DEVELOPMENT AND EVALUATION OF THE ONTRACK DIABETES PROGRAM:

AN AUTOMATED, WEB-BASED TYPE 2 DIABETES SELF-MANAGEMENT AND DYSPHORIA INTERVENTION

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Abstract

This thesis by published papers represents a program of research with the overarching objective of the development and evaluation of a novel, web-based Type 2 diabetes self-management and dysphoria intervention. An initial review of the impact of telemedicine in supporting self-management in diabetes found that its impact was limited. A web-based mode of delivery was selected, as it provided greater access, further options for support strategies, and a greater opportunity for a novel contribution to the field.

Social Cognitive Theory was selected as the principal theoretical foundation underpinning the intervention, given the substantial empirical support it has obtained. The principle of patient empowerment was seen as fundamental to supporting effective chronic disease self-management, and was therefore applied as a major guiding principle.

The project had three consecutive stages, each of which gave a foundation for the next stage. The aim of the first stage was to obtain an understanding of the experiences of individuals living with Type 2 diabetes, their perceived needs for extra support, and suggestions for web-based support program content. The second stage aimed to use this information during development of the intervention, in order to build the web-based program upon the ethos of patient empowerment and personalised support. Finally, a pilot trial was conducted, which was aimed to gain a preliminary indication of the program's (i) effectiveness in improving clinical, psychological, and behavioural outcomes, (ii) user satisfaction, acceptability, usability, perceived ease of use and utility, and (iii) feasibility of implementation.

The project was comprised of studies that utilised both qualitative and quantitative methods. Stage 1 involved qualitative, semi-structured interviews of 13 adults with Type 2 diabetes and 12 general practitioners (GPs) to gain their perspectives on experiences related

to living with Type 2 diabetes and the types of additional support that patients required. Thematic data analysis was used to identify categories and sub-categories, following which a comparison was made between the perspectives of the two samples.

Paper 2 reports an exploration of patients' and physicians' perspectives on self-perceived barriers and facilitators to effective Type 2 diabetes self-management; emotional challenges associated with living with diabetes, and needs for extra support. Suggestions for areas that should be addressed in a web-based support program were explored. Aspects that enhanced and challenged effective self-management were derived, and significant overlap in the categories derived from the GP and patient samples was evident. The frustrations, uncertainties, depression and anxiety experienced by Type 2 diabetes patients strongly suggested the need for improved emotional and psychological support. In addition, the two samples provided useful suggestions for elements in a web-based support program.

Stage 2 of the project involved program development, at which point the intervention was named OnTrack Diabetes. A series of processes that included designing program features, which comprised written content for information resources and interactive tools as well as information technology development, were involved. Two papers were produced at this stage (Papers 3 and 4), which outlined these processes.

Paper 3 described the design of the studies in the PhD project, as well as plans for the main randomised controlled trial to evaluate the program. Paper 4 described the specific steps involved in creating the program, from producing the written content to information technology development and implementation.

Stage 3 was a randomised controlled pilot trial to evaluate the OnTrack Diabetes program. A sample of 38 adults with Type 2 diabetes living in Australia was enrolled. This trial evaluated the feasibility of study procedures, and provided a preliminary indication of the program’s effects on clinical, behavioural, and psychological outcomes. Qualitative user evaluations provided indications of program uptake, acceptability, usability, and utility. One paper (Paper 5) was produced from this stage. Paper 5 reported results from the pilot randomised controlled trial. The paper made comment on trends produced in the data in terms of clinical, emotional, and behavioural outcomes, and users’ perceptions of the program.

Overall, the project has made an important contribution to the scientific literature in its contributions to providing a foundation for research into the potential efficacy and feasibility of implementing automated, web-based support for Type 2 diabetes self-management and dysphoria. This trial represented the first known intervention of its kind in Australia. Outcomes provided details on the structures and processes required to produce a web-based support program of this nature, and further indicated that there is scope to extend upon web-based intervention for Type 2 diabetes self-management and associated dysphoria.

Submitted Manuscripts and Publications from the PhD Program

Paper 1

Cassimatis, M., & Kavanagh, D.J. (2012). Effects of Type 2 Diabetes Behavioural Telehealth Interventions on Glycaemic Control and Adherence: A Systematic Review. *Journal of Telemedicine and Telecare,18*(8), 447-450. doi:10.1258/jtt.2012.GTH105. Journal Impact Factor = 1.274.

Paper 2

Cassimatis, M., Kavanagh, D.J., & Smith, A.C. (2013). Perceived Needs for Supported Self-Management of Diabetes: A Qualitative Investigation of Potential for A Web-based Intervention. *Australian Psychologist*, *49*, 75-85. Journal Impact Factor: 0.607.

Paper 3

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. (2013). Study Protocol of The OnTrack Diabetes Project: Randomised Trial of An Automated, Interactive, Web-based Type 2 Diabetes Self-management and Dysphoria Intervention. *Journal of Medical Internet Research*. *Accepted with revisions Jan 2014*. Journal Impact Factor: 4.07.

Paper 4

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. (2013). Development of the OnTrack Diabetes Program and Design of a Randomized Controlled Evaluation Trial. *Journal of Medical Internet Research. Accepted with revisions Jan 2014*.

Paper 5

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. (2013). Evaluation of a Self-guided, Interactive Web-based Type 2 Diabetes Self-management and Dysphoria Support Program: OnTrack Diabetes Pilot Study Results. *Journal of Medical Internet Research*. *To be submitted.*

Note

The below ancillary publications were produced during the time of the PhD program of research (i) during employment on the Telephone-Linked Care Diabetes Project at the University of Queensland and (ii) as the result of the Candidate's Post Graduate Diploma of Psychology thesis results. However, as these projects are unrelated to the research program undertaken for the PhD project the below publications are not discussed within the thesis.

Ancillary Publications

(i) Bird, D., Oldenburg, B., **Cassimatis, M.**, Russell, T., Ash, S., & Courtney, M. et al. (2010). Randomised Controlled Trial of An Automated, Interactive Telephone Intervention To Improve Type 2 Diabetes Self-management (Telephone-Linked Care Diabetes Project): Study Protocol. *BMC Public Health, 10*, 599. doi:10.1186/1471-2458-10-599.

(ii) May, J., Andrade, J., Kavanagh, D.J., Feeney, G.F.X., Gullo, M., Statham, D.J., Deas, J., Connolly, J., **Cassimatis, M.**, Young, R.M., & Connor, J.P. (2014). The Craving Experience Questionnaire: A Brief, Theory-Based Measure of Consummatory Desire and Craving. *Addiction*, PMID: 24400950.

Conference Presentations on PhD Project Outcomes

Cassimatis, M., Kavanagh, D.J., Hills, A., Smith, A., & Scuffham, P. Web-Based CBT for Type 2 Diabetes: Considerations in Bridging the Rural and Remote Divide. *Australian Association of Cognitive Behavioural Therapy (AACBT)* C*onference*. Adelaide, Australia, 24 October 2013.

Cassimatis, M., & Kavanagh, D.J. Effects of Behavioural Telehealth Interventions on Glycaemic Control and Adherence in People with Type 2 Diabetes: Presentation of A Systematic Review. *Global Telehealth* 2012. Sydney, Australia. 28 November 2012.

Cassimatis, M., & Kavanagh, D.J. Development and Evaluation of OnTrack Diabetes: An Automated, Web-based Type 2 Diabetes Self-management and Dysphoria Intervention. *AACBT*. Sanctuary Cove, Australia. 18 October 2012.

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. Development and Evaluation of OnTrack Diabetes: An Automated, Web-based Program to Support Type 2 Diabetes Self-management and Dysphoria. *Australian Disease Management Association; ADMA Conference*. Melbourne, Australia. 24 September 2012.

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. Development and Evaluation of OnTrack Diabetes: An Automated, Web-based Type 2 Diabetes Self-Management and Dysphoria Support Program. *QUT E-psychology Conference*. Brisbane, Australia. 16 August 2012.

Cassimatis, M. & Kavanagh, D.J. Online Type 2 Diabetes Self-management Support: A Qualitative Study to Inform Design of the OnTrack Diabetes Program. *International Society for Research on Internet Interventions; ISRII Conference*. Sydney, Australia. 12 April 2011.

Research Funding/ Scholarship Relevant to the PhD

QUT Faculty of Health Postgraduate Research Award (QUTPRA) for Masters of Applied Science (Research) candidature before articulating to a PhD (2010).

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Mitsubishi Incorporated for OnTrack Diabetes project costs - $10 000 per annum (2010 - 2014).

A Post-doctoral Fellowship grant from the Wesley Research Institute commenced in March, 2013.

Note to PhD thesis examiners:

You are welcome to access the OnTrack Diabetes program for the purpose of reviewing its contents as part of the work of the PhD Candidate. Please use the following details to log in to the program:

OnTrack Diabetes homepage URL: ontrack.org.au/diabetes/

Username: examinerphd@gmail.com

Password: examiner

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Glossary of Abbreviations

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
DASS-21	Depression, Anxiety and Stress Scales, (brief)
GP	General Practitioner
HbA1c level	Glycosylated haemoglobin assay level
HRQOL	Health-related quality of life
IDF	International Diabetes Federation
RCT	Randomised controlled trial
T2D	Type 2 diabetes
WHO	World Health Organisation

Statement of Original Authorship

The work presented in this PhD thesis has not been produced previously or submitted at QUT or any other higher education institution. All work contained herein is original work, except where appropriate references are made to others' work.

QUT Verified Signature

Signature:

Mandy Cassimatis

Date: 13/07/2014

Statement of Contribution of Co-Authors for Thesis by Published Paper

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the QUT ePrints database consistent with any limitations set by publisher requirements.

In the case of this chapter:

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., & Scuffham, P.A. (2013). Evaluation of The OnTrack Diabetes Program: 3-Month Outcomes of A Randomised Controlled Pilot Trial. *Journal of Medical Internet Research.* Journal Impact Factor: 4.07.

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Contributor	Statement of contribution*
Mandy Cassimatis Cassimatis 21/03/2014	Implemented all stages of the OnTrack Diabetes pilot trial, including the design of study measures, participant recruitment and data collection, data analyse and writing up of results into this manuscript.
David Kavanagh	Guided the PhD candidate on data analyses, and the development and design of the OnTrack Diabetes program. Provided editorial feedback on the manuscript.
Andrew Hills	Provided editorial feedback on the manuscript to the candidate.
Anthony Smith	Provided editorial feedback on the manuscript to the candidate.
Paul Scuffham	Provided editorial feedback on the manuscript to the candidate.

Principal Supervisor Confirmation

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David Kavanagh		24/08/2014
Name	Signature	Date

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1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the QUT ePrints database consistent with any limitations set by publisher requirements.

In the case of this chapter:

Cassimatis, M., Kavanagh, D.J., Hills, A.P., Smith, A.C., Scuffham, P.A., Edge, S., & Gibson, J. (2014). Development of the OnTrack Diabetes Program and Design of a Randomized Controlled Evaluation Trial. *Journal of Medical Internet Research.* Journal Impact Factor: 4.07.

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Contributor	Statement of contribution*
Mandy Cassimatis [signature] 21/03/2014	Co-wrote OnTrack Diabetes program sections with author two; performed IT program coding; and drafted manuscript. Finalised manuscript based on co-authors' editorial feedback.
David Kavanagh	Co-wrote OnTrack Diabetes program content with the PhD candidate, and guided program development. Informed design of the trial and provided editorial feedback on the manuscript.
Andrew Hills	Provided editorial feedback on the manuscript. Assisted with informing design of the trial and suggested program inclusions and procedures.
Anthony Smith	Provided editorial feedback on the manuscript. Had input into informing design of the trial and suggested program inclusions and procedures.
Paul Scuffham	Provided editorial feedback on the manuscript. Had input into informing design of the trial and suggested program inclusions and procedures.
Steven Edge	IT programmer for OnTrack Diabetes. Reviewed accuracy of manuscript sections that include IT-related content; gave editorial feedback.

Contributor	Statement of contribution*
Jeremy Gibson	IT programmer for OnTrack Diabetes. Reviewed accuracy of manuscript sections that included IT-related content; provided editorial feedback.

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3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
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Contributor	Statement of contribution*
Mandy Cassimatis 21/03/2014	Performed practical aspects of the OnTrack Diabetes project; constructed first draft and revised the final version of the manuscript following editorial input from the co-authors.
David Kavanagh	Designed the protocol of the project that is described in this manuscript in collaboration with the PhD candidate. Provided editorial feedback on the manuscript to the candidate.
Andrew Hills	Collaborated with the PhD candidate and author two regarding the project's design/ protocol. Provided editorial feedback on the manuscript to the candidate.
Anthony Smith	Liaised with the PhD candidate and author two regarding project design. Provided editorial feedback to the candidate on the manuscript.
Paul Scuffham	Reviewed study protocol and measures. Provided editorial feedback to the candidate on the manuscript, and input into health economics statistical analyses methods.

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2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
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Cassimatis, M., Kavanagh, D.J., & Smith, A.C. (2013). Perceived Needs for Supported Self-Management of Diabetes: A Qualitative Investigation of Potential for A Web-based Intervention. *Australian Psychologist, 49*(2), 75-85.

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Contributor	Statement of contribution*
Mandy Cassimatis 21/03/2014	Conducted qualitative interviews which form the results of this paper, transcribed interviews and performed thematic analysis of participants' responses; drafted the manuscript and conducted final review prior to submission.
David Kavanagh	Assisted the PhD candidate with study design; collaborated with the candidate regarding data analysis; assisted with structuring the manuscript and provided editorial comments.
Anthony Smith	Liaised with authors one and two about the study design; provided editorial feedback on written expression, structure and presentation of the manuscript.

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Statement of Contribution of Co-Authors for Thesis by Published Paper

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1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
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Cassimatis, M., & Kavanagh, D.J. (2012). Effects of Type 2 Diabetes Behavioural Telehealth Interventions on Glycaemic Control and Adherence: A Systematic Review. *Journal of Telemedicine and Telecare,18*(8), 447-450. doi:10.1258/jtt.2012.GTH105.

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Mandy Cassimatis 21/03/2014	Conducted literature search and review; summarised the results of the review; wrote the first draft of the manuscript and performed final editing according to co-author's feedback prior to manuscript submission.
David Kavanagh	Collaborated with the candidate on rating the papers included in the review on their relevance and suitability. Provided comments and editorial suggestions on the paper.

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

David Kavanagh
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Bandura once said, “...there is a fortuitous element in some of the events they may encounter in their daily lives. Yet, it is such fortuitous encounters that often play a prominent role in shaping the course of lives,” and that is how I would explain how I got to have the fortuitous experience of undertaking this PhD project. It might take me another PhD to really outline the people who I should be thankful to for shaping my journey during the past three years, but I’ll keep it brief.

First and foremost – David Kavanagh. Thanks for your faith and trust in me and my abilities. Getting to do this project – not just any PhD – has changed my life, and that is the best statistically significant outcome that I could have asked for. I appreciate the opportunity that you gave me to run my “own” project, and I hope that I have done you proud.

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CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 Structure and Overview of the PhD Program of Research

1.1.1 Overview of the PhD Research Program

This thesis by publication used qualitative and quantitative methods to develop and evaluate a novel, automated, web-based Type 2 diabetes self-management and dysphoria support program in a sample of Australian adults aged 18 – 75 years. This Chapter provides an overview of PhD program of research, an introduction to the topic and background literature on the issues that are addressed. Specifically, these issues include Type 2 diabetes and comorbid mood disorders, Type 2 diabetes self-management, patients' perspectives on self-management, and relevant web- and non-web-based interventions. Attempts made by the health system to meet the needs of Type 2 diabetes patients for extra self-management support are summarised. The chapter demonstrates the urgent requirement for Type 2 diabetes self-management intervention that can provide outreach and cost-effectiveness.

Section 1.2 describes issues presented by comorbid dysphoria and diabetes in detail, and explains the inextricable links between these conditions. The importance of addressing comorbid psychological and emotional symptoms in diabetes self-management interventions is discussed. A review of qualitative empirical research on patients' experiences living with Type 2 diabetes is presented in Section 1.3, with a focus on research that explored physicians' views. The importance of the doctor-patient relationship to effective diabetes self-management is demonstrated. Qualitative research is primarily used, with some references to quantitative studies so that patients' experiences can be elucidated with minimal bias. The need to assess both patient and physician views to gain a comprehensive account of treatment adherence issues is suggested by the marked variations in their perspectives. Section 1.4 presents a summary of Type 2 diabetes self-management interventions, including reports on the efficacy of particular intervention components and evaluations of non-web-based and web-based interventions. The novelty in providing combined diabetes self-management and dysphoria support using the web is demonstrated. Section 1.5 outlines the premise and theoretical underpinnings of Bandura's (1977) Social Cognitive Theory (SCT; Bandura, 1977) and relates the theory to the objectives and aims of this project.

1.1.2 Structure of the Research Program

Figure 1 shows the sequence of stages involved in this project and the papers that were produced in accordance with each progressive stage. The research project comprised three, consecutive stages, each of which formed a foundation for progression to the next stage.

Stage 1

Aims: (i) To explore telehealth mode of diabetes self-management intervention delivery.

(ii) To explore: barriers and facilitators to Type 2 diabetes self-care, emotional challenges, perceived acceptability of online support, and suggestions for program content.

Methods: (i) Systematic literature review on telehealth

(ii) Qualitative, semi-structured interviews with a sample of Type 2 diabetes patients (*n*=13) and GPs (*n*=12).

Papers

(i) **Paper 1**: Examined effects of behavioural telehealth interventions on glycaemic control and diabetes self-care.

(ii) **Paper 2**: Reported on categories and sub-categories derived from interviews; discussed commonalities and differences; indicated suggested online program content.

Stage 2

Aims: (i) To establish project protocol

(ii) To develop web-based Type 2 diabetes self-management and dysphoria intervention program.

Methods: (i) Designed protocol linking Stages 1 to 3 + main randomised controlled trial.

(ii) Program content and information technology programming development.

Papers

Paper 1: Described project design and sequences of studies involved in the project.

Paper 2: Outlined development of the OnTrack Diabetes program, including steps used and details about content.

Stage 3

Aims: (i) To evaluate program's efficacy to improve clinical, psychological/ emotional, behavioural, and quality of life outcomes; and

(ii) To evaluate users' uptake, perceived acceptability, usability, utility, ease of use, and implementation feasibility of the program.

Methods: Randomised controlled pilot trial implemented over 3 months with a sample of 38 Australian adults with Type 2 diabetes.

Paper

Paper 5: Reported effects of OnTrack Diabetes on primary and secondary outcomes and user evaluations of the program.

Figure 1. Overview of the OnTrack Diabetes Project Undertaken in the PhD Research Program.

1.1.3 Overview of PhD Research Program Stages

Stage 1 of the research program involved two preliminary steps that were integral to establishing the overall research project (Figure 1). First, an exploration of the effects of behavioural telehealth interventions on Type 2 diabetes self-care and glycaemia (Paper 1, displayed in Chapter 2) was used to gain information about the current status of interventions being delivered by phone; the most common form of intervention delivery to date. The review provided mixed evidence on the efficacy of telehealth interventions and provided information about the scope of currently available telehealth interventions. It was concluded that there was nothing additional to contribute to current evidence that was within the foreseeable scope of this research project and hence the more novel approach of web-based intervention was chosen.

The second part of Stage 1 examined patients' lived experiences with Type 2 diabetes, which established a foundation that informed the design of the intervention (Paper 2). The decision to use a patient empowerment approach to diabetes self-management was supported by the qualitative study. This study also explored the views of physicians in understanding patients' experiences in managing Type 2 diabetes so that their perceived gaps in currently available supports might be addressed in the intervention. As discussed in Section 1.4, to gain a comprehensive understanding of the difficulties entailed in Type 2 diabetes self-management it was considered important to have the views of physicians who were highly involved in its treatment and who would bring insight into the areas that the intervention would ultimately address. It was also important to determine whether a web-based support program could gain the support of primary care physicians, who were expected to heavily influence their patients' engagement in diabetes-related interventions.

The paper indicated that patients commonly experienced emotional challenges related to Type 2 diabetes which they tended not to communicate to their physicians. Many common categories across the two samples were derived from the interview responses. However, physicians tended to relate diabetes self-management difficulties to practical issues while patients indicated that daily emotional stressors related to diabetes management and fears for their health prognosis compromised their practise of adequate self-care. Both samples indicated that they perceived web-based Type 2 diabetes self-management and dysphoria support to be potentially acceptable.

Stage 2 involved designing the project's protocol and developing the web-based program. The project protocol is presented in Paper 3, which demonstrated how each stage of the project formed the basis for further stages. Development of the OnTrack Diabetes program was presented in Paper 4, which included detailed descriptions of each of the steps involved, from the incorporation of Stage 1 results into program content to launching the program live-to-air and its implementation. There was little prior literature to inform the project protocols for RCTs of web-based interventions and few studies had reported web-based program development at the initial stage of the project. Therefore, Papers 3 and 4 were based on the original approaches to project design and development that were used in this project. The contributions of the PhD candidate to the program's development are described in Table 1, below.

Table 1. Demonstration of PhD candidate's contribution to development of the web-based intervention.

Section of Program	Tool	Contributions
Eating Well & Feeling Healthy	Ideas About Eating Well	Candidate created fun healthy eating change options. Imagery exercise new. Good Things About My Idea customised to Eating Well… Weighing up the Pros & Cons & Deciding What To Do from OnTrack Alcohol & Depression. Fold-up Summary Card by candidate and DK.
	Guidebook page – My Eating Goal Feeling Confident – My Eating Goal	Created by Candidate. Wording changed to apply to eating.
	Enjoyable Eating	My Enjoyable Foods list created by candidate. My Daily Menu of Enjoyable Foods adapted from IT logic for Activities I Enjoy from OnTrack Alcohol & Depression.
	My Enjoyable Eating Routine	Adapted by candidate from IT logic for OnTrack Alcohol & Depression Fun Activity Planning Tool.
	Problem Solving To Eat Well	Wording changed from OnTrack Alcohol & Depression. Problem Solving to apply to diabetes & eating.
	Saying No	Some wording changes from Alcohol & Depression program. Saying No tool - to apply to eating well.
Health Routines	Ideas About Health Actions	IT logic from Activities I Enjoy (in OnTrack Alcohol & Depression). Candidate created options for My Health Action Ideas & Good Things About My Idea. New Imagery activity by candidate & DK. Things That Might Get In The Way, Weighing Up The Pros & Cons, & Deciding What To Do from Alcohol & Depression. My Health Action Idea fold-up summary card – by candidate & DK.

Section of Program	Tool	Contributions
	Feeling Confident – My Health Action Goals	From OnTrack Alcohol & Depression. Feeling Confident tool - applied to diabetes & health actions.
	Planning My Health Action Goal	Wording changed from OnTrack Alcohol & Depression Planning tool to apply to diabetes and health actions.
	Guidebook page – My Blood Glucose Level goal	Created by candidate.
More On Health Routines	Things In My Health Routine	My Health Actions lists created by candidate. Daily, Weekly & Regular health actions pages created for OnTrack Diabetes.
	Planning My Health Routine	IT logic from OnTrack Alcohol & Depression Fun Activity Planning tool. New IT logic created to include daily, weekly & regular health actions. Wording created by candidate for diabetes & health routines.
	Problem Solving To Keep In Routine	Wording changed from OnTrack Alcohol & Depression Problem Solving tool to apply to diabetes & health action obstacles.
Thinking Well & Feeling Fine	Activities I Enjoy	Wording changed from Activities I Enjoy tool from OnTrack Alcohol & Depression – e.g. options added to activity list, wording applied to diabetes & mood.
	Fun Activity Planning	From Fun Activity Planning in OnTrack Alcohol & Depression.
	Making A Relationship Stronger	From OnTrack Alcohol & Depression.
	Guidebook page – My Mood Goal	Created by candidate.
More On Thinking Well & Feeling Fine	Emotionally Risky Situations	IT logic & tool structure from Risky Situations tool in OnTrack Alcohol & Depression. Candidate re-worded tool to apply to diabetes and dysphoria & refined & added options to lists – e.g. My Most Risky Situations.

Section of Program	Tool	Contributions
	Planning For Emotional Challenges	Adapted for diabetes and dysphoria from Planning For Risky Situations Tool in OnTrack Alcohol & Depression.
Keeping On Track	What's Getting Better	From OnTrack Alcohol & Depression.
	New Horizons	From OnTrack Alcohol & Depression.
	Setting Goals That Work	From OnTrack Alcohol & Depression.
	Challenges Keeping On Track	Adapted from Problem Solving For Risky Situations tool in OnTrack Alcohol & Depression.
	Planning For A Challenge	Adapted from Planning For Risky Situations tool in OnTrack Alcohol & Depression.
Mindfulness resources		Selected from OnTrack Alcohol & Depression.
Videos		From OnTrack Alcohol & Depression.
Information resources		Written by candidate.
My Diary	Mood self-monitoring tool	From OnTrack Alcohol & Depression
	Blood glucose self-monitoring tool	Created for OnTrack Diabetes by candidate & DK.
	Physical activity & Nutrition goal self-monitoring tools	Created for OnTrack Diabetes by candidate & DK.
	Appointment-setting function	From OnTrack Alcohol & Depression.
What I've Done		From OnTrack Alcohol & Depression.
How I'm Doing		Automated feedback graphs created by IT professionals.
Offline Monitoring card		Created by candidate & DK.
Program lay-out		From OnTrack Alcohol & Depression.
Graphic design of program interface		Created by graphic designer with candidate's input.

The PhD candidate was involved in collaborating with Principal Supervisor David Kavanagh in structuring the OnTrack Diabetes program regarding program content inclusions, interactive tool design and sequencing, and graphics. Due to budgeting constraints, the eXtensive Mark-up Language (XML) coding for the majority of the program's tools was based on exclusive XML coding that was developed for the OnTrack Alcohol and Depression program. Relevant videos and mindfulness resources from the OnTrack Alcohol and Depression program were also included in OnTrack Diabetes for budgeting purposes. The candidate checked each page that went into the OnTrack Diabetes program and made refinements and/ or added content to the majority of pages that were included from the OnTrack Alcohol and Depression program. Further, a number of pages, including the guidebook pages that are presented between the program tools, were created specifically for OnTrack Diabetes.

The candidate coded the web pages for OnTrack Diabetes using XML coding that was taught by the Information Technology (IT) professionals. Following this, a IT professional from Kavanagh's OnTrack team checked and made refinements to the programming as required. The candidate guided the IT professionals on establishing the OnTrack Diabetes administration system and database, which included the study's call calendar, reminders for participant follow-ups, and participant data. These professionals were also responsible for programming the self-monitoring tools, automated feedback graphs, variations in IT logic for various tools (e.g. Planning My Health Routine), the logistics of user access to surveys, automated emails, program access, and randomisation to study conditions.

