

The LISTEN Study

Plain Language Statement and Consent Form

Adult with diabetes

Date: December 2021

Full Project Title: LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability

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Associate Investigators: Dr Shikha Gray and Jennifer Halliday, ACBRD, Deakin University, Carolyn Hines and George Company, Diabetes Victoria and Kim Henshaw.

Thank you for your interest in the 'LISTEN' study.

You are invited to take part in this research because you are 18 years or older, living with diabetes, and may benefit from emotional support with managing your diabetes.

In this study, we will test two strategies to support the emotional wellbeing of adults with diabetes. We want to know if these strategies are helpful for people with diabetes.

Taking part means that you may receive up to 4 telehealth sessions with an allied health professional or be provided with links to resources about emotional health and support services. You will also be invited to complete 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.

At the end of this page, you will be asked if you consent to take part in this project. You will then be asked some survey questions to make sure that the project is suitable for you.

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

YOUR PARTICIPATION IS VOLUNTARY

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study, you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

WHAT IS THIS STUDY ABOUT?

Living with and managing diabetes can be emotionally challenging. It can lead to low mood, distress, anxiety or frustration. People may also feel 'burned out' or overwhelmed with managing diabetes. Emotional setbacks can make it harder for people to manage their diabetes. We know from past research that people benefit when emotional support is provided by health professionals.

In this project, there will be two support strategies tested

1. We will test whether a skills-based program (LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network) is helpful for adults with diabetes who are experiencing emotional concerns. LISTEN is a brief, evidence-based program designed to provide people with problem-solving skills. These skills may help people to manage the daily challenges of diabetes and also to improve their emotional well-being. LISTEN is delivered via telehealth, by diabetes allied health professionals, including diabetes educators, dietitians, nurses, who have been trained in the program.
2. We will compare LISTEN with support strategies currently available to people with diabetes. This includes receiving links to resources specifically for people with diabetes and their emotional wellbeing, links to support services and if needed referral to their GP to discuss the best support for their emotional wellbeing.

We will test if LISTEN is effective for improving emotional wellbeing; we will also collect data on the cost of delivering LISTEN; and explore if it is practical to provide this service to people with diabetes.

We aim to recruit 300-390 adults with diabetes into the study.

WHO CAN TAKE PART?

To be eligible for this study, you must:

- be an adult (≥ 18 years) with diabetes
- currently living in Australia
- currently experiencing emotional distress
- have access to the internet via a computer, laptop, tablet or smart phone

If you participated as volunteer training case for this study, you are not eligible to take part.

If you consent to take part in this study, you will be directed to a brief online survey to check that you are eligible to participate. The survey will have questions about you and your emotional wellbeing.

If you do not meet the eligibility criteria, you will be notified immediately and will not be able to proceed further. You may be provided with links to resources and mental health services that can support you with your mental health.

WHAT WILL TAKING PART INVOLVE?

Completing three online surveys:

- The **first** survey will be upon entry to the study. You will be directed to this survey after you agree to take part (and you are eligible).
- The survey will have questions about you, your diabetes and your emotional wellbeing.

- 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.
- The **second** survey will be emailed to you eight weeks later and the **third** survey will be emailed to you at 6-months.
- The follow-up surveys will have questions about your emotional wellbeing. You may also be asked to provide feedback on strategies that you have used to support your emotional wellbeing since the start of the study.
- Each survey will take 20-30 minutes to complete

After you have completed the **first** online survey on entry into the study, you will be allocated to one of two groups. You may be allocated to the intervention (LISTEN) or control (standard care) group. You have a 50% chance of being assigned to each group (like tossing a coin).

You may be invited to:

- Provided with links to written resources for people with diabetes, about emotional health and mental health support services and if needed, a referral to your GP to discuss the best support for your emotional wellbeing (standard care).

OR

- Receive up to 4 weekly support sessions with a diabetes allied health professional i.e. diabetes educators, nurses, and dieticians (intervention)
 - The sessions will be via phone or video call.
 - Each session will last about 45-60 minutes.
 - The allied health professional will support you in setting personal goals and in using problem-solving skills. You will be given worksheets and resources to use between sessions.
 - To ensure the sessions are being delivered correctly, we will ask for some of your sessions with the allied health professional to be audio-recorded. These recordings will be reviewed by the research team and will be kept confidential.

If you are in the intervention group, you may also be

- Invited take part in a telephone/zoom interview and provide feedback on the sessions. The interview would take around 30 minutes to complete and would be recorded.
- Provided with a referral to your primary health care provider (e.g. general practitioner, GP) to discuss how you are feeling emotionally. The letter will outline your participation in the LISTEN sessions and reason(s) for participation (e.g. that you may be experiencing diabetes distress or mental health problems).

Note: as part of the study, you will not be asked to make changes to your diabetes management plan.

