DEAKIN UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE
PROJECT DESCRIPTION/PROTOCOL

Instructions for preparing the project description/protocol

1. The purpose of the Project Description is to provide the scientific and academic background and context of a research project.
2. A Project Description is a **mandatory** component of a submission using the Human Research Ethics Application (HREA).
3. The section headings in this Project Description template represent a structure for presentation of information about a research project that meets the needs of an ethics review body.
4. Not all headings or sub-headings in this template are relevant for each research project. Where a question is not relevant please enter NA into the response box. Please do not delete the question.
5. Researchers may use visual aids embedded in the project description/protocol to assist in describing their project where appropriate (e.g. images, videos etc.).
6. Submissions of clinical trial proposals may use alternative protocol templates, such as the SPIRIT statement.
7. Researchers may choose to submit an existing document (such as a protocol or project description that has already been developed) instead of developing a new document.
8. If researchers choose to submit an existing document instead of using one of the templates provided, they may need to provide indications to the ethics review body of where in the submitted document the content corresponding to the relevant fields in the template are located.
9. There is no need to duplicate information in the HREA into the Project Description or vice versa.
10. Language that is understandable to non-technical reviewers should be used.

COVID-19

Please indicate whether:

☐ Your project is not designed to align with current COVID-19 restrictions and

a. will be delayed until all restrictions are lifted and
b. will be modified with approval prior to commencement if unforeseen flow-on effects from the virus raise new ethical issues OR

X Your project will be conducted once approval is granted and you have described in this application how the project's design aligns with:

a. The current COVID-19 restrictions,
b. Deakin's COVIDSafe Management Plan and
c. Any applicable COVIDSafe Activity Plan in place for high COVID risk activities.

☐ Where your project may include COVID-19 related risks, please acknowledge that you have taken into consideration the information provided on the FAQs - Human Research Ethics site.

Please indicate whether your research will include direct or indirect questions related to the participants' lived experience of COVID-19? Yes ☐ No X

a. If Yes, tick to confirm you have:

☐ Included an appropriately tailored version of the following statement in your Plain Language Statement:

Low risk projects only

"While it is not expected that participating in the research will cause you to feel distress, 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 [insert appropriate contact details for your participants e.g. Beyond Blue, Lifeline, Suicide Call Back Service, Headspace, Kids Helpline etc.]."

Higher than low risk projects

"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 [insert appropriate contact details for your participants e.g. Beyond Blue, Lifeline, Suicide Call Back Service, Headspace, Kids Helpline etc.]."

X As applicable, included the same statement at the conclusion of your survey/ questionnaire/ research instruments.

b. And that you will:

X Immediately review all research data for any disclosures of heightened distress, suicidal ideation or attempts or self-harm. Researchers who are unable to review their data immediately or who need clarification on what kind of time frame constitutes an acceptably prompt review, should contact research-ethics@deakin.edu.au to discuss their options.

X Report disclosures as described above on the FAQ website.

1. Project details:

1.1 Please provide the project title: LISTEN - Low Intensity mental health Support via a Telehealth Enabled Network for adults with diabetes and CVD: Effectiveness and scalability

1.2 Please provide an acronym for the project (if appropriate): LISTEN

1.3 Please provide the project description/protocol version number: Version 5.0_March 2023

2. Project Team Roles & Responsibilities:

2.1 Please provide the names, affiliations, positions and responsibilities of individuals involved in the project beyond those outlined in the HREA (e.g. technical or support staff).

Jennifer Halliday, Associate Research Fellow and PhD candidate (ACBRD/Deakin University)

Responsibilities: Jennifer Halliday is an early career researcher who has expertise and an interest in developing mental health interventions to upskill health professionals in diabetes care. Jennifer will provide input into the project design, development and contribute to manuscripts reporting on the project findings.

George Company, National Diabetes Services Scheme (NDSS) Help Centre Manager (Diabetes Victoria)

Responsibilities: George Company will assist with recruitment of participants with diabetes via NDSS Helpline for the effectiveness trial (Objective 3) and oversee the program integration into NDSS Helpline services.

Kim Henshaw, Stakeholder (consumer representative, person with diabetes)

Responsibilities: Kim Henshaw brings the consumer's perspective and will consult with the team throughout the study. Kim has a wealth of experience in increasing the capacity of the workforce to

effectively and respectively engage with consumers. Kim will facilitate stakeholder engagement i.e. people with diabetes and ensure their views are represented in the project.

3. Resources:

3.1 Please provide details of the resources necessary for the project to be conducted, and the funding or support being sought or secured.

This project will be supported by funding from the Medical Research Future Fund's (MRFF) Targeted Translation Research Accelerator (TTRA) initiative for diabetes and cardiovascular disease (awarded $748,384; see **Appendix A** for outcome letter) and in-kind and cash support from our project partners: Diabetes Australia, Diabetes Victoria ($789,317). In addition, this project is receiving in-kind support from Deakin and La Trobe University. The funding support is sufficient to ensure the project meets its stated objectives.

4. Background:
Please provide:

4.1 A lay summary of the literature review (approximately 1 A4 page)

Of the 1.4 million Australians with diabetes, two thirds have cardiovascular disease (CVD) and 50% experience emotional or mental health problems, including diabetes distress, depression and anxiety.(1, 2) Mental health problems are associated with sub-optimal self-management, diabetes-related complications, reduced quality of life, and increased health care costs. (3-6) Undoubtedly, COVID-19 has made the situation worse. People with chronic conditions included diabetes are at greater risk of more serious illness if they become infected;(7) and our previous research has highlighted that COVID-19 contributes to increased distress, stigmatisation and social isolation.(8)

Our previous work demonstrates that people with diabetes have a desire to discuss their emotional health with diabetes health professionals (HPs)(9) and place value on their diabetes HPs showing empathy and having an understanding of the challenges faced in self-managing their condition.(10), Limited psychological support is available in Australia for people with diabetes/CVD. For the majority, mental health problems are of mild-to-moderate severity and would benefit from early intervention services that may prevent symptoms from progressing to more severe levels of psychological distress (e.g. major depressive disorder). 'Low intensity' mental health (LIMH) support focuses on supporting self-management and skills development; it is short-term, and provides a key service platform within a stepped care[1] approach. These interventions typically do not require delivery by a mental health professional and there is encouraging evidence for their effectiveness and cost-effectiveness.(11)

In the wake of the current pandemic, novel approaches to service delivery are clearly needed to ensure that all Australians with diabetes have access to appropriate mental health support. Two successful global mental health strategies are relevant in the context of COVID-19. The first is the training of (non-mental) health professionals to expand the provision of LIMH services.(12) Diabetes HPs are well placed to deliver evidence-based strategies for the prevention and early intervention of emotional and mental health problems in people with diabetes. Indeed, previous research demonstrates that people with diabetes have a preference for receiving emotional support from their HP rather than a psychologist.(13) The second strategy is the use of technology to deliver health services.

At its core, the LISTEN solution provides individuals with diabetes of whom 70% will also have CVD with practical skills in *problem-solving*, a fundamental skill in self-managing chronic conditions.(14)

[1] An evidence-based, staged system comprising a hierarchy of interventions, from the least to the most intensive, matched to the individual's needs

Interventions that promote problem-solving skills are effective for improving mental health outcomes.(15) Problem Solving Therapy (PST) is an evidence-based, psychological intervention in which the person is supported by the allied health professional (AHP) to learn about and apply problem-solving strategies in a structured way to support both their mental and physical health. A low-intensity version, of ~4 sessions has been developed, suitable for delivery by a broad range of AHPs in various settings.(16-18) Meta-analyses demonstrate that PST is significantly more effective than no treatment, attention/placebo, and treatment as usual in treating mental health problems and in reducing subthreshold symptoms, resulting in a significantly larger effect sizes.(19, 20)

Low-intensity PST has been adopted within the Improving Access to Psychological Therapies (IAPT) program in England. IAPT experience shows its scalability – now operating in all 209 local health regions in England, having served 1.1 million people over 10 years,(21) representing 16% of the community prevalence of subthreshold depressive and anxiety symptoms. More than three quarters of those completing a course of IAPT treatment have at least one session of low-intensity PST.