Finally, Stage 3 comprised the pilot randomised controlled trial (RCT) of the OnTrack Diabetes program. A sample of 38 Australian adults with Type 2 diabetes who were aged 18 – 75 was enrolled in the trial. Aims of the pilot trial were: (i) to evaluate the program's efficacy in improving Type 2 diabetes self-management and dysphoria symptoms; (ii) to evaluate the program's efficacy in improving self-care behaviours, diabetes self-efficacy and quality of life, and (iii) to evaluate user perceptions of the program's acceptability, usability, user satisfaction, and feasibility of implementation. The three experimental conditions included: (i) Wait-List Control: received usual diabetes care from Baseline to 3-months Post-Baseline; (ii) Full Intervention: received access to the full OnTrack Diabetes program from Baseline to 3-months Post-Baseline; and (iii) Brief/ Modified Intervention: received access only to information resources on diabetes self-care, and the physical activity module from Baseline to 3 months Post-Baseline. While the pilot trial results showed that there were no significant differences between groups in primary or secondary outcomes over 3 months duration, findings revealed high user evaluations and implementation feasibility. These results provided scope for the upcoming main RCT of the OnTrack Diabetes program.

The manuscripts and papers in this thesis are presented in the form in which they were submitted or accepted to scientific journals. Therefore, the way in which the various papers were formatted differs according to particular journal specifications.

1.1.4 Section Summary and Conclusions

This section provided an overview of the PhD research program, its overarching objective, and the individual aims for each of the three, consecutive stages that comprised the project. Links between the papers that emanated from each stage of the project are shown in Figure 1, above.

1.2 The Type 2 Diabetes and Dysphoria Epidemic

Type 2 diabetes has become a global threat to morbidity, mortality, and health system resources to the extent that authorities have described the condition as a crisis (International Diabetes Federation, IDF, 2012a). Over 371 million people globally, or 8.3% of the world's population are estimated to have diabetes, with 85 – 90% of cases being Type 2 diabetes (IDF, 2012b). Diabetes was responsible for an estimated 4.8 million deaths globally for people aged 20 – 79 years in 2012 (IDF, 2012b), and this number has been projected to double between 2005 and 2030 (World Health Organisation, WHO, 2012).

Long-term micro- and macro-vascular complications are strongly associated with inadequate glycaemic control over time, as excess glucose damages small capillaries and large blood vessels within the body. Consequently, diabetes is one of the leading causes of blindness, peripheral neuropathy resulting in limb amputation, and chronic kidney disease (WHO, 2012). Furthermore, cardiovascular disease is the primary cause of death for half of those with diabetes and kidney failure is responsible for 10 – 20% of mortalities in this population. The overall mortality risk for individuals with diabetes is at least double that of the non-diabetic population (WHO, 2012) and 50% of deaths in people with diabetes occur in those under 60 years of age (IDF, 2012b). An estimated 471.6 billion dollars was spent on the global diabetes burden in 2012 (IDF, 2012b). With diabetes prevalence continuing to increase world-wide, the condition is expected to impose further substantial strains on the public health purse, with countries at both ends of the developmental extreme being impacted (IDF, 2012b). Thus, effective prevention and intervention measures that can assist to curb this issue at the broader public health level are urgently required as the diabetes epidemic threatens to spiral out of control.

Australia has the fifth-highest prevalence of diabetes when ranked against other OECD countries (IDF, 2012b). In 2011–12, 4% of Australians had diabetes, and Type 2 diabetes accounted for 85.3% of cases, affecting 746 716 individuals (Australian Bureau of Statistics, ABS, 2013). It is estimated that at least half of Type 2 diabetes cases remain undiagnosed (Barr et al., 2006; IDF, 2012b) such that there are, in fact, 1.9 million people affected (IDF, 2012b). Furthermore, Australia's diabetes prevalence has increased by more than double from 1.5% of the population in 1989-90 to 4.1% in 2007-08 (ABS, 2011b), from which point it has not declined (ABS, 2013). This trend is a likely reflection of the increased public recognition and screening of Type 2 diabetes from the early 1990's; increases in the survival rates of those affected due to advances in treatment strategies; and/ or an increase in the number of cases (Magliano et al., 2009). Diabetes is most prevalent in those aged 65 – 74 years. Therefore, its prevalence is expected to continue rising as Australia's population distribution becomes primarily concentrated in the middle to older age cohorts, and due to increases in life expectancy over time (Magliano et al., 2008).

Diabetes is an Australian National Health Priority Area (NHPA) due to the high rates of diabetes-related morbidity and mortality. Diabetes is responsible for the Australia's fourth-highest burden of disease, comprising 8.2% of the total burden (Australian Institute of Health & Welfare, AIHW, 2012a). Diabetes and related causes were responsible for 5.4% of deaths in 2007 (AIHW, 2010a). Diabetes remains the leading cause of blindness in those aged 30 – 69 years, non-trauma-related lower limb amputations, end-stage kidney disease, and cardiovascular disease (primarily heart disease and stroke) (WHO, 2011a). In 2007 – 08, over ½ of Australians with diabetes reported having a physical disability or impairment. Almost ¼ of these individuals stated that diabetes was the condition that was primarily responsible for their disability (AIHW, 2010a). Further, diabetes-related disabilities tended to increase with age (ABS, 2011b). Diabetes-related costs to the Australian government comprised 2% of total disease expenditure, at approximately $990 million in 2011 – 2012, excluding out of pocket expenses and National Diabetes Services Scheme subsidies (AIHW, 2012a). Further excluded from this costing were intangible losses to individuals, their families and society. Specifically, the significant losses to work productivity, functioning and quality of life (Schram, Baan, & Pouwer, 2009) that inevitably result from diabetes-related psychological and emotional impacts were not accounted for in these cost estimates.

1.2.1 Prevalence of Affective and Mood Disorders in Diabetes

Mental health disorders are another key Australian NHPA, with anxiety disorders affecting an estimated 14% of Australians and affective disorders affecting 6% over a 12-month point-prevalence, and accounting for the leading cause of Australia’s disability burden (Begg et al., 2007). Government health expenditure on mental health services was in excess of $6.3 billion in 2009 – 10 (AIHW, 2012b). Mental health disorders were found to be significantly more common in those with, compared to those without, comorbid physical health conditions (AIHW, 2011). Depression and anxiety are considered to be causal (Wulsin, Vaillant, & Wells, 1999) and consequential (Wilhelm, Mitchell, Slade, Brownhill, & Andrews, 2003) factors of physical health conditions.

In 2007 – 08, an estimated 17.4% of people with diabetes aged 16 – 85 years had a comorbid lifetime mental health disorder (anxiety, affective disorder, or substance use disorder) with active symptoms in the past 12 months [National Health Survey (NHS): Summary of Results, 2007-2008]. Anxiety disorders were the most prevalent specific mental disorders within this group. Further, the 2007 – 08 NHS indicated that a significantly greater proportion (41.6%) of adults with diabetes reported experiencing medium to very high levels of psychological distress compared with the 32.2% of the non-diabetic population that was affected. Mental disorders and psychological distress were significantly more common in females than males, both in the diabetic and non-diabetic populations.

There is currently a paucity of high quality data on the prevalence of mood comorbidities in the diabetic population, with the most recent figures becoming outdated. Furthermore, psychological distress and comorbid mood disorders are frequently under-reported and often remain undiagnosed in people with diabetes due to factors including lack of regular screening by health care professionals and patients' poor treatment-seeking behaviours (Chen et al., 2011). Additionally, comorbid mood disorders may go unrecognised in patients, as dysphoric symptoms including tiredness, withdrawal from social events, excessive worry and lack of motivation may be confused with symptoms of Type 2 diabetes (Alberti, 2002). Therefore, available data on the current prevalence, morbidity and mortality rates associated with comorbid diabetes and mental health disorders present conservative estimates. Overall, the evidence indicates that diabetes and comorbid mood disorders present significant challenges to individuals' well-being and pose particular challenges to health systems globally.

1.2.2 Type 2 Diabetes Aetiology

Type 2 diabetes is defined by progressive impairment of the body's sensitivity to insulin due to insulin resistance, and/ or deficiency in insulin secretion, with one or both of these effects being present at diagnosis (WHO, 2006). Inadequacies in glucose metabolism result, causing elevated plasma glucose levels. The initial onset of Type 2 diabetes is preceded by a phase between normal glycaemia and diabetes; a condition termed 'prediabetes', which is characterised by Impaired Glucose Tolerance (IGT) and/ or Impaired Fasting Glucose (IFG; WHO, 2006). The presence of abnormalities in glucose metabolism is identified by an oral glucose tolerance test (OGTT). This involves testing 8-hour fasting plasma glucose level prior to, and 2 hours following, ingestion of a 75 g oral glucose load.

IGT is indicated by a fasting plasma glucose level <7.0 mmol/l (126 mg/dl) and a 2-hour plasma glucose ≥ 7.8 and <11.1 mmol/l (140 mg/ dl & 200 mg/ dl; WHO, 2006), in which case fasting blood glucose levels are elevated above normal but lower than the level at which a Type 2 diabetes diagnosis is made (Dixon & Webbie, 2006). IFG is represented by a fasting plasma glucose level of 6.1 to 6.9 mmol/ l (100 mg/ dl to 125 mg/ dl) and a 2-hour plasma glucose level <7.8 mmol/l (140 mg/ dl; WHO, 2006). In IFG, fasting blood glucose levels are normal but blood glucose levels following food consumption remain raised for longer than normal (Dixon & Webbie, 2006). Individuals with prediabetes are 10 – 20 times more likely to develop Type 2 diabetes than those with normal glucose tolerance (Barr et al., 2006). A Type 2 diabetes diagnosis is determined by fasting plasma glucose of ≥7.0 mmol/l (126 mg/ dl) or 2-hour plasma glucose ≥ 11.1 mmol/l (200 mg/ dl; WHO, 2006). Alternatively, glycosylated haemoglobin (HbA1c) assay level, which is a marker of the integrated average glucose level for the past 8 – 12 weeks (Nathan, Turgeon, & Regan, 2007), is used as a diagnostic indicator, with the cut-point for Type 2 diabetes diagnosis being ≥ 6.5%.

Wide-scale efforts have been made to implement early diagnostic strategies for Type 2 diabetes, including screening using the Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK; Chen et al., 2011). However, diagnosis is commonly delayed for some time following the condition’s onset due to its typically asymptomatic nature in the early stages (IDF, 2012b). Therefore, plasma glucose levels are often elevated for substantial duration by the time hyperglycaemia symptoms become apparent. Consequently, approximately 50% of patients present with at least one diabetes complication at diagnosis (IDF, 2009a).

The aetiology of Type 2 diabetes is linked to a genetic predisposition in some individuals as it is 50% heritable (WHO, 2006). However, modifiable lifestyle risk factors, which primarily include overweight or obesity, insufficient physical activity, and unhealthy dietary intake, have an established causal role in Type 2 diabetes aetiology (Shaw & Chisholm, 2003). Furthermore, these risk factors can exacerbate progression to Type 2 diabetes from impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Australian health data from 2007 – 08 indicated that Type 2 diabetes risk increases proportionally with the extent of excess weight. For example, obese men were twice more likely to have had Type 2 diabetes (12%) than overweight men (6%), or men whose weight was in the normal or underweight range (5%). Women in this study demonstrated the same pattern (AIHW, 2010a).

In 2011 – 2012, 63.4% of Australians were overweight or obese, and 66.9% were sedentary or had low levels of exercise in the week prior to the interview, with physical activity levels declining with age (ABS, 2013). Furthermore, these risk factors are implicated in the development and progression of diabetes-related complications and other medical comorbidities due to their strong associations with glycaemic control and additional risk factors, including hyperlipidaemia and hypertension (Barr et al., 2006). Clustering of particular risk factors, including hypertension, dyslipidaemia, IGT or IFG, and abdominal obesity, has been termed the metabolic syndrome, and is associated with a two- to three-fold increased risk of developing Type 2 diabetes (Barr et al., 2006; Chew, Gan, & Watts, 2006).

Type 2 diabetes is typically diagnosed in individuals aged 40 years and over. Risk factor trends for Australians between 1995 and 2007–08 demonstrated an increase in overweight and obesity in all age groups, and the proportion of physically inactive adults remained over 50% (AIHW, 2012c). Consequently, large proportions of Australians risk developing Type 2 diabetes. Although it is most commonly seen in adults, Type 2 diabetes also occurs in children, and its incidence in the younger population is also rising (WHO, 2011b).

A further risk factor for Type 2 diabetes is depression, which has been shown to precede Type 2 diabetes diagnosis in 60% of cases (Black, 2006). Depression has been shown to have bi-directional associations with both Type 2 diabetes and cardiovascular disease (Clarke & Currie, 2009), with the effects of their relationship being as strong as that for other standard risk factors, including high cholesterol (Bunker, Colquhoun, Esler, & al, 2003). Risk factors typically occur in a cluster and lead to multiple comorbidities. For example, Type 2 diabetes, cardiovascular disease and chronic kidney disease are risk factors for each other (AIHW, 2009), largely due to their common causal factors. While efforts are at large in Australia to reduce these risks they are typically resistant to change. Thus reducing the incidence of Type 2 diabetes and its deleterious health outcomes remains a challenge.

1.2.3 Projections for Diabetes Prevalence

Diabetes prevalence has risen substantially above previously projected estimates for the present time. In Australia, diabetes prevalence has trebled in under 20 years, escalating from an estimated 193 000 diagnoses, or 1.3% of the population in 1989 – 90 to 818 200, or 3.9% of Australians in 2007 – 08 (AIHW, 2010a), at which point it has remained stable (AIHW, 2012a). Major causes for this increase include the ageing Australian population, reduced mortality for those living with diabetes, greater awareness and screening, and increased incidence due to lifestyle factors including the rising obesity "epidemic" (Colagiuri, Colagiuri, Yach, & Pramming, 2006; Wild, Roglic, Green, Sicree, & King, 2004; Zimmet, Alberti, & Shaw, 2001). In 1999 – 2000, IGT or IFG was estimated to affect 16.3% of Australians (Dunstan et al., 2002). Projections predict an increase in the proportion of those with prediabetes (Barr et al., 2006) along with an increase in modifiable lifestyle risk factors(Begg et al., 2007), and hence estimate a continual rise in Type 2 diabetes prevalence.

Diabetes' prevalence is predicted to increase in every country around the world (IDF, 2012b). Predictions indicate that in 2030 diabetes' world-wide prevalence will have risen to 438 million (IDF, 2009a), or will be two-thirds greater than the 2008 prevalence (WHO, 2012). Further, projections indicate that Australia's diabetes prevalence will increase by 221% from the 2003 estimate of 1.073 million cases, to 3.449 million cases in 2033 (Begg et al., 2007; Magliano et al., 2009). Continuation of 2000 – 2005 trends in diabetes prevalence through to the year 2025 would result in 38% of Australians aged 25 years developing diabetes in their lifetime (Magliano et al., 2008). The number of daily adjusted life years for those with diabetes is also expected to increase by 1.8% each year until 2023 (Begg, Vos, Barker, Stanley, & Lopez, 2008), presenting Australia's health system with an increasingly dire challenge. By 2023 Type 2 diabetes is predicted to become the leading cause of disease burden for males and the second leading cause for females (Begg et al., 2007). Diabetes is projected to incur the highest associated rise in economic burden on Australia's health care budget, with an estimated increase of 401% from $1.4 billion in 2002 – 03 to $7 billion in 2032 – 2033 (Vos, Goss, Begg, & Mann, 2007).

1.2.4 Type 2 Diabetes Management

International standards recommend the use of glycosylated haemoglobin assay (HbA1c) level as an indicator of glycaemic control (WHO, 2006). Long-term glycaemic control is strongly associated with the incidence and progression of diabetes complications (Stratton et al., 2000), as is the control of risk factors including dyslipidaemia and hypertension. Maintaining or improving glycaemic control to be at the recommended HbA1c level of $\leq$ 7.0% (Colagiuri, Dickinson, Girgis, & Colagiuri, 2009) has been shown to prevent or delay the incidence of microvascular (Stratton et al., 2000) and macrovascular (The ADVANCE Collaborative Group, 2008) complications. Each 1% decline in HbA1c level has been shown to produce a 21% overall risk reduction in complications (DCCT Research Group, 1993). The uptake and maintenance of regular physical activity, balanced nutritional intake, medication adherence, and blood glucose self-monitoring are strongly associated with adequate glycaemic control. Therefore guidelines on the management of Type 2 diabetes refer to these behaviours as essential treatment components of the Type 2 diabetes treatment regime (Colagiuri et al., 2009; IDF, 2012a; WHO, 2012).

Accordingly, the ultimate goals of Type 2 diabetes management are to achieve and maintain adequate glycaemic control (HbA1c level < 7%), lipid levels, and hypertension (Del Prato et al., 2005). A generic, step-wise treatment approach is recommended to normalise and maintain glycaemic control, with the stage at which Type 2 diabetes is diagnosed and its progression typically determining the prescribed treatment (IDF, 2012c). Most patients are initially advised to undertake lifestyle management alone, including regular physical activity and a healthy diet, provided that there is sufficient insulin production and insulin sensitivity to maintain adequate glycaemic control. Over time patients are often required to take anti-hyperglycaemic agents which are continued until up-titration to maximum dosage is reached, at which point additional anti-hyperglycaemic tablets are prescribed. Pancreatic insulin production typically continues to diminish and insulin resistance increases over time until the body is unable to produce and/ or utilise insulin sufficiently even with anti-hyperglycaemic tablets. Patients are then required to undertake insulin therapy to achieve recommended targets for glycaemic control [UK Prospective Diabetes Study (UKPDS) Group, 1998]. Whilst regular blood glucose self-monitoring may facilitate Type 2 diabetes management during its early stages, it becomes essential when patients are on insulin therapy (Colagiuri et al., 2009). Efforts to improve the long-term prognosis of Type 2 diabetes patients have involved physicians being urged to prescribe diabetes medications relatively promptly following diagnosis (Del Prato, 2005).

1.2.5 Type 2 Diabetes Treatment Adherence

At least 95% of the responsibility for diabetes management is up to the patient (Anderson, 1985). Effective Type 2 diabetes self-management is fundamental to patients' short- and long-term physical and mental health prognoses. However, long-term difficulties maintaining healthy lifestyle behaviours tend to remain problematic following Type 2 diabetes diagnosis. Conventionally, the term “adherence” is preferred to “compliance”, as the latter denotes that patients have a choice in following recommendations made by health professionals, rather than simply being required to follow orders (Haynes, Taylor, & Sackett, 1979). This change in terminology reflects the shift toward valuing chronic disease patients as active decision-makers in the treatment process, and the encouragement of health professionals to consult with them as such. The doctor-patient relationship is now commonly encouraged to promote patient concordance which involves pooling the patient’s and health care provider’s expertise and engaging in shared decision-making (Suraci, Mulas, Rossi, Gentile, & Giorda, 2012).

Non-adherence to recommended self-care regimens is as high as 38 – 75% in diabetes patients (Helmer & Harrington, 2004). Although non-adherence may occur in lapses rather than being continuous (Kirkley & Fisher, 1988), the accumulative risk of diabetes complications with hyperglycaemic episodes over time warrants concern (Stratton et al., 2000) and urgent intervention. In response to this need, numerous studies have attempted to uncover the reasons for patient non-adherence to prescribed treatments. A commonly identified factor that threatens adherence is the complexity of the Type 2 diabetes treatment regimen (Ingersoll & Cohen, 2008).

Behavioural changes are difficult to motivate in Type 2 diabetes patients, particularly due to this population’s typically inadequate practise of self-care prior to diagnosis. In Australia, 61.3% of the population has a body mass index in the overweight/ obese range; 71.6% has sedentary or low activity levels; and 93.8% has inadequate fruit and/ or vegetable consumption (NHS: Summary of Results, 2007-2008). Accordingly, behavioural risk factors common to Type 2 diabetes and mood disorders, including overweight/ obesity, physical inactivity and poor nutrition occur in a large proportion of Type 2 diabetes patients (AIHW, 2009). Difficulties changing lifestyle habits result in continued exposure to risk factors that lead to poor diabetes-related outcomes. Concordantly, a review of coaching strategies for improving the health outcomes of people with Type 2 diabetes concluded that motivating patients to make positive health behaviour changes was potentially the most challenging aspect of managing the condition (Cherrington, Wallston, & Rothman, 2010). However, the need for health professionals to modify their behaviour toward patients to facilitate change was also asserted, indicating that behavioural change at the patient level depends heavily on external factors, including the doctor-patient relationship, as well as personal factors.

A number of quantitative studies that have investigated barriers to effective diabetes self-management have revealed a range of issues. Chronic disease patients typically experience non-adherence to their treatment regimen due to motivational difficulties maintaining behavioural self-management, effects of emotional comorbidities at various periods, and disease non-acceptance (Fisher, Thorpe, DeVellis, & DeVellis, 2007). Whilst qualitative exploration of this issue has the advantage of obtaining an unbiased account of patients' views, a quantitative approach is often applied. Barriers reported in studies exclusively on diabetes self-management have frequently included medication costs, forgetting to take medications (Odegard & Gray, 2008), patient health beliefs causing reluctance to take prescribed medications (Mann, Ponieman, Leventhal, & Halm, 2009), low self-efficacy for medication-taking (Chao, Nau, Aikens, & Taylor, 2005; Sacco & Bykowski, 2010), treatment regime complexity (Fisher, Glasgow, Mullan, Skaff, & Polonsky, 2008), fear of hypoglycaemia (Barnett et al., 2010), and reduced social motivation for self-care (Egede & Osborn, 2010).

Quantitative studies provide a relatively broad perspective on adherence issues that may be addressed in standardised treatment interventions. However, these studies appear to be less rich sources of information on which to base personalised self-management interventions. Alternatively, a qualitative exploration of patients' needs and preferences for self-management support may be more appropriate for this purpose. Using a qualitative approach enables the achievement of an in-depth understanding of patients' lived experiences in managing Type 2 diabetes, which concedes with the essential aspect of patient empowerment in diabetes management (Anderson et al., 1995; Williams, McGregor, Freedman, & Deci, 2004).

1.2.6 Quality of Life and Type 2 Diabetes

Quality of life is an important marker of self-perceived physical and social functioning and mental health (Commonwealth of Australia, 1999). Improving quality of life in people with Type 2 diabetes is a cornerstone of diabetes management (Del Prato et al., 2005) with significant implications including improved treatment adherence (Mukherjee et al., 2009) and reduced mortality risk (Kleefstra et al., 2008). The self-perceived health status of Australians with Type 2 diabetes is significantly lower than that of the general population. Latest figures indicated that 42% rated their health status as fair or poor, with this proportion being identical for people with cancer who rated themselves in the same category, and second only to those with a profound or severe disability (ABS, 2008).

Results from the most recent National Survey of Mental Health and Well-being (2007 – 08) showed that quality of life declined as a function of increased disability (ABS, 2008). Concurrently, empirical research has indicated a significant, inverse relationship between diabetes complications and quality of life (UKPDS, 1999). Significant reductions in quality of life have also been found as glycaemic control worsens (Imran, Ismail, Naing, & Wan Mohamad, 2010; Tapp et al., 2006). In addition, factors associated with Type 2 diabetes self-management, which include treatment regime complexity (Franciosi et al., 2001; Lau, Qureshi, & Scott, 2004; Stack & al., 2011), hypoglycaemic events (Barnett et al., 2010) and weight gain, have demonstrated significant negative impacts on quality of life (Herman, 1999; Tapp et al., 2006). The maintenance of such factors may confound the association between improvements in glycaemic control and quality of life that have been reported in some studies (Ahroni, Boyko, Davignon, & Pecoraro, 1994; Kleefstra et al., 2005). Therefore, reduced quality of life as a function of diabetes management tends to impact individuals at both ends of the glycaemic spectrum. These findings suggest that improved glycaemic control alone may not suffice to produce improvements in individuals' perceived experience of living, and accordingly that ongoing support for diabetes self-management and additional factors, such as mood, is most likely necessary (Fisher, Brownson, O'Toole, & Anwuri, 2007).

Deteriorations in quality of life, particularly in terms of self-perceived physical functioning, have been shown to occur during impaired glycaemic control (IFG or IGT), when hyperglycaemia is generally asymptomatic. Furthermore, these declines tend to progress following Type 2 diabetes diagnosis (Tapp et al., 2006). In people with known Type 2 diabetes, subjective hyperglycaemia symptoms have shown associations with health-related quality of life independently of HbA1c levels (Kleefstra et al., 2005). Furthermore, increases in treatment regimen demands, including increased blood glucose self-monitoring and intensive insulin therapy, have been shown not to improve patients' quality of life (Commonwealth of Australia, 1999; DCCT Research Group, 1993; de Grauw, van de Lisdonk, van Gerwen, van den Hoogen, & van Weel, 2001; Goddijn et al., 1999; UKPDS, 1999). Together, this evidence suggests that lifestyle and psychological factors, including self-perceptions of Type 2 diabetes rather than the presence of the condition itself, can negatively impact on quality of life (Arcega-DomÃnguez, Lara-MuÃ±oz, & Ponce-De-LeÃ³n-Rosales, 2005). Therefore, targeting these factors in interventions aimed to improve quality of life in people with Type 2 diabetes would appear to be important.

Comorbid mental health disorders present substantial barriers to the achievement of satisfactory quality of life in people with diabetes. Recent survey data revealed that individuals suffering from comorbid physical and mental health conditions reported feeling significantly less pleased with their quality of life compared with individuals affected by a physical condition or mental disorder alone (ABS, 2008), and were approximately twice as likely to report being ‘out of role’ for more than 7 of the past 30 days (ABS, 2008). Together, the evidence conveys that taking a holistic approach to individuals’ experiences in living with Type 2 diabetes might most effectively assist with improving quality of life in this population.

1.2.7 Health Care for Australians with Type 2 Diabetes

Type 2 diabetes and dysphoria constitute two of the highest burdens to the Australian health care system at present (AIHW, 2012a). First-world countries such as Australia characteristically have the facilities, services, personnel and financial resources to meet the IDF Global Guidelines recommended standards of care (IDF, 2012a). However, there remains limited diabetes self-management support, particularly for those with comorbid dysphoria, due to the rising extent of diabetes-related disease burden. In 2010 – 11 Type 2 diabetes was the primary cause for major hospital admissions, with more than half of all in-patient hospital admissions being for diabetes-related eye complications. Other Type 2 diabetes-related primary causes of in-patient admissions included multiple complications, kidney disease, circulatory problems, poor diabetes control and hypoglycaemia (AIHW, 2012a). In 2007 – 08 individuals who were hospitalised for diabetes were more likely to have a comorbid mental health condition on their records (8.4%) than patients who were hospitalised for other conditions (7.5%) (AIHW, 2011). Individuals hospitalised with diabetes were primarily from the most and least advantaged socioeconomic quintiles (AIHW, 2011).

