Supplementary File 1. Plain Language Statement and Consent Form

Attitudes towards insulin therapy for people with type 2 diabetes

Plain Language Statement and Consent Form

Date: May 2020

Full Project Title: Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)

Principal Investigators: Dr Elizabeth Holmes-Truscott and Professor Jane Speight, The Australian Centre for Behavioural Research in Diabetes (ACBRD), Deakin University

Associate Investigators: Dr Edith Holloway, ACBRD, Deakin University; Professor Timothy Skinner, Department of Rural Health, La Trobe University; Associate Professor John Furler, Department of General Practice, The University of Melbourne; Professor David O'Neal, St Vincent's Hospital, The University of Melbourne; and Dr Virginia Hagger, School of Nursing and Midwifery, Deakin University.

Dear participant,

You are invited to take part in this research project because you have type 2 diabetes, are aged between 18 and 75 years of age and take oral medication to manage your diabetes. In this study, we are investigating people's attitudes towards injecting insulin. We are also testing online resources about medications for type 2 diabetes. We want to know which resource(s) is the most useful for people with type 2 diabetes, who have questions or concerns about injecting insulin. Taking part involves exploring the web-based resource(s) and completing three online surveys over 6 months.

Below you can read further information about the study, so that you can decide if you would like to take part. Please take the time to read this information carefully. You can also print a copy of the PDF *(hyperlink to ethics approved version of the PLS inserted here)* or ask the study team for a hard copy to be sent to you. Ask the study team questions about anything you don't understand or want to know more about.

If you consent to taking part in this study, please click the box at the end of this webpage.

What is the purpose of this research?

Insulin is very effective for lowering blood glucose levels. Your doctor may recommend injecting insulin if other medications are unable to keep your blood glucose within your target range. However, people with type 2 diabetes may have concerns or questions about starting insulin. The purpose of this study is to test whether web-based resource(s) are useful for people with type 2 diabetes who have questions or concerns about starting insulin injections. The findings of this research may be used to inform what online resources about medications are available for people with type 2 diabetes in the future. We expect a total of 392 adults with type 2 diabetes will take part in this study.

Who can take part?

You can take part in this study if you:

- have type 2 diabetes and are currently taking oral medication to manage your diabetes. If you are currently, or have in the past, used self-administered injectable treatment for any illness or condition (for example insulin) you are NOT eligible to take part in the study.
- are between 18 and 75 years of age
- are able to read and speak English
- currently live in Australia
- have access to the internet and a computer (desktop, laptop) or tablet

You are not eligible to take part if you participated in the associated Pilot Study (between October and December 2019): Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 2: Pilot Study).

What does taking part involve?

Taking part in this study will involve:

- Accessing and viewing a web-based resource(s) about medications for type 2 diabetes. You will be asked to do this at least once (and as many times you like) over a 2-week period.
- Completing three online surveys. The first survey will be upon entry to the study, the second survey will be emailed to you two weeks later and the third survey will be emailed to you at 6-months.
- Each survey will take 20 minutes to complete.
- The survey will include questions about you (age, gender, education), your diabetes, attitudes and knowledge about insulin, your understanding about diabetes and some questions about how diabetes makes you feel.
- You will also be asked to provide your name and email address. This is so we can link each of your surveys together and look at any changes in your responses over time. Any information you share with us will remain confidential.

After you have completed the first online survey on entry into the study, you will be allocated to one of two groups. You will receive a link to one of two web-based resources on insulin and type 2 diabetes. You have a 50% chance of being assigned to each group (like tossing a coin). You will have two weeks to explore the resource(s) allocated to you. We will send you an e-mail reminder during the two-week period to look at the resources. You will then be sent follow-up surveys at 2 weeks and 6 months.

Taking part in this study does not involve any change to your diabetes management or changes to the medications you take.

Who is conducting this study?

Deakin University is conducting this study with funding from Sanofi-aventis Australia Pty Ltd (Sanofi). The study is coordinated by researchers (Principal Investigators) at The Australian Centre for Behavioural Research in Diabetes (ACBRD), a partnership for better health between Diabetes Victoria and Deakin University. The Principal Investigators take responsibility for the study. Participants will only be contacted by the research team including the principal investigators, the study project manager or research assistant.

Are there any benefits for me personally?

People take part in studies like this for many reasons. For example:

- Taking part offers an opportunity to learn about and inform new diabetes research;
- Taking part offers an opportunity to think about your diabetes and reflect on your experiences;
- Taking part in research will help us to help other people with diabetes (either now or in the future).

In addition, participants who complete the study (i.e., access the web-based resource(s) and complete all three surveys) will be entered into a prize draw to win one of 20 $100 department store gift cards that can be used at over 20 major retail stores in Australia.

Are there any risks to me?

No, we do not believe that this study will cause you any harm or put you at risk of harm. **The study surveys include questions that may be sensitive or personal in nature (e.g. feelings about living with diabetes, income and employment status). However, we do not expect any question to cause you any distress.** If you should become upset during the survey, you may stop completing the questions at any time. We encourage you to contact the researchers to discuss this. The researchers will be understanding and supportive. You have the right to refuse to answer any question that makes you uncomfortable.

If, as a result of participation, you do become distressed, you may wish to seek further information and support from beyondblue: Beyondblue – National Information Line Ph: [redacted] or visit: http://www.beyondblue.org.au/

If you have any questions about your diabetes following the survey, we encourage you to contact your health professional or to call the National Diabetes Services Scheme Helpline: [redacted].