Our previous pilot work has demonstrated that PST reduces diabetes distress and subthreshold depressive symptoms, and produces clinically significant improvements in glycated haemoglobin (HbA1c) among adults with diabetes-related retinopathy.(22) Furthermore, we have demonstrated the feasibility of training AHPs to deliver PST, via telephone, with high fidelity,(23, 24) resulting in clinical value for the benefit of end-users.(23)

We will evaluate the clinical and psychosocial outcomes of LISTEN (see Section 7.1) via a two-arm individual-level pragmatic randomised controlled trial. Pragmatic trials are designed to evaluate the effectiveness of interventions in real-world conditions.

4.2 A rationale/justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice)

Diabetes is a major risk factor for cardiovascular disease (CVD), with national prevalence data indicating that ~70% of people with diabetes have CVD.(25) Diabetes and CVD are both highly comorbid with mental health conditions. 1.4 million people in Australia have diabetes,(26) of whom one in two experience mental health problems.(27) This includes clinically diagnosable mental health disorders (e.g. major depression, anxiety disorders), as well as diabetes distress, and mild-moderate (subthreshold) depressive and anxiety symptoms. Similarly, 1.2 million Australians have CVD,(28) of whom around 40% experience depression (subthreshold and clinical)(29) and 15% experience anxiety.(30)

Despite this burden, around two-thirds of people with diabetes/CVD do not receive mental health support.(31, 32) This is concerning given that mental health problems are associated with the onset/progression of diabetes complications, heart disease, major adverse cardiac events and mortality.(33, 34) This population experiences multiple barriers to receiving mental healthcare including: stigma, cost, lack of awareness about available support,(35) mobility and transport.(32) This gap in mental healthcare is recognised as a national priority in the *Australian National Diabetes Strategy 2016-2020.*(36) Similarly, guidelines strongly advocate for screening, referral and treatment for depression in people with CVD.(29, 37)

The recommended first-line treatment for subthreshold symptoms, and to prevent progression to major disorder, are low-intensity mental health support.(38, 39) This is defined as evidence-based psychological intervention, that promotes self-help and skills development, is brief, low-cost and accessible (e.g. via telephone/online/group) in order to enhance mental health and wellbeing on a community-wide basis, using minimal intervention for maximum benefit.(11) Such services should form an integrated part of a stepped care system. The Australian Government *Productivity Commission Inquiry Report* on Mental Health (2020) identified that low-intensity services are a critical gap in our mental health care system, and recommended expanding low-intensity programs delivered via telehealth to ensure community access.(40)

In this project we will evaluate the effectiveness and cost-effectiveness of the LISTEN intervention. The intervention will be delivered via telehealth, by AHPs employed by Diabetes Australia including diabetes educators, nurses, and dieticians, who have undertaken our brief, evidence-based training program. Our research shows that people with diabetes want to talk about their mental health.(9) Furthermore, they prefer to receive emotional support from their diabetes AHPs than from psychologists.(13) This is because AHPs understand the complexities and demands of chronic conditions. LISTEN enables development of problem-solving, one of seven core diabetes self-management behaviours.(41)
The LISTEN intervention integrates key strategies and guidelines,(36, 37) and aims to overcome known barriers to receiving mental health support, by:
(1) building on existing community-based infrastructure and government investment to provide nationally consistent and equitable low-intensity mental health support, and;
(2) upskilling non-specialist mental health workforces in evidence-based psychological intervention
(3) tele-mental health[2] has the potential to alleviate many barriers (such as fear of contracting COVID-19 and geographical constraints) that stand in the way of people seeking or receiving emotional and mental health support from HPs who understand diabetes.

This project will generate robust clinical outcomes data (2-arm pragmatic randomized control trial) and detailed evaluation of costs (economic evaluation and budget impact modelling) our partners need to inform clinical and commercial translation of LISTEN into a sustainable service, designed to have immediate and lasting positive impact on the mental health of Australians with diabetes.

More effective integration of research evidence into health policy and service delivery: International guidelines call for early integration of psychological support into diabetes care.(42) This project has global relevance, and will be an exemplar of effective integration of research evidence into policy and practice, for how early psychological intervention can be provided in a coordinated, accessible, equitable and sustainable way. The project seeks to address the crucial next step by testing the real-world implementation and effectiveness of LISTEN.

4.3 The research questions/aims/objectives/hypothesis

The overall project aim is to evaluate if LISTEN (Low Intensity mental health Support via Telehealth Enabled Network) delivered via telehealth, by trained AHPs, and administered via Diabetes Australia is a feasible (Objective 2 and 5), effective (Objective 3) and cost-effective (Objective 4) model for improving mental health outcomes in adults with diabetes. We will systematically identify barriers to adoption and implementation of the LISTEN intervention (Objective 5).

We hypothesis that LISTEN will:

- decrease diabetes distress and depressive and anxiety symptoms significantly after 6 months, compared to usual care;
- be cost-effective, with an incremental cost-effectiveness ratio likely to fall below the commonly used threshold of $50,000/quality-adjusted life years (QALYs);
- be more effective when program fidelity is high, which can be influenced through the use of active implementation strategies.

5. Project Design:
Please provide details of:

[2] Tele-mental health refers to the use of information and communications technologies, including videoconferencing, to deliver mental health care remotely. It reduces or eliminates the need for travel for both patients and clinicians and delivers cost-effective remote services while maintaining quality of care

The research project setting

5.1 This may include physical sites, online forums and alternatives

The research will be conducted online and remotely through:

• LISTEN service delivery: phone or video calls (e.g. using Skype or Zoom) between allied health professionals (AHPs) and adults with diabetes participating in the LISTEN program using Diabetes Australia infrastructure

• Collection of effectiveness data: online distribution of surveys developed via Qualtrics (survey development software)

• phone/zoom interviews with participating AHPs, people with diabetes and stakeholders from our partner organisations to explore barriers to adoption and implementation of LISTEN

6. Methodology:

6.1 The methodological approach

We will conduct an effectiveness-implementation hybrid type 1 design informed by the RE-AIM framework.(43) RE-AIM provides a structure for assessing health interventions beyond efficacy, with a focus on translatability into real world settings. The RE-AIM dimensions include reach (R), effectiveness (E), adoption (A), implementation (I), and maintenance (M). We will use mixed-research methods to conduct this project.

Objective 1: Program management, partnership engagement and governance

Methods: Establish a project board responsible for strategic decision making, risk management, outcomes and budget. We will also engage and consult with stakeholders of LISTEN (across our partner organisations) and end-users (people with diabetes) to ensure appropriate trial design and data collection.

Objective 2: To Competently train 4 to 10 NDSS Helpline AHPs in the delivery of LISTEN with demonstrated fidelity

Methods: Between 4 and 10 (and two reserves) diabetes AHPs (nurses, dieticians with diabetes experience) will complete a 4-day workshop following an established training program. The LISTEN training workshops will be delivered by Dr Edith Holloway (EH; Investigator) and Dr Shikha Gray (SG; Associate Investigator). The four-day workshop is derived from an established training program which has demonstrated high-level performance results among trainees (i.e. nurses, social workers, and psychologists). Adapted from an established PST training program(44), the workshops comprise of learning modules that both explain the theory of PST and provide practical skills for facilitating LISTEN sessions, including opportunities to role play a session. Intervention resources (i.e. session narratives, worksheets, checklists, client resources, and the treatment manual adapted for AHPs in Australia) will be provided to AHPs and explained in detail during the workshops. The workshops and training also focus on strategies to strengthen AHPs skills in empathic listening and encouraging support-seeking behaviour. AHPs will be guided on how to address common barriers that people with diabetes may experience in seeking support from a general practitioner (GP) or mental health professional. AHPs will also be familiarised with the mental health referral pathways and processes. Workshops will be conducted via Zoom or in-person (dependant on COVID-19 restrictions). AHPs will be invited to complete pre (**Appendix 6**) and post LISTEN training workshops online surveys (**Appendix 7**). The surveys will take 15-20 minutes to complete.