The 2009 – 2010 Bettering the Evaluation and Care of Health (BEACH) survey results revealed that diabetes was the fourth-most common chronic condition seen by general practitioners (GPs). Diabetes had accounted for 2.4% of all problems managed that year, which comprised 3.7 per 100 patient encounters, which represents a significant increase from the rate in 2000 – 01 of 2.8 per 100 encounters (Britt et al., 2011). Further, individuals with mental health conditions most commonly consulted a GP for initial help for their symptoms (Britt et al., 2011). In 2010 – 11, there were an estimated 13.9 million mental health-related encounters with GPs, which represented an increase of 4.8% from 2006 – 07 (Britt et al., 2011). Depression and anxiety were the two mental-health problems most frequently managed by GPs in 2010 – 11. The first-line treatment for mental health problems by GPs was prescribed or recommended medications. Psychological counselling and advice were the second-most common mental health-related treatments that GPs provided, and referrals to psychologists and other specialised mental health care were the third-most common approach. Mental health problems in diabetes patients often remain unaddressed due to practical constraints such as time limitations (Presseau, Sniehotta, Francis, & Campbell, 2009), and GPs' difficulties in knowing how to approach patients' psychological issues (Hajos, Polonsky, Twisk, Dain, & Snoek, 2011; Peyrot et al., 2005; Sturk et al., 2007). Therefore, additional patient support is needed.

Health system initiatives are aimed to improve access to and the affordability of specialist health services for chronic disease and mental health patients. The Better Access Initiative, which provides patients with a Medicare subsidy for allied health consultations (Medicare program: expanded coverage for outpatient diabetes self-management training and diabetes outcome measurements) was launched by the Australian Government in 2006. Accordingly, the average number of mental health-related services that were accessed showed a 34% increase between 2005 – 06 and 2009 – 10 (AIHW, 2012a). Patients with diabetes are encouraged to access a GP annual cycle of care, which includes a sequence of steps that includes regular screening and thus the early detection of complications (AIHW, 2012a).

While the need for emotional and psychological support for diabetes patients is well recognised (Adriaanse et al., 2008; Fisher, Thorpe, et al., 2007; Peyrot et al., 2005), significant improvements are needed to achieve the provision of adequate care. Current allowances of up to 10 Medicare-subsidised visits to a mental health professional each year are unlikely to be sufficient to treat ongoing emotional difficulties, particularly for those facing significant behavioural and psychological problems. The lower socioeconomic bracket represents a disproportionately large proportion of the Australian Type 2 diabetic population, and is somewhat disadvantaged in the Australian health care system. Furthermore, current government initiatives commonly remain unutilised by target populations. For example, in 2010 – 11 just 18% of people with diabetes completed a cycle of annual care, despite the fact that GPs are the commonest diabetes management primary care providers (Britt et al., 2011). Furthermore, during that year just 1 in 5 patients with a mental health condition were recorded as having a GP mental health treatment plan.

Patients' reluctance to access mental health services in the primary care setting may prevent them from receiving needed support. For example, the majority (86%) of people with a diagnosed mental disorder reported that in 2007 – 08 they had not used services for their mental health problem in the previous 12 months (AIHW, 2010b). Of those who did access mental health services during this time, 26% reported feeling that their need for counselling was, at best, only partially met, and a further 29% indicated feeling that their need for information was, at best, partially met (ABS, 2011a). More regular and ongoing forms of support may assist with better meeting the self-management and mental health needs of people with diabetes. Whilst ecological and service-based initiatives to provide extra support to diabetes patients are important, this data indicates that additional patient-level support is required.

1.2.8 Rural and Regional Health in Australia

Geographic remoteness is a significant and widely recognised ecological barrier to those with Type 2 diabetes receiving adequate self-management, emotional and psychological support. Rural and regional areas are hereby referred to according with the ABS Australian Geographical Classification (ASGC; 2010), as areas outside of Major cities (ABS, 2010). In 2003, females living in rural and remote areas were 1.3 times more likely to report having diabetes than those living in Major cities (AIHW, 2008). Rates of death due to diabetes were higher in non-urban than within metropolitan populations (AIHW, 2012a), and Standardised Mortality Ratios (SMRs) indicated a positive relationship between increasing geographic remoteness from city regions and death rates from diabetes (Dunn, Sadkowsky, & Brockway, 2006). In 2002 – 04, diabetes caused 6% of ‘excess’ deaths in rural and regional areas (AIHW, 2007).

Australians residing in non-urban areas were more likely to exhibit multiple lifestyle risk factors for chronic disease, with higher proportions more commonly having reported four or more risk factors than those living in Major cities (AIHW, 2012a). In particular, higher levels of saturated fat intake (as indicated by measures of whole milk consumption), insufficient physical activity, tobacco smoking (AIHW, 2012a), and risky levels of alcohol consumption have been found in Australians living in Remote or Very remote areas compared with those in Major cities. Concurrently, diabetes complications have shown higher prevalence and severity in non-urban populations, in which hospitalisations for lower-limb amputations, rates of long-term vision loss and cardiovascular disease have been shown as substantially higher than in metropolitan populations (AIHW, 2012a). Furthermore, levels of health literacy are lower in people living outside Major cities (AIHW, 2012a), which is associated with poorer self-assessed health status and which has significant implications for effective diabetes self-management.

Rural and remote dwellers face significant barriers to receiving adequate health care due to factors typically associated with rurality (AIHW, 2008). Specifically, factors include geographic isolation and limitations to the availability of health services and health care providers; access issues presented by transport and communication restrictions; and higher rates of socioeconomic disadvantage (AIHW, 2008). An estimated 20% of all primary health care providers across Australia service the 29% of the population that resides in non-urban areas (Catanzariti, Faulks, & Water, 2007), which seriously limits the likelihood that patients can receive the regular and ongoing support that they need. Access and availability issues exacerbate the inherent challenges associated with Type 2 diabetes self-management and psychological intervention. Further, they suggest that effective intervention requires going beyond the scope of traditional services and rather looking to provide a support system that offers greater availability and access, as well as wider outreach to this population.

1.2.9 Section Summary and Conclusions

This section discussed the escalating impact of diabetes on a global and national scale. The latest statistics on diabetes prevalence and impacts were used to demonstrate the urgent need for effective, wide-spread intervention.

1.3 Depression, Anxiety, Distress and Type 2 Diabetes

‘Mental health’ refers to having proficient wellbeing to enable the realisation of one’s potential, ability to cope with life stressors, satisfactory work productivity, and to make community contributions (WHO, 2010). The International Classification of Disease (ICD) – 10th revision classification of mental and behavioural disorders defines a mental disorder as “the existence of a clinically recognisable set of symptoms or behaviour associated in most cases with distress and with interference with personal function” (WHO, 1992, p. 5). The prevalence of mental health problems is substantially higher in people with, than those without diabetes, which supports the bidirectional nature of the diabetes/depression relationship. Mental health problems and diabetes have common risk factors and outcomes. In particular, both have been shown to significantly undermine physical and mental wellbeing, and further to debilitate quality of life (AIHW, 2011).

1.3.1 Psychological Distress and Type 2 Diabetes

Severe psychological distress, referring to high or very high levels of overall psychological strain or pain (ABS, 2001), is more prevalent in people with, than in those without diabetes (ABS, 2004-05). Levels of psychological distress tend to increase as a function of physical disability. In the 2007 National Survey of Mental Health and Wellbeing, 23.8% of Australians with diabetes reported having some form of restriction or disability compared with 36.1% of the general population (ABS, 2008). Higher levels of physical disability are associated with increased stress in the face of personal stressors than lower levels of physical disability (ABS, 2011a). People with diabetes commonly reported having poor self-perceived physical and mental health status, which can exacerbate psychological distress (AIHW, 2010a). Additional risk factors for distress in people with Type 2 diabetes included lower educational status (Peyrot & Rubin, 1997), being female (Lustman, Griffith, Clouse, & Cryer, 1986; Peyrot & Rubin, 1997), lack of social support (Whittemore, D'Eramo Melkus, & Grey, 2005), being unmarried (August & Sorkin, 2010), and being from an ethnic minority group (Manderson & Kokanovic, 2009).

1.3.2 Dysphoria and Type 2 Diabetes

Dysphoria hereby refers to psychological and emotional problems that are characterised by symptoms of an affective or anxiety disorder and/ or psychological distress. Depression is characterised by, “a state of gloom, despondency or sadness lasting at least two weeks. The person usually suffers from low mood, loss of interest and enjoyment, and reduced energy. Their sleep, appetite and concentration may be affected” (AIHW, 2011, p.32). Anxiety disorders refer to, “...excessive feelings of apprehension, worry, nervousness, and stress” (AIHW, 2011, p.36) and include the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV-TR) classification of Generalised Anxiety Disorder (GAD; American Psychiatric Association, 2000).

Comorbid diabetes and dysphoria represents one of Australia’s most dire health challenges to date. In 2007, 6.2% of Australians aged 16 – 85 years reported having experienced an affective disorder, and 14.4% reported experiencing an anxiety disorder in the previous 12 months (ABS, 2008). In 2010, mental disorders were the third-leading contributors to Australia’s total burden of disease (AIHW, 2010a). Similarly, to diabetes, non-fatal burden comprised the majority of disease burden attributable to anxiety and depression (AIHW, 2010a). Specifically, they accounted for the loss of an estimated 203 000 daily adjusted life years (DALYs), or 7.1% of total DALYs for Australians per annum (Begg et al., 2007). Projections for 2023 predicted that anxiety and depression will remain within the top five conditions responsible for Australia’s disease burden. Australian health system expenditure on mental health services has increased by an average of 5.2% per annum between the years 2000 – 01 and 2005 – 06, to an estimated $2.7 billion (ABS, 2009a).

Depression and anxiety accounted for the top two mental health-related problems managed in the Australian health care system, and hence were responsible for the majority of this expenditure.

Depression and anxiety have shown a two- to three-fold prevalence in individuals with Type 2 diabetes compared with those in the general population (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001). Depression occurs in 27% of people with Type 2 diabetes according to self-report scales and 9% based on clinical diagnostic interviews, and is more prevalent in women than in men (Anderson et al., 2001). GAD has been reported to affect 14% of people with diabetes (Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002).

Subsyndromal depression and anxiety symptoms are substantially more prevalent than clinical presentations of these disorders. For example, findings of a longitudinal study indicated that depressive symptoms and distress were each 60 – 73% times more prevalent than clinical affective and anxiety disorders (Fisher et al., 2008). A meta-analysis of anxiety disorders prevalence in people with diabetes indicated that 40% of participants in the included studies had elevated anxiety levels and 14% had GAD (Grigsby et al., 2002). Another study that measured depression and diabetes-specific distress in a sample of Type 2 diabetes patients reported that 24% had subclinical depression symptoms compared with 11% who were clinically depressed (Kokoszka, Pouwer, Jodko, Radzio, Mućko et al., 2009).

In up to 50 – 75% of cases depression remains undiagnosed in people with diabetes even at clinical levels (Leppävuori, 2010; Pouwer, Beekman, Lubach, & Snoek, 2006). A study conducted in the United States found that failure to diagnose depression was significantly higher in Type 2 diabetes patients than in people without diabetes (Li et al., 2009). Reasons may include that symptoms of dysphoria are mistakeable for those of hyperglycaemia, such as fatigue, and/ or that sadness, hopelessness, or anxiety may be confused for natural consequences of diabetes. Therefore, dysphoria and associated negative outcomes are likely to persist in people who have Type 2 diabetes long before intervention is sought.

Dysphoria symptoms have more serious health and psychological outcomes for people with diabetes than for those without diabetes (Lustman, Griffith, & Clouse, 1988). Comorbid depression/ anxiety with diabetes is significantly related to substantially reduced engagement in diabetes self-care (Bell et al., 2000; Ciechanowski, Katon, & Russo, 2000; Gonzalez, Safren, et al., 2008), including medication adherence (Gonzalez et al., 2007), foot care (Scollan-Koliopoulos, Walker, & Bleich, 2010), and participation in physical activity and dietary adherence (Katon et al., 2010). Associated consequences include poor glycaemic control (Anderson et al., 2002; Lustman et al., 2000; Pouwer et al., 2010; Pouwer & Snoek, 2001), increased risk of diabetes complications (Black, Markides, & Ray, 2003; de Groot, Anderson, Freedland, Clouse, & Lustman, 2001; Williams et al., 2010), impaired functionality (Pawaskar, Anderson, & Balkrishnan, 2007), reduced quality of life (Ali et al., 2010; Chyun et al., 2006; Papelbaum et al., 2010; Schram et al., 2009), cardiovascular disease (Katon et al., 2004) (particularly in women; Clouse et al., 2003; Pan et al., 2011), and a higher risk of mortality (Egede, Nietert, & Zheng, 2005; Zhang et al., 2005). Even subclinical levels of anxiety and depression have been associated with such effects (Black et al., 2003; Gonzalez, Fisher, & Polonsky, 2011; Gonzalez et al., 2007). Further, depression tends to inhibit the seeking of treatment and social support in Type 2 diabetes patients (Egede & Osborn, 2010), which increases the likelihood of its progression to clinical symptoms.

United States research has estimated health care costs to patients with comorbid depression and diabetes being 4.5 times higher than those for patients with diabetes alone (Egede, Zheng, & Simpson, 2002). Another study estimated the difference to be 70% (Simon et al., 2005). Subclinical dysphoria severely impacts the health and functioning of diabetes patients (Cuijpers, Smit, & Willemse, 2005; Kokoszka, Pouwer, Jodko, Radzio, MuÄ‡ko et al., 2009) and thus exerts substantial financial strains on health care systems. Therefore, intervention is warranted even at subclinical levels.

The precise causal mechanisms involved in the association between dysphoria and Type 2 diabetes remain unclear (Musselman, Betan, Larsen, & Phillips, 2003). However, diabetes and mood disorders (referring to depression and anxiety) are commonly reported to have a bidirectional relationship (Knol et al., 2006). The Consequence Model portrays dysphoria in diabetes patients as resulting from negative self-relevant cognitions, including low self-efficacy, that arise from failure to meet self- or other-imposed standards for treatment goals (Sacco et al., 2005). Further, the model proposes that physiological symptoms caused by poor adherence and inadequate glycaemic control play a role in affective pathology (Sacco et al., 2007). The relationship between Type 2 diabetes treatment adherence and dysphoria is proposed to be mediated by low levels of self-efficacy and physiological diabetes-related symptoms, such as diabetes complications and hyperglycaemia.

Factors believed to be implicated in successful diabetes management are thought to be associated with self-efficacy. With Type 2 diabetes, these factors may include physical activity, dietary and health regime adherence, and weight loss or maintenance. Poor adherence resulting in failure to meet a desired treatment target is proposed to result in low self-efficacy and depression (Sacco et al., 2005). This model is supported by research that reported positive associations between diabetes complications or demands of the treatment regimen and dysphoric mood (Chyun et al., 2006; de Groot et al., 2001; Peyrot & Rubin, 1997). Studies in which affective symptom severity has shown a significant negative relationship with glycaemic control (Anderson et al., 2002; Lustman et al., 2000) also support the Consequence model.

The Antecedent Model suggests that dysphoria is present prior to the onset of Type 2 diabetes. This model proposes that activation of the hypothalamic-pituitary-adrenal axis in response to dysphoria stimulates the sympathetic nervous system (Black, 2006) and thereby leads to alterations in glucose transport functions; increases in the activation of immune-inflammatory responses, and the release of counter-regulatory hormones. These processes are proposed to contribute to insulin resistance in bodily cells and/ or to pancreatic β-islet cell dysfunction (Black, 2006). In obese individuals, depressive behaviour may also be induced by the expression of excess TNF-α in the adipose and muscle tissue, leading to insulin resistance (Wing, Phelan, & Tate, 2002). Thus, depression is proposed to increase the physiological risks for developing impaired glucose tolerance and hence, in many cases, leads to Type 2 diabetes.

The Antecedent Model further proposes that stress is implicated in Type 2 diabetes etiology. Stress is associated with the release of counter-regulatory hormones in the brain, including glucagon, glucocorticosteroids, growth hormones and catecholamines, which counteract the processes by which insulin reduces blood glucose levels (Sapolsky, Romero, & Munck, 2000). Further, stress causes blood glucose levels to rise rapidly due to the release of epinephrine and glucagon following which blood glucose levels remain elevated for hours due to glucocorticoid and GH action (Munck & et al., 1990). The antecedent model suggests that Type 2 diabetes and depression have common biochemical risk factors. Further, it is proposed that as well as reducing the individual’s tendency to participate in essential self-care behaviours, affective disturbance in individuals with Type 2 diabetes impairs the body’s effective utilisation of insulin via these physiological processes, resulting in hyperglycaemia (Sapolsky et al., 2000).

Scientific literature supporting this view includes a meta-analysis which revealed that in people with Type 2 diabetes the risk of developing depression was 15%, and people with Type 2 diabetes had a 60% increased risk of depression (Mezuk, Eaton, Albrecht, & Golden, 2008). Concurrently, depressive symptoms have been shown to persist despite improvements in glycaemic control (Ciechanowski, 2003; Lustman, Griffith, Clouse et al., 1997) or the onset of diabetes complications (Lustman et al., 1988; Paschalides et al., 2004), which suggests that rather than simply being a consequence of diabetes control, depressive symptoms can exist independently. These findings demonstrate that in interventions that are aimed to improve diabetes self-management it is essential to address dysphoria symptoms.

Dysphoria has demonstrated impairing Type 2 diabetes self-management and glycaemic control via interactive cognitive and physiological effects. Therefore, while stress management may help to prevent Type 2 diabetes, urgent intervention that incorporates long-term dysphoria symptom management is crucial for those who already have diabetes (Egede & Ellis, 2010). Evidence indicates that in many cases dysphoria symptoms preceded and possibly were implicated in the development of Type 2 diabetes, and hence that people with diabetes have a long-standing predisposition to poor mental and physical health outcomes. Furthermore, it is foreseeable that diabetes-specific stressors are highly likely to incur an additional burden in this vulnerable population.

There may be differential associations between the various forms of dysphoria (depression, anxiety and psychological distress) and physiological and psychological outcomes (Fisher et al., 2009; Fisher et al., 2007; Gonzalez et al., 2011). For example, the Edinburgh Type 2 Diabetes Study demonstrated that symptoms of depression were related to abdominal obesity and cardiovascular disease, whilst anxiety was not significantly related to these outcomes (Labad et al., 2009). Despite differences in the effects of various types of dysphoric mood on well-being, each psychological and emotional symptom presentation tends to significantly impact the wellbeing of people with diabetes, albeit in various ways. Furthermore, psychological, psychosocial and ecological diversity between individuals is likely to influence the impacts of psychological and emotional symptoms on outcomes. In turn, these effects are likely to differ over time as a function of changes in the point-prevalence of symptoms. Therefore, it is essential that personalised psychological and emotional support that caters for individual diversities on an ongoing basis is provided to the highest possible degree (Fisher et al., 2007).

1.3.3 Diabetes-Specific Distress and Type 2 Diabetes

Diabetes-specific distress refers to stress that is specifically related to the emotional, physical, and psychological burden associated with diabetes and its management (Fisher et al., 2008). Diabetes distress involves issues including fear of diabetes complications (Scollan-Koliopoulos et al., 2010), anger related or unrelated to conflict with family and health professionals (Fisher et al., 2007; Polonsky et al., 1995), which has been shown to negatively impact on diabetes self-care (Scollan-Koliopoulos et al., 2010), and poor glycaemic control (Adriaanse et al., 2008; Fisher, Glasgow, & Strycker, 2010; Fisher, Mullan et al., 2010; Fisher et al., 2008).

Distinctions between the effects of depression and diabetes-specific distress on wellbeing have in particular attracted much empirical interest (Fisher et al., 2009; Fisher et al., 2007; Gonzalez et al., 2011). Identifying these differences has been popularised as a means of seeking to provide symptom-specific, and hence optimally effective, intervention (Gonzalez, Delahanty, Safren, Meigs, & Grant, 2008). Research findings have indicated that the point-prevalence of diabetes distress (18%) is significantly higher than that of major depressive disorder (10.7%; Fisher, Glasgow et al., 2010). Furthermore, diabetes-specific distress has shown significant relationships with glycaemic control and diabetes self-care, whilst Major Depressive Disorder (MDD) and dysphoria did not (Fisher, Glasgow et al., 2010; Fisher et al., 2008; Fisher et al., 2007). However, other research has reported a significant relationship between diabetes-specific distress and depression such that diabetes-specific distress was more prevalent in those with a history of MDD (Fisher et al., 2009) and those with current clinical or subclinical depression (Adriaanse et al., 2005; Kokoszka et al., 2009). This relationship may be understood in the context of research that has demonstrated a mediation effect of diabetes-specific distress on the relationship between depression and glycaemic control (van Bastelaar et al., 2010). Overall, findings emphasise the importance of targeting diabetes-specific distress, particularly in patients who exhibit depressive symptoms.

Symptom amplification, which is characteristic of depression (Ludman et al., 2004), has been shown to heighten emotional vulnerability in the face of diabetes-related issues, and to thereby increase the likelihood of experiencing distress. Personal stressors including negative life events and non-chronic stressors can significantly impair optimum diabetes self-management (Albright, Parchman, & Burge, 2001; Fisher et al., 2009; Goetsch, Abel, & Pope, 1994) and glycaemic control (Fisher et al., 2009; Skaff et al., 2009). Similarly to depression, general life stressors are likely to increase vulnerability to the effects of diabetes-specific stressors. External stressors are likely to compound the effects of diabetes-specific distress on glycaemic control and emotional well-being (Fisher et al., 2009). Indeed, relaxation and stress management training in diabetes patients has demonstrated producing significant positive effects on blood glucose control (Attari, Sartippour, Amini et al., 2006; Surwit, 2002) and mood (Stenstrom, Goth, Carlsson et al., 2003). Given the inter-related effects of diabetes-specific and external stressors, diabetes self-management interventions should ideally utilise a holistic approach that targets the discussed psychological and emotional issues.

1.3.4 Section Summary and Conclusions

This section reported the high prevalence of dysphoria in people with Type 2 diabetes and the deleterious impacts on individuals' physical and mental health that are linked to comorbid mood disorders. Numerous empirical studies have investigated the differential effects of various types of emotional dysregulation, including depression, anxiety and diabetes-specific distress, in people with diabetes. However, conventional intervention approaches would ideally aim to improve the identification and management of all types and severities of dysphoria in this population.

1.4 A Qualitative Overview of Patients' Perspectives on Type 2 Diabetes Self-Management

The issue of diabetes treatment non-adherence is universal (Vermeire et al., 2005), with significant influences including personal beliefs, motivations, psychological strengths and weaknesses, and various external factors (Peyrot et al., 2005). Once typically seen to affect the upper class due to over-indulgence in unhealthy foods and leading a leisurely lifestyle, Type 2 diabetes now more commonly affects the lower socioeconomic bracket of society. This class typically experiences significant external barriers to effective disease self-management which include financial difficulties making it difficult to afford mediations and healthy food, poor access to fitness facilities, and infrequent allied health support (IDF, 2012b). Further challenges for this group include educational limitations, which increase the risk of poor health literacy (Forbes, While, Griffiths, Ismail, & Heller, 2011), unemployment, reduced social support, and mental health issues (AIHW, 2012a); all of which are significantly associated with poor diabetes self-care and outcomes (Nam, Chesla, Stotts, Kroon, & Janson, 2011; Yamashita & Kart, 2011).

Interpersonal barriers, including psychological issues (Adili, Larijani, & Haghighatpanah, 2006), health beliefs (Alderson, Foy, Glidewell, McLintock, & House, 2012; Klok, Sulkers, Kaptein, Duiverman, & Brand, 2009), and diabetes-related attitudes and perceptions (Siminerio, 2008; Vermeire et al., 2007), can also impair adequate diabetes self-care. Qualitative research has revealed that Type 2 diabetes patients are commonly confused about the purpose of their prescribed treatment (Hayes, Bowman, Monahan, Marrero, & McHorney, 2006; Nair, Levine, Lohfeld, & Gerstein, 2007). Patients' health beliefs represent a further barrier to treatment adherence, and in particular underlie attitudes towards following prescribed medication regimes (Mann et al., 2009). Additional, self-reported reasons for medication non-adherence in Type 2 diabetes patients include their refusal to commence anti-hyperglycaemic agents or insulin, and medication side-effects (Khan, Lasker, & Chowdhury, 2011). Fear of hypoglycaemia has also been shown to significantly undermine patients' adherence to diabetes medications, and has an increasing effect as the treatment regime becomes more complex (UKPDS Group, 1998). Weight gain is another deterrent to medication adherence which longitudinal research indicates is a typical consequence of sulfonylurea and insulin therapy (UKPDS Group, 1998). A further issue is forgetting to take medications (Odegard & Gray, 2008). Often these issues are overlapping in the same individual, and combined these factors present substantial difficulties for medication adherence.

Patients' perceived treatment burden is another factor that commonly affects adherence to pharmacological treatment (Cobden, Niessen, Barr, Rutten, & Redekop, 2010; Odegard & Capoccia, 2007; Vermeire, Van Royen, Coenen, Wens, & Denekens, 2003). A systematic review of studies on medication adherence in patients with chronic illnesses found a negative relationship between Type 2 diabetes medication adherence and the number of medications in the treatment regimen (Penfornis, 2003), which is supported by other, diabetes-specific empirical studies (Rubin, 2005). A study of 446 diabetes patients in the United States reported that many considered the burden of following a healthy diet to equate to that of taking anti-hyperglycaemic tablets. Further, when weight loss was required, following a diet was equated to the burden of taking insulin (Vijan et al., 2005). Wide variation in patients' perceptions of diabetes treatment burden suggest it is important to explore the variety of experiences related to managing diabetes to understand the range of potential effects on treatment adherence.

A further significant barrier to effective self-management is lifestyle inflexibility resulting from strict adherence to the Type 2 diabetes treatment regime. A particular caveat in this domain occurs when patients are unable to take medications on time or eat to routine. An international study that enrolled 123 people with Type 2 diabetes from four European countries and the United States found that difficulties with adhering to a routine in addition to problems with modifying alcohol intake and diet were common across countries (Frandsen & Kristensen, 2002). Even after lifestyle changes were successfully implemented, patients typically resumed past patterns of behaviour in the long-term. The presence of common risk factors such as overweight/ obesity (Mier, Medina, & Ory, 2007; Schultz, Sprague, Branen, & Lambeth, 2001; Wycherley et al., 2010) and physical comorbidities (Ahroni et al., 1994) presents further self-management limitations, particularly in terms of physical activity adherence. Psychosocial resources have been shown to promote the maintenance of recommended lifestyle behaviours, which indicates that implementing social and systemic intervention can support patients in overcoming barriers to change (Barrera, MacKinnon, Strycker, & Toobert, 2008; Beverly, Miller, & Wray, 2008; Fisher et al., 2012; Kirk & Leese, 2009).