MEDICARE BENEFITS SCHEDULE (MBS) AND/OR PHARMACEUTICAL BENEFITS SCHEME (PBS)

After you have provided consent to participate in this project, you will be asked to sign a separate consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The purpose of collecting this data is to understand other health services you may be using and whether the LISTEN intervention impacts the services that you use.

The consent form is sent securely to Services Australia who holds MBS and PBS data confidentially. Signing this consent form is voluntary. If you decide not to sign the MBS/PBS consent form it will not affect your participation in the LISTEN Study and you will still be eligible to take part.

WHO IS CONDUCTING AND FUNDING THIS STUDY?

The study is being coordinated by researchers at the Australian Centre for Behavioural Research in Diabetes (ACBRD), a partnership for better health between Diabetes Victoria and Deakin University.

This project received funding from the Australian Government's Targeted Translation Research Accelerator (TTRA) program, delivered by MTPConnect. MTPConnect 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). Reports summarising the findings from the project will be shared with MTPConnect. Your personal and contact details will not be shared with MTPConnect.

In addition, this project is in partnership with Diabetes Australia/The National Diabetes Services Scheme, Diabetes Victoria and the Australian Diabetes Educators Association.

The Lead Investigator takes responsibility for the study. Participants will only be contacted by the research team including the Lead Investigator, the study Project Manager or Psychologist.

WHAT ARE THE BENEFITS TO ME IN TAKING PART?

Research shows that people who experience distress related to their diabetes, can benefit from emotional support from a health professional.

- By taking part in this study, you may learn (or strengthen existing) problem-solving skills. These skills may help you manage the emotional aspects of living with diabetes.
- By taking part in this study, you will be helping us to learn if different strategies are helpful for improving emotional wellbeing in people with diabetes.
- In addition, participants who complete the study (i.e. complete all three surveys) will receive a \$30 e-gift card that can be used at over 20 major retail stores in Australia.
- Participants who are randomly selected to take part in interviews to provide feedback on the LISTEN sessions will receive a \$25 e-gift card that can be used at over 20 major retail stores in Australia.

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).

ARE THERE ANY RISKS TO ME AND HOW WILL THOSE RISKS BE MANAGED?

We do not believe you will be at risk of harm. However, during the study, you will be asked to reflect on the challenges you face with your diabetes. This may feel uncomfortable or upsetting.

If you should become upset during the study (e.g., when completing online surveys, the phone interview, or during/between sessions), you can skip any questions in the survey (or interview) and you may stop the survey, interview or sessions 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. The research team includes a psychologist (Dr Gray) who will be able to assist with your concerns. If you feel distressed during a session, you will have the immediate support of the allied health professional on the call.

If, as a result of participation, you do become distressed, you may wish to seek further information and support. We can assist you in accessing alternative or additional support, if that is what you want.

In addition to the risks outlined in this document, we recognise the challenging circumstances the COVID-19 pandemic has caused for many community members. As such, we would like to highlight that if you, or those close to you are experiencing distress, or are in need of additional support, you are encouraged to contact beyondblue: Beyondblue – National Information Line Ph: 1300 224 636 or visit: <http://www.beyondblue.org.au/>

If taking part in the study raises any questions about your diabetes, we encourage you to contact your usual health professional or to call the NDSS Helpline: 1800 637 700.

WILL TAKING PART IN THIS STUDY COST ME ANYTHING, AND WILL I BE PAID?

Taking part in the study will not cost you anything. Participants who complete the study (i.e. complete all three surveys) will receive a \$30 e-gift card that can be used at over 20 major retail.

CAN I WITHDRAW AT ANY TIME?

Your involvement in the study is completely voluntary. If you do not want to take part in this study you do not have to. You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

Choosing not to participate or choosing to participate and then withdrawing, will not affect your relationship with the research team, ACBRD, Deakin University, Diabetes Australia/NDSS, Diabetes Victoria or the Australian Diabetes Educators Association. Choosing not to take part in this study will not affect your current and future medical care in any way.

If you decide to withdraw while answering the initial online survey (next pages), simply exit the browser window.

You can withdraw from the study at any time by completing and signing the 'Participant Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

When withdrawing, you can elect for any information you've shared with us to be removed from our analysis. However, once the study is closed, your data will be de-identified, which means we will be unable to delete any information you shared with us that we cannot match to you.

WHAT INFORMATION ABOUT ME WILL BE COLLECTED?

We will record the following information:

- Your name and contact details
- Survey data: information about you, your diabetes and your emotional wellbeing, your feedback about different emotional support strategies.

If you participate in the sessions with a diabetes allied health professional:

- The number of sessions you complete.
- Some of your sessions with the diabetes allied health professional will be audio recorded. These will be reviewed by the research team and will help the research team to better understand if the program is being delivered by the allied health professional as described in their training.
- We may also collect any worksheets that you complete during/between sessions to assist with training and supervision. The diabetes allied health professional will make session notes to assist in their own reflection of their work.
- Case notes during the sessions and, if applicable, a referral to further mental health support may also be recorded and summarized in the project reports.