Following this, AHPs will deliver LISTEN to consenting adults with diabetes (volunteer 'training cases) under clinical supervision from a psychologist (Associate Investigator SG), with a maximum of 4 participants (considered sufficient to achieve competency, see below). Participants who volunteer to

be training cases will receive a maximum of four weekly LISTEN sessions of 45–60-minute duration. With participants' consent, the recorded sessions will be reviewed by SG using the established fidelity tool Problem-solving therapy Adherence and Competence (PST-PAC) Scale (45) ; see **Appendix 14**). The PST-PAC examines fidelity to technical skills, adherence to the problem-solving steps, process tasks, communication and interpersonal effectiveness, and global competence based on the complexity of the client presentation. Competency and fidelity to the intervention components are rated from 0 (*very poor*) to 5 (*very good*). Feedback will be provided to AHPs by the psychologist (SG), via videoconference, following each session. The supervision sessions will be for 30-60 minutes duration. Once AHPs achieve a satisfactory rating for a minimum of 2 training cases, they will be deemed competent to deliver LISTEN for the RCT (Objective 3). Our pilot study (*DUHREC Project Reference*: 2020-297) demonstrated that four training cases was sufficient for AHPs to achieve competency. AHPs will be provided with further training and support and the opportunity to work with an additional training case if needed and if they wish to remain in the project.

Following delivery under supervision, AHPs will be invited to complete a third online survey (**Appendix 7**). The survey will take 15-20 minutes to complete and include rating scales and open-ended questions about their level of satisfaction with the supervised training, further training and support needs and suggestions for improvement.

Objective 3: Generate clinical outcomes data on the effectiveness of LISTEN

Methods: Conduct 2-arm pragmatic individual-level RCT (target sample size N=454-604) to provide evidence of the effectiveness of LISTEN compared to usual care.

Recruitment: Recruitment will be primarily via the NDSS registrant database. Recruitment is described in detail in Section 7.4 (see **Appendix 16** for study recruitment flyer).

Consent and screening for eligibility: People with diabetes who are interested in participating will be directed to a Qualtrics page containing a plain language statement and consent form (PLSCF). An online PLSCF will describe the purpose of the study to participants, the procedures to be followed, the risks and benefits of participation and contact details (email address and telephone number) for the research team in the event of any queries or questions. Prior to completing any study component (i.e. responding to screening questions to determine eligibility), potential participants will need to tick a box to confirm they have read and understood the PLS and consent to taking part. Participants will also be asked to sign a Services Australia consent form to access their Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data. Signing this consent form is voluntary. If they decide not to sign the MBS/PBS consent form it will not affect their participation in the LISTEN Study and they will still be eligible to take part.

Following provision of informed consent, participants will be asked to complete eligibility screening questions (**Appendix 9**; see Section 7.2 for eligibility criteria and Section 13 for a summary of the screening questions). Eligibility will be automatically determined based on responses to the questions. Those who are not eligible (as determined through the screening survey) will immediately be notified and provided with links to the NDSS emotional health factsheets (practical, evidence-based resources about recognising and addressing emotional health problems: https://www.ndss.com.au/living-with-diabetes/health-management/mental-health/). Those not eligible for the project because of indications of 'severe diabetes-distress and moderate-severe symptoms of depression or anxiety' (see Section 7.2) will also be provided with links to external mental health support (e.g. Beyond Blue) and a recommendation to speak with their primary health care provider (e.g., general practitioner). The contact details for a member of the research team will be provided on the Qualtrics form should the individual wish to discuss support available.

Randomisation: Eligible participants will be directed to complete an online (pre-intervention) baseline survey. Following baseline assessment, eligible participants will be randomised to

intervention or control (usual care), using a computer-generated program, to ensure allocation concealment. Randomisation (using stratified random permuted blocks) will be conducted in random blocks (4, 6 or 8), stratified by diabetes type, gender and age (<60; ≥60 years old). Researchers and data analyst will be blinded to group allocation.

The intervention group will receive LISTEN (1-4 weekly sessions; 45-60 minutes each), delivered via telehealth by a trained AHP.

Intervention: The core of LISTEN, problem-solving skills,[3] provides participants with guidance and support to identify problems that may be contributing to their psychological distress; identify clear goals; brainstorm multiple solutions; weigh up pros and cons for each; choose a preferred solution; make a specific action plan to implement it; evaluate the outcomes from the previous session. Participants will work through up to four identified problems causing psychological distress. Participants will receive information and worksheets that will help support them between sessions and plan meaningful and enjoyable activities during the week. Strategies for working through problems that cannot be 'solved' will also be addressed. In addition, AHPs will encourage support-seeking behaviours. They will discuss how and when to seek support from mental health services, and how address their barriers for seeking support from a general practitioner or mental health professional.

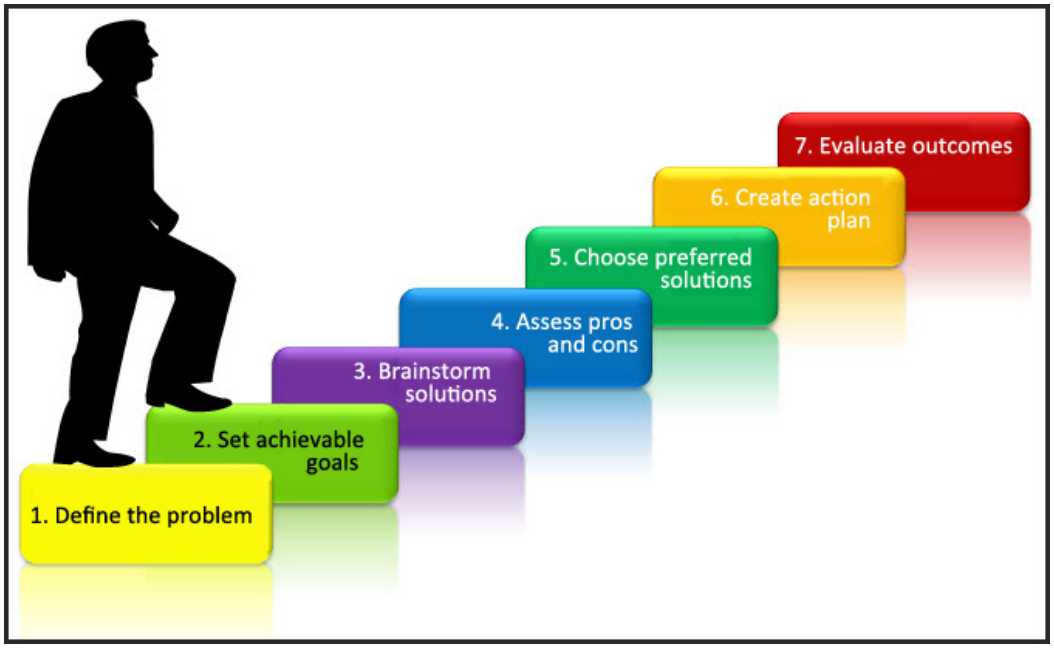

Figure 1. The seven problem-solving skills in the LISTEN program[4]

Control: The control group will receive usual care including weblinks to NDSS factsheets about mental health (freely available on the NDSS website: https://www.ndss.com.au/living-with-diabetes/health-management/mental-health/), as well as links to external mental health support (e.g. Beyond blue) and if needed, a referral to their GP to discuss the best support for their emotional wellbeing. Recruitment will be primarily via the NDSS registrant database.

Outcomes: The primary outcome, diabetes distress, will be assessed at 6 months (primary endpoint) using the Problem Area in Diabetes (PAID) scale. Secondary outcomes will include: depressive and anxiety symptoms, assessed using the Kessler Psychological Distress Scale (K10),(46), emotional wellbeing (WHO-5),[48] and the Coping Self-Efficacy Scale (CSES).(47) The immediate effect (8

[3] Problem Solving Therapy is an evidence-based psychological intervention. The version of PST used in this study is based on a manualised, low-intensity version specifically developed for busy clinic settings that has been adapted for this context with the permission of the authors (Prof Mark Hegel and Prof Patricia Arean).

weeks) of the intervention will also be evaluated. The minimum dose (number of sessions) needed for a significant reduction of the primary outcome, and the clinical/demographic characteristics associated with dose/effect will be evaluated. Baseline demographic and clinical characteristics will be collected. Assessments will be online using Qualtrics TM. The PLSCF, screening questions and baseline survey (**Appendix 9**) and 8-week and 6-month follow-up surveys (**Appendix 10**) are attached. The surveys take 20-30 minutes to complete.