Furthermore, cultural affiliation can significantly impact on engagement in Type 2 diabetes self-management. This is particularly due to the impact of culture on the way that individuals make sense of Type 2 diabetes, which influences their approach to accepting and managing the condition (Khan et al., 2011). Cultural minority groups are less likely to have the ability and skills necessary to undertake a prescribed treatment regimen (Nam et al., 2011). For example, in a U.S.-based study, American non-immigrant women reported using more complex self-management techniques compared with Slavic immigrant women, with differences in hypoglycaemia awareness and education having disadvantaged the Slavic women in their self-management efforts (Barko, Corbett, Allen, & Shultz, 2011).

Individuals from ethnic minority groups have been found to experience less self-perceived control over their Type 2 diabetes than those in major cultural groups due to their generally poorer understanding of the condition and its management (Chlebowy, Hood, & LaJoie, 2010; Song, Lee, & Shim, 2010). Furthermore, there is often a mismatch between the usual diet of ethnic patients and the dietary guidelines they are recommended (Kochinor, Stronks, Nicolaou, & Haafkens, 2011). Frustration and emotional distress associated with failing to achieve treatment targets may be piqued in patients who also face pressure to adapt to a foreign lifestyle. Overall, there is a range of precluding factors that sabotage adherence to the diabetes treatment regime and individuals' holistic well-being, with cultural diversity often serving to exacerbate the inherent challenges.

The doctor-patient relationship has demonstrated bearing a fundamental impact on adherence to the Type 2 diabetes treatment regime (Nam et al., 2011; Vermeire et al., 2007). Qualitative studies on patients' perspectives on self-management have indicated that doctors provided insufficient information and/ or explanation of the diabetic treatment regime. This resulted in confusion about putting treatment recommendations into practise, and subsequently treatment non-adherence (Vermeire et al., 2003). Patients consequently used their own judgements to manage their diabetes, which often resulted in inadequate self-management. Another study indicated that patients who felt they had a poor understanding of required self-management tasks and their purposes reported experimenting with prescribed treatments to personally assess the risks and benefits (Nair et al., 2007).

Furthermore, patients have reported that their doctors failed to acknowledge their difficulties with understanding diabetes and their self-management efforts (Bissell, May, & Noyce, 2004; Wellard, Rennie, & King, 2008). Consequences may include treatment non-adherence (Ciechanowski, Katon, Russo, & Walker, 2001; Schillinger, Bindman, Wang, Stewart, & Piette, 2004), and the augmentation of diabetes-related emotional difficulties. Accordingly, patients have reported valuing collaborative communication with their primary care physician, and that this tends to enhance their diabetes treatment adherence (Nagelkerk, Reick, & Meengs, 2006; Schillinger et al., 2003). Evidence from these studies indicates that improvements in understanding between primary care providers and people with diabetes are needed to limit the adverse consequences of current inadequacies on diabetes self-management. Overall, diabetes patients have reported their acceptance of physicians' primarily task-oriented approach in consultations. However, they indicated that physicians' acknowledgement of their patients' psychosocial and emotional challenges and incorporation of this into their communication with them would facilitate their self-management (Alberti, 2002).

Qualitative research into physicians' perspectives on Type 2 diabetes self-management has revealed that physicians were commonly attuned to patients' difficulties with treatment adherence. Physicians appeared to understand the difficulties associated with adhering to a complex treatment regime; issues with motivation to maintain diabetes self-care into the long-term; and the frequency and effects of emotional and psychological problems on diabetes self-care (Belle Brown et al., 2002). General Practitioners (GPs) have reported experiencing problems with their Type 2 diabetes patients' knowledge deficits regarding the condition and patients' minimisation of the risk of diabetes complications. Further, GPs have reported becoming frustrated when patients failed to meet targets for health behaviour and metabolic control (Wens, Vermeire, Royen, Sabbe, & Denekens, 2005).

Further qualitative studies on physicians' views of patients' reluctance to initiate insulin therapy have revealed that physicians were generally unaware of patients' common experience of fear about being on insulin and their diabetes progression (Ratanawongsa et al., 2012; Tan et al., 2011). In addition, patients' perceptions of being a failure for needing insulin therapy (Tan et al., 2011) along with psychological insulin resistance, which refers to patients' emotional and psychological difficulties accepting their need for insulin (Brod, Kongsø, Lessard, & Christensen, 2009), were commonly unrecognised by physicians in the study. Cultural diversity was seen by physicians to enhance typical barriers to insulin administration and adherence in general (Patel, Stone, Chauhan, Davies, & Khunti, 2012).

Difficulties in Type 2 diabetes self-management stem from the effects of dynamic, interactive factors related to the patient, physician, and system (Belle Brown et al., 2002). The doctor-patient relationship significantly impacts on diabetes self-management, as the attitudes, beliefs and treatment decisions of physicians have been shown to elicit or accentuate barriers to appropriate self-care (Puder & Keller, 2003). The phenomenon of clinical inertia, which relates to physicians forestalling the recommendation of particular treatments, is common in Type 2 diabetes patients, particularly with regards to insulin initiation (Suraci et al., 2012; Zafar, Davies, Azhar, & Khunti, 2010). Physicians have reported making personalised treatment decisions for their patients based on factors including financial status, perceived likelihood of adherence, demographics, and the presence of diabetes complications (Grant et al., 2009). Physicians are required to interpret patients' psychosocial and psychological readiness for therapy in making these judgements, which patients may not clearly communicate (Nam, Chesla, Stotts, Kroon, & Janson, 2011). Globally, patients have reported that effects of the doctor-patient relationship exceed those of health system limitations on their self-management (Vermeire et al., 2007).

Additionally, patients have reported that attempts by their physicians to motivate diabetes self-management were perceived as poorly construed and/ or purely unhelpful. Examples included the use of "shock tactics" to scare patients into improved self-care, placing pressure on patients to better self-manage, and threats to refer patients to hospital or increase their treatment intensity (Wens et al., 2005). Further, some physicians have reported interpreting patients' desire for autonomy as non-compliance (Matthews, Peden, & Rowles, 2009). A study that explored physicians' and patients' views on diabetes self-management revealed that both groups experienced self-blame when treatment targets were not achieved

(Beverly et al., 2012). However, patients were uncertain about how their physicians felt, and both samples reported communication difficulties in the doctor-patient relationship.

1.4.1 Section Summary and Conclusions

Overall, although miscommunication between patients and physicians has commonly been acknowledged, there remains a need for a better understanding of the dynamics of the patient-physician relationship. Furthermore, the apparent divergence in the perspectives of patients and physicians indicates the need to explore the views of both to gain a comprehensive picture of self-management successes and shortcomings. Therefore, interventions to complement physician care that are based on both patients' and physicians' accounts are most likely to meet the range of needs for additional Type 2 diabetes self-management support.

1.5 An Overview of Type 2 Diabetes Self-Management Interventions

Chronic disease patients are required to implement consistent, long-term disease self-management to achieve optimum well-being (Bodenheimer, Lorig, Holman, & Grumbach, 2002), and Type 2 diabetes patients face the burden of implementing a multi-faceted treatment regime each day. Concurrently, reports of people living with chronic diseases have indicated that they find maintaining effective self-management to be the most difficult aspect of living with a chronic disease (Harris et al., 2007). Current Australian guidelines that specify standards of diabetes care recommend adhering to a self-care routine comprised of four major components that each influence glycaemic control (Colagiuri et al., 2009).

Recommended components are associated with significant improvements in glycaemic control and other metabolic outcomes, and include regular participation in: blood glucose monitoring (Bond, 2006; IDF, 2009b; Liebreich, Plotnikoff, Courneya, & Boule, 2009; Meigs et al., 2003), physical activity (Balducci et al., 2012; Iijima et al., 2012; Kadoglou et al., 2012; Richert, Webb, Morse, O'Toole, & Brownson, 2007; Sigal, Kenny, Wasserman, & Castaneda-Sceppa, 2004; Trenell, Hollingsworth, Lim, & Taylor, 2008; Zisser, Sueyoshi, Krigstein, Szigiato, & Riddell, 2012), healthy nutritional intake (Adam, Evans, & Koopmanschap, 2003; Al Mazroui et al., 2009; Barclay, Gilbertson, Marsh, & Smart, 2010; Dämon, Schätzer, Höfler, Tomasec, & Hoppichler, 2011; Josephine, Frans, & Warren, 2003), and medication adherence (Mazroui et al., 2009; Haynes, Ackloo, Sahota, McDonald Heather, & Yao, 2008; Lawrence, Allison, Chen, & Demand, 2008). Results from randomised controlled lifestyle intervention studies with Type 2 diabetes patients have indicated that addressing these components is cost effective, at least partly due to reduced medication requirements (Redmon et al., 2010). Further, economic cost-benefit analyses conducted in 2010 revealed that the economic burden of diabetes will be significantly reduced in the U.S. within the next 20 years with significant improvements in Type 2 diabetes self-management (Fitch, Iwasaki, & Pyenson, 2010). Therefore, Type 2 diabetes self-management intervention entails numerous patient- and system-related advantages.

1.5.1 Intervention Issues with Dysphoria and Type 2 Diabetes

The extreme prevalence and impact of dysphoria in Type 2 diabetes patients has prompted the requirement of regular, ongoing symptom screening in order that adequate intervention be provided as early as possible (Fisher et al., 2008; Pelletier, Jethwani, Bello, Kvedar, & Grant, 2011; Pouwer, 2009). Pharmacotherapy for depression and anxiety has demonstrated efficacy in improving affective symptoms. However certain antidepressants cause hyperglycaemia [e.g. nortriptylene (Lustman, Griffith, Clouse et al., 1997)], whilst others have hypoglycaemic effects (Goodnick, Henry, & Buki, 1995), which may induce diabetes-related distress (Barnett et al., 2010). Poor metabolic control may worsen dysphoria and reduce responses to pharmacotherapy for depression/anxiety (Lustman & Clouse, 2005). In addition, increasing patients' treatment regime complexity inevitably exacerbates adherence issues (Ingersoll & Cohen, 2008). Furthermore, over time the risk of dysphoria tends to increase with the complexity of the Type 2 diabetes treatment regimen (IDF, 2012c) and is more persistent and recurrent in people with than in those without diabetes (Lustman, Griffith, Freedland, & Clouse, 1997). The bidirectional relationship between dysphoria and diabetes urges the need for early symptom intervention and ongoing support.

A recent meta-analysis on the efficacy of various interventions for depression compared pharmacotherapy, psychotherapy and both approaches combined. Moderate combined effect sizes were found for improvements in glycaemic control and depressive symptoms (van der Feltz-Cornelis et al., 2010). Psychotherapy demonstrated the largest effect size, which may be reflective of its common incorporation of diabetes self-management intervention. Collaborative care, comprising a stepped-care intervention combined with pharmacotherapy, was successful in reducing depressive symptoms but did not significantly improve glycaemic control. Similarly, a systematic review that included three randomised controlled trials (RCTs) on depression and glycaemic control in people with Type 2 diabetes concluded that while CBT produced improvements in depressive symptoms, there were no improvements in glycaemia (Wang, Tsai, Chou, & Chen, 2008).

A further systematic review on the effectiveness of combined depression and diabetes self-management interventions indicated that both diabetes and depression must be addressed in order to achieve optimum improvements in physiological and psychological outcomes (Wang, Tsai, Chou, & Chen, 2008). However, a review of treatments for depression in people with diabetes indicated that no interventions focused on targeting both diabetes self-management and dysphoria (Markowitz, Gonzalez, Wilkinson, & Safren, 2011). Targeting both issues may be required to produce optimum impacts on glycaemic control and mood, and hence for the most positive long-term outcomes.

Physical activity interventions appear to offer a promising alternative solution to the shortcomings associated with pharmacotherapy for dysphoria. Physical inactivity is linked to depressed mood in people with diabetes (Lysy, Da Costa, & Dasgupta, 2008), and regular exercise has demonstrated producing positive effects on depression (Aylin, Arzu, Sabri, Handan, & Ridvan, 2009), anxiety (Reddy et al., 2011) and self-efficacy (Netz, Wu, Becker, & Tenenbaum, 2005), as well as improving glycaemic control by its effects on glucose metabolism and insulin resistance (Cauza et al., 2005; Thomas, Elliott, & Naughton, 2006). Physical activity may also promote increased circulation to small and large blood vessels and thereby reduce the risk of diabetes complications (Praet & van Loon, 2009). Further, physical activity reduces common risk factors for both dysphoria and Type 2 diabetes, which include overweight/obesity (Ackermann, Finch, Brizendine, Zhou, & Marrero, 2008; Hills et al., 2010) and cardiovascular risk (Djousse, Driver, & Gaziano, 2009; Hordern et al., 2008; Marwick et al., 2009; Warburton, Nicol, & Bredin, 2006).

Although there are associations between poor nutritional intake and dysphoria, there is no known evidence on the effects of specific dietary interventions on dysphoria in people with Type 2 diabetes (ABS 2009; Bell et al., 2012). Multi-faceted diabetes self-management interventions are commonly applied, which make it difficult to identify the independent effects of the intervention's individual components.

1.5.2 Non-Web-Based Type 2 Diabetes Self-Management Interventions

A wide range of interventions aimed to improve Type 2 diabetes self-management and clinical, physical, and quality of life outcomes have been trialled. Interventions have ranged from targeting a single aspect of diabetes self-management (e.g. Hudon et al., 2008) (Kim, 2005) to multi-faceted treatments that targeted lifestyle behaviours and health routine adherence (Bird et al., 2010).

Diabetes education is widely recognised as an essential component of diabetes self-management in Australian and global guidelines (Colagiuri, Girgis, Eigenmann, Gomez, & Griffiths, 2009; IDF, 2012a). Patients must have the information to enable their proficiency in skill development for effective self-management (Bodenheimer et al., 2002; Fisher, Kohut, Schachner, & Stenger, 2011; Hicks, 2010). Diabetes education has demonstrated empowering patients by facilitating their understanding of the importance of adequate self-management and methods to achieve it (Anderson et al., 1995; Williams et al., 2004). However, presenting information about risk factors (Edwards et al., 2006), clinical parameters and diabetes treatment targets without concomitant behavioural intervention has shown to be ineffective (Stark Casagrande et al., 2012). Diabetes education alone has rarely produced significant improvements in diabetes self-care (Duke, Colagiuri, & Colagiuri, 2009; Glasgow & Osteen, 1992; Verheijden et al., 2004).

Where diabetes education has produced significant improvements on clinical outcomes, structured education programs such as the Diabetes X-PERT program have typically been used. Diabetes X-PERT was a patient-centred, group program that incorporated empowerment principles and discovery learning (Deakin & Whitham, 2009). When the effects of participating in six, 2-hour group sessions of diabetes self-management education were compared with usual care, significant improvements were found on HbA1c, weight, cholesterol, self-empowerment, foot care, and dietary intake in the intervention group. The inclusion of ongoing guidance and peer support and the structured nature of this intervention probably contributed to these effects. There is substantial evidence that supports the promotion of self-determination in people with Type 2 diabetes to facilitate self-management (Anderson et al., 1995; Deakin, Cade, Williams, & Greenwood, 2003; Howorka et al., 2000; Williams et al., 2004). Hence, a number of current interventions incorporate interactive features to improve users' sense of autonomy and responsibility for self-care (Couper, 1996; Zoffmann & Lauritzen, 2006).

Psychological and emotional support is a further fundamental component of diabetes self-management intervention (Fisher, Delamater, Bertelson, & Kirkley, 1982). The interactive effects of psychological, emotional and behavioural factors on disease self-management must be considered when designing treatment interventions and particularly when targeting populations at increased risk for dysphoria (Fisher, Thorpe, McEvoy DeVellis, & DeVellis, 2007). Accordingly, whilst behavioural interventions have a positive impact on diabetic outcomes, physical activity and nutrition (Concha et al., 2009; Fisher et al., 2007; Ismail, Winkley, & Babe-Hesketh, 2004), they are unlikely to remediate psychological and emotional issues. A systematic review of behavioural medicine interventions in diabetes found that they produced significant improvements in glycaemic control, diabetes distress, self-efficacy, self-management, proactive coping, and psychological symptoms (Plack, Herpertz, & Petrak, 2010). Seven of the 10 RCTs in the review included cognitive-emotive components, which included motivational interviewing, self-efficacy skills training, and coping skills training. A further five of the 15 included studies were categorised as purely “psychological interventions”, which demonstrates the significance of addressing psychological/ emotional factors in self-management interventions, even if they are primarily behaviourally-based.

Further, even physical activity interventions that have demonstrated short-term success in improving emotional regulation and diabetes self-care behaviours (Colley et al., 2008; Neumann & Frasch, 2009), failed to maintain effects into the long-term without the inclusion of psychological or emotional support. Motivation tends to wane over time as depressive symptoms increase, in which case physical activity participation is unlikely. In these cases, patients would potentially be left without required mood support or intervention.

Multi-faceted lifestyle interventions aimed to improve behavioural self-management and glycaemia in people with Type 2 diabetes have demonstrated efficacy (Eakin et al., 2010; Toobert et al., 2003). The Mediterranean Lifestyle Program trial, which involved a weekend retreat followed by 24 months of regular meetings for post-menopausal women with Type 2 diabetes, has had the longest-lasting positive effects on lifestyle behaviours to date. Improvements in nutrition and stress management lasted 5 years post-intervention and physical activity changes lasted for up to 1 year (Toobert, Strycker, Barrera, & Glasgow, 2010). Difficulties providing long-term, ongoing, cost-effective lifestyle interventions have resulted in the use of advances in telecommunications technology, including mobile phones, smart phones, tablets and the internet.

In the past decade telehealth services have increasingly been used as a means of lifestyle intervention delivery, including for people with diabetes (Earle, Istepanian, Zitouni, Sungoor, & Tang, 2010). Telehealth interventions have shown cost-effectiveness (Noel, Vogel, Erdos, Cornwall, & Levin, 2004) and can assist with reducing strains on the health care system while offering regular, convenient and ongoing delivery. Popular interventions delivered by phone have included motivational counselling by trained health coaches or nurses (Eakin et al., 2010; Orr et al., 2006; Sacco, Malone, Morrison, Friedman, & Wells, 2009), peer support telephone calls (Dale, Caramlau, Lindenmeyer, & Williams, 2008) and m-health (mobile phone applications) that provide feedback on goal attainment and/or reminders via short message service (SMS) texts (de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2008; Morrow, Menard, Ridolfo, & Leirer, 2003; Upadhyay, Kokalj Kokot, Kokalj Kokot, Car, & Svab, 2007; Vodopivec-Jamsek, de Jongh, Gurol-Urganci, Atun, & Car, 2008).

Studies have demonstrated that these interventions can improve diabetes self-care including healthcare appointment attendance (Morrow et al., 2003), exercise and foot care, diet, depression symptoms (Sacco et al., 2009), and HbA1c testing adherence (Orr et al., 2006). While telehealth can offer appropriate short-term intervention delivery, however, it requires the ongoing involvement of numerous trained staff, particularly in the case of nationwide implementation. Additionally, patients may experience less autonomy in their decision-making and/or a reduced sense of control in the context of continuous telephone coaching that provides frequent follow-ups. Rapid developments in web-based programs and applications have resulted in recent empirical attention on the web as an alternative means of intervention delivery.

1.5.3 Web-Based Diabetes Self-Management Interventions

Evaluations of web-based interventions have demonstrated the effectiveness of a web-based modality for Type 2 diabetes self-management intervention delivery (Ramadas, Quek, Chan, & Oldenburg, 2011). A surge has occurred in the development and evaluation of web-based diabetes self-management interventions particularly during the past decade, since McKay and colleagues' (2002) randomised trial of the Diabetes Network (D-Net) self-management and peer support intervention (McKay, Glasgow, Feil, Boles, & Barrera Jr, 2002). Nonetheless, further empirical studies on web-based chronic disease self-management programs are required, as inter-study heterogeneity has made it difficult to draw overall conclusions about their efficacy (Andersson, Ljotsson, & Weise, 2011), particularly given that intervention studies in this area to date are relatively short-term and have failed to investigate effects on a range of emotional, psychological, and self-care outcomes.

Australia has one of the largest proportions of computer and internet access per person in the world. In 2008-09, 72% of Australian households had internet access, with its availability in regional areas rapidly improving (ABS, 2009b). Online diabetes support programs may be more cost-effective (Brownson, Hoerger, Fisher, & Kilpatrick, 2009) than structured face-to-face and telehealth self-management programs, which incur substantial financial and time costs (Istepanian et al., 2009). Furthermore, online support programs offer broader and more frequent long-term accessibility than face-to-face interventions, and thus are reasonably well suited to supporting individuals in rural and regional locations (Glasgow, Vogt, & Boles, 1999). Finally, the regular, mostly reliable, ongoing and 24-hour accessible support that is possible via the web may be ideal for meeting the needs of people with Type 2 diabetes (Fisher, Brownson, O'Toole, & Anwuri, 2007). In this sense, the web may supersede the challenges that are inherent in other methods of self-management intervention delivery (Norris, Lau, Smith, Schmid, & Engelgau, 2002).

Pilot trials of web-based diabetes self-management programs that included informational, educational, and/or social support have reported finding high user acceptance and usability (Armstrong & Powell, 2008; Eyombo, 2009; McTigue et al., 2009; Pagliari et al., 2003; Schroter et al., 2011; Thomas & Elliott, 2009). In addition, novice computer users (McKay et al., 2002) as well as seniors (≥ 60 years; Wang, Balamurugan, Biddle, & Rollins, 2011; Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004) have demonstrated their willingness to use a web-based program to support their diabetes self-management. Furthermore, web-based programs have shown to be effective in improving clinical and behavioural self-management outcomes in people with diabetes. An example is a recent review of computerised patient education in chronic disease patients in which the independent effects of included interventions were specified. Results indicated that online interactive interventions that were focused solely on educational and/or instructional content significantly improved daily blood glucose levels among participants with diabetes. The authors concluded that face-to-face physician consultations should be complemented with interactive, online support to improve patient outcomes (Verhoeven, Tanja-Dijkstra, Nijland, Eysenbach, & van Gemert-Pijnen, 2010). An online nutrition information program containing cooking ideas, instructions, and facts about healthy eating produced significant improvements in knowledge, health beliefs & self-reported eating behaviours in a middle aged cohort with Type 2 diabetes (Ritzwoller, Toobert, Sukhanova, & Glasgow, 2006). As knowledge can heighten self-efficacy (Bandura, 1990), such an intervention may provide the impetus for initial mastery experiences related to nutrition self-care, which may be maintained with ongoing socio-cognitive support.

Another study evaluated the implementation of a 10-week physical activity impact trial. Experimental conditions included a condition that received a web-based, skill-building intervention; a condition that received exercise instruction in addition to three exercise labs each week, and a control group that received only physical activity instructions. Results indicated that significant improvements in self-regulation, vigorous activity, and outcome expectancies were equivalent for the first two (intervention) conditions, but no significant improvements were found in the control condition (Gougeon, Carrington, & Field, 2006). These results indicated that participation in an online SCT-based intervention can produce as much cognitive motivation as attending regular physical activity training sessions, and further that physical activity information alone has no such benefits. Health information is most likely to be insufficient for the prevention or remediation of diabetes-related self-management and affective challenges that patients commonly experience in the long-term (Fisher et al., 2007). Rather, supplementing diabetes education with coping skills training and providing behavioural self-management enhancement strategies can have ongoing effects and increase user retention (Unick et al., 2011). This issue is important, since drop-out rates for minimal therapist-assisted online psychological support programs can be as high as 82%, and have a weighted average of 31% (Melville, Casey, & Kavanagh, 2010).

Web-based diabetes self-management support programs based on social cognitive theory (SCT) and cognitive behavioural therapy (CBT) have demonstrated that improvements in clinical outcomes can be reasonably well maintained. A 2-year trial of a web-based intervention that featured SCT-based methods to modify illness attributions in seniors with diabetes showed that improvements in HbA1c level, weight and cholesterol level were maintained at 6 months post-intervention (Wantland et al., 2004). Lorig and colleagues (2010) trialled a web-based, therapist-assisted intervention for Type 2 diabetes self-management that was based on CBT techniques to support diabetes education, skill building, and support for stress (Lorig et al., 2010). The group that received e-mail feedback and reinforcement did not show differential clinical or behavioural improvements compared with the group that received the web-based program only. Significant improvements in self-efficacy and patient activation were found in both groups at 6 months post-baseline while a control group that received neutral health information showed no significant changes in any outcome (Lorig et al., 2010). Failure to produce or maintain significant improvements in clinical parameters including HbA1c level from directly post-intervention to 12 months post-intervention indicated difficulties in producing long-term maintenance effects via web-based intervention. Considering that web-based intervention delivery enables long-term implementation, further exploration of its propensity to do so warrants further exploration.

A randomised trial of the effects of combined therapist and computer-based nutrition support for diabetes patients revealed promising results for dietary intake (Stevens, Glasgow, Toobert, Karanja, & Smith, 2003). In the trial, 616 women were randomised to one of two experimental conditions. The intervention condition received a moderate-intensity nutrition intervention that involved two, 45-minute counselling sessions and 20 minutes using an interactive, computer-based intervention followed by two, brief follow-up phone calls. The control group received information that was unrelated to nutrition. The intervention condition demonstrated significant improvements in fat, fruit and vegetable intake that were maintained at 1 year post-intervention (Stevens et al., 2003). These studies indicated that web-based programs that include health education materials and skills training with ongoing support can significantly improve diabetes self-management.

Social support is integral to effective diabetes self-management (Albright et al., 2001; Fisher et al., 2012; Fisher et al., 1998; Hunt et al., 2012; Weinger, 2007) and emotional and affective well-being (Kokoszka, Pouwer, Jodko, Radzio, MuÄ‡ko, et al., 2009; Snoek et al., 2011). Prior research indicated that people with diabetes reported that the inclusion of a web-based community (Oh & Lee, 2012), peer support forum (Barrera, Glasgow, McKay, Boles, & Feil, 2002), or web-based interactions with a nurse (Bond, Burr, Wolf, & Feldt, 2010) in a web-based support program increased their perceived social support. Peer social support via online interventions has been included in recent web-based programs and typically involves the use of chat rooms, blogs, and forums (Lorig et al., 2010).

