Research Data Management Plan

Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)	
Research Project Team	
Principal Investigators	Dr Elizabeth Holmes-Truscott and Professor Jane Speight, The Australian Centre for Behavioural Research in Diabetes (ACBRD), Deakin University
Associate Investigators	Dr Edith Holloway, ACBRD, Deakin University; Professor Timothy Skinner, Department of Rural Health, La Trobe University; Associate Professor John Furler, Department of General Practice, The University of Melbourne; Professor David O'Neal, St Vincent's Hospital, The University of Melbourne; and Dr Virginia Hagger, School of Nursing and Midwifery, Deakin University
Other project team members who have access to the research project data	Mr Hanafi Husin, Statistician and Mr Christopher Todaro, Research Assistant participant tracking and recruitment, The Australian Centre for Behavioural Research in Diabetes (ACBRD), Deakin University
Research Project Data Details	
Data custodian	Dr Elizabeth Holmes-Truscott
Data Management Plan Created by	Dr Elizabeth Holmes-Truscott and Dr Edith Holloway
Date created	20/02/2020 (version 2)

1. Research Project Details

1.1 Research Project Title

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

1.2. Project summary

Injecting insulin is the most effective treatment for diabetes, however, one in four adults with type 2 diabetes (T2D) delay initiation due to negative attitudes towards insulin. Few evidence-based interventions exist to address these issues and none widely available in Australia. This study aims to test whether web-based resource(s) are useful for people with T2D who have questions or concerns about starting insulin. Three hundred and ninety-two adults who currently take oral medication to manage their T2D will be recruited through the National Diabetes Services Scheme registry and the ACBRD (and affiliated organisations) websites, e-newsletters/blogs and social media. Following consent to take part and completing the baseline survey, participants will receive a link to one of two web-based resources on insulin and T2D. They will have two weeks to explore the resource(s) allocated to them. Participants will also complete two follow up surveys at 2 weeks and 6 months.

2. Research Project Data Details

2.1. Summary of the Research Project Data

The proposed research will include data from approximately 392 participants. Participants are Australian adults with type 2 diabetes who currently use oral medication for the treatment of type 2 diabetes (and have no prior experience of self-administered injectable treatment for any illness or condition) at the time of randomisation.

In this study we will be collecting and using self-reported personal, sensitive and health information. Each participant will be invited to complete 3 online surveys over 6-months. Data will include qualitative and qualitative (free text) data. In addition, we will collect website (intervention) usage data via google analytics.

2.2. Summary of any Ethical, Confidentiality or Privacy Considerations

This research project involves human participants. We have applied for ethics approval to conduct this research study from the Deakin University Human Research Ethics Committee (committee review date 20 April, 2020). This research project will be conducted in compliance with the conditions of the ethics committee approval (*Project Reference: TBC*), the NHMRC National Statement in Ethical Conduct in Human Research 2007 (Updated 2018)

All information provided by participants will remain confidential. At no time will the results identify any participant within the study. No names or identifiers will be used in any discussions of the research or in any reports that come out of the project, nor will any individual outcomes (case studies) be presented.

The collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information associated with this research project will be in accordance with the Deakin University Research Data and Primary Materials Management Procedure and are detailed in the associated ethics application (*Project Reference: TBC*) and study protocol (Protocol SA-2017-11697, version 2.2d, 19 February 2020). The current data management plan includes specific details not otherwise set out in the associated ethics application and study protocol.

3. Research Project Data Storage, Retention and Dissemination Details

The principal investigator is responsible for data collection and management of materials from this research project.

3.1. Data storage and security

A data dictionary will be developed for this research project ensuring transparency and uniformity across all of the data collected. This will be developed by the principal investigator, statistician and project manager.

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.

All participant survey data will be stored in a database (Qualtrics™) via the Deakin University secure network. Only the research team will have access to this password-protected Qualtrics account. At the conclusion of the study all Qualtrics data and website usage data will be downloaded and linked according to participant ID. 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 the Human Research Ethics Application (HREA). De-identified quantitative participant data, including participant ID, will be saved as an IBM SPSS file. Thus, the data will be re-identifiable. Safety follow-up interview data (related to any reported adverse events) will be stored electronically (i.e. audio files). All data will be stored in a secure Deakin University computer file accessible only by the Deakin University research project team noted on the HREA.

