview questions.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study will explore some of your views about long-term insulin pumping. Thinking about the answers to these questions may be distressing to some people. If you want to discuss this further, you could talk to your GP or diabetes nurse. If taking part in this study makes you feel uncomfortable or distressed, then the research team may be able to help you obtain psychological support. This might be counselling through your GP or through the outpatient diabetes clinical psychologist.

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 identify diabetes management areas that may be useful for you to focus on in the future. You may wish to discuss this with your health professionals.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you and you will not be reimbursed for travel to the interview. Please talk to the research team if you require a taxi.

WHAT IF SOMETHING GOES WRONG?

There is a chance that some of the questions asked could make you uncomfortable. As mentioned above, if this occurs then the research team will be able to help you get the support you need.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information about you and your study participation. This includes the answers to the semi-structured questionnaire and the results of the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.
With your permission we will also look at your hospital records for specific health information which helps to inform the study. These include: HbA1c levels, medical history, how long you have been on an insulin pump.

<u>Identifiable Information</u>
Identifiable information is any data that could identify you (such as your name, date of birth, or address). Only diabetes researchers will have access to such information.

- Your GP will be notified of your participation in this study with your consent
- Notifying your GP is important. If study participation causes distress, then this allows proper follow-up to be arranged.

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.

<u>De-identified (Coded) Information</u>
To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the diabetes researchers. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so

that you can be identified by your coded data if needed. If results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your identifiable information is held in the Diabetes Outpatients building during the study and is only accessible to the research team involved. After the study it is kept on a hospital computer for 10 years, then destroyed. All storage will comply with local data security guidelines.

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 information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small. It may increase in the future as people find new ways of tracing information.

This research includes information about your age range, medical conditions and insulin pump experiences. It is possible that this research could one day help people in the same age group as you. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatism or discriminate against members of the same group as you.

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 interviews or 1000minds questionnaires and the use of information about you, 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:

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. Currently, older people with type 1 diabetes tend to be of European descent. This makes it unlikely that we will have anyone of Māori ethnicity included in the study. If we do identify a patient included in the study as Māori, we will make sure that their data is protected and will not be recognizable. Also, we have consulted with the local Te Whatu Ora Māori research advisor. After the study is completed, he will advise us about how best to present study findings to local Māori communities.

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 or Helen Heenan.
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?

You will be provided with a summary of the overall results of the study by May 2024 after our final participant has taken part in the study.

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 Central Health and Disability Ethics Committee 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	*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 cultural 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

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Consent Form

Ageing well with diabetes technology

Please tick to indicate you consent to the following:

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdrew may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Person signing on behalf of participant who is sight impaired Yes ☐

Name: _____ Relationship: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Participant Information Sheet

Ageing well with diabetes technology

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.: 2023 EXP 19329

You are invited to take part in 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, and it will not affect the care you receive. 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. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

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VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

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WHAT IS THE PURPOSE OF THE STUDY?

Insulin pumps improve diabetes care. This study looks at how people over 65 years in New Zealand with type 1 diabetes or similar, use these pumps. Right now, we do not know much about how safe and practical these pumps are for people with type 1 diabetes over 65 years old. Soon, funding will be available for more people to use these pumps. People with diabetes are living longer, healthier lives. This means more people over the age of 65 years might use pumps in the future. This study aims to give healthcare professionals (such as doctors, nurses and dietitians) key information to provide better care for people with diabetes as they reach retirement age.

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This study has been developed in partnership with the local diabetes society and diabetes-related health care professionals.

Here is what we need from you:

1. With a researcher you will use a software called 1000minds (https://www.1000minds.com/about). It will show you statements about what is possibly important for you to talk about during your clinic visits. You will choose which statement matters more to you. For example, you might pick between talking about: A) meeting blood sugar targets (HbA1c) or B) making sure your diet goals are met. You will be given around 19 questions each with 2 statements to choose from (like the example above).

2. You will answer some questions in a private interview with a researcher. They will ask you questions about your insulin pump. This might be things like how you are using your insulin pump, and if you face any difficulties with using it now, or that you may foresee in the future (such as - if your eyesight is getting worse).

It will take about 30 minutes for you to complete both the 1000minds survey and the interview questionnaire. This will all happen in either Diabetes outpatients, the Diabetes Christchurch building (Carlyle St) or via video communication such as Zoom.

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researcher, completing the 1000minds online survey. Then, you will have another 15 minutes to answer the interview questions.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

The study will explore some of your views about long-term insulin pumping. Thinking about the answers to these questions may be distressing to some people. If you want to discuss this further, you could talk to your GP or diabetes nurse. If taking part in this study makes you feel uncomfortable or distressed, then the research team may be able to help you obtain psychological support. This might be counselling through your GP or through the outpatient diabetes clinical psychologist.

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 identify diabetes management areas that may be useful for you to focus on in the future. You may wish to discuss this with your health professionals.

WILL ANY COSTS BE REIMBURSED?

Taking part in the study will not bring any cost to you and you will not be reimbursed for travel to the interview. Please talk to the research team if you require a taxi.

WHAT IF SOMETHING GOES WRONG?

There is a chance that some of the questions asked could make you uncomfortable. As mentioned above, if this occurs then the research team will be able to help you get the support you need.

WHAT WIL HAPPEN TO MY INFORMATION

During this study the research staff will record information about you and your study participation. This includes the answers to the semi-structured questionnaire and the results of the 1000minds questionnaire. You cannot take part in this study if you do not consent to the collection of this information.
With your permission we will also look at your hospital records for specific health information which helps to inform the study. These include: HbA1c levels, medical history, how long you have been on an insulin pump.

<u>Identifiable Information</u>
Identifiable information is any data that could identify you (such as your name, date of birth, or address). Only diabetes researchers will have access to such information.

- Your GP will be notified of your participation in this study with your consent
- Notifying your GP is important. If study participation causes distress, then this allows proper follow-up to be arranged.

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.

<u>De-identified (Coded) Information</u>
To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the diabetes researchers. Instead, you will be identified by a code. The research team will keep a list linking your code with your name, so

that you can be identified by your coded data if needed. If results of the study are published or presented, you would not expect to be identifiable.

Security and Storage Of Your Information

Your identifiable information is held in the Diabetes Outpatients building during the study and is only accessible to the research team involved. After the study it is kept on a hospital computer for 10 years, then destroyed. All storage will comply with local data security guidelines.

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 information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small. It may increase in the future as people find new ways of tracing information.

This research includes information about your age range, medical conditions and insulin pump experiences. It is possible that this research could one day help people in the same age group as you. However, it is also possible that research findings could be used inappropriately by others to support negative stereotypes, stigmatism or discriminate against members of the same group as you.

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 interviews or 1000minds questionnaires and the use of information about you, 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:

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. Currently, older people with type 1 diabetes tend to be of European descent. This makes it unlikely that we will have anyone of Māori ethnicity included in the study. If we do identify a patient included in the study as Māori, we will make sure that their data is protected and will not be recognizable. Also, we have consulted with the local Te Whatu Ora Māori research advisor. After the study is completed, he will advise us about how best to present study findings to local Māori communities.

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 or Helen Heenan.
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?

You will be provided with a summary of the overall results of the study by May 2024 after our final participant has taken part in the study.

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 Central Health and Disability Ethics Committee 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	*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 cultural 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

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

Consent Form

Ageing well with diabetes technology

Please tick to indicate you consent to the following:

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given enough time to consider whether to participate in this study.		
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdrew may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Person signing on behalf of participant who is sight impaired Yes ☐

Name: _____ Relationship: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____