Objective 4: To evaluate the cost-effectiveness and health economic benefit of LISTEN

Methods: A within trial economic evaluation will be undertaken from health sector and partial societal perspectives. The cost to deliver the LISTEN intervention will be undertaken using financial records and micro-costing methods. Within the trial, all study participants will be asked to complete a brief resource use questionnaire at 8 weeks and 6 months to collect information about healthcare resources used and lost productivity. They will also be asked to complete the four-dimension Assessment of Quality of Life (AQoL4D) instrument,(48) a generic health related quality of life instrument that provides preference-based utility scores used to calculate quality-adjusted-life-years (QALYs). QALYs are an outcome metric combining quality and quantity of life used by health technology assessment agencies such as the Australian Pharmaceutical Benefits Advisory Committee. Participants will also be asked for consent to access their Medicare and Pharmaceutical Benefits data (**Appendix 5**).

After the trial-based economic evaluation is complete, a modelled economic evaluation is also planned. This will allow estimates of the costs and outcomes associated with LISTEN across the population of Australia and over a longer time horizon.

Objective 5: Exploring barriers and enablers to Reach, Adoption and Implementation

Methods: Semi-structured qualitative interviews, informed by the RE-AIM Framework, with key stakeholders

Partner organisations: Key stakeholders (n=5-16) across the partner organisations will be invited to participate in the interviews. Participants will include the AHPs who will deliver the LISTEN intervention (see **Appendix 1** for PLSCF and **Appendix 11** for interview schedule), as well as key staff involved in implementation and decision making (see **Appendix 4** for PLSCF and **Appendix 13** for interview schedule).

People with diabetes: A random sample of intervention participants (N=20-30) will be invited to complete a semi-structured interview, purposively sampled based on characteristics including diabetes type, age group (see **Appendix 3** for PLS and **Appendix 12** for interview schedule).

The purpose of the interviews is to explore barriers and enablers to delivery of LISTEN and to identify factors important for implementation and sustainability. This will include perceived usefulness for people with diabetes, resources required for implementation and sustainability, barriers to participants with diabetes receiving LISTEN via telehealth, and preferred modalities, satisfaction with the LISTEN sessions and suggestions for improvement.

The interview will be conducted with a member of the research team who has not been involved in training or supervising the AHPS, via phone or zoom, and will take 20-30 minutes to complete. With the participant's consent (see **Appendix 1**, **Appendix 3** and **Appendix 4**), interviews will be audio recorded. Thematic analysis will be used to analyse the data.

In addition, observational data will be captured during the trial. For example:

Reach - rate of uptake and representativeness of sample;

Adoption - the number of participants completing LISTEN, program/session duration and dose, AHPs' engagement and retention during the training and delivery;

Implementation - evaluation of existing implementation strategies, (training/supervision, clinical pathways)

6.2 The rationale for choices of method/s (tied to project aims/objectives)

There is a large evidence-base to support the LISTEN program: 1) Problem-Solving Therapy (PST), has been shown to be effective in reducing distress, depression, and anxiety in a variety of settings and patient populations (including adults with diabetes and CVD), 2) our previous pilot work (*DUHREC Project reference: 2020-297*) provides preliminary data to support the feasibility and acceptability of training AHPs to deliver LISTEN via telehealth.

This design promotes examination of both (cost) effectiveness and implementation outcomes, rapidly moving knowledge from research to implementation.(49)

7. The participants including:

7.1 A description and the number of participants

Allied Health professionals: 4 to 10 (plus two 'back-ups')

People with diabetes: Up to 40 'volunteer training cases' (max 4 assigned per AHP) (Objective 2), 454-604 trial participants (Objective 3) and a subsample of the trial participants (n=20-30; Objective 5).

Key stakeholders from partner organisations: 5-16 AHPs who deliver LISTEN, project leads and decision makers (Objective 5)

7.2 The inclusion and exclusion criteria

To be eligible to participate, AHP participants must meet the following criteria:

- qualified allied health professional experienced in providing diabetes treatment and/or education to adults with diabetes (a minimum of 12 months working in a diabetes setting)
- previous training or experience in supporting people with emotional problems
- willingness and availability to undertake the training and deliver the LISTEN program

To be eligible to participate as a training case (Objective 2) or participate in the effectiveness trial (Objective 3) people with diabetes must meet the following criteria.

- living in Australia
- aged 18 years or older
- have a diagnosis of diabetes (with or without CVD)
- have a total score of 25 or greater on the Problem Areas In Diabetes (PAID) scale, indicating at least mild diabetes distress
- have a score less than 6 on the four-item Patient Health Questionnaire (50) (PHQ-4; a score greater than or equal to 6 indicates moderate-severe symptoms and warrants further assessment and follow-up)

The following pathways for people with diabetes will be applied depending on their scores:

Table 1: Eligibility criteria for the RCT (Objective 3) in terms of mental health screening

Participants' score on:		**Criteria**	**Eligible**
PAID (0-100)	*PHQ-4*		
Total <25	<6	No/minor diabetes distress and no/mild general symptoms	No[a]
Total <25; and ≥2 on ≥3 items[#]	<6	Mild diabetes distress and no/mild general symptoms	Yes
Total 25-75	<6	Moderate-to-severe diabetes distress but no/mild general symptoms	Yes
Total >75	<6	Severe diabetes distress but no/mild depressive or anxiety symptoms	Yes
Total >75	>6	Severe diabetes distress plus at least moderate depressive or anxiety symptoms	No[b]

Score of ≥2 on a PAID item = at least moderate problem;
[a.] Offered referral to NDSS factsheets about emotional health;
[b.] Provided with resources / referral to MH services and/or a referral to their GP

To be eligible to participate in the semi-structured interviews (Objective 5), stakeholders from the partner organisations must be an AHP who is a consenting participant in the project, or is a staff member employed at one of the partner organisations who is involved in the service delivery of the LISTEN intervention.

7.4 Your participant recruitment strategies and timeframes (as required in addition to that outlined in the HREA)

Allied Health professionals: will be recruited via newly appointed and existing AHPs who provide 'on-call' services via Diabetes Australia. Diabetes Australia will oversee the recruitment of newly appointed and existing AHPs during the first two months of the project. Recruitment adverts will clearly describe what is involved in the project, the expectations from the position and time commitment. Interested AHPs can apply for the position directly through our partners who will be responsible for advertising the positions. The volunteer AHPs will be provided with a Plain Language Statement (**Appendix 1**) and their informed consent will be required before they can participate in the project. Existing AHPs who provide 'on-call' services via the NDSS Helpline will be provided up to two weeks to consider participation. Diabetes Australia will commit four to 10 diabetes AHPs to participate in the project and two additional diabetes AHP to participate in the workshop only.

People with diabetes:

1) 'Training cases' (Objective 2). Recruitment of target sample (N=≤40) is planned for a 2-month period.

Participants who consent to being volunteer 'training cases' (**Appendix 2**) will be recruited via the NDSS Registry, of whom, approximately 1.4 million people are registered. The NDSS will send out invitations, via e-mail, directly to registrants who have consented to be contacted about research. The research team will not have access to potential participant's details unless they contact us regarding the study, or they enrol into the study.

The final number of people with diabetes recruited to volunteer for 'training cases' will be determined by the AHPs' ability to deliver LISTEN as intended (as determined by the PST-PAC fidelity measure – see **Section 8.1** and **Appendix 14**).

Volunteer 'training cases' (adults with diabetes who) are interested in participating will be directed to an online (Qualtrics) survey. The Qualtrics survey will begin with a PLS and consent form (**Appendix 2**). Following provision of informed consent, participants will be asked to complete eligibility questions online. Eligibility will be automatically determined based on responses and ineligible participants will be thanked for their interest in the study. Eligible participants will be

directed to complete an online baseline survey to collect demographic and clinical information about the participant (**Appendix 8**).

Volunteer 'training cases' (participating adults with diabetes) will be e-mailed a $50 e-Gift card on completion of the study (i.e. complete pre-post online surveys and a minimum of one LISTEN session) as a token of appreciation and to aid recruitment.

2) Effectiveness trial (Objective 3) and cost-effectiveness (Objective 4). Recruitment of target sample (N=454-604) is planned for a 6-month period.

The primary method of recruitment will be a national e-mail using the NDSS Registry. The NDSS will send out invitations directly to potential participants. The research team will not have access to potential participant's details unless they contact us regarding the study, or they enrol into the study. Our prior experience using the NDSS database for recruitment purposes indicates a response rate of approximately 15%. Thus, to recruit a sample of up to N=454 participants, study invitations, and 2- week follow-up reminders, must be sent to a random sample of at least N=2,600 NDSS registrants. E-mail invitations will be staggered over the 6-month recruitment period.