A recent Korean study tested the effects of computer-mediated social support in web-based communities on patient empowerment and doctor-patient communication (Oh & Lee, 2012). Following their interaction within the web-based community, patients reported significantly increased perceived social support from its members. In addition, they reported an increased sense of empowerment, which they felt assisted with improvements in doctor-patient communication. Hence, improvements in social support and patient empowerment that are enhanced by web-based programs may have flow-on effects to the doctor-patient relationship. However, social support that is viewed by patients as being inappropriate to their needs may exacerbate depression (Bond et al., 2006). Web-based forums may also expose individuals to inaccurate health-related information, which necessitates constant monitoring by administrators. Providing tools that motivate patients to increase their social support networks outside of the web program may be an effective alternative.

No known trials to date have investigated the effects of web-based interventions on users' development of and access to social support networks in the real world. The importance of social support to physical and psychological wellbeing, particularly in chronic disease patients, indicates the requirement for trials that investigate this possibility. Evidence of positive effects and the best way to go about implementing this feature would inform the incorporation of social support enhancement into future interventions (Toobert et al., 2010).

1.5.4 Web-Based Diabetes and Dysphoria Interventions

Wide-spread acknowledgement of the need to address psychological and emotional issues in diabetes self-management interventions has prompted a rise in the number of interventions that include emotional support components. Web-based treatments for depression and anxiety have demonstrated producing significant improvements in symptoms, including in patients with diabetes (Andersson et al., 2005; Meeuwissen, Holleman, de Jong, Nuyen, & Cim, 2011). In particular, web-delivered CBT has demonstrated equivalent efficacy to face-to-face CBT in treating depression (Hedman, Ljótsson, & Lindefors, 2012). Affective symptom severity has been shown not to modify the effectiveness of web-based CBT support in diabetes patients (van Bastelaar et al., 2012), which indicates that this form of intervention may be suitable to treat symptoms on a long-term basis. Web-based intervention delivery has also demonstrated appropriateness for addressing diabetes-specific and mood-related issues, and has shown high user acceptability in these contexts (van Bastelaar, Cuijpers, Pouwer, Riper, & Snoek, 2011).

In the Netherlands, a minimal-guidance, web-based CBT intervention both for people with type 1 and Type 2 diabetes and depression was adapted from a CBT intervention for depression ("coping with depression course") by incorporating diabetes-specific topics (van Bastelaar et al., 2011). The program included a mood self-monitoring tool and participants were encouraged to record their blood glucose levels to note any relationship between blood glucose control and mood. There was also an online library from which participants could print out texts to create their own compilation of relevant materials. The program provided a structured sequence of eight, weekly lessons that required the completion of homework tasks which involved watching brief videos of people living with diabetes. Homework was reviewed by a specially trained "coach," and automated email reminders were sent if participants failed to submit homework tasks within the week. Following a 2-week period, participants received an email advising them that failure to submit homework within the following week would result in being regarded as having dropped out of the trial. An RCT with a sample of 255 (*n*= 125 intervention; *n*= 130 wait-list control) indicated that at 1 month post-baseline there were significant improvements in the primary outcome of depressive symptoms. However, no statistically significant improvement was found for HbA1c level (van Bastelaar, Pouwer, Cuijpers, Riper, & Snoek, 2011).

A further RCT of a web-delivered, CBT-based diabetes self-management and depression intervention (nullDiabetergestemd.nlnull; DbG) is currently being implemented in the Netherlands (van Vugt, 2012). This program also offers participants guided self-help, and preliminary implementation trial results indicated that patients reported satisfaction with the program's availability and willingness to self-refer to it. However, health professionals reported that it was important for professionals to refer patients to the program and also of their awareness of patients' participation in the program.

A 6-month pilot RCT of a web-based program (mydiabetesliving.com) that is aimed to provide Type 2 diabetes self-management and mood intervention is in progress in Bristol, the UK (McKenzie, Montgomery, Bennert, Kessler, & Gregor, 2012). Initially, the psychological needs of people with Type 2 diabetes were explored using qualitative focus groups and a design workshop. The workshop revealed a theme that represented a complex relationship between patients' objective physical body and how they experienced it subjectively. Further, participants reported that they valued the anonymity provided by web-based support. Program development was built upon interview data. As the trial is currently underway, data analyses remain in progress.

Empirical research on web-based interventions aimed to target both Type 2 diabetes self-management and psychological/ emotional health is currently limited. Therefore, information about the efficacy of these interventions, their practicality for treating emotional issues, and the processes involved in their development and evaluation, are required.

1.5.5 Empirical Considerations in Developing Web-based Interventions

Increasing developments in the area of electronic medical records to facilitate chronic disease management by providers and share health information with patients have prompted trials of their effectiveness. In particular, trials of online interactive health application (IHCA) with health care provider interfaces for people with diabetes have yielded positive results in terms of their effectiveness and acceptability (Quinn et al., 2008; Venmans, Gorter, Hak, & Rutten, 2008). A systematic review that included 24 studies on IHCAs for people with chronic diseases indicated that the applications significantly improved knowledge, social support, clinical and continuous behavioural outcomes, and positive influences on self-efficacy (Murray, Burns, See Tai, Lai, & Nazareth, 2005). Trials of patient portals have indicated that increasing patients' awareness of their clinical status can motivate improved self-management. However, in light of the evidence presented in Chapter 4 regarding the importance of the doctor-patient relationship to self-care, the increased contact with health care providers that these interventions involves is likely to contribute to their efficacy. This indicates that integrating web-based diabetes management support programs into general practice is likely to be beneficial.

Intervention complexity has been a source of debate in chronic disease self-management. A review of RCTs of interventions aimed to increase medication adherence in people with diabetes revealed that complex interventions produced the greatest long-term effects in diabetes self-management adherence and treatment outcomes (Haynes et al., 2008). Specifically, these interventions featured combinations of information, reminders, self-monitoring, reinforcement, counselling, and family improvements. It is plausible that an approach encompassing complex interrelationships between individual, psychosocial and environmental factors involved in Type 2 diabetes self-management would optimise efficacy. Consistent with this idea, Xu and colleagues (2008) recommended that diabetes self-management interventions be designed to influence the personal factors of knowledge, self-efficacy and beliefs, as well as interpersonal areas of support for family members, and patient-provider communication skills (Xu, Toobert, Savage, Pan, & Whitmer, 2008).

Alternatively, there is evidence that simple, low intensity approaches are efficacious (Glasgow et al., 2006). In fact, comparisons between low- and high- intensity interventions have indicated that the two approaches have equivalent efficacy (Hansen et al., 2009). Furthermore, it is unclear whether adding components such as peer support (Glasgow, Boles, McKay, Feil, & Barrera, 2003) and/ or reinforcement e-mails for achieving self-care goals (Lorig et al., 2010) produces additional benefits for study outcomes over the effects of a web-based intervention alone.

Overwhelming people with multiple task demands may increase their risk of depression (Odegard & Capoccia, 2007). Patients with Type 2 diabetes have commonly reported feeling that their treatment regimens are already onerous (Bailey & Kodack, 2011). Further increases to the treatment burden are likely to undermine treatment effects and increase participant attrition. Aiming to improve one or two target behaviours may actually have a snowball effect on other behaviours, either by setting the occasion for implementing the new behaviours, or by bringing the individual into contact with influences that encourage behaviour change (Baer et al. 1876, as cited in Fisher et al. 1982). Therefore, while using a multi-faceted approach to diabetes self-management intervention may seem logical, minimally invasive or low intensity interventions may offer similar benefits with the benefit of minimising participant burden.

A further uncertainty regarding web-based intervention design is whether an individualised or standardised treatment approach should be used. In a recent systematic review on the efficacy of personally tailored, web-based chronic disease self-management interventions, tailored interventions were shown to be no more efficacious than the standardised ones (Radhakrishnan, 2012). A standardised approach that offers users the opportunity to address personalised issues has potential to be an efficacious, acceptable and cost-effective option.

1.5.6 Section Summary and Conclusions

Overall, evidence on the efficacy of traditional treatment for Type 2 diabetes self-management and dysphoria (e.g. psychotherapy, diabetes education, and self-management programs) remains mixed. This uncertainty is congruous in the technological intervention arena, and particularly in the case of web-based interventions. Further research is needed to illuminate the effects of web-based interventions, which have the potential to maximise outreach, accessibility and ongoing provision of support, while minimising costs.

1.6. Social Cognitive Theory as a Theoretical Foundation for the OnTrack Diabetes Project.

Individuals do not exist in a vacuum, but rather are influenced and exert influence upon the social and ecological environments in which they exist. Various theories focus primarily on interpersonal factors as determinants of chronic disease and behavioural self-management in general (Ajzen, 1991; Ajzen & Fishbein, 1980). However, evidence that wider ecological, psychosocial and personal influences have significant roles in health behaviours (Fisher et al., 2005; Harris, 2003; Peyrot et al., 2005) warrants taking a broader perspective of chronic disease self-management. In particular, Type 2 diabetes has multifaceted implications for individuals' lifestyles and social relationships (Akimoto et al., 2004; Albright et al., 2001; Beverly et al., 2008), and environmental influences can derail self-management efforts (Barrera et al., 2008; De Greef, Van Dyck, Deforche, & De Bourdeaudhuij, 2011). A holistic approach that encompasses these realities was considered to be most suited to this program of research.

Social Cognitive Theory (SCT; Bandura, 1977) takes a socio-ecological approach to human behaviour that accounts for the complex, interactive nature of environmental, intrapersonal and interpersonal processes (Bandura, 1986). SCT acknowledges the instrumental role of systemic and psychosocial interactions as potential facilitators and barriers to positive behavioural enactment, including in relation to health behaviours (Bandura, 2004b). SCT provides an appropriate model for conceptualising issues involved in diabetes self-management, and is well supported by empirical research as an effective theoretical basis upon which to establish chronic disease self-management interventions (Dunn, Andersen, & Jakicic, 1998; Liebreich et al., 2009; Plotnikoff, Lippke, Courneya, Birkett, & Sigal, 2008; Strychar, Elisha, & Schmitz, 2012). Therefore, SCT is the principle theoretical underpinning of this program of research. The principle of patient empowerment is seen as a potential facilitator of non-invasive disease self-management and improved quality of life, and hence this aspect of the empowerment model was also included.

1.6.1 Social Cognitive Theory

SCT is based on a model of triadic reciprocal determinism (Bandura, 1977), in which one's behaviour, interpersonal factors including cognition, affect and biological processes, and environmental influences operate in dynamic, mutually interactive relationships. SCT understands human functioning from an agentic perspective, wherein humans are purported to be both the products and the producers of their own environments (Bandura, 1989). The uniqueness of humans is in their ability for self-reflective action, in which thoughts are acted upon, and reflection of the outcomes is then performed. This process assists individuals to determine their thought accuracy by cognitive comparisons of the expected and actual outcomes (Bandura, 1986). Hence, humans are denoted as proactive creators of their environments, rather than simply as exhibiting behavioural reactions in response to stimuli. SCT conceives of behaviour as a bidirectional, interactive determinant rather than as exerting a unidirectional influence on outcomes, or as solely produced from cognitive determinants. This conceptualisation of behaviour differentiates SCT from other health-related theories that refer to behaviour as the culmination of mental processes.

SCT proposes that humans have a range of innate capabilities that assist in shaping their behaviour and choice of environment. Forethought, or the ability for cognitive guidance, involves cognitively representing the predicted consequences of intended actions. These representations then serve the basis for deciding about whether or not to enact an intended behaviour (Bandura, 1986). Self-reflection involves considering alternative courses of action, which involves weighing up the costs and benefits in terms of predicted consequences, and judging one's own capabilities to perform the actions. The potential for differences between predicted and actual outcomes that result from environmental uncertainties exposes individuals to the risk of experiencing undesirable consequences.

Self-reflective capability is a potential source of human motivation, as the anticipatory cognitive conceptualisation that guides intended actions can increase motivation for their performance (Bandura, 1986). It is essential that forethought occurs close in timing to the behavioural event, as distantly temporal goals do not tend to produce current motivation. However, cognitive representations of short-term events can motivate current behaviour or self-regulation (Bandura, 1988). This concept is referred to as the future- or expanded-time perspective, and is an important aspect of human survival, as it enables individuals to base their actions upon considerations of the longer-term consequences.

Self-reflection is also purposeful in enabling associations to be made between actions and their outcomes, which is necessary for expected outcomes to have any self-regulatory or motivational function. SCT proposes that a process of verification of thought accuracy forms the basis for guiding future actions (Bandura, 1977). Enactive verification involves individuals directly experiencing the outcomes of their actions. Vicarious verification involves observing the effects that someone else’s actions produce. Persuasory verification entails using others’ judgements to come to conclusions about the accuracy of one’s thoughts; and logical verification involves using cognitive rules of self-reference to extract further knowledge from what is already known (Bandura, 1986). In combination with its interactions with other capabilities in the self-system the process of self-reflection enables individuals to plan desired courses of action, set goals, and self-motivate.

Self-regulation is based on the practice of forethought, which it translates into incentives and cognitive guidance to implement action. Humans are considered to actively process and transform situations rather than simply to form reactions to them (Bandura, 1978). Behavioural self-regulation involves setting personal incentives or goals; using self-regulation to guide this process before taking action. To do so, it is necessary that people have knowledge about what they are doing, and regularly self-observe and evaluate their behaviour according to internal personal standards. Motivation, affect, and behaviour are essentially governed by these internal standards and evaluative self-reactions. Therefore, goal-setting and self-monitoring are integral components of this process (Bandura, 1978). However, individuals must selectively activate the process of self-evaluation, and this tendency is subject to a range of situational influences (Bandura, 1978) that may instead result in self-evaluative disengagement. For example, conceptions formed during self-regulatory processes are in part the result of direct or socially mediated environmental transactions, which emphasises that two-way causal processes are implicated in the relationship between thought and action. Consequently, social and environmental determinants are presented as possible caveats or enablers to both motivation and the performance of intended behaviours as a function of their interdependent effects with personal factors, including self-referent thoughts (Bandura, 1986). However, through its deterministic effects on action, self-influence enables humans some freedom to act on their self-generated thoughts, which is the essence of self-regulation.

Self-referent thoughts are critical to behavioural self-regulation. SCT holds that the central and most pervasive of these thoughts is self-efficacy, which is defined as the belief in one’s capabilities to take control of circumstances that affect their life, including in their ability to implement desired courses of action (Bandura, 1977). Belief in one’s personal capability to produce desired results is argued to be fundamental to the optimisation of performance attainments. Rather than serving as an incentive, self-efficacy is conceptualised as a foundational constituent of personal achievements.

High self-efficacy is proposed to be an essential component of human accomplishment and wellbeing (Bandura, 1988). Self-efficacy strongly influences the thoughts, feelings, and actions of individuals and concurrently, their self-motivation. It has an essential role in the decisions that individuals make about how to act, how much effort they should invest in tasks, and how long they will endure in their performance before giving up in the face of challenges. Rather than being a pervasive and unchanging trait, self-efficacy is characterised by situation and time specificity (Bandura, 1989) — that is, it varies across different occasions and contexts. This characteristic offers a potential for improvement via targeted intervention. SCT acknowledges that knowledge and performance skills are also essential to successful performance accomplishments. However, self-efficacy influences whether individuals make effective use of their skills (Bandura, 1998).

SCT outlines four principal sources of information that influence the development and maintenance of self-efficacy (Bandura, 1977). The first is mastery experiences, which are the achievement of desired performance accomplishments, or goals. Experiencing success in one's goal pursuit increases mastery expectations, but repeated failures typically lower them. However, repeated successes can reinforce efficacy strength to an extent that persistence in one's pursuit is maintained even when occasional failures occur, and both self-efficacy and later persistence can be strengthened if determined and sustained effort results in eventual success. Although self-efficacy tends to be context-specific, enhanced self-efficacy can generalise to other situations in which self-doubts resulted in preoccupation with personal inadequacies (Bandura, 1977), which suggests the potential for a flow-on effect of self-efficacy enhancements in one area of diabetes self-care to other self-care areas.

The second source of self-efficacy is vicarious experience, which involves making inferences from observations of other individuals' behaviour to form self-referent symbolic representations (Bandura, 1977). These representations involve extracting information about ways to obtain desired outcomes (and thereby, gain confidence that they can be achieved) by observing others. In this way, humans are able to learn from the experiences of others in deciding which course of action to take. This is one way in which SCT accounts for the effects of individuals' social milieu on their behaviour (Bandura, 1977).

Verbal persuasion represents the third principal source of self-efficacy proposed in SCT, and refers to process by which people are persuaded to believe in their capabilities to have control over and/ or to cope with difficult situations (Bandura, 1977). A number of factors, including personal beliefs and perceived trustworthiness of the source, can impinge on the success of this method in increasing self-efficacy, and it is not as powerful a contributor to self-efficacy as are experienced performance accomplishments. Negative experiences such as failures easily overturn mastery expectations that are based on verbal persuasion. However, when situations are arranged to facilitate success, persuasion that one has the capability to overcome performance challenges can be effective (Bandura, 1986). Many behavioural self-management interventions, including psychotherapy, incorporate verbal persuasion: SCT predicts that attention to the potential vulnerability of this approach is needed, for it to have strong and lasting impact. .

The fourth source of self-efficacy is the person's physiological state, including their level of fatigue or other physiological need, and their emotional state. Appraisals of physiological arousal are used to inform judgements about self-perceived control of potentially aversive outcomes (Bandura, 1977). High arousal characteristically results in reduced performance attainments, evoking awareness of deficits and self-doubts about one's coping abilities (Bandura, 1989; Kavanagh & Bower, 1985). Interventions that promote relaxation and increasing self-perceived ability to exercise control over potential threats may increase reduce the risk of avoiding or withdrawing from challenging situations, and foster effective coping.

Self-efficacy is centrally influential to the cognitive formulation of anticipatory scenarios. High self-efficacy is associated with the production of success scenarios that provide positive cognitive guidance for behavioural implementation and the cognitive envisagement of positive solutions to potential obstacles to success. Low self-efficacy is linked to the anticipation and visualisation of failure scenarios and preoccupation with potential pessimistic outcomes, which tends to limit motivation and subsequently reduce performance attainments (Bandura, 1989).

Perceived self-efficacy and cognitive simulations interact in a bidirectional fashion, such that high self-efficacy is likely to result in the investment of increased effort towards goal pursuits, which is more likely to lead to goal attainment, and the subsequent cognitive reinforcement of achievements further strengthens perceived self-efficacy (Bandura, 1989). In contrast, low self-efficacy is characterised by self-doubt, which results in the exertion of less effort and persistence. Socio-cognitive functioning is optimised in individuals with a resilient sense of self-efficacy, who tend to attempt difficult tasks as challenges rather than exercising avoidance, and exercise enhanced endurance and quickly resume high self-efficacy in the face of setbacks. Furthermore, they tend to set higher goals to which they are likely to remain highly committed and their positive outlook results in enhanced cognitive functioning and performance attainments.

In addition to self-efficacy, SCT proposes that determining key elements in human motivation, affect and behaviour, are the person's outcome expectancies from a particular behaviour (Bandura, 1977). While the person may believe they are capable of successful performance, the net value of the expected outcomes from that performance will determine whether the behaviour occurs. Conversely, the expectation that desired outcomes will be obtained is insufficient to elicit an attempt to obtain the outcome if an individual does not believe in their ability to succeed in that attempt (Bandura, 1999). Consolidation of positive outcome expectations therefore joins self-efficacy as a critical element in an effective treatment.

1.6.2 Self-Motivation via Self-Monitoring and Goal-Setting

SCT proposes that goal setting largely exerts its motivational effects on behaviour via self-referent processes, including self-evaluation of performance according to internal, personal standards (Bandura, 1989). Goals essentially define the conditions that individuals must meet in order to experience positive self-evaluation, and thus are a potential source of intrinsic reward. Similar to the negative feedback control loop proposed in control and dual-processing theories, SCT purports that perceived discrepancies between personal standards and performance induce action to reduce these discrepancies (Bandura, 1989). Feedback is thus instrumental to maintaining motivation, as is the constant re-evaluation and setting of new, challenging goals. When internal personal standards are met, individuals tend not to take further action. However, new challenges evoke motivation to fulfil the discrepancy. The practice of constant goal revision to set increasingly challenging goals is fundamental to maintaining motivation and to subsequent increases in performance attainments (Bandura, 1989). Self-efficacy has a major role in determining the types of goals that individuals set from the beginning, and in how much effort they will exert in striving to master performance accomplishments. Therefore, self-efficacy is influential in individuals' propensity to exercise control over their motivation.

Self-monitoring is an important sub-function in the self-regulatory process, which is affected by affective states and self-beliefs (Bandura, 1991). Ideally, self-monitoring is undertaken in temporal proximity to execution of the intended behaviour, as this presents continuous information and thereby enables the individual to exercise self-influence in revising their behavioural strategies closest in timing to the event (Bandura, 1991).

Furthermore, self-monitoring should be performed continuously rather than intermittently, as this encourages individuals' regular attention to their performance.

Motivation for self-monitoring is best obtained on variables for which individuals wish to elicit change, as this ensures the effects of self-evaluation in terms of goal progress, as opposed to indifferent self-observation. It is also important that individuals self-monitor their successes rather than their failures, which may diminish attempts at making performance accomplishments unless possible causes and suggestions for corrections are identified.

Although the effects of self-observation are characteristically temporary, they can be highly resistant to change, and may last into the longer term in relation to relatively easily modifiable activities (Bandura, 1991). SCT thus represents both goal-setting and self-monitoring as fundamental aspects of successful behaviour change. Whilst self-monitoring can produce little or no effects, in certain cases, as discussed, providing individuals with the tools to effectively undertake goal-setting and receive performance feedback may facilitate their motivation to implement desired behavioural changes.

1.6.3 Mood, Emotions and Social Cognitive Theory

Highly related to the effects of self-efficacy on the mastery of performance accomplishments is the bidirectional relationship between self-efficacy and affective state. Low self-efficacy, characterised by one's perception that they cannot control potential threats, increases the likelihood that they will develop depression and stress (Bandura, 1989). Perceived inefficacy to stop aversive cognitions is a key determinant of distress (Bandura, 1999), with low self-efficacy beliefs exhibiting enduring influences on behaviour such as engagement in avoidance behaviours, regardless of whether cognitive arousal is present at the time (Bandura, 1989). Conversely, a high sense of efficacy to cope with threats or challenges results in reduced stress and anxiety due to its transformative effects on perceptions of the environment (Bandura, 1999).

SCT proposes that depressive affect is produced and/ or maintained by perceived inefficacy in a number of ways. First, when individuals attempt to meet unrealistic personal standards that are attached to their self-worth and this results in failure, they devalue any progress they have made and experience depression (Bandura, 1999). In turn, depression results in the weakening of self-efficacy beliefs which generates a downward cycle (Bandura, 1999).

A second suggested pathway is via the effects of a low sense of social efficacy, which leads to problematic interactions with current relationships and the failure to form new ones. Evidence that social support provides a buffer to the effects of chronic stressors and the contributions of social isolation and loneliness to the development and maintenance of depressive symptoms (Lin, Ye, & Ensel, 1999) supports this theory. Thirdly, SCT proposes that depression manifests via cognitive generation as the result of low perceived efficacy to control ruminative thought processes (Bandura, 1999). The complex interactions between environmental, psychosocial, and interpersonal factors that account for affective symptoms demonstrate the importance of addressing behavioural and socio-ecological constituents in interventions that target mood disorders.

1.6.4 SCT Applied to Diabetes Self-Management

Empirical evidence supports a positive association between diabetes self-management and self-efficacy (Aljasem, Peyrot, Wissow, & Rubin, 2001). Self-efficacy has been shown to predict future adherence to diabetes care regimens (Kavanagh, Gooley, & Wilson, 1993), and also to mediate participation in self-care behaviours related to effective diabetes management (Hunt et al., 2012; Senécal, Nouwen, & White, 2000; Snoek, 2002; Strychar et al., 2012), including physical activity (Blanchard et al., 2007; Dutton et al., 2009; Plotnikoff, Trinh, Courneya, Karunamuni, & Sigal, 2011; Smith, Avis, & Assmann, 1999; White, Terry, Troup, & Rempel, 2007). However, a range of factors mediate the relationship between self-efficacy and diabetes self-management, including social support (Kim & Kang, 2006; Xu et al., 2008), illness perceptions (Toobert et al., 2010), functionality (Bond et al., 2006), and health beliefs (Chao et al., 2005). Depression is negatively related to self-efficacy, and this is particularly the case in those with chronic conditions (Noh et al., 2010; Quinn et al., 2011). Depression and anxiety mediate self-efficacy for participation in positive health behaviours including glycaemic control (Cherrington et al., 2010). Further, self-efficacy has demonstrated mediating the relationship between engagement in self-care behaviours in those with diabetes and affective disorders (Wagner, Tennen, & Osborn, 2011). This evidence demonstrates the social cognitive complexity of factors involved in addressing diabetes self-management and psychological/ emotional issues.

Levels of stress and depression experienced in difficult situations are theorised to be dependent on one’s belief in their coping abilities in the context of that situation, including in chronic disease (de Ridder & Schreurs, 2001). Factors including illness beliefs and symptom interpretation impact on self-efficacy to cope with the condition (Bandura, 1986). Low self-efficacy for diabetes management is a significant risk factor for inadequate diabetes control (Fursse, Clarke, Jones, Khemka, & Findlay, 2008), depression (Bandura, 1989) and stress (Bandura, 1990). Outcome expectancies that specifically refer to diabetes include the belief that adequately self-managing the condition is likely to prevent or delay complications. Low self-efficacy may be a risk factor for inadequate Type 2 diabetes self-management by magnifying the perceived threat of diabetes to psychosocial, physical, or role functioning, life satisfaction, self-esteem and/or morale (Castelnuovo et al., 2011). These effects may be implicated in the high comorbidity between diabetes and dysphoria, and suggest that targeting self-efficacy in diabetes self-management interventions may facilitate their efficacy.

Gist and Mitchell (1992) emphasised the importance of perceived variability and control of self-efficacy determinants in behavioural change (Bond et al., 2007). Perceived control is generally higher over internal than external factors, and when determinants are variable in the short-term, as opposed to remaining stable. Resistance to changes in self-efficacy is highest when the causes of performance are perceived to be uncontrollable with low variability. In Type 2 diabetes patients, perceived control over internal, physiological factors is likely to be compromised at times, for example when hypo- or hyperglycaemic symptoms occur. Further, perceived stability of the condition may result in a sense of loss of control, leading to resistance to changes in self-efficacy because the patient is likely to attribute his or her performance to uncontrollable factors that remain stable over time, or are likely to recur. Tasks perceived to be difficult, such as adherence to a complex treatment regime, may be avoided to reduce the risk of failure and diabetes-imposed threat to one's lifestyle. Findings that diabetes symptom severity mediates the relationship between self-care and self-efficacy (Chen, Wei, Huang, & Lin, 2011) support this view. Furthermore, the Consequence Model proposes that perception of control is a fundamental constituent of the relationship between depression and diabetes (Sacco & Bykowski, 2010).