3.2. Research Project Data Storage Arrangements

Survey data will be stored electronically on a password protected computer, on a secure Deakin University shared drive, accessibly only to the research project team listed on the HREA.

3.3. Research data format

The quantitative data files will be available in Excel, SPSS, and Stata formats. Qualitative data will be available in excel and NVivo.

3.4. Data analysis

Quantitative data will be imported from Excel into SPSS and STATA files for analysis. All analyses will be performed using Stata/SE 16.0 or IBM SPSS Version 25. Descriptive statistics (frequencies, proportions and measures of central tendency) will be used to explore and describe participants baseline demographic, clinical characteristics; psychosocial data at baseline and following ups, and as well as resource acceptability and Google Analytics data at follow ups. Categorical and binary data will be summarised using counts and proportions, and continuous data using the mean and standard deviation. Where continuous data distributions are skewed, the median and interquartile range will be calculated.

An intention-to-treat (ITT) approach will be adopted whereby participants will be analysed according to the arm they were allocated, and all participants will be included in the analysis. A linear mixed effects model will be used to estimate the difference in the primary outcome (attitudes towards insulin; mean Insulin Treatment Appraisal Scale [ITAS] negative score) between the arms at 2 weeks and 6 months using restricted maximum likelihood estimation. Treatment arm and all three time-points (baseline, 2 weeks and 6 months) will be included as fixed effects in the model. Random effects will be used to account for repeated participant measures. The outcome measure will be adjusted by the stratification factor (gender), as well as age, diabetes duration and education should these be imbalanced between the arms at baseline.

Secondary outcomes and continuous psychosocial process evaluation outcomes (e.g. will be analysed using the same modelling approached described above. An ordinal logistic mixed effects model will be used to quantify differences in the willingness to begin insulin therapy (secondary outcome) between the arms at the various time points.

Generalised linear mixed effects models assume any missing data is missing at random. This assumption will be tested in a sensitivity analyses whereby a pattern mixture model will be used to determine whether study conclusions would change should the missing data not be missing at random.

For the qualitative data generated by free-text responses to open-ended questions, data will be retained in an excel file. Thematic analyses will be used to explore and identify key themes about participant's experiences of the resources to inform future developments. Common themes will be identified for participants' likes and dislikes about the resources and how they could be improved.

3.4. Research project data sharing

De-identified study data may be shared with the funding body, including survey results and any safety events regarding their medical products, for research and audit purposes. De-identified data will be transferred via e-mail in a password encrypted excel file. The funding body (Sanofi) will not have any access to personally identifying information collected (e.g. contact details). This is communicated to participants in the Plain Language Statement and Consent Form.

The ACBRD Foundation Director will be the custodian of the data in the event that the principal investigator(s) leaves the University. The data will remain securely stored on the shared Deakin University network.

3.5. Future use the research project data

Any data collected from this study is intended to be used solely for this research project and will not be shared or made available to any third party or used for any unrelated future research and non-research purposes. However, the research team or the study funders may use the information collected/and or data in a closely related project, or an extension of the current research project. This information will be de-identified. This is communicated to participants in the Plain Language Statement and Consent Form.

3.6. Research Project Data Retention Requirement

In accordance with government requirements, data will be stored for 15 years from the date of publication of the findings and then disposed of by erasing of electronic files under the direction of the IT manager. No secondary analysis of the data is planned.

3.7. Research Project Data Embargo Period

The data will be embargoed from open sharing until the final publication of all journal articles associated with this research project, or a one year after the conclusion of the research project, whichever comes sooner.

3.8. Intellectual property

All data will be collected in Australia in accordance with Australian copyright laws.

Deakin University hold the copyright and intellectual property for any research data generated through this research project.

In accordance with the Deakin University Intellectual Property Policy, should a member of the research team cease employment with Deakin University, they are not entitled to use or transfer any Intellectual Property created in the course of employment without the express permission of Deakin University.

3.9. Data management training for project team

All project team who are in any way involved in the collection, storage, analysis, transfer or management of the data will receive the data management plan (version 1, and any subsequent updated versions). They will be asked to read the document in full and agree to the conditions outlined in the data management plan.

3.10. Review of data management plan

The data management plan (version 1) will be reviewed and updated (as necessary) on a monthly basis during the active trial period (May 2020 – Feb 2021). In the instance where

the data management plan is updated, it will be saved as a new version number (including the date) Previous versions will be retained.