In addition, the study will be advertised on the ACBRD website, e-newsletter/blogs and social media (Twitter, Facebook) via the researchers' affiliated professional accounts (e.g. Deakin University, ACBRD; see **Appendix 16** for Recruitment Flyer). Australian diabetes charities, organisations and associations (e.g. Diabetes Australia, Diabetes Victoria and other state diabetes organisations) will be notified of, and encouraged to promote, the study through similar online means including the research section on their websites, e- newsletters sent to people with type 2 diabetes (e.g. 'Loop', 'Membership Maters'), as well as their Facebook and twitter accounts. Investigators and colleagues will be asked to consider circulating the study flyer (**Appendix 16**) amongst their networks.

People with diabetes who are interested in participating will be directed to an online (Qualtrics) survey. The Qualtrics survey will begin with a PLS and consent form (**Appendix 3**). Following provision of informed consent, participants will be asked to complete eligibility questions online. Eligibility will be automatically determined based on responses and ineligible participants will be thanked for their interest in the study. Eligible participants will be directed to complete an online baseline survey to collect demographic and clinical information about the participant (**Appendix 9**).

Those who are not eligible (as determined through the screening survey) will be provided with links to the NDSS emotional health and diabetes factsheets (practical, evidence-based resources about recognising and addressing emotional health problems and resources for support). In addition to receiving links to mental health fact sheets, those not eligible for the project because of indications of 'severe diabetes distress and moderate-severe symptoms of depression or anxiety' (see **Section 7.2**) will be provided with links to mental health support services (e.g. Beyond Blue) and recommended to speak with their primary care provider (e.g. general practitioner).

Participating adults with diabetes will be e-mailed a $30 e-Gift card on completion of the study (i.e. complete baseline, 8-week and 6-month follow-up online surveys) as a token of appreciation and to aid recruitment.

3) Exploring barriers and enablers to Reach, Adoption and Implementation (Objective 5).

- Recruitment of 5-16 stakeholders from partner organisations will include AHPs enrolled in the study as well as key staff from partner organisations who are involved in service delivery.

- A random sample of participants assigned to the intervention group will be invited to take part. We will continue to recruit intervention participants until the target sample (minimum 20) is reached.

Recruitment will commence in year 2 of the project.

Participating adults with diabetes in the intervention group who are randomly selected to take part in the semi-structured interviews will be e-mailed a $25 e-Gift card on completion of the study (i.e. complete phone/zoom/skype interview) as a token of appreciation and to aid recruitment.

7.5 Your approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA)

Allied Health professionals: Participating AHPs will be newly employed staff who apply to undertake this role, or existing AHPs employed by Diabetes Australia who actively express an interest and desire in taking part in the study. They will be aware of the study requirements and expectations of their involvement before agreeing to take on the role and consenting to take part in the study. The research team will direct AHPs to an online PLSCF (**Appendix 1**). The PLSCF will describe the purpose of the study, the procedures to be followed, the risks and benefits of participation and contact details (email address and telephone number) for the research team in the event of any queries or questions. Prior to completing any study component, AHPs will need to tick a box to confirm they have read and understood the PLS and consent to taking part. Consent will be voluntary and free from coercion. AHPs will be encouraged to print a copy of the PLSCF for their records.

People with diabetes: All recruitment advertisements for volunteer 'training cases' (adults with diabetes; Objective 2) and participants with diabetes (effectiveness trial; Objective 3) will have a link directing people to an online Qualtrics survey. The Qualtrics survey will begin with the PLSCF (**Appendix 2** and **Appendix 3**). Participants will have the option to download the PLSCF if preferred and will also be able to request for a hard copy of the forms to be posted to them. Participants will need to have read the PLSCF and have agreed to take part in the project (through the online consent form) before they can proceed to the eligibility screening and baseline survey. As described in **Section 7.4**, people will be informed of their eligibility to take part in the project on completion of the eligibility screening survey.

Stakeholders: AHPs and participants allocated to the intervention group will be asked to provide consent to take part in the semi-structured interviews (**Appendix** 2: AHPs and **Appendix 3:** participant with diabetes). Staff involved in service delivery will be required to read and sign an electronic consent form (Appendix 5: Stakeholders) prior to taking part in the interviews.

7.6 If necessary, the type of consent provided to different participant groups, when and where, and any arrangements to confirm that consent

Allied Health Professionals: The PLSCF will be made available to the AHPs via an online Qualtrics link (**Appendix 1**). The PLSCF will describe the study's purpose and procedures, the risks and benefits of participation and contact details (email address and telephone number) for the research team in the event of any queries or questions. Prior to completing any study component (i.e. responding to initial survey), potential participants will need to tick a box to confirm they have read and understood the PLS and consent to taking part. The researchers will then follow up with the participating AHPs by phone to verbally confirm their consent before arranging training dates.

People with diabetes: All advertisements relating to the project will have a link that directs people to a Qualtrics-hosted online PLSCF (**Appendix** 2: AHPs and **Appendix 3:** participant with diabetes). An online PLSCF will be developed and will describe the purpose of the study to participants, the procedures to be followed, the risks and benefits of participation and contact details (email address and telephone number) for the research team in the event of any queries or questions. Prior to completing any study component (i.e. responding to screening questions to determine eligibility), potential participants will need to tick a box to confirm they have read and understood the PLS and consent to taking part. Consent will be voluntary and free from coercion. Participants will be encouraged to print a copy of the PLSCF for their records. The consent procedure will be online.

Stakeholders: Stakeholders from the partner organisations will be e-mailed an electronic copy of the PLSCF. Prior to taking part in the interview, they are required to sign and return the PLSCF confirming that they have read and understood the information and consent to taking part in the project.

Participating AHPs, people with diabetes and stakeholders from the partner organisations will be informed that they can withdraw their consent at any time by contacting the research team or completing the 'Withdrawal Form'.

7.7 If necessary, details of who will be confirming or re-negotiating consent with participants and the process/es that will be undertaken

Not applicable

8. Research Activities:

What you are going to do? Please include:

8.1 The participant commitment

Allied Health Professionals: 12-months (to participate in the LISTEN training, delivery, 3 online surveys, 1 phone/zoom semi-structured interview)

People with diabetes: 6-months (to participate in 3 online surveys). Participants randomised to the intervention arm will receive up to four 45-60-minute LISTEN sessions (estimate of 4-6 week per participant). It is recommended that the sessions run weekly to reinforce the skills learnt. A random sample of participants in the intervention group will also be invited to participate in a 20–30-minute semi-structured feedback interview (**Appendix 12**) via phone or videoconference (Objective 5).

Stakeholders: In addition to AHPs and people with diabetes (intervention group), key stakeholders from partner organisations will be invited to complete a semi-structured interview (via phone/video conference) at a convenient time within a four-week period. The interview will take 20-30 minutes to complete.

8.2 The project duration

2-years (please **Appendix B** for the project timeline)

8.3 Any participant follow-up

Allied Health Professionals: will be invited to complete three brief online surveys to explore satisfaction with the training program (Objective 2). The surveys will be: (1) on entry into the study (baseline/pre-training; **Appendix 6**), (2) following the LISTEN workshops (**Appendix 7**), and (3) following the completion of their supervised training (**Appendix 7**). Following delivery of the intervention during the effectiveness trial, a random sample of AHPs will be invited to complete a semi-structured interview (**Appendix 11**) to explore barriers and facilitators to the delivery of LISTEN in diabetes support services (Objective 5). Interviews will be arranged at a convenient time within a four-week period.

People with diabetes: will be invited to complete three online surveys: on entry into the study (baseline), post-intervention (8-week follow-up) and at 6-month follow-up. A random sample of intervention participants will be invited to complete a semi-structured interview (**Appendix 12**) following the intervention to explore acceptability and satisfaction with the LISTEN program, suggestions for improvement and preferences for modality to participate in the LISTEN intervention (Objective 5).

9. Data Collection/Gathering:

9.1 What information are you going to collect/gather? (as required in addition to that outlined in the HREA)

The following data will be collected:

Objective 2: Allied Health Professional Training

Observational data

During the training stage, all sessions delivered by AHPs ('training cases') will be audio-recorded and assessed for competency using the PST-PAC (**Appendix 14**) strictly for training and supervision purposes. The sessions will be reviewed by two researchers to ensure the intervention is being delivered as intended and to assess inter-rater reliability. AHPs (and 'training cases') are required to provide consent for the sessions to be recorded

Online surveys (**Appendix 6** and **Appendix 7**)

Basic demographic and employment history.