The research team and the allied health professionals will treat your information with strict confidentiality. The following measures will be taken:

- All information will be stored in password-protected folders on the Deakin University secure networks.
- Only the Deakin research team will have access to all the information you share.
- The diabetes allied health professional will only have access to: your initial survey data, any session recordings, any worksheets you complete. These will be saved on a secure Diabetes Victoria server. They will not have access to the feedback you provide to the research team in the surveys at the end of the sessions.

Please note that if you were to disclose being at risk of harm to yourself or someone else, we would be legally required to seek assistance from an appropriate service. In this case, we will not be able to maintain confidentiality.

WHAT WILL HAPPEN TO MY INFORMATION AT THE END OF THE STUDY?

Any information you share with us will remain strictly confidential, except where disclosure is required by law.

- What Diabetes Victoria will do: Diabetes Victoria, as an organisation, will keep a record of the fact that you took part in the sessions and the number of sessions you completed. This information is required by the organisation and recorded on their case notes. They will not share this information with anyone outside of the organisation. Recordings of the sessions will be sent by the allied health profession to the Deakin research team in a password protected file

immediately following the session. Recordings will be deleted from Diabetes Victoria's server in accordance with the organisation's policy and procedures.

- What the Deakin research team will do: we will keep all your data in a password-protected folder on the Deakin University server that can only be accessed by Deakin researchers. We will de-identify your data: we will remove your name/contact details from any survey, interview or session files or recordings. 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.

We may publish or present results of the study in academic journals, at conferences, and in diabetes magazines and newsletters. A plain language summary of the overall study findings will be published on ACBRD website. You can access any study reports on the ACBRD website (www.acbrd.org.au). No-one will be able to identify you from what we publish or present.

It is possible that in the future we may share anonymous (de-identified) data from the surveys with researchers who want to do further analysis. No-one will be able to identify you from the data we share.

At the end of the 6-month survey, if you agree to be contacted by the ACBRD, you will be added to the ACBRD e-newsletter distribution list for news about study results and may be contacted about future opportunities to take part in research.

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.

THE LISTEN INTERVENTION

If the results from this project show that LISTEN is helpful and practical to deliver to people with diabetes, LISTEN may be rolled out across Australia and available to access via the National Diabetes Services Scheme (NDSS). At the end of the 6-month follow-up survey, participants will be asked if they would like to be contacted if/when LISTEN becomes publicly available.

WHO SHOULD I CONTACT IF I HAVE ANY QUESTIONS ABOUT THE STUDY?

If you would like further information or have any questions about the study, please contact:

- Dr Edith Holloway (eholloway@acbrd.org.au t: (03) 924 46382), Project Manager
- Dr Christel Hendrieckx (e: chendrieckx@acbrd.org.au, t: (03) 924 46590), Lead Investigator

Please note that this study has been approved by Deakin University's Human Research Ethics Committee (DUHREC), reference number 2021-412.

COMPLAINTS

If you have any concerns about your rights as a participant or any complaints about any aspect of the study, you may contact: The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au. Please quote project number 2021-xxx.

Consent Form

Adult with diabetes

Date: December 2021

Full Project Title: LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability

Reference Number: 2021-412

If you would like to participate in this study, and agree with each statement, please indicate by ticking the box at the bottom of the page.

I have read the Plain Language Statement and I understand that:

- My decision to take part in the study is voluntary
- Taking part in the study means:
 - Completing three online surveys: on entry into the study, 8 weeks and 6-months later
 - I may be:
 - Invited to take part in up to four (45-60 minute) sessions with a diabetes allied health professional.
 - These sessions will be delivered via telehealth (i.e., telephone or videoconference).
 - Some of my sessions with the with a diabetes allied health professional will be audio-recorded for supervision purposes.
 - A telephone/zoom interview with a member of the research team to provide feedback on the sessions.
 - provided with a referral to my primary health care provider (e.g. GP) to discuss how I am feeling emotionally.
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OR

- Be provided with links to resources and services that can support me with my emotional health and if needed, a referral to my GP to discuss support for my emotional wellbeing.
- I will be asked to sign a consent form authorising the study to access your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data. Signing this form is voluntary.
- I may withdraw at any time without impacting my relationship with any organisations involved in the study
- the research team and participating diabetes allied health professionals will not reveal my identity or personal details to anyone external
- I can download a copy of the Plain Language Statement and Consent form to print or save: PDF

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

Withdrawal Form Adult with diabetes
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To be used for participants who wish to withdraw from the project

Date: December 2021

Full Project Title: LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability

Reference Number: 2021-412

*******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 'LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability'. 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 once the study is closed. This is because my data will be de-identified and merged with other people's data. 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.....

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