Perceived availability of support may attenuate the effects of low self-efficacy on perceived diabetes-imposed threat by providing a foreground for more adaptive reactions to stressful situations (Toobert et al., 2010). Considering the behavioural, medical and psychological issues implicated in living with Type 2 diabetes, it is essential to acknowledge and target the integral social and cognitive factors in Type 2 diabetes self-management interventions (Fisher et al., 1982).

1.6.5 Section Summary and Conclusions

Evidence presented in this section indicates that SCT has indicated appropriateness as a theoretical basis for a Type 2 diabetes self-management and dysphoria intervention. The theory is consistent with the underlying aims of this project, which include developing an intervention that fundamentally promotes patient empowerment and addresses the behavioural and psychological/ emotional needs of people with Type 2 diabetes, while accounting for the influence of intrapersonal and ecological factors.

CHAPTER 2

EFFECTS OF TYPE 2 DIABETES BEHAVIOURAL TELEHEALTH INTERVENTIONS ON GLYCAEMIC CONTROL AND ADHERENCE: A SYSTEMATIC REVIEW

2.1 Notes

Citation for this paper:

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Authors' contributions to this paper:

The candidate is the first author and was responsible for conducting the literature search and review. The second author is the Principal Supervisor of the candidate, and collaborated with her on rating the papers included in the review on their relevance and suitability for inclusion. Following this, the candidate summarised results of the review and drafted the review paper. The second author then provided comments and editorial suggestions on the paper before it was submitted for publication by the candidate.

Overview of this paper:

This paper contributes to the scientific literature as the first review of telehealth interventions that are primarily based on behavioural self-management components. The research question that inspired this review was: Do telehealth interventions for people with Type 2 diabetes provide evidence of efficacy in improving behavioural self-management and glycaemic control?

GTH2012/Cassimatis

Effects of Type 2 diabetes behavioural telehealth interventions on glycaemic control and adherence: a systematic review

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Running head: Internet video-calls

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Summary

We reviewed the effect of behavioural telehealth interventions in Type 2 diabetes on glycaemic control and diabetes self-management. The databases CINAHL, Medline and psychINFO were searched in August 2012. Peer-reviewed journal articles that were published in English with a randomised controlled trial design using a usual care comparison group, and in which the primary intervention component was delivered by telehealth, were selected. Relevant outcome measures were glycaemic control and one or more diabetes self-care area of: diet, physical activity, blood glucose self-monitoring (BGSM) or medication adherence. Interventions were excluded if they were primarily based on a telemonitoring. The search retrieved 1027 articles, from which 49 were selected based on their title and abstract. Fourteen articles (reporting 13 studies) met the eligibility criteria for inclusion. Four studies reported significant improvements in glycaemic control. Five of eight studies on dietary adherence reported significant treatment effects, as did five of eight on physical activity, four of nine on blood glucose self-monitoring, and three of eight on medication adherence. Overall, behavioural telehealth interventions show promise in improving the diabetes self-care and glycemic control of people with Type 2 diabetes.

2.2 Introduction

Diabetes is responsible for the eighth-highest burden of disease in Australia. Type 2 diabetes accounts for 92% of the burden due to diabetes (Begg et al., 2007), and affects 3.8% of Australians (Barr, Cameron, Shaw, & Zimmet, 2005). Glycaemic control is strongly associated with diabetes-related morbidity and mortality (Stratton et al., 2000), with higher glycaemia predicting increased physical, mental, psychological and psychosocial comorbidities. Improvements in glycaemia to the recommended glycosylated haemoglobin (HbA_{1c}) level of ≤7% (R. Colagiuri et al., 2009) are significantly related to a reduced risk of micro- and macro-vascular complications (Holman, Paul, Bethel, & al, 2008). Maintaining essential diabetes self-care practises that include regular physical activity, healthy eating, blood glucose self-monitoring (BGSM) and medication adherence is integral to achieving this.[4] However the majority of diabetes patients remain poorly controlled (HbA_{1c}≥8%), which indicates that regular, accessible and effective Type 2 diabetes self-management support is required.

Telehealth may assist Type 2 diabetes patients by improving accessibility to health care services. This may be of particular importance in rural and regional areas. Currently 26% (230,700) of Australians with diabetes live in inner regional, and 12% (110,400) in outer regional or remote areas (AIHW, 2011). Whilst general practitioners (GPs) are the primary care providers for patients with Type 2 diabetes, only 20% of all GPs are based outside metropolitan city areas (AIHW, 2008). Telehealth also presents a convenient, cost-effective way for patients with mobility or motivational problems to receive regular support, including the elderly and patients with complicated diabetes.

Telehealth applications including telephone counselling, videoconferencing and educational telephone-based interventions have been favourably received with good acceptability and uptake by Type 2 diabetes patients (Verhoeven et al., 2007). Telehealth interventions have also shown efficacy in improving psychosocial, psychological and clinical outcomes in diabetes (Wu, Forbes, Griffiths, Milligan, & While, 2010). Previous reviews of diabetes self-management telehealth interventions have reported the effect of both isolated telephone support (Graziano & Gross, 2009) and multi-component interventions. Whilst behavioural interventions and ongoing support are acknowledged as being cornerstones for effective Type 2 diabetes self-management (Fisher et al., 2005) the efficacy of behavioural telehealth interventions specifically aimed at improving glycaemic control and diabetes self-care remains unexplored.

We have therefore conducted a systematic literature review of the effects of behavioural Type 2 diabetes telehealth interventions.

2.3 Methods

The EBSCOHOST research databases CINAHL (Cumulative Index to Nursing and Allied Health Literature), Medline and psychINFO were searched using the terms: (diabet* and random*) and (tele* or mobile or SMS or smart phone or video* or ehealth). There was no limit on the date of publication.

Eligible studies were peer-reviewed journal articles published in the English language that reported evaluating the effects of telehealth interventions on glycaemic control and at least one diabetes self-care outcome out of: physical activity, diet, blood glucose self-monitoring, and medication adherence. Studies had to be randomised controlled trials and included either a usual care comparison, or an active treatment control (where the telehealth condition received the same treatment). Included studies had a sample comprising adults (≥18 years) with the majority having Type 2, rather than type 1 diabetes. The intervention could not primarily be telemonitoring, and must have been exclusively for diabetes management. Studies where medication titration was a major component were excluded, as intensive medication therapy would confound the effects of behavioural change on glycaemic control. Abstracts and titles were screened, and those that appeared to fulfil the eligibility criteria were retrieved (as were ones where eligibility was not able to be determined from the abstract). Backward and forward searches of retrieved articles and relevant systematic reviews were performed to identify additional potentially eligible studies.

The Cochrane Collaboration's tool for assessing risk of bias (Higgins & Green, 2008) was used as a marker for each study's internal validity. Assessments were performed by indicating a yes/no judgement on each of the six domains of validity, and studies deemed to have a high risk of bias were excluded from the review. Data from each study was abstracted and stored in a spreadsheet that included the study's purpose, nature of the intervention, study conditions, outcomes and results.

2.4 Results

A total of 49 full papers were examined for eligibility, and 14 articles reporting on 13 studies were included in the review. The study processes and outcomes of the included studies are summarised in Table 1.

Interventions

The majority of study interventions involved participants receiving regular telephone calls from trained staff who were mainly study nurses (Anderson, Christison-Lagay, Villagra, Liu, & Dziura, 2010; Frosch, Uy, Ochoa, & Mangione, 2011; Maljanian, Grey, Staff, & Conroy, 2005; Piette, Weinberger, Kraemer, & McPhee, 2001; Piette, Weinberger, & McPhee, 2000; Sigurdardottir, Benediktsson, & Jonsdottir, 2009) but also psychologists/social workers (Wolever et al., 2010), PhD (Kim & Oh, 2003) and Master's (Nesari, Zakerimoghadam, Rajab, Bassampour, & Faghihzadeh, 2010) students. An exception was the study by Bell *et al.* (Bell, Fonda, Walker, Schmidt, & Vigersky, 2012) in which each participant was sent 30- to 60-second video messages via their mobile phone every 24 hours on diabetes self-care topics. Two studies (Piette, 2000; Piette et al., 2001) involved participants receiving automated telephone disease management (ATDM) calls to supplement nurses' follow-up calls. All interventions included diabetes education.

The active intervention period ranged from 5 weeks (Frosch et al., 2011; Sigurdardottir et al., 2009) to 12 months (Anderson et al., 2010; Piette et al., 2001; Piette et al., 2000; Walker et al., 2011) and periods for final outcome assessments ranged from 3 months (Kim & Oh, 2003; Maljanian et al., 2005; Nesari et al., 2010) to 12 months post-baseline (Anderson et al., 2010; Bell et al., 2012; Maljanian et al., 2005; Piette et al., 2001; Piette et al., 2000; Walker et al., 2011). In most studies (69%), endpoint measures were taken directly post-intervention. Five studies assessed short-term maintenance (Bell et al., 2012; Frosch et al., 2011; Maljanian et al., 2005; Sigurdardottir et al., 2009; Trief et al., 2011), with the longest interval between post-intervention and final assessments being 6 months (Bell et al., 2012).

Glycaemic control

Four (Bell et al., 2012; Kim & Oh, 2003; Nesari et al., 2010; Walker et al., 2011) of thirteen studies reported significant treatment effects on glycaemic control. Three also reported significant treatment effects on diabetes self-care (Kim & Oh, 2003; Nesari et al., 2010; Walker et al., 2011). Two (Kim & Oh, 2003; Nesari et al., 2010) assessed all four self-care outcomes in addition to glycaemic control, and reported significant improvements in them all. The majority of significant results for glycaemic control were measured directly following the active intervention period, at 3 months (Kim & Oh, 2003; Nesari et al., 2010) or 12 months (Walker et al., 2011). In Bell *et al*.'s study (Bell et al., 2012) significant improvements in HbA_{1c} were seen 3 months into the 6-month intervention, but were not maintained at the 6-month post-baseline assessment.

Whilst five studies reported on the dosage of intervention received by intervention group participants (Bell et al., 2012; Frosch et al., 2011; J. D. Piette et al., 2001; Piette et al., 2000; Walker et al., 2011) only two of them evaluated dosage relationships with glycaemic outcomes (Bell et al., 2012; Walker et al., 2011). Both reported significant intervention dosage effects on glycaemic improvements. Walker *et al*.'s study (Walker et al., 2011) -- a telephone intervention offering ≥10 calls over a year -- indicated that intervention group participants completing more than five telephone calls had a significantly greater reduction in HbA_{1c}. Bell *et al*. (Bell et al., 2012) found significant between-group interactions for HbA_{1c} at the 3-month post-baseline follow-up, but no differences at 12 months post-baseline, which was 6 months post-intervention. However, further analyses revealed that "persistent viewers" (who viewed >10 video messages a month) experienced a significant reduction in HbA_{1c} of 0.6% over 12 months, compared with "early cessation" participants who did not view the videos or stopped viewing videos within 2 months post-enrolment.

Dietary adherence

Five of eight studies (63%) that assessed the effects of interventions on dietary adherence reported significant improvements (Anderson et al., 2010; Kim & Oh, 2003; Nesari et al., 2010; Sacco et al., 2009; Walker et al., 2011). In four of these, dietary improvements were found directly following the active intervention (Kim & Oh, 2003; Nesari et al., 2010; Sacco et al., 2009; Walker et al., 2011). There was no notable distinction between the type of dietary and lifestyle intervention offered by studies reporting significant improvements in diet and ones where no significant effect was found (Frosch et al., 2011; Sigurdardottir et al., 2009). While Kim & Oh's positive study (Kim & Oh, 2003) included dietitian reviews of patient meal plans, Trief *et al*.(Trief et al., 2011) used dietary goal setting as the primary focus of their telephone counselling intervention, but found no significant dietary improvements. Differences in the study populations may have accounted for the difference in results: in Trief *et al*.'s study (Trief et al., 2011), most participants were obese, and dietary changes may have presented a significant motivational hurdle.

Physical activity

Statistically significant treatment effects were reported in five of eight studies (63%) that assessed physical activity participation (Frosch et al., 2011; Nesari et al., 2010; Sacco et al., 2009; Walker et al., 2011; Wolever et al., 2010). Three of these (Frosch et al., 2011; Sacco et al., 2009; Wolever et al., 2010) did not find improvements in glycaemic control. Sustained exercise can reduce insulin resistance and improve glycaemic control (Thomas et al., 2006) and most studies only tested for effects on glycaemic control immediately post-intervention. A delayed effect of increased physical activity on glycaemic control may have occurred, provided that behavioural changes were maintained. Furthermore, different types of physical activity (e.g. resistance vs. aerobic) has differential impacts on glycaemia (Tompkins, Soros, Sothern, & Vargas, 2009). Measures that are sensitive to specific activity changes would help to determine the clinical value of reported improvements.

Blood glucose self-monitoring

Four of nine studies (44%) that measured BGSM found significant improvements in frequency (Kim & Oh, 2003; Nesari et al., 2010; Piette et al., 2001; Piette et al., 2000). Studies reporting significant effects required participants to regularly self-report their blood glucose levels to the researcher or nurse, indicating possible effects of accountability on monitoring. However, the findings should be interpreted with caution, as self-report surveys rather than objective assessments were used both for regular BGSM reports during the study and study outcome measures. Only one study (Bell et al., 2012) provided diabetes supplies at no cost to participants. The cost of increased BGSM may have been a deterrent to increasing self-monitoring in some participants.

Medication adherence

Eight studies assessed medication adherence, with only three (Nesari et al., 2010; Piette et al., 2000; Wolever et al., 2010) (38%) reporting significant improvements. In Walker *et al*.'s study (Walker et al., 2011), significant improvements in medication adherence were reported on ASK-20 items, but not on items from the Morisky Adherence Scale. Only one study reported the intervention group experiencing significant improvements in glycaemia as well as medication adherence (Nesari et al., 2010). However, significant improvements in three other diabetes self-care outcome measures relevant to the present review also occurred, and those changes may have collectively influenced glycaemic improvements. The study of Walker *et al*. (Walker et al., 2011) was the only one to compare medication adherence in insulin-dependent compared with non-dependent Type 2 diabetes: It found no significant difference between these sub-groups. Future studies should include analyses of changes in medication adherence within diabetes treatment sub-groups to detect any mediating effects of treatment burden.

Study quality and validity

Overall, improvements in study quality and validity of reporting are required, with internal validity being moderate at best amongst the studies. In five studies, it was unclear whether allocation was concealed (Kim & Oh, 2003; Maljanian et al., 2005; Piette, 2000; Trief et al., 2011; Wolever et al., 2010), presenting a risk of exaggerated treatment effects (Higgins & Green, 2008). Most studies used relatively small sample sizes (Bell et al., 2012; Kim & Oh, 2003; Nesari et al., 2010; Sacco et al., 2009; Sigurdardottir et al., 2009; Trief et al., 2011; Wolever et al., 2010), which may have resulted in difficulties detecting significant treatment effects. Trief *et al*. (Trief et al., 2011) cited individual differences between study conditions as a potential source of bias in their results. Most studies used samples comprised mainly of ethnic and socioeconomic minorities (Anderson et al., 2010; Bell et al., 2012; Frosch et al., 2011; Kim & Oh, 2003; Nesari et al., 2010; Piette et al., 2001; Piette et al., 2000; Walker et al., 2011; Wolever et al., 2010), presenting problems for external validity.

2.5 Discussion

Considerable heterogeneity between study processes and outcomes meant that it was difficult to draw firm conclusions. However, the present review demonstrated that behavioural telehealth interventions can significantly improve both glycaemic and diabetes self-care outcomes in Type 2 diabetes patients. Of the diabetes self-care outcomes that were examined, physical activity and dietary adherence most commonly demonstrated improvements in response to telehealth.

The longest study post-intervention follow-up period was only 6 months (Bell et al., 2012). Longer intervals between post-intervention and final endpoint follow-up measures would provide a better indication of the longevity of treatment effects and enable detection of “sleeper” (delayed) effects. This may also assist with determining optimum times for booster appointments in real-world implementations of telehealth interventions.

In order to optimise the effect of telehealth for Type 2 diabetes, systematic evaluations of different dosages and durations of interventions are also needed, as are studies of specific subgroups of patients (e.g. insulin dependent/non-dependent). Only two studies in the present review reported relationships between intervention exposure and clinical improvements, with both revealing stronger effects from more substantial interventions (Bell et al., 2012; Walker et al., 2011).

The studies reviewed typically had samples of poorly controlled Type 2 diabetes patients. Whilst that allows significant treatment effects to be detected, it excludes participants who may benefit from a behaviourally focused telehealth intervention. As shown in Piette *et al.* (Piette et al., 2001) and Wolever *et al.* (Wolever et al., 2010), sub-group analyses according to HbA_{1c} allow the detection of treatment effects in cohorts of participants within higher baseline HbA_{1c} ranges. Undertaking sub-group analyses may be a solution for including individuals with reasonable glycaemic control in behavioural telehealth trials for diabetes. Furthermore, a focus on community sampling, rather than recruiting primarily from diabetes outpatient clinics and/or from minority groups, would enable greater generalisability of results.

Finally, research in this field requires substantial improvements in study methodology, including blind assessment and allocation concealment. Clearer reporting of study processes and outcomes would enable methodological quality and more confident conclusions to be drawn from reviews.

Table 1. Study characteristics

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
Anderson, D.R. (2010)	295 (149 Usual care; 146 Intervention); NR; 58%; 8.0%; NR; mostly Hispanic or African American; Type 2 diabetes	(1) TAU (2) Unscripted calls from nurse - brief clinical measures, self-care education, BGSM review, mailed educational materials.	(2) 12 months Call intensities: (i) HbA1c ≥ 9%: weekly, (ii)<9%: biweekly, (iii)≤ 7%: monthly. Follow-up: 6 & 12 months	HbA1c: NR Diet: Brief Dietary Assessment survey (fruit and vegetable intake) Physical activity: Rapid Assessment of Physical Activity (RAPA)	**HbA1c** **NS**. 6 & 12 months post-baseline - Group x Time. **NS**. Within-group. **Diet** **N.S**. 6 & 12 months post-baseline – Group x Time. **NS**. Within-group.
Bell, A.M. (2012)	64 (33 Usual care; 31 Intervention); 58y; 45%; 9.3%; NR; mostly African American, obese; Type 1 or 2 diabetes	(1) TAU: Received glucose meter and strips, broad-band enabled cell phone and services for 6 months. (2) TAU + 30 – 60-sec video SMS's on diabetes self-care topics.	(2) 6 months SMS's: 24-hourly. Follow-up: 3, 6, 9 & 12 months	HbA1c: High performance liquid chromatography (HPLC; COBAS C 111 Analyzer) BGSM: Data upload frequency.	**HbA1c** *****3-months post-baseline – Group x time (P=.02). **NS**. 6-, 9- & 12-months post-baseline. **NS**. Within-group. **BGSM** **NS**. Group x Time. **NS**. Within-group.
Frosch, D.L. (2011)	201 (100 Usual care; 101 Intervention); 55.5y; 48.5%; 9.6%; 10y; mostly African American or Latino & obese; Type 2 diabetes	(1) TAU: Received 20-page diabetes education brochure. (2) TAU + 24-minute DVD program; booklet "Living with Diabetes" + phone coaching sessions with diabetes nurse.	(2) 5 weeks ≤ five phone sessions. Session 1: ≤60 min; 2 & 3:≤30 min; 4 & 5:≤15 min. Follow-up: 1	HbA1c: HPLC Diet, exercise, BGSM, medication: Summary of Diabetes Self-Care Activities (SDSCA) Survey	**HbA1c** **NS**. Group x Time. *****Time effects across groups (P<.001). **Diet** **NS**. Group x time. *Time effects across groups (P<.001). **Exercise** ***** 6 months post-baseline – Group x Time (P=.04). **NS**. Time effects across groups.

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
Frosch, D.L. (2011)			& 6 months		**BGSM** **NS**. Group x Time. *****Time effects across groups (P=.03). **Medication** **NS**. Group x Time: (i) taking most medications, (ii) all medications. * 1 & 6 months post-baseline - Time effects across groups, (i) (P=.01), (ii) (P<.001).
Kim, H. (2003)	50 (25 control; 25 intervention); 60.3y; 70%; 8.5%; 13.7y; South Koreans, half < middle school; Type 2 diabetes	(1) TAU (2) Diabetes care booklet & daily diet log; phone calls from PhD student - continuing education, reinforcement of diet & exercise; medication recommendations & frequent BGSM. Diet recommendations mailed from Dietitian after daily diet log review.	 (2) 3 months Calls ≥ twice/wk for 1 mth; weekly for months 2 & 3. Calls, *M*=25 min. Follow-up: 3 months	HbA1c: HPLC (Variant II, Bio-Rad Hercules) Diet, exercise, blood glucose testing, medication-taking: Self-Reported Adherence Questionnaire (Kim, 1999)	**HbA1c** *****Group x Time (P=.0001). ***** Within-group: intervention decline (P<.05); control increase (P<.05). **Diet** *****Group x time (P=.006). *****Within-group improvement - intervention (P<.05). **Exercise** **NS**. Group x time. **NS**. Within-group. **BGSM** *****Group x time (P=.024). *****Within-group improvement - intervention (P<.05). **Medication** **NS**. Group x time. **NS**. Within-group.
Maljanian, R. (2005)	336 (160 control, 176 intervention); 58y; 53.3%; 7.9%; NR; mostly Caucasian, overweight; Type 1 or 2 diabetes	(1) TAU: 3 diabetes education classes; individual visits with Registered Nurse & Nutritionist; collaborative care management with written evaluations andrecommendation	(1) Classes= 4 hours each (2) 3 months Calls: weekly. Call 1, *M*=15-20	HbA1c: HPLC (Bayer DCA 2000 Analyzer) or collected from participant's Physician BGSM: Diabetes Quality Improvement Project (DQIP) items	**HbA1c** **NS**. Group x time. **NS**. Within-group. **BGSM** **NS**. Group x time. **NS**. Within-group.

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
Maljanian, R. (2005)		for Primary Care Provider. (2) TAU + phone calls from Research Nurse - education & self-management skills reinforcement.	min; other calls, *M*=5-7 min. Follow-up: 3 & 12 months		
Nesari, M. (2010)	61 (31 control; 30 intervention); 51.6y; 71.7%; 9.0%; NR; mostly Iranian, overweight; Type 2 diabetes	(1) TAU: 3-day diabetes self-care education program. (2) TAU + phone calls from Master's nursing student on health behaviours, education, & medication adjustment according to glucose levels.	(1)Each session =60 min (3/day) (2) 3 months Calls: twice/wk for 1 mth; weekly for months 2 & 3. Calls, *M*=20 min. Follow-up: 3 months	HbA1c: HPLC (Pars Azemoo) Diet, exercise, BGSM, medication-taking: Level of adherence; Self-reported questionnaire (developed by research staff)	**HbA1c** *****3 months post-baseline – intervention better. (P<.001). * Within-group decline - intervention (P<.001). **Diet** *****3 months- intervention better (P<.001). *Within-group improvement – both groups (P<.001). **Exercise** *****3 months post-baseline – intervention better (P<.001). *****Within-group increase - intervention (P<.001). **BGSM** *****3 months post-baseline – intervention better (P<.001). **NS**. Within-group. **Medication** *****3 months post-baseline – intervention better. (P=.001). *****Within-group increase – intervention (P<.001)
Piette, J.D. (2001)	272 (140 control; 132 intervention); 60.5y; 28.65%; 8.1%; NR; department of veterans affairs patients, overweight; Type 1 or 2 diabetes	(1) TAU (2) Outbound automated telephone disease management (ATDM) calls with self-assessments (BGSM readings,	 (2) 12 months ATDM calls: biweekly, *M*= 5- 8 min (+ promotion messages);	HbA1c: NR BGSM, medication-taking (problems): NR (phone interview)	**HbA1c** **NS**. Between-groups. *****12 months post-baseline – Baseline HbA1c ≥8.0% - intervention better (P=.04); Baseline HbA1c ≥9.0% - intervention better (P=.04). **BGSM** *****12 months post-baseline –

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
Piette, J.D. (2001)		self-care activities, symptoms, medical care use); health promotion messages (optional) + nurse follow-up	nurse calls: weekly, *M*=29 min. Follow-up:12 months		intervention better (P=.05). **N.S** Within-group. **Medication** **NS**. Between-groups. **NS**. Within-group.
Piette, J.D. (2000)	280 (124 control; 124 intervention); 54.5y; 73%; 8.7%; NR; mostly Hispanic or Caucasian, overweight; Type 1 or 2 diabetes	(1) TAU (2) Outbound ATDM calls with self-assessments (BGSM readings, self-care, symptoms, medical care use); "health tips", diet & exercise self-care module (optional) + nurse follow-up	 (2) 12 months ATDM calls: biweekly, *M*=5-14 min; nurse calls: weekly, *M*=20 min. Follow-up:12 months	HbA1c: NR BGSM, medication: Self-report survey questions	**HbA1c** **NS**. Group x time. **BGSM** *****12 months post-baseline - intervention better (P=.03). **NS**. Within-group. **Medication** *****12 months post-baseline – intervention better (P=.003).
Sacco, W.P. (2011), Sacco, W.P. (2009)	62 (31 control; 31 intervention); 52y; 58%; 8.5%; 9.5y; mostly Caucasian, obese; Type 2 diabetes	(1) TAU (2) Phone coaching - BGSM review to identify causes of "out of range" readings; help translating broad goals into weekly implementation intentions; problem-solving; reinforcement of positive changes.	 (2) 6 months Weekly calls – 3 months; biweekly – 3 months. Initial intake call, *M*= 53.63 min; other calls, *M*= 17.38 min. Follow-up: 6 months	HbA1c: Baseline - medical records (majority HPLC; Bayer DCA 2000 Analyzer); follow-up – lab values Diet, exercise, BGSM, medication: SDSCA Survey	**HbA1c** **NS**. Group x time. **Diet** *****Group x time (P<.05). **Exercise** *****Group x time (P<.001). **BGSM** **NS**. Group x time. **Medication** **NS**. Group x time.
Sigurdardottir, A.K. (2009)	53 (25 control; 28 intervention); 60.7y; 32%; 8.0%; 8.7y; mostly overweight; Type 2 diabetes	(1) TAU (2) One face-to-face session with Nurse Educator - diabetes knowledge, dietary & exercise	 (2) 5 weeks Face-to-face session = 1-2 h; five calls, *M*= 15-20	HbA1c: NR Diet, exercise, BGSM: 12 Items from SDSCA Survey	**HbA1c** **NS**. Group x time. *****3 months baseline – within-group decline – both (P<.05). **NS**. 6 months post-baseline – within-group. **Diet**

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
		behaviour survey items; guided goal-setting; discussed obstacles to change; then five phone coaching sessions.	min. Follow-up: 3 & 6 months		**NS**. Group x time. *****6 months post-baseline – within-group – intervention (P=.027). **Exercise** **NS**. Group x time. *****6 months post-baseline – within-group – intervention (P=.045). **BGSM** **NS**. Group x time. *****6 months post-baseline – within-group – intervention (P=.013).
Trief, P. (2011)	44 (13 control; 12 individual intervention; 12 couples intervention); 59.9y; 63.6%; 8.3%; 13.4y; mostly obese, all couples – 1 partner with T2D	(1) TAU: Two diabetes education sessions & meal plan review by phone. (2) Individual: TAU + phone sessions on dietary goal-setting, two on emotions re. Diabetes (3) Couples: TAU + phone sessions including partner on collaborative problem-solving.	(2 & 3) 3 months Nine phone sessions. Follow-up: 3 & 6 months	HbA1C: HPLC (DCA 2000 A1C Analyzer) Diet, BGSM: SDSCA Survey	**HbA1c** **NS**. Group x time. **NS**. Within-group. **Diet** **NS**. Group x time. **NS**. Within-group. **BGSM** **NS**. Group x time. **NS**. Within-group.
Walker, E.A. (2011)	526 (264 control; 262 intervention); 55.5y; 67.1%; 8.6%; 9.2y; mostly Black and Hispanic, overweight; Type 2 diabetes	(1) TAU: Diabetes education materials mailed after randomisation. (2) TAU + phone calls from Health Educator - medication adherence, problem-	(2) 12 months ≥10 calls, 4- to 6-week intervals, *M*=14.1 min.	HbA1c: "Dry-dot" Method (mail-out kits) Diet (number days/week following healthy eating plan); exercise (number days ≥30 min exercise); self-care: SDSCA survey; medication: Morisky Adherence Scale	**HbA1c** *****Group x time (P=.009). **Diet** *****Group x time (P<.05). **Exercise** *****Group x time (P<.05). **Medication** **NS**. Group x time.