Feedback on training. We will conduct data regarding 1) satisfaction with the program and the training as well as further training and support needs; 2) acceptability and difficulties encountered with the delivery of LISTEN; 3) suggestions for how we can improve the LISTEN training program.

Volunteer 'training cases' (adults with diabetes) will be invited to complete baseline and post-intervention (8-week follow-up) surveys (**Appendix 8**) to explore feasibility and acceptability of the outcome measures for the effectiveness trial, as well as to explore their satisfaction with the LISTEN sessions and suggestions for improving the program.

Semi structured (zoom/phone) interview (**Appendix 11**)

AHPs views on the barriers and enablers to delivery of LISTEN and to identify important factors for implementation and sustainability. The interview schedule is adapted from previously published research.(51)

Objective 3: Effectiveness Trial

Observational data

Program fidelity: During the trial, 20% of sessions will be audio-recorded at random. The sessions will be reviewed by two researchers to assess if the service is being delivered as intended.

We will record the number of people with diabetes recruited into the trial, ease of recruitment (i.e., the time (days) taken to recruit and enrol 454-604 consenting eligible participants), retention of participants in the program (i.e., participant completes at least one LISTEN session and declines further sessions if <4 are completed) , the number of LISTEN sessions completed by participants and retention rate (i.e., proportion of enrolled participants who submit a 8 week and 6-month follow-up survey).

Online surveys (baseline, 8 weeks, and 6-month follow-up) (**Appendix 9** and **Appendix 10**)

We will collect demographic and self-reported clinical data (e.g. age, location, type and duration of diabetes, treatment type).

At each time point, participants with diabetes will be asked questions related to their emotional wellbeing. The primary outcome, diabetes distress, will be assessed at 6-months (primary endpoint) using the Problem Area in Diabetes (PAID) scale. Secondary outcomes will include: the Kessler Psychological Distress Scale (K10)(46), emotional wellbeing (WHO-5)[48] and the Coping Self-Efficacy Scale (CSES) (47) and will be assessed at 6-months. The immediate effect (8 weeks) of the intervention will also be evaluated. Process outcomes: Self-report ratings for goal attainment (Goal Attainment Scale; **Appendix 15**) will be collected during the LISTEN sessions.

At the 8-week follow-up, participants randomised to the intervention group will be asked, using rating scales, to report on their engagement and level of satisfaction with the LISTEN sessions. Those who receive <4 sessions will be asked about their main reasons for declining further sessions.

We will also record the number of participants requiring a referral for additional mental health support, including the links and resources provided.

Objective 4: Economic evaluation

Online surveys (baseline, 8 weeks, and 6-month follow-up) (**Appendix 9** and **Appendix 10**)

Within the randomised trial, data will be collected including the AQoL4D,(48) a generic instrument to generate quality-adjusted-life-years (QALYs). At each follow-up, all participants will complete questions about resource use and productivity impacts (absenteeism and presenteeism). Participants will be asked for consent to access their Medicare and Pharmaceutical Benefits data.

We will also record the cost of delivering LISTEN (including time required for AHPs training, supervision, delivery of the sessions).

Objective 5: Barriers and enablers

Semi-structured phone/zoom/skype interviews

To explore barriers to adoption and implementation of LISTEN, informed by the RE-AIM Framework, with key stakeholders across our partner organisations and end-users (people with diabetes).

AHPs (**Appendix 11**)

The interview will explore AHPs views on the barriers and enablers to delivery of LISTEN and to identify important factors for implementation and sustainability. The interview schedule is adapted from previously published research.(51)

Participating adults with diabetes (***Appendix 12***)

A random sample of participants allocated to the intervention group will be invited to take part in semi-structured interviews via phone/zoom. The interview schedule includes questions about program satisfaction, perceived usefulness of the program, suggestions for improving the program and preferences for delivery modality.

Key staff from partner organisations (***Appendix 13***)

The interview will explore views on the barriers to adoption and implementation of LISTEN, resources required to ensure sustainability and suggestions of how LISTEN can be integrated into routine practice.

9.2 Data collection/gathering techniques: How will you collect/gather the information?

We will use a combination of online surveys and semi structured interviews conducted via phone or zoom/skype as well as observational research.

9.3 Impact of and response to participant withdrawal

Participants are free to withdraw from the study at any time upon their request, for any reason. Participants who request to be withdrawn from the study will be asked to nominate, but not required to provide, a reason for withdrawal. They will be invited to voluntarily share any feedback via email. Withdrawing from the study will not affect their relationship with the researchers, the ACBRD, Deakin University, Diabetes Australia/NDSS, Diabetes Victoria and the Australian Diabetes Educators Association.

Participants will be withdrawn from the study if they are not able to be contacted following randomisation and notified of their group allocation, or if they request to withdraw at any point during the active component of the project. Participants who withdraw will be offered resources about emotional health (NDSS factsheets), links to mental health support (e.g. Beyond Blue) and recommended to speak with their primary health care provider (e.g. general practitioner).

10. Data Management:

10.1 How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather? (as required in addition to that outlined in the HREA)

ACBRD: All participant survey data (including participants' name and contact details along with their eligibility) will be stored in a database (QualtricsTM) on the Deakin University School of Psychology/ACBRD shared networked drive which will be protected by password and up to date cyber security software. Only the Deakin project members listed in the HREA will have access to this password protected Qualtrics account. At the conclusion of the study all Qualtrics data and acceptability data will be downloaded and linked according to participant unique ID. Qualtrics data will be transferred to IBM SPSS. At this stage, identifiable information (email, name) with linking participant ID will be separated from study data and stored in a password-encrypted excel spreadsheet, only accessible to Deakin University project members listed on this protocol and HREA. De-identified quantitative participant data, including participant ID, will be saved as an IBM SPSS file. Thus, the data will be re-identifiable. LISTEN session recordings between AHPs and volunteer 'training cases'/participating adults with diabetes and worksheets will be saved on the Deakin University Deakin University School of Psychology/ACBRD shared networked drive which will be protected by password and up to date cyber security software only accessible to the two Deakin researchers. Qualitative interview data (audio recorded using a computer-based recording device e.g. in-built in Zoom or Skype) will be saved on the Deakin University School of Psychology/ACBRD shared networked drive which will be protected by password and up to date cyber security software. Only Deakin University project members listed on the HREA will have access to this password protected recordings. Audio recordings containing no identifying information will be transcribed by an external professional transcribing service. De-identified data will be imported into NVivo.

Once all people who expressed interest in the study have been followed-up with and the trial is underway, the names and contact details of those not eligible to take part in the project will be deleted. All data files will be clearly labelled with the date and an accurate description of the file (e.g., yearmonthday_file description_version number). Any manipulation or changes made to the data file will be saved with a new version number (as per the above labelling guide) and previous versions retained for record. These will also be recorded and logged in e-mail correspondence.

We do not plan to post the data on a data sharing repository however we would be willing to share the data for secondary analyses with specific future researchers on request, if the project had ethics approval from a Human Research Ethics Committee and the researchers were willing to sign a Data Sharing Agreement that documents how the researchers intend to use the data and how it will be transferred, stored and disposed of. Only the anonymous data from surveys and interviews would be

provided and participants will be informed in the PLSCF of the potential that the anonymous data may be provided to other researchers for secondary analyses (**Appendix 3**).

The data will be stored on a Deakin University Secure Server for a minimum of 15 years following the final publication of the current project, after which it will be destroyed.

Include a data management plan in accordance with National Statement 3.1.45 and 3.1.56.

As per Deakin University's "code of good practice research" the data will be kept for a minimum of 15 years after the last publication of the study. This length of time has been chosen to ensure that there is time to collect all relevant data and also time to review data for publications arising from the project. After a minimum of 15 years from the date of the last publication, data will be destroyed. Information collected in digital form will be deleted (this includes: Survey program, SPSS spreadsheets, other spreadsheets, graphs, audio files, transcripts, and notes and descriptive data). All participants will be informed of how their de-identified information will be collected, stored, used, distributed, and destroyed (in the PLSCF). All surveys will be developed and distributed via Qualtrics online using the Deakin University licencing agreement. As all members of the research team have extensive experience in the field of psychology, diabetes mental health, and research design, no further training will be required to fulfil the aims of the proposed research project.