Can I withdraw at any time?

Yes. **You are free to withdraw from this study at any time**. If you decide not to take part while completing an online survey, you can stop the survey and notify a member of the research team. Deciding not to take part (or to withdraw) will not affect your relationship with the ACBRD, Deakin University, Diabetes Victoria, or the study funder (Sanofi). If you withdraw from the study before, during, or immediately after you have completed the online surveys, we can remove any information you have shared from our analysis. However, once the study is closed your data will be de-identified and merged with other people's data. This means that you will not be able to withdraw the information you shared because we will not know which data are yours.

What will happen to my information?

Any information you share with us will remain strictly confidential. The survey data will be stored in a database via the Deakin University secure network. Only the research team will have access to the password protected data. Once we have collected all of the data and are ready to analyse the results, the survey responses will downloaded and de-identified. These files will not include any identifying information about you. Identifiable information (for example your email, name) will be stored in a password-encrypted excel spreadsheet. Any personal details you share about yourself (e.g. surname, contact details) for the purposes of enrolling you into the study will be destroyed (electronic files to be deleted) after you have completed the final survey. Safety follow-up interview data will be stored electronically (i.e. audio files). All data will be stored in a secure Deakin University computer file accessible only by the ACBRD research team. In accordance with government requirements, your data will be stored for at least fifteen (15) years following the publication of the results and then destroyed by erasing electronic files and shredding paper copies.

The overall results of the study may be published or presented in academic journals, at conferences, and in diabetes magazines and newsletters. Participants will be able to access any publications or reports resulting from the study on the ACBRD website (www.acbrd.org.au). No-one will be able to identify you from any of the information we publish or present. The study funder may request access to the de-identified data. These data will not include any information that could be used to identify you. We will take great care to protect your identity. Your privacy is very important to us.

Who is funding this project?

This project forms part of an Investigator Sponsored Study (SA-2017-11697) which is supported by Sanofi-aventis Australia Pty Ltd (Sanofi). Sanofi has no involvement in the study design, data analysis or interpretation and will not have any access to personally identifying information collected (e.g. contact details). De-identified study data may be shared with Sanofi, including survey results. Your personal and contact details will not be shared with Sanofi.

If you share with us (via the study surveys, e-mail or phone) any adverse events (safety issues) associated with therapeutic goods (e.g. medications) during your involvement with this study, we are required to report these to Sanofi. This could include any adverse events associated with the funder's products. Therefore, all the data that we collect from you will be screened for adverse events that may be associated with medications you take now or have taken in the past. In the event that you report an adverse event, we will contact you and ask a small number of additional questions (e.g. medication brand, dose, symptoms etc). If you decide not to answer the questions, this will not affect your participation in the study.

In addition, the researchers will notify the Deakin University Human Research Ethics Committee (DUHREC) of any adverse incidents, events, reactions that have a possible causal relationship with this research.

Has this study been approved by an Ethics committee?

Yes. This study has been reviewed and approved by Deakin University's Human Research Ethics Committee (DUHREC), reference number 2020-073.

Who can I contact about this study?

If you would like further information or have any questions about the study, please contact:
Dr Elizabeth Holmes-Truscott (e: [redacted] t: [redacted]),

Professor Jane Speight (e: [redacted] t: [redacted]), or

Dr Edith Holloway (e: [redacted] t: [redacted]), at the ACBRD.
To find out more about the work of the ABCRD, you may like to visit the website: www.acbrd.org.au.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:
The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125,
Telephone: [redacted], email: [redacted]. Please quote project number 2020-073.

Consent Form

Please tick the box at the bottom of the page to indicate your agreement with each statement.

- I have read and I understand the Plain Language Statement.
- I freely agree to participate in this project according to the conditions in the Plain Language Statement.
- I have access to a copy of the Plain Language Statement and Consent form to print and keep.
- I understand and consent to completing three online surveys: at entry into the study, two-weeks and 6-months later. I will also be invited to explore web-based resources about type 2 diabetes and injecting insulin.
- I understand that if I report any adverse events (safety issues) associated with therapeutic goods (e.g. medications) I will be contacted and asked a small number of additional questions. If I decide not to answer the questions, this will not affect my participation in the study.
- I understand that the research team will not reveal my identity or personal details to anyone outside the research team, including where information is published or presented in any public form about this research study.
- I understand that the research team or the study funders may use the information I share in a closely related project, or an extension of the current research project, and that this information will be de-identified.

☐ **I have read and understood the information above and agree to take part in this study.**

I am ready to start completing the Attitudes Towards Insulin Study

Withdrawal Form

To be used for participants who wish to withdraw from the project

Date: May 2020

Full Project Title: Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)

Reference Number: 2020-073

***********IMPORTANT***********

Complete this form and return it to us only if you decide to WITHDRAW from the above-named study.

I wish to withdraw from participating in the study entitled 'Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)'. I do not want to take part in any additional study activities ***and*** I do not want the information I have already provided to be included in any analysis or study publications. I understand that withdrawing the information I have already provided will not be possible after completion of the second survey. I understand that withdrawing from the study will not adversely affect my relationship with any of the organisations conducting this study. I understand that withdrawing from the study will not affect the care or treatment I receive from any health professionals.

Participant's name (please print) .....

Participant's signature..... Date.....

Dr Elizabeth Holmes-Truscott

The Australian Centre of Behavioural Research in Diabetes

570 Elizabeth St, Melbourne, VIC 3000

T: [redacted]

E: [redacted]