Study	Sample characteristics (No; mean age; % female; mean baseline HbA_{1c}; mean y since diagnosis; population type)	Study conditions (1) Control condition (2) Intervention condition 1 (3) Intervention condition 2	Duration, intensity and follow-up times	Reported outcomes (relevant to review) and associated measures	Effects of interventions
		solving, goal-setting, communication, planning medical visits, diet, physical activity.	Follow-up: 12 months		
Wolever, R.Q. (2010)	56 (26 control; 30 intervention); 53y; 77%; 8.0%; 11y; mostly African American; Type 2 diabetes	(1) TAU (2) Integrative Health coaching by phone with trained social worker/ psychology graduate coaches. Guided in creating vision of health and long-term goals. Wheel of Health used to guide conversations; received educational materials.	 (2) 6 months 8 weekly calls; 4 biweekly. Final call 1 mth later. Calls, *M*=30 min. Follow-up: 6 months	HbA1c: lab values Exercise - (How many times/week exercised ≥ 15-20 minutes in past mth)" Medication: Morisky Adherence Scale, ASK-20 items.	**HbA1c** **NS**. Group x time. *****6 months post-baseline – within-group – intervention HbA1c≥7% (P=.03). **Exercise** *****Group x time (P=.026). **Medication** *****Group x time, ASK-20 survey (P=.036). **NS**. Group x time – Morisky Adherence Scale *****6 months post-baseline – within-group – intervention (ASK-20, P=.001; Morisky, P=.004)

NR, not reported
NS, not significant ($P \geq 0.05$)
*$P<0.05$
TAU, treatment as usual

2.6 Chapter Summary and Conclusions

This review provided information about whether it would be wise use telehealth as the mode of intervention delivery for this research project. On the basis of the evidence, it was decided that telehealth has been explored in Type 2 diabetes intervention to a large degree, and that we might offer no superior efficacy to that demonstrated. Furthermore, as part of the initial exploratory stage of the project, the review contributed to forming the foundation of the qualitative study in the next chapter, as it provided the impetus for exploring a technological means of intervention delivery that did not involve telehealth with participants, namely being the web-based modality.

CHAPTER 3

PERCEIVED NEEDS FOR SUPPORTED SELF-MANAGEMENT OF DIABETES: A QUALITATIVE INVESTIGATION OF THE POTENTIAL FOR A WEB-BASED INTERVENTION

3.1 Notes

This paper has been published in the Australian, peer-reviewed journal, *'The Australian Psychologist'*.

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Authors' contributions to this paper:

The candidate, who is the first author, conducted the qualitative interviews upon which this paper is based and was responsible for transcribing the interviews, thematic analysis of participants' responses, and drafting the manuscript. The co-authors are both members of the candidate's supervisory team. The second author collaborated with the candidate on the derivation of categories from the data. Both co-authors provided editorial suggestions on the manuscript.

Overview of this paper:

This paper contributes to the scientific literature as one of the few studies in Australia that provides insight into the experiences of living with Type 2 diabetes from patients' and practitioners' perspectives using a qualitative approach. The paper forms the second part of the project's exploratory stage and forms a foundation for optimising the incorporation of patient empowerment into the intervention.

Perceived Needs for Supported Self-Management of Type 2 Diabetes: A Qualitative Investigation of the Potential for a Web-Based Intervention

Abstract

The estimated one million Australians with type 2 diabetes face significant risks of morbidity and premature mortality. Inadequate diabetes self-management is associated with poor glycaemic control, which is further impaired by comorbid dysphoria. Regular access to ongoing self-management and psychological support is limited, especially in rural and regional locations. Web-based interventions can provide complementary support to patients' usual care. Semi-structured interviews were undertaken with two samples that comprised (i) 13 people with type 2 diabetes, and (ii) 12 general practitioners (GPs). Interviews explored enablers and barriers to self-care, emotional challenges, needs for support, and potential web-based program components. Patients were asked about the potential utility of a web-based support program, and GPs were asked about likely circumstances of patient referral to it. Thematic analysis was used to summarise responses. Most perceived facilitators and barriers to self-management were similar across the groups. Both groups highlighted the centrality of dietary self-management, valued shared decision-making with health professionals, and endorsed the idea of web-based support. Some emotional issues commonly identified by patients varied to those perceived by GPs, resulting in different attributions for impaired self-care. A web-based program that supported self-management and psychological/emotional needs appears likely to hold promise in yielding high acceptability and perceived utility.

200 words

Keywords: behavioural self-management, chronic disease, diabetes, emotional disorders, health psychology, online intervention, e-health, qualitative research.

3.2 Introduction

Type 2 diabetes is one of the most significant health issues to date, affecting an estimated 1.9 million Australians, with numbers rising (IDF, 2012b). Modifiable lifestyle risk factors including lack of physical activity, poor nutrition, and obesity are major contributors to type 2 diabetes etiology and glycaemic control (AIHW, 2012a). Treatment non-adherence is exceedingly common in type 2 diabetes patients, with the uptake and maintenance of key lifestyle factors being a major challenge (Peyrot et al., 2005). The link between diabetes self-management and glycaemic control is strong (DCCT Research Group, 1993), placing these patients at increased risk of diabetes complications, which include blindness, amputation, and chronic kidney disease (IDF, 2009a). Patients with diabetes are also at significantly greater risk of cardiovascular disease after adjustment for other risk factors (Stratton et al., 2000). Therefore, behavioural self-management intervention is essential to improve the health outcomes of people with type 2 diabetes, with physical activity and nutrition being fundamental components (Colagiuri et al., 2009).

Dysphoria is significantly associated with inadequate diabetes self-management, and is at least twice more common in people with diabetes than in the general population (Ali et al., 2006). Dysphoria impairs functioning and quality of life and increases the risk of diabetes complications and premature mortality, both by its direct effects on metabolic status and by affecting the maintenance of health behaviours (Fisher et al., 2007). Further, it tends to recur and persist for longer periods in diabetes patients (Fisher et al., 2008). However, dysphoric mood remains largely unrecognised and subsequently is under-treated in diabetes patients (Li et al., 2010; Pouwer, 2009). This is particularly the case with subclinical symptoms, which exert significant impacts on diabetes self-management (Gonzalez et al., 2007).

In Australia, diabetes is one of the commonest chronic conditions managed by general practitioners [GPs; (Britt et al., 2012)]. GPs have indicated that psychological counselling about modifying lifestyle factors including weight, nutrition and physical activity, is one of their most common roles in type 2 diabetes patient consultations (AIHW, 2010b). However, both intrapersonal [e.g. low self-efficacy; (Bambling et al., 2007)] and system-level barriers (Zhang, Van Leuven, & Neidlinger, 2012) prevent GPs from addressing these issues in sufficient depth. It is also difficult for primary care practitioners to provide the frequency or intensity of support for self-management that may be required (Fisher et al., 2007), and this is particularly the case when patients present with comorbid psychological and/ or emotional issues (Hajos et al., 2011).

A variety of factors further complicate patients' access to regular diabetes self-management support (Delamater, 2006). For example, embarrassment about sub-optimum self-management or stigma about dysphoria may inhibit people from seeking assistance. The greater geographical spread and lower ratio of practitioners in non-metropolitan regions means that residents in remote locations face particular challenges in obtaining sufficient help from practitioners. In Australia, almost one third of people with diabetes face these 'inequity of access' issues (AIHW, 2011). A different support model is warranted—one that is less reliant on the physical location of the health workforce and more easily accessible where and when support is needed.

Rapid advances in technology are fast making web-based provision of type 2 diabetes self-management interventions a feasible alternative to traditional face-to-face treatment (Griffiths & Christensen, 2007). However, there have been no Australian trials of web-based type 2 diabetes self-management support interventions. Implications for providing combined diabetes self-management and emotional support to type 2 diabetes patients include reduced strains on the health care system, and increased outreach of motivational and emotional support to rural and remote areas that is more convenient and accessible.

We intended to develop a web-based program that would provide reliable and ongoing informed, motivational, and emotional support to improve type 2 diabetes self-management and dysphoria symptoms. Patient empowerment refers to "...helping patients discover and develop the inherent capacity to be responsible for one's own life" (Funnell et al., 1991). Empowerment has been shown to enhance motivation for diabetes self-care, with its emphasis on respecting patients' decision-making being fundamental to the psychological and emotional processes associated with implementing effective self-care. Based on past chronic disease research (Anderson et al., 1995; Deakin et al., 2003; Mark, 2010) and the Diabetes Australia guidelines (Colagiuri et al., 2009), we wanted to ensure that patient empowerment was a key factor in the intervention. In order to have a firm basis for design of such a program a critical initial step was to explore the perspectives of patients and GPs on type 2 diabetes self-management and emotions, and examine the role that such a program could potentially have. We considered that the reliance of type 2 diabetes patients on GPs as primary carers for their disease management necessitated also obtaining the views of GPs on barriers and enablers with which patients commonly present during treatment. Further, information about GPs' insights into patients' experiences may assist with efforts to enhance patient outcomes by promoting additional effective strategies and aiming to fulfil patients' unmet needs. These responses would help articulate issues that challenge and influence success with diabetes self-management.

Self-management of diabetes is influenced by an array of complex, inter-related factors associated with individual, social, and ecological domains (Fisher et al., 2005). Situations specific to each individual create unique challenges and enhancers of self-care (2002). Personalised self-management interventions may be needed to best cater for the extensive variety of diabetes self-management challenges that patients face according to their socioeconomic, interpersonal, and intrapersonal circumstances (Bandura, 1986; Fisher, Brownson, O'Toole, Anwuri, & Shetty, 2007). Accordingly, the present study uses a qualitative, individualised approach that enables unique facilitators and barriers to self-care, as well as personally relevant emotional experiences, to emerge. Further, consideration of these issues in the context of those identified in the recent literature and implementing strong theoretical (namely, Social Cognitive Theory and the Theory of Planned Behaviour) foundations is aimed to provide a conventional, evidence-based framework for the intervention. Results from this trial inform the development of a menu of components within the web-based support program, from which users can select ones that best address their individual needs and most closely match their preferences. This qualitative research forms the first, fundamental step in empowering patients to achieve better type 2 diabetes self-management and wellbeing via a novel web-based self-management program.

3.3 Method

Participants

Participants in the patient sample (Study 1a) were: aged 18-75 years, diagnosed with type 2 diabetes ≥ 3 months ago, and living in Brisbane, Australia. Recruitment took place at a Diabetes Australia – Queensland Expo. Eligible individuals provided their telephone and e-mail contact details, and preferred times for further contact and interview. GPs (Study 1b) were in current practice and had experience treating type 2 diabetes patients. Recruitment involved calling and sending letters to the general practice managers of 16 medical practices in Brisbane, and by direct personal approaches of individuals with type 2 diabetes who attended Diabetes Australia – Queensland expos.

Measures

Participant characteristics/demographics

Assessed patient characteristics included age, gender, occupation, relationship status, duration of type 2 diabetes, diabetes treatment regimen, types of practitioners involved in their diabetes care, accessed support for diabetes self-management and self-perceived diabetes status. GPs completed a survey that assessed their age, gender, and duration of treating type 2 diabetes.

Kessler-10 (K10)

The patient sample completed the K10, which comprises 10 items assessing the frequency of symptoms of distress over the previous 30 days. The scale has sound internal consistency and external validity for use in a type 2 diabetic population (Kessler & Mroczek, 1994).

Research Questions Explored Using Semi-Structured Interviews

A qualitative, semi-structured interview was used to explore: (a) facilitators and challenges in relation to effective type 2 diabetes self-care in general, and physical activity and healthy eating in particular; (d) emotional challenges associated with having type 2 diabetes; and (e) suggestions for web-based support program content. Patients were asked about circumstances in which they would use web-based type 2 diabetes self-management support, and GPs were asked about circumstances where they would refer patients to such a program.

Procedure

Interviews with the patient sample took place at the Wesley Research Institute and the Queensland University of Technology, both in Brisbane, Australia. Interviews with GPs took place at their practices or by phone. All participants completed the preliminary survey (Study 1a: demographic survey and K-10 scale; Study 1b: GP characteristics), followed by the semi-structured interview. All interviews were audio recorded, with participants' consent. Approval for this study was granted by the relevant ethics and management committees - Uniting Care Human Research Ethics Committee (#Cassimatis9111) and the Queensland University of Technology University Human Research Ethics Committee (#1100000783).

Analytic Strategy

Interview data were transcribed verbatim, categories (major themes) and sub-categories (minor themes) were derived based on common responses amongst the patient and GP samples. Thematic analysis was used to analyse and present categories and sub-categories (Charmaz, 2006). Categories were derived separately for patients and GPs, and commonalities and variations in responses were then identified.

3.4 Results

Sample characteristics

Patients (*N*= 13; 46% male) had a mean age of 57.1 (*SD*= 7.8) years and a mean type 2 diabetes duration of 7.2 (*SD*= 3.8) years. The majority (85%) were on anti-diabetes medication, with over 50% on diet, physical activity, tablets and insulin. Most (>65%) saw a GP for their primary diabetes management. Almost half the sample reported seeing an endocrinologist, though visits were typically less frequent than to their GP and often were restricted to occasions when they had management difficulties. Patients' average K-10 was 16.3 (*SD*= 5.4, Range= 8 – 24), which indicates moderate symptoms of depression, anxiety, and/or psychological distress. Most classified their diabetes control as mostly or fairly unstable, and 28% claimed that it was good or excellent.

The GP sample comprised 12 practitioners (8 males) who were located in practices within the region of Brisbane, Australia, and had been treating type 2 diabetes for an average of 26 years (*SD*= 9.3).

Attitudes and perceptions regarding diabetes management

Table 1 displays themes around the attitudes and perceptions of the patient and GP samples regarding type 2 diabetes management. Variations in responses between GPs and patients primarily occurred within sub-categories, rather than between major categories. Responses to questions about facilitators and barriers to general type 2 diabetes self-management, participation in physical activity, and healthy eating also had very similar categories. Where there was significant overlap, categories from these three domains were collapsed into common major categories. Categories that related specifically to only one domain of self-care are presented separately.

Table 1. Common Categories and Sub-Categories on Facilitators of Type 2 Diabetes Self-Management

Common categories	**Common sub-categories**	**Patient Sample**	**GP Sample**
Informational support	General diabetes self-management	Wider range of information sources	Mainly doctors, allied health, leaflets
	Physical activity – enjoyable & appropriate options	Variety of activities	Light, incidental exercise, stretching
	Nutrition – recipes, food groups, effects of foods on blood glucose		
Social support	Partner	Others with diabetes	
	Family	Counsellor	
	Friends	Weight loss group	
Doctor-patient relationship	Patient treatment choice	Directive approach by doctor	Proactive doctor
	Good communication	Explanation about treatment	Reasons and barriers to change
	Doctors help to understand diabetes		
Motivational support	Reminders	Accountability to health professional	Short-term incentives for self-care (energy, well-being…)
	Goal-setting blood glucose, clinical targets (weight, blood pressure…)		
	Monitoring – blood glucose, HbA1c	Diet and Exercise	Clinical parameters (blood pressure, cholesterol, urinary albumin)
	Feedback – HbA1c, blood pressure, cholesterol		
Psychological support	Acceptance of type 2 diabetes	Self-discipline/ “willpower”	
		Own reasons to improve health	
Plan/ preparedness	Routine – testing blood glucose at same time each day; fitting self-care including activity into daily routine	Eat according to a routineDiet preparation – pack own food, choose from online menu before dining out	
	Having a plan – physical activity plan		
Morbidity salience	Timing in disease – early, before anti-diabetic medications	Threat of diabetes complications	When a complication is diagnosed

Themes and Sub-themes across Facilitators and Barriers to Self-Care

Tables 2 and 3 present the common major categories and sub-categories that were derived from interview responses regarding facilitators of and barriers to effective type 2 diabetes self-management, as perceived by both the patient and GP groups. Patients specified more sub-categories for facilitators and barriers to self-management than did GPs. Patients indicated that accessing a broad range of informational supports facilitated their diabetes self-management; whereas being inadequately informed about diabetes self-management and processes of the disease was cited as a substantial barrier to adequate self-care. However, GPs often cited patients' lack of health literacy as a barrier to their understanding of diabetes, rather than primarily attributing it to a paucity of specific information, as the patient sample had. GPs generally assumed that patients were well informed about reasons for insulin therapy and attributed patients' reluctance to commence insulin to practical concerns and psychological barriers, rather than to confusion, which was reported by most of the patient group.

Both samples indicated that having options for appropriate and enjoyable physical activities were helpful in encouraging greater involvement in physical activity. Alternatively, being unsure about suitable and convenient activities was indicated by both groups as significantly limiting patients' likelihood of physical activity participation. GPs suggested that patients commonly held misconceptions about what constitutes physical activity. Nutritional information was regarded by both groups as fundamental to dietary adherence. Confusion about the effects of various foods on blood glucose levels, healthy alternatives to unhealthy food choices, and diabetes-friendly diet was regarded by both samples to be detrimental to patients' efforts to maintain a healthy diet as well as being a source of hopelessness and frustration. Psychosocial pressures presented major challenges to dietary adherence and physical activity. In particular, eating out was commonly reported as a barrier, and some patients reported only dining out rarely due to difficulty finding healthy options on the menu.

Patients mentioned more forms of social support than did GPs, indicating that members of their wider networks, including neighbours, facilitated their diabetes self-management. In contrast, GPs mainly focused on the role of family members. Both patients and GPs said that a communicative patient-practitioner relationship supported diabetes self-management. While many patients advocated that their doctors use a directive approach, none of the GP sample mentioned this technique as a facilitator of self-care.

Patients said that accountability to health professionals motivated their self-management, and reported that they put more effort into improving their glycaemic control and self-care shortly before an appointment. Follow-up calls from health professionals, setting goals for blood glucose, assessing clinical parameters including weight, and providing progress feedback were considered to promote improved self-care. Patients who kept an exercise and/ or diet log reported that this helped them maintain their motivation. Both patients and GPs said that acceptance of type 2 diabetes and the receipt of psychological support were also important factors. Patients emphasised a perceived importance of "willpower" for effective self-management but GPs did not specify this factor.

Both samples regarded having a plan and following a routine, including having set times for monitoring blood glucose and medication adherence, undertaking physical activities, and having meals, to be facilitative. Dietary preparedness, including packing healthy foods and viewing restaurant menus online before dining out was also reported by patients to assist their nutritional adherence. While patients said that awareness of the potential for diabetes complications motivated them to practise better self-care, GPs focused on the motivational power of having an actual diagnosis of a diabetes-related complication. Accordingly GPs suggested that a key factor in patients' lack of awareness of the consequences of type 2 diabetes was its asymptomatic nature, particularly in the disease's early stages. In contrast, patients said they were aware of the consequences of poor self-management from the time of type 2 diabetes diagnosis.

Emotional challenges associated with type 2 diabetes

Table 3 summarises the common categories from patients and GPs concerning the emotional challenges presented by type 2 diabetes.

Table 2. Categories and Sub-Categories on Barriers to Effective Type 2 Diabetes Self-Management

Common Categories	**Common Sub-categories**	**Patient Sample**	**GP Sample**
Lack of information/ understanding	Appropriate physical activities Conflicting nutrition information	Type 2 diabetes causes, progression Reasons blood glucose fluctuates Ideal BGSM & med timing, purposes Not enough time to ask GP questions Nutritional values	Do not understand consequences Asymptomatic = no need to manage Poor health literacy Physical activity misconceptions Do not understand diet
Psychosocial pressures	Social diet/ alcohol-related pressures Family responsibilities Relationship conflict	Special/ family occasions Friends/ family give unhealthy foods Eating out/ travelling	“Psychological factors”
Medication-taking barriers	Forget medications/ BGSM Medication side effects “No point” to BGSM	Get “sick of” BGSM Avoid testing high blood glucose Work– no time, deprioritise self-care	Resist treatment regime complexity Difficulties accepting changes
Resistance to insulin initiation	Fear needles Self-perceived failure Feel responsible for going on insulin	Belief exercise & diet control OK Fear insulin permanence Confused re effects of insulin Fear weight gain	“Mental hurdle” for patients
Practical limitations	Financial costs – medications, health appointments, healthy food Physical activity- weather, no time, tiredness Eating on the run	Costs of diabetes supplies–lancets, test strips Eat high energy food “to stay awake” Limited restaurant menu options	Costs of individual exercise
Motivational issues	Diabetes chronicity- adherence over time Comorbidities take priority Sense of defeat	Want a break from treatment Tiredness/ exhaustion Weight gain, high HbA1c, poor BGLs	Oppose living within boundaries Asymptomatic – no immediate biofeedback
Psychological issues	Stress – work, family, diabetes Emotional toll- treatment complexity	Stress- fear complications Emotional eating, disinhibition, alcohol	Depression

Table 3. Categories and Sub-Categories on Emotional Challenges Associated with Having Type 2 Diabetes.

Common Categories	**Common sub-categories**	**Patient Sample**	**GP Sample**
Reaction to initial diagnosis	"shock" and "fear" Feel responsible for onset	Uncertainty about lifestyle implications 'Forced acceptance' of diabetes Sense of powerlessness Regret– past lifestyle (self-blame) Anxiety about complications	Difficulties accepting chronicity "Denial" reaction/ difficulty taking ownership Boosts in self-care motivation "Psychological factors" to deal with Fear of treatment regime commitment
Resistance to anti-diabetes medications	Fear of lifestyle restrictions Frustration – side effects Frustration, depression-treatment complexity, adherence issues Self-blame for not preventing medications Perceived failure for taking insulin	Fear– medication taking control of body; weight gain Embarrassment about injecting insulin Discomfort- Perceived stigma re injecting	"Mental hurdle" for patients
Difficulties accepting diabetes chronicity	Depression- non-adherence; need to maintain lifestyle changes Distress– boundaries	"Battle metaphor" Worry- consequences of going off track	"Emotional battle"– lifestyle changes required to keep good diabetes control
Difficulties managing type 2 diabetes	Frustration, worry- high blood glucose/ fluctuations; not meeting treatment targets Avoidance/ non-adherence Depression	Hopelessness/ powerlessness Guilt- not achieving treatment targets	Anger, distress- treatment complexity
Distress related to future health prognosis	Current complications Depression- comorbidities Worry- impending physical impairment	Fears of developing complications Uncertainty- effects on body Anxiety- poor glucose control Frustration - physical limitations	Distress→ Self-care motivation increase Dysphoria pattern related to diabetes progression

Reaction to initial diagnosis

Most patients and GPs initially discussed patients' reactions to the diabetes diagnosis. Patients said that uncertainty about the implications of diabetes for their lifestyle and long-term wellbeing resulted in distress and feeling 'down'. One woman recollected:

> So I just say to myself the only thing...how come I got to this stage to have this? And that's the thing, is that it worries me, and that's it. There's nothing I can do to change it.

Many patients reported feeling guilty upon receiving the diagnosis and were upset about being responsible for its development. A middle-aged woman who had been overweight before her diagnosis said:

> It comes back to that emotional thing about, have I really, seriously...has my pancreas really done the dinner, and that's it for me, and I can't ever return back to normal...

GPs acknowledged the emotional impact of a type 2 diabetes diagnosis, and commonly attributed this reaction to difficulties patients had with accepting diabetes' chronicity. They unanimously reported that the shock experienced by patients at diagnosis resulted in an initial boost of motivation to make positive lifestyle changes, largely to avoid going on diabetes medications. Many patients also reported this reaction and its motivation.

While some patients reacted to distress over the diagnosis by making lifestyle changes, for some, a sense of powerlessness undermined any attempt to manage their diabetes. A middle-aged man said he never attempted to follow his doctor's treatment recommendations:

> ...you sort of realise the uselessness of doing anything. I mean, I take my medication, and that's about all. If my sugar is high, what can I do about it?

In general, patients said that feelings of initial shock at diagnosis eventually gave way to acceptance of their diabetes and awareness of its implications for their lifestyle. However, anxiety about its effects on the body remained, and was present in most of patients, from the newly diagnosed to those who had the disorder for ten years or more. In contrast, GPs suggested that patients were initially unaware of the consequences of type 2 diabetes.

Resistance to anti-diabetes medications

All patients and many GPs reported a reluctance to take anti-diabetes medications, especially insulin. Patients commonly reported frustration due to medication side effects. A male in his 60's who suffered erectile dysfunction, claimed it was exacerbated by his oral medication.