Diabetes Australia/Diabetes Victoria: Diabetes Australia and Diabetes Victoria have strict privacy and confidentiality policies, which participating AHPs will need to abide by. As part of the organisational procedures, all participating adults with diabetes allocated to the intervention group will have a case created against their name (including name and contact details). The AHPs will record that the participant (adult with diabetes) has taken part in the LISTEN program and any recommendations made by the AHP (i.e., resources or referrals to other services). The worksheet with problems/goals/actions plans etc, specific to the LISTEN program will be attached to the case notes for each individual participant. In addition, a copy will be sent to ACBRD to facilitate supervision and support of AHPs. The case records created for study participants is covered in Diabetes Victoria's Document and Records Management policy. These case notes are considered as Medical Records and are stored for 7 years after the last occasion as per the Health Records Act 2001 Schedule 1 HPP4. Principle 4—Data Security and Data Retention.

The recorded LISTEN sessions with participants will be sent to the ACBRD via a secure, encrypted e-mail at the end of each session. Once received by the ACBRD, they will be deleted from the Diabetes Australia/Diabetes Victoria system using strict protocols. This process will follow for both the 'training cases' (Objective 2) and the trial participants with diabetes (Objective 3).

11. Data Analysis:

11.1 How will you measure, manipulate and/or analyse the information that you collect/gather?

The primary and secondary outcomes will be measured using validated scales. Primary outcome: Diabetes distress (measured using the Problem Area in Diabetes (PAID) scale); secondary outcomes: depressive and anxiety symptoms (measured using the Kessler Psychological Distress Scale (K10), emotional well-being (measured using the WHO-5), coping self-efficacy (measured using the Coping Self-Efficacy scale). Analyses will be conducted on an intention-to-treat (ITT) basis. Repeated measures analysis of variance (ANOVA), or a mixed model analysis (residual maximum likelihood (REML) method) will be used to analyse the primary and secondary outcomes.(52) The null hypothesis, that there is no interaction between assessment time (baseline and T6 months) and trial arm (Control vs Intervention), will be tested using an F-test conducted at the 5% significance level (α=0.05). In the event that some participants have missing assessments at T6 months, the analysis of variance will be replaced by a mixed model analysis using the REML method. A per protocol set (PPS) will be defined prior to any analyses and will be used for a sensitivity analysis of the primary endpoint.

Qualitative data from semi-structured interviews will be de-identified, transcribed verbatim and imported into NVivo. Thematic analyses will be used to explore and identify key themes about participant's experiences of the LISTEN intervention, preferences for modalities and suggestions for improvement as well as perceived barriers and facilitators to adoption and implementation reported by stakeholders from partner organisations.

11.2 Please describe your matching and sampling strategies

The sampling strategy is outlined in section 7.4. Briefly, the primary method of recruitment will be a national e-mail using the NDSS registry. The NDSS will send out invitations directly to potential participants. The research team will not have access to potential participant's details unless they contact us regarding the study, or they enrol into the study (See 7.4 for more details on recruitment). Matching will not be undertaken as participants will be randomised once they have consented to being involved in the study (see 11.3).

11.3 Please outline how you will account for potential bias, confounding factors and missing information

Within the sample that respond positively to being involved in the study, potential bias will be accounted for by randomising to either the intervention or study arm. This will be done using a permuted block approach and will not be undertaken directly by the study team. In the event of missing information/data, this will be accounted for by using mixed model analysis described in section 11.1. Due to the nature of recruitment we will not be able to account for any biases that may exist between those who enrol in the study and those that did not respond to the email invitation.

11.4 Please include your statistical power calculation

We base our estimates upon Rees et al's (22) 6-month diabetes distress (measured with the Diabetes Distress Scale).(3) Assuming an alpha of 5%, we estimate requiring a total sample of N=226-302 participants (n=113-151 per arm), which will allow us to detect an effect size of 0.3 (Cohen's d) with power of 0.8-0.9. Allowing for a 50% attrition rate, we aim to recruit 454-604 participants. Based upon prior experience using the NDSS database for recruitment purposes, with a response rate of approximately 1.5%, we estimate to recruit a sample of N=454 participants, study invitations, and 2- week follow-up reminders, must be sent to a random sample of at least N=30,267 NDSS registrants. E-mail invitations will be staggered over the 6-month recruitment period (see **Section 7.4**).

The revised sample size calculation (amended from the study protocol V4 December 2022) is informed by a review of the completion rates for the incoming 8-week follow-up survey. We currently have a 71% response rate (i.e., ~30% attrition rate) across both the control and intervention groups (N=143/198). We have discussed this with the project statistician and the attrition rate for the 6-month survey is expected to be similar. As such, we anticipate the attrition rate across both time points to be 40-50%.

12. Data Linkage:

12.1 What linkages are planned or anticipated?

People with diabetes consented to participate in the randomised pragmatic trial will also be consented to allow access to their Medicare Benefit Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. This process is governed by Services Australia and requires completion of a separate consent form (**Appendix 5**). The data that is provided will cover the same time frame of study participation and the data will be linked by a unique study identifier to the other trial data. The benefit of using MBS and PBS administrative data is its accuracy for identifying specific service use and the cost paid by the commonwealth government and the out-of-pocket costs paid by

participants. MBS/PBS data is complete and is not prone to recall bias which is an important limitation of resource use questionnaires. The MBS/PBS data will be requested at the end of the trial after the last follow-up of the last trial participant to ensure all resource use during the trial period (including follow-up) is captured.

13. Outcome measures:

13.1 Please describe your outcome measures

Objective 2: LISTEN Allied Health Professional Training

AHP competency and fidelity will be assessed using the adapted Problem-Solving Adherence and Competence Scale (PST-PAC; **Appendix 14**).

Objective 3: Effectiveness Study (RCT)

Baseline demographic measures will be gender, age, education, marital status, employment status and clinical characteristics.

Primary outcomes: Diabetes distress will be assessed with the Problem Area in Diabetes (PAID) scale (46). Responses on the PAID will be summed and transformed to generate a scale score from 0-100, with ≥40 indicative of severe diabetes distress. The PAID scale has excellent reliability, validity and sensitivity to change.48, 49

Secondary outcomes: Depressive and anxiety symptoms (Kessler Psychological Distress Scale (K10)), emotional well-being (5-item World Health Organization Well-Being (WHO-5) Index),(53). Coping strategies will be assessed using the Coping Self-Efficacy Scale (CSES).(47)

The immediate effect (8 weeks) and sustained effect (6 months) of the intervention on diabetes distress, depressive and anxiety symptoms and secondary outcomes will also be evaluated.

Process outcomes. The Goal Attainment Scale will be used to evaluate the extent to which participants' individual goals are achieved. Quality-adjusted-life-years (QALYs) – important for Objective 4 – will be generated using the Assessment of Quality of Life 4 dimension (AQoL-4D),(48) a generic health-related quality instrument. We will also investigate the minimum number of sessions needed to achieve significant initial and sustained reductions in diabetes distress. These findings will inform the economic evaluation

Objective 4: Economic evaluation

A detailed costing will be undertaken using financial data and micro-costing methods. Within the trial, participants will be asked to complete a brief resource use questionnaire to collect information about other health care resources used and lost productivity. The AQoL-4D is a 12 item self-completed questionnaire that will also be collected. The scoring algorithm provides a total utility score on a scale from 0 to 1 based on Australian preferences for specific health states represented within the response items. The utility values at each time point are then used to calculate quality-adjusted-life-years (QALYs) using the area under the curve method.

Objective 5: Barriers and enablers to reach and implementation

Reach: Response rates and time to recruit the target sample will be monitored via the online registration system (Qualtrics). We will examine response rates by diabetes type, age group, and regional/remote areas.

Adoption: We will document AHPs' engagement and retention with program delivery during the effectiveness trial (WP3) as well as the number and characteristics (e.g. state) of AHPs continuing to deliver LISTEN during the trial. We will explore barriers and enablers to adoption of the LISTEN intervention via semi structured interviews with a random sample of the intervention group

Implementation: We will record the duration and number of training sessions needed for AHPs to achieve competency; the number of participants completing program; program duration and dose, and session duration. To evaluate the relationships, we will review a random selection (20%) of LISTEN session audio-recordings, including the intended program content and therapeutic techniques used.

Barriers and enablers to *Reach*, *Adoption*, *Implementation* and *Sustainability* will be explored using semi-structured telephone interviews with key stakeholders. We will adapt an interview guide developed and published previously (51) and informed by the Consolidated Framework for Implementation Research (CFIR).(54)

Table 2. Summary of the outcome measures collected
Participants: people with diabetes/CVD

Concepts	Variables or Measures	Timepoint			
		Screening	Pre-intervention (Baseline)*	Post-intervention (8-weeks)	6-month follow-up
Demographics and clinical characteristics	Place of residence (country, state), diabetes diagnosis	X			
	Name, contact details, age, gender, country of birth, relationship status, employment status, highest education		X		
	Type of diabetes, diabetes duration, current management regimen		X		
	General physical and mental health co-morbidities		X	X	X
Psychosocial	PAID (diabetes distress)	X		X	X
	PHQ-4 (screening - depressive/anxiety symptoms)	X			
	K10 (depressive/anxiety symptoms)		X	X	X
	WHO-5 (emotional well-being)		X	X	X
	CSES (coping skills)		X	X	X
Process outcomes	Goal-attainment Scale				X
Ecconomic evaluation	AQoL-4D		X	X	X
	Resource use and productivity impacts questionnaire			X	X

Satisfaction with LISTEN	Rating scales, reasons for engaging in <4 sessions			X	
Satisfaction with LISTEN, barriers and enablers to program adoption	Semi-structured phone/zoom interviews (rating scales and open-ended survey questions				X
Participants: diabetes AHPs					
Concept	**Measures**	Timepoint			
		Pre-training	Supervised training	Post-training	During trial
Demographic and professional characteristics	Age, gender	X			
	Qualifications, prior work experience, prior training in mental health	X			
Program fidelity	Problem-Solving Adherence and Competence Scale (PACS), session recorded and reviewed		X		X
Training needs and expectations, satisfaction, suggestions for improvement	Online survey (likes/ dislikes/areas for improvement)	X	X	X	
Barriers and enablers to adoption/ implementation	Semi-structured interview (informed by RE-AIM, CFIR)				X
Participants: stakeholders (partner organisations)					
Concept	**Measures**	Timepoint			
		Pre-training	Supervised training	Post-training	During trial
Demographic and professional characteristics	Age, gender	X			
	Qualifications, prior work experience, prior training in mental health	X			
Barriers and enablers to adoption/ implementation	Semi-structured interview (informed by RE-AIM, CFIR)				X

* pre-intervention' survey measures will be completed at the same time as the screening survey

14. For research involving an investigational drug or device as part of a clinical trial:
14.1 What is/are the drug(s) and/or device(s):

- Approved name
- Trade name (if any)
- Manufacturer
- Supplier of drug/device (e.g. manufacturer/pharmacy)
- Approved therapeutic indication, dosage/duration in Australia
- Believed mode of action
- Dosage regimen
- Mode of excretion
- Known adverse events
- Known contra-indications or warnings
- If arrangements have been made for a Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project

15. Results, Outcomes and Future Plans:

15.1 Please outline your plans for return of results of research to participants – include an ethically defensible plan in accordance with National Statement 3.1.65 or 3.2.15 or 3.3.36-3.3.61, as appropriate.

All participants (people with diabetes and AHPs) will be advised that the findings of the research project will be reported in research publications and conference presentations, and a plain language summary will be published on the ACBRD website.

15.2 Please describe your plans for dissemination and publication of project outcomes

Project outcomes will be used for journal publications and conference presentations. Interim and final reports will be prepared for the funding body (MTPConnect).

15.3 Please list other potential uses of the data at the end of the project

De-identified data may be shared with researchers for secondary analyses as recommended by the National Statement on Ethical Conduct in Human Research. All participants will be informed of the potential for sharing of data with researchers for secondary data analysis in the PLS and Consent form and can choose not to participate as a result of this information.

The funders (MTPConnect) will be provided with reports that summarise the findings from the study. They will not be provided with any personal or identifiable participant data, but rather a summary of the findings.

Similarly, the Australian Government Department of Health and other partner organisations (i.e. Diabetes Australia and Diabetes Victoria) may be provided with reports that summarise the findings from the study. They will not be provided with any personal or identifiable participant data, but rather a summary of the findings. The purpose of the reports is to support implementation and scalability of the LISTEN intervention.

15.4 Please detail the project closure processes

The project will be closed once all the follow-up data have been collected.

15.5 Please outline your plans for sharing and/or future use of data and/or follow-up research

Due to recommendations outlined by the National Statement on Ethical Conduct in Human Research, de-identified data may be shared with researchers for the purposes of secondary data analyses following completion of the current study. Although no plans have been made for secondary analyses at this time, participants will be informed in the Information from of the potential for secondary analyses in the future. Data files must be stored for a minimum of 15 years following the last publication from the current project, after which all data files will be destroyed.

15.6 Please describe any anticipated secondary use of data

N/A

DECLARATION AND SIGNATURES

I/We, the undersigned declare that the information supplied in this application (including the attached original application) is true and accurate to the best of my/our knowledge.

I/We the undersigned have read the *National Statement on Ethical Conduct in Human Research* and accept responsibility for the conduct of the project detailed in this application in accordance with the principles contained in the Statement and any other conditions laid down by Deakin University Human Research Ethics Committee.

I/We the undersigned, declare that where the research project may involve contact with a child or young person under the age of 18, I/we have a current Working with Children Check.

Principal investigator

Name: Dr Edith Holloway

Signature 

Date: 03/10/2022

Associate investigator

Name: Dr Christel Hendrieckx

Signature 

Date: 03/10/2022

Associate investigator*

Name: Prof Jane Speight

Signature  Date: 03/10/2022

Associate investigator

Name: Prof Timothy Skinner

Signature  Date: 03/10/2022

Associate investigator

Name: Prof Cathy Mihalopoulos

Signature  Date: 03/10/2022

Associate investigator

Name: Assoc/Prof Vincent Versace

Signature  Date: 03/10/2022

Associate investigator

Name: A/Prof Adrienne O'Neil

Signature  Date: 03/10/2022

Associate investigator

Name: Dr Virginia Hagger

Signature 

Date: 03/10/2022

Associate investigator

Name: Dr Shikha Gray

Signature  Date: 03/10/2022

Associate investigator

Name: Carolyn Hines

Signature  Date: 03/10/2022

Associate investigator

Name: Jennifer Halliday

Signature  Date: 03/10/2022

Associate investigator

Name: George Company

Signature  Date: 03/10/2022

Associate investigator

Name: Kim Henshaw

Signature  Date: 03/10/2022

Associate investigator

Name: Dr Ros Le Gautier

Signature  Date: 03/10/2022

Associate investigator

Name: Sarah Manallack

Signature  Date: 03/10/2022

Associate investigator

Name: Ben Harrap

Signature  Date: 14/12/2022

Student investigator* (please add additional signature blocks if required)

Name:

Signature Date:

Name:

Signature Date:

***All research staff involved in the project must sign the project description/protocol. Please add additional signatures blocks as required.

ACKNOWLEDGMENT OF HEAD OF SCHOOL*/DIRECTOR OF RESEARCH

I the undersigned acknowledge that the Faculty has considered and approved the academic worth of the project described in this application.

Name: Prof Jane McGillivray

Signature: Date:

*If the Head of School (or similar) is also a member of the research or supervisory team, a more senior member of University staff e.g. Dean or Associate Dean (Research) must sign the project as authorising officer.

A Project Description is a **mandatory** component of a submission using the Human Research Ethics Application (HREA).

Please submit all documents via email to <research-ethics@deakin.edu.au>.

Deakin University is collecting your personal information on this form for the primary purpose of processing your human research ethics application. It will also use this information for monitoring your compliance with the approved protocol. For these purposes Deakin may also provide this information to potential research participants, past or current research participants, or other interested parties in your research. You are not required to provide the information requested, however if the information is not provided, Deakin may not be able to process your ethics application. Deakin manages personal information it holds, including requests by individuals for access to their personal information, in accordance with the Privacy and Data Protection Act 2014 (Vic). Deakin's Privacy Policy may be viewed on Deakin's Policy Library. Information on privacy at Deakin is available at http://www.deakin.edu.au/footer/privacy. Questions about privacy may be directed to the Privacy Officer on (03) 5227 8524 or by email to privacy@deakin.edu.au.

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