> I still take the tablets...and I grit, and I yell, and I scream a bit, and my wife says, "Just calm down," but I think you do sort of then think, "Well hell, I don't want it to get any worse, you know."

Patients voiced their concerns about medications taking control of their body and further restricting their lifestyle, particularly as the complexity of the treatment regime increased. Even patients already taking insulin who claimed it improved their blood glucose levels and gave them more energy, discussed wanting to "get off the insulin, or at least reduce the dose I'm on." Some patients said they were embarrassed to inject themselves, and believed that there was a public stigma about using needles. A female in her early 60's reported feeling uncomfortable about discussing her fears about injecting insulin with her doctor, who had told her that it was "silly" to feel that way.

Patients commonly perceived that insulin therapy was preventable or reversible if they could exercise enough "willpower" in adhering to lifestyle recommendations. Patients idealised a life without diabetes medication. A male who had been on insulin for the past 8 years said:

> ...as they say, it's not a lifetime thing with type 2 (diabetes). You can manage it, and if you get on top of it, manage it with your diet, which is great. And that's your challenge, your goal; to be insulin free and tablet free, and I think if you can strive for it, it's a good challenge; strive for it.

Surprisingly, most patients who expressed similar beliefs indicated that their view was endorsed by their GP or endocrinologist.

Patients commonly described having received warnings from their doctors that they would need to take tablets or insulin if they did not improve their exercise and diet. The negative connotation commonly associated with requiring medication, appeared to exacerbate their anxiety and reluctance about commencing it. Perhaps as a result of the idealisation of non-pharmacological diabetes management, patients on insulin reported guilt and a sense of being at fault or having failed.

GPs commonly expressed concerns that resistance to commencing insulin was impairing their patients' glycaemic control. They acknowledged that most patients were afraid to start insulin, but regarded its resolution as an issue that needed to take its own course.

Difficulties accepting the chronicity of type 2 diabetes

Patients and GPs indicated that one of the most common emotionally challenging aspects of having type 2 diabetes was its chronic nature. Many patients used the "battle metaphor" in describing their attempts to achieve good diabetes control, and three women cried as they discussed their experiences. One commented:

> ...it's just that constant bringing yourself back on track and just remembering that it is one day at a time, basically.

Another described the constant discipline required to effectively manage type 2 diabetes as:

> ...a constant battle to do what's right and to try and keep away from what's wrong.

A third described it as:

> ...the constant battle, I think...the battle to get it into a manageable state and keeping it there is...I think for me, the biggest emotional thing, as you can tell."

Patients commonly regarded Type 2 diabetes as inflicting an eternal boundary on their lifestyle flexibility, with no leniency for lapses in their health behaviours. One woman reflected:

> ...I always want to keep it (diet and exercise) under control anyway, but I guess this is going to keep me....going: I can't stop doing what I'm doing. I guess it's about no choice. When you feel that you have no choice, it's no longer an option for you.

GPs acknowledged patients' distress and frustrations about the need for long-term commitment to lifestyle and treatment regimens and commonly said that this issue severely affected patients' self-management. Substantial congruence was seen in patients' and GPs' views about the emotional impact of diabetes, although patients went into more depth in describing their experiences.

Difficulties managing type 2 diabetes

Patients commonly reported distress about problems with control of their diabetes, particularly when they had expended great effort in their attempt. GPs also noted that this caused patients frustration and distress. One patient summed up the views of many:

> ...you just get to a stage where it's unmanageable, and then it [HbA1c level] goes out, and I think, 'What have I changed?' and I've changed nothing. Even when you're thoroughly on track, and you're doing everything you're supposed to, it's still all over the shop, so that's hard.

Some patients reported avoiding blood glucose self-monitoring because they did not see the point, but this was rare. More commonly, they reported avoiding self-monitoring when they thought their blood glucose level was high. Some reduced the frequency of testing to avoid negative emotional impacts from detection of fluctuations:

> I've tried not to do too many blood glucose tests during the day because I do fluctuate a fair bit in the day time. It's very, very worrying.

GPs reported similar observations:

> A lot find it hard to continue to monitor and evaluate their diabetes when their control is not very good.

They empathised with patients' anger and distress concerning their treatment regimen. Some reported that patients sometimes directed anger toward their practitioners:

> ...if they don't see a quick response in their blood sugars, they'll come back and say to me, "I stuck to that diet you gave me that time, and look at this! My blood sugars have been awful and I've actually put on a kilo." They don't see the point, and that's a difficult challenge.

Distress related to future health prognosis

Patients reported distress and worry about their future health, and particularly about developing diabetes complications, and GPs also reported this issue. This emotional response was exacerbated by difficulties controlling blood glucose levels, and many patients reported that it increased with the duration of inadequate blood glucose control. A woman who had been diagnosed 6 months prior to the interview and who had difficulties balancing her weight and medications, said:

> ...the longer it's unmanageable, I think the greater the possibility that complications will occur, and I know that I've got to get it to a manageable state to forestall the complications.

In contrast, no GP described patient distress over potential complications, instead suggesting that patients only realised the consequences of inadequate diabetes control when actually diagnosed with a complication. Some GPs described the patients' dysphoria as typical of chronic diseases in general:

> I find that with any chronic disease, any change in their condition is a whole, new grieving step. Each time something changes they have to reacquaint themselves with the idea of having diabetes all over again.

There was consensus amongst GPs that a diabetes complication reminded patients of their mortality and the importance of self-care to prevent further physical and emotional debilitation. GPs reported that patients' motivation for self-care increased at the onset of a complication. They reported noticing a pattern of dysphoria that was related to the stages of type 2 diabetes progression, from diagnosis to the disease endpoint.

Many patients reported worry about limitations to their physical abilities, and frustration that these limitations would restrict their activity and impair their ability to improve glycaemic control. Feelings of loss were common, as reported by a middle-aged patient:

> I had this awful thought once when I was out walking, that I may never be able to run again, and as I was a very, very active teenager and 20 year old...that was a real shock to me.

Declines in physical ability were commonly attributed by patients, including those in their 40's and 50's, as normal ageing. Having diabetes seemed to bring reflections on a range of reduced physical capabilities to attention, which accentuated frustration and distress. Lack of perceived physical capability was commonly cited as a barrier to being active. As stated by a woman in her 40's:

> It's just the fact that I'm getting older, it's getting harder, and I can tell you everything that's the right thing to do, but actually doing it is the...hardest thing.

Table 4. Patients' and GPs' Suggestions for Online Program Content Inclusions.

Common Categories	Common sub-categories	Patient Sample	GP Sample
Self-monitoring tools	Blood glucose levels HbA1c level Diet Exercise	Emotions	Blood pressure, cholesterol, urinary albumin Weight
Feedback	*Goal progress – clinical parameters*	Daily blood glucose levels	Reinforcement - self-care targets
Information	Nutrition Physical activity	General type 2 diabetes Medications – purposes, effects Referrals to health professionals Frequently asked questions section Contact with health professional/s	Diabetes complications Worksheets – how insulin changes blood glucose levels, dosage guide Foot care – how to check feet, signs of complications… Instructions on finding own pulse
Motivational support	Appointment reminders Self-care reminders - emails	Help with the "psychology of it" (self-management) Social support – chat room/ forum Emotional support – help with feeling down	Motivational tools Physical activity/ stretching videos

Suggestions for online program inclusions

Patients' and GPs' suggestions for online program inclusions are presented in Table 4. Overall, patients were in favour of using an online diabetes support program. Just one patient indicated that she would not use such a program, as she opposed the use of technology in general, including mobile phones. Common suggestions for components to incorporate in an online diabetes support program overlapped with patients' and GPs' perceived barriers and facilitators to adequate diabetes self-management. Additionally, many patients suggested including a chat program or blog site, and access to e-mail contact with a health care professional in the program.

Patients considered the benefits of an online support program to include anonymity to discuss private health issues and for, “Somewhere you could go when you’re having a really bad day”. Patients said online information would be easier to refer to than paper-based information, and it would be useful to have more regular support between seeing health care professionals. Two patients did not own a computer but claimed they would use an online program from a friend’s house or library. Patients indicated that they would find an online diabetes support program, “really helpful”.

In contrast to the patient sample, GPs suggested presenting information about the consequences of poor glycaemic control, including photographs of retinas inflicted by diabetic retinopathy, and foot complications that were not too graphic. They indicated that patients should be able to relate to the included content, and indicated that they would most likely refer their younger type 2 diabetes patients (< 60 years) to an online support program. The cross-cultural relevance of the program was mentioned as a dictating factor in one doctor’s decision about whether to refer ethnic patients to the program. GPs emphasised the importance of knowing that the program was established by reputable professionals. Their own familiarity with the nature of the program’s content in the first instance was also cited as an important determinant of their referral likelihood. In general, GPs supported referring their patients to an online diabetes self-management support program, with the major contention being that older patients may have difficulty using it. However, some suggested taking older patients through instructions on how to use the program as a solution.

Overarching themes that summarised responses to each of the questions were identified that describe the major areas facing patients in managing type 2 diabetes. Specifically, these themes were centred on the areas of: practical, psychosocial, and psychological/ motivational factors. A primary practical constituent that was considered fundamental to effective diabetes self-management by patients and GPs was informational support. Both samples indicated that lack of adequate information undermined effective diabetes self-management and resulted in confusion when patients attempted to make day-to-day decisions about diet and medications. Accordingly, patients reported that lack of understanding accentuated emotional difficulties in coping with diabetes. In addition, having the practical means to enable effective self-care, including adequate financial resources, environmental conditions for physical activity, and access to healthy food choices, were also important to stable self-management. Under the broad theme of psychosocial support, social support from partners, family members, and friends was considered to be essential to effective self-care. In addition, the doctor-patient relationship was considered a key influence of patients' self-management behaviours. Psychological and motivational support was seen as vital by both samples to enable optimum emotional well-being and the maintenance of recommended self-care. In particular, issues including daily work-related and interpersonal as well as diabetes-related stress and feeling depressed were emphasised by patients as problematic to their well-being and self-care. Patients reported that these issues tended to increase their resistance to consistent medication-taking and in particular their dietary adherence. GPs indicated that emotional disturbance in patients was particularly common, and that this tended to influence their efforts to effectively supporting patients with their self-management.

Links to online support program components

Overall, interview results provided useful feedback from patients and GPs regarding their experiences managing type 2 diabetes. Specifically, the importance of using a holistic approach in supporting the effective day-to-day management of the condition was emphasised. The relevance of emotional support as a key influential factor to self-care was made clear by both samples, as well as practical and psychosocial support.

3.5 Discussion

Overall, the perceptions of patients and GPs showed close correspondence, although patients' reports were more detailed and more thoroughly emphasised ongoing, daily challenges than GPs' reports. It appeared that patients may not fully share their emotions and related concerns with their GPs, which may be due to a number of factors, including the time-limited nature of medical consultations, inadequate screening for emotional issues in diabetes patients, and difficulties in communication [2002; (Maddigan, Majumdar, & Johnson, 2005)]. While GPs acknowledged that patients sometimes struggled with emotional issues, especially in relation to initial diagnosis and to insulin therapy, they most commonly explained patients' barriers to self-care in terms of practical factors.

Findings of the current study are consistent with an ecological perspective on diabetes management, which emphasises the contributions of individual, psychosocial and ecological factors in optimal diabetes management (E. B. Fisher et al., 2005). Our results are also consistent with those of the Diabetes Attitudes, Wishes and Needs (DAWN) Study, which indicated that social relationships are crucial to assisting patients to implement effective coping strategies in managing their diabetes Alberti, 2002). The present study confirmed that a social support network can be conducive to encouraging physical activity and dietary adherence, and may also buffer against some barriers to self-care, such as eating to alleviate loneliness or depression. However, similar to the DAWN Study results (Alberti, 2002), the current study found that some family influences detrimentally affected patients' diabetes self-management. For example, many patients and GPs recognised that family pressures including relationship conflict and demands by children led patients to fail to prioritise diabetes management. Further, these situations induced stress, which affected patients' capacity for self-care.

Although K-10 scores suggested that there were no extremely distressed patients in our sample, most participants in the patient group exhibited emotional vulnerability as they discussed their experiences. This was particularly evident as they described the challenges involved in daily diabetes self-management, in particular when it was difficult to maintain adequate blood glucose control, with many unable to understand why this was occurring. Self-blame was common amongst patients, particularly when they did not fully adhere to their treatment regimen. Beverly and colleagues (Beverly et al., 2012) recently reported that physicians also feel responsible for their patients' difficulties in meeting treatment targets, although that was not seen in the current study. In future, GPs' own emotional responses to management of type 2 diabetes would be a useful vantage point from which to further unpack patient-provider issues in diabetes self-management intervention.

The need for additional behavioural self-management, emotional, and motivational support was unanimously expressed by patients. This result was consistent with baseline findings of the landmark Australian study, Diabetes MILES (management and impact for long-term empowerment and success), which emphasised the importance of behavioural, psychological and psychosocial support if diabetes patients are to optimise their wellbeing and health outcomes (Speight, Browne, Holmes-Truscott, Hendrieckx, & Pouwer, 2012).

Most patients were enthusiastic about the idea of a web-based diabetes self-management support program. Two participants who did not own a computer said they would happily use the program at a friend's house or library, and only one was adamant that they would not use any technological support, including a mobile phone. Most GPs indicated that they would refer any type 2 diabetes patients who were interested in a web-based support program. They argued that technology might be difficult for older patients to use. One GP suggested making the program available in an outpatient clinic or medical surgery so that patients could be shown how to use it, or alternatively offering a set of “stepped tutorials” to learn how to use the program. In fact, previous web-based type 2 diabetes self-management interventions specifically trialled in older type 2 diabetes populations have demonstrated reasonable acceptability, utility and usability (Bond et al., 2007; Cho & et al., 2010).

Overall, interview findings demonstrate external validity when compared with other research studies on facilitators and barriers to diabetes self-care (Beverly et al., 2012; Hayes et al., 2006; Nam et al., 2011) and on emotional experiences in managing the condition (Beeney, Bakry, & Dunn, 1996). Being a qualitative study, this research has the limitation of potential sample bias. It was acknowledged that the sample was chosen primarily from the Brisbane area, in which case they may have differential views to those of patients and GPs residing in more remote areas. However, this limitation is tempered by the fact that the purpose of the research was used to provide information about type 2 diabetes patients’ personal experiences with the condition, and GPs views that would serve to complement, rather than replace, current empirical research in informing the development of an online support program. Further limitations include the relatively small sample size, which limits the generalisability of findings to the current study cohorts. Time limitations also prevented a rural or remote sample from inclusion in the study. However, the authors were able to garner challenges faced by rurally residing type 2 diabetes patients from the literature, whilst the program aims to meet personalised emotional and self-management challenges that may affect both rural/ remote and metropolitan-residing patients. In light of these limitations, web-based program content was aimed to be developed using a strong evidence basis from the current literature and the professional expertise of research team members and additional allied health professionals. Findings from the present study indicate the potential for assisting patients with managing a variety of challenges that are associated with type 2 diabetes self-management and dysphoria using a web-based program.

What is already known about this topic

- Adherence to optimal diabetes self-management is a significant community health issue
- Depression and anxiety symptoms are 2-3 times more common in people with diabetes.
- For optimum efficacy, diabetes self-management interventions should address emotional as well as behavioural self-management issues.
- People with diabetes in rural and regional areas face additional barriers to receiving self-management support.

What this paper adds

- Both patients and practitioners identify dietary self-management is their key challenge.
- Emotional issues that are experienced by people with type 2 diabetes only partially correspond with those reported by practitioners.
- A need for additional motivational and practical support for emotional challenges and self-care, including a web-based program, is identified by both patients and practitioners.

3.6 Chapter Summary and Conclusions

This paper emphasised patients' needs for additional psychological, emotional and Type 2 diabetes self-management support from both patient and practitioner perspectives. Further, results indicated that the web was considered acceptable to this population as a means of intervention delivery. These outcomes were fundamental to Stage 2 of the research program, in which responses informed the content that was included in the OnTrack Diabetes program.

CHAPTER 4

STUDY PROTOCOL FOR A TRIAL OF THE ON-TRACK WEB-BASED PROGRAM FOR SELF-MANAGEMENT OF TYPE 2 DIABETES AND DYSPHORIA

4.1 Notes

This manuscript has been submitted to the international, peer-reviewed journal, '*Journal of Medical Internet Research'*.

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Authors' contributions to this paper:

The candidate is the first author, who carried out practical aspects of the OnTrack Diabetes project, drafted and revised the final version of the manuscript following edits from the co-authors. The second, third, and fourth authors are members on the candidate's PhD supervisory team. The second author was responsible for shaping the project protocol that is outlined in this paper, in collaboration with the candidate. All co-authors provided editorial feedback on the paper to the candidate.

Overview of this paper:

This paper formed the initial part of Stage 2 in the research program. It contributed to the scientific literature by making clear the sequence of stages involved in developing a novel intervention, which made clear the relevance of each stage in the research program.

Study Protocol for a Trial of the OnTrack Web-based Program for Self-management of Type 2 Diabetes and Dysphoria

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Abstract

Background: Type 2 diabetes prevalence is rising, with the majority of affected people having inadequate disease self-management. Depression, anxiety and diabetes-specific distress present additional challenges to motivational issues experienced by patients in relation to self-care. Internationally, health systems struggle to deliver routine specialist services which are equally accessible across the population. The popularity of web-based intervention delivery among people with diabetes is increasing, as it has the potential to provide frequent, accessible support, regardless of time and location. This paper describes the study protocol of an Australian national randomised controlled trial of the OnTrack Diabetes program. OnTrack Diabetes is an automated, interactive, self-guided, web-based program aimed at improving and maintaining glycaemic control, diabetes self-care and dysphoria symptoms in patients with Type 2 diabetes.

Objective: The objective of this paper was to report on the stages involved in the development and evaluation of the OnTrack Diabetes program in order to elucidate the processes involved in this trial. The aim of this was to inform researchers about the sequence of stages adopted in creating a web-based intervention of this nature and to enable associations to be established between trial processes and outcomes.

Methods/Design: Three stages are involved in the processes of program development, pilot testing, and the main trial of the OnTrack Diabetes program. Initially, qualitative interviews of General Practitioners and people with Type 2 Diabetes were undertaken to inform program content. Study 1 is a three-arm, randomised-controlled pilot trial that tests program functionality, effectiveness, and user acceptability and satisfaction. Pilot trial arms include: (i) wait-list control – undertakes usual diabetes care for three months post-baseline followed by full-program access; (ii) brief, modified (physical activity) arm – receives access to a brief, modified version of the program, which includes access to diabetes information resources and the physical activity module from baseline to trial endpoint; and (iii) full intervention – receives full program access from baseline to trial endpoint. The main RCT (Study 2) implements two study conditions which include: (i) wait-list control – undertakes usual diabetes care for three months post-baseline, followed by access to the full OnTrack Diabetes program, and (ii) full intervention – receives full program access from baseline to trial endpoint. Measures are at baseline, 3-, 6-, and 12-month follow-up for the pilot and main trial. Primary outcomes are glycosylated haemoglobin A1c (HbA1c) level and depression, anxiety, and diabetes-specific distress. Secondary outcomes are diabetes self-care adherence, self-efficacy, and quality of life. Cost-effectiveness, access to community resources and program uptake, acceptance, perceived usability, utility, and user satisfaction, and implementation feasibility will also be evaluated.

Results: This trial is currently ongoing with funding support from the Wesley Research Institute in Brisbane, Australia, and with clinical trial registration from the Australian and New Zealand Clinical Trials Registry (Registration number: ACTRN12612000620820).

Discussion: This is the first known trial of an automated, self-guided, web-based support program that uses a holistic approach in targeting both Type 2 diabetes self-management and dysphoria. Findings will inform the effectiveness and practicality of implementing such a program in the real-world context, including in rural and regional locations.

KEYWORDS

Type 2 diabetes; depression; anxiety; self-management; internet; web; online; intervention; randomised; protocol

4.2 Introduction

Diabetes affects an estimated 346 million people globally and Type 2 diabetes accounts for 85 - 90% of all cases (WHO, 2011a). In Australia, Type 2 diabetes affects 3.8% of the population and the direct healthcare were estimated to cost Australians AUD$828 (1AUD = 1.04USD) million per annum 2004-05 (AIHW, 2008). Diabetes is the eighth-highest burden of disease, and Type 2 diabetes accounts for 92% of this burden (AIHW, 2012a). With the rapidly rising prevalence of diabetes the impact of inadequate diabetes self-management continues to increase, and resulting diabetes complications and premature mortality become more urgent to address. Diabetes is the leading cause of blindness, end-stage renal disease and lower limb amputation in the world (WHO, 2011a). Moreover, the effects of diabetes on quality of life, mental health, work productivity and other intangible losses are substantial and add further to diabetes-related burden.

Depression (Ali et al., 2006; Anderson et al., 2001) and anxiety (Grigsby et al., 2002) are significantly more prevalent in people with diabetes than in the general population. Co-morbid mental health conditions are barriers to effective diabetes self-care (Gonzalez, Safren, et al., 2008) and further increase diabetes-related governmental costs (Egede et al., 2002). Dysphoria complicates the achievement of adequate glycaemic control through several mechanisms. Comorbid depression and/or anxiety with diabetes predispose individuals to diabetes-specific distress (Fisher et al., 2009; Kokoszka, Pouwer, Jodko, Radzio, MuÄ‡ko, et al., 2009), affecting glycaemic control (Fisher, Mullan, et al., 2010), both directly (via physiological mechanisms), and by increased vulnerability to self-care non-adherence (Gonzalez et al., 2008; Katon et al., 2010; Scollan-Koliopoulos et al., 2010). Even subclinical manifestations such as dysphoria are associated with clinically deleterious outcomes, including reduced self-care (Gonzalez, Safren, et al., 2008), poorer glycaemic control (Anderson et al., 2002; Pouwer et al., 2010), increased incidence and progression of diabetes complications (de Groot et al., 2001; Williams et al., 2010) and greater disability (Von Korff et al., 2005). Stress additionally contributes to other common physical co-morbidities in diabetes patients, including the metabolic syndrome and cardiovascular disease (Kyrou & Tsigos, 2009). The combined effects of inadequate glycaemic control and dysphoria on morbidity and mortality in people with diabetes (Egede et al., 2005; Zhang et al., 2005) calls for urgent intervention.

Prior research indicates the need for behavioural diabetes self-management interventions to incorporate psychological and emotional support components for optimum efficacy (Fisher et al., 2007). Improvements in diabetes self-care are strongly associated with improved glycaemic control (Asche, LaFleur, & Conner, 2011; Holman et al., 2008), which indicates that providing behavioural intervention to support diabetes self-care can be successful in improving diabetes-related clinical and self-care outcomes (Heinrich, Schaper, & de Vries, 2010). However, improvements in glycaemic control are not generally associated with significant improvements in mood (Fisher et al., 2007). Conversely, psychological treatments for depression and anxiety in people with diabetes do not reliably produce improvements in glycaemic control (Ismail et al., 2004). However, diabetes self-management interventions do not typically address both issues, and perhaps partly as a result, single-focused interventions report limited success in improving both glycaemic and psychological outcomes (Wang et al., 2008). In addition, trials on self-management interventions are often followed up over relatively short periods (e.g. 6 months or less (Ramadas et al., 2011)), preventing assessment of their long-term effects.

Internationally, health systems have limited capacity to provide adequate Type 2 diabetes self-management support and intervention (AIHW, 2008). System-level barriers include a shortage of health professionals and inadequate availability of services and resources in geographically rural and remote regions. Health practitioners are challenged by practitioner/patient communication barriers, time-limited medical consultations, an inability to provide required psychological interventions (Peyrot et al., 2005), and a lack of standard guidelines for dysphoria screening in diabetes. Patient-level barriers to appropriate care include complexity of the Type 2 diabetes treatment regime (Odegard & Capoccia, 2007), poor recognition of dysphoria symptoms (National Institute for Health and Clinical Excellence., 2010; Pouwer, 2009), patients' failure to acknowledge a need for support, and lack of motivation to significantly improve lifestyle behaviours (Hayes, McCahon, Reeve Panahi, Hamre, & Pholman, 2007). While deficiencies in the availability of highly cost-effective diabetes self-management interventions continue, health systems will remain challenged to meet the demands for additional support to enable optimum diabetes self-management. This shortcoming will particularly affect patients at risk of psychological comorbidities (Anderson et al., 2001).

Recent evidence demonstrates that web-based diabetes self-management interventions have good potential efficacy, feasibility, user acceptance, and uptake (Ramadas et al., 2011). Web-based programs offer potentially cost-effective, easily accessible, and ongoing support with wide-spread dissemination and outreach (Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006). They can encourage early recognition of dysphoria symptoms, suggest strategies for addressing these symptoms and assist patients to overcome reluctance to seek psychological treatment, within an anonymous or safe and confidential context. Web-based diabetes support programs have demonstrated producing statistically significant improvements in clinical, behavioural (Glasgow et al., 2003; Glasgow et al., 2006; Liebreich, Plotnikoff, Courneya, & Boulé, 2009), psychological, emotional, and psychosocial outcomes (Bond et al., 2010). Additionally promising is the high uptake and acceptability of online Type 2 diabetes self-management support programs by users, including mature (Bond et al., 2007) and novice diabetic users (McKay, King, Eakin, Seeley, & Glasgow, 2001).

Recently trialled web-based diabetes self-management programs based on Social Cognitive Theory [SCT (Bandura, 1986)] have demonstrated effectiveness (Anderson-Bill, Winett, & Wojcik, 2011; Liebreich et al., 2009; Lorig, 2010). Central tenets of SCT include self-efficacy, or one's belief in their capabilities to execute desired courses of action, and outcome expectancies, or personal predictions of likely outcomes resulting from certain courses of action (Bandura, 1986). SCT encompasses the key recommendations in national practice guidelines for diabetes management (Australian Centre for Diabetes Strategies, 2010). These include encouraging patient empowerment (promoting self-efficacy), ongoing monitoring of target outcomes (self-evaluation), and providing diabetes education (instructions). SCT thereby provides a theoretical avenue by which to address both behavioural self-management and emotional issues (Bandura, 2004b). Self-efficacy has significant positive associations with behavioural outcomes including physical activity participation (Plotnikoff et al., 2008; Plotnikoff et al., 2011), nutrition intake (Nouwen et al., 2011; Savoca & Miller, 2001), weight loss (Winett, Tate, Anderson, Wojcik, & Winett, 2005) and diabetes self-care (Weinger, Butler, Welch, & La Greca, 2005), as well as with emotional outcomes, including depression (Sacco et al., 2007) symptoms, in people with diabetes.

Web-based diabetes self-management programs have demonstrated producing positive effects on psychological and emotional outcomes, but there are some inconsistencies in their results and further data are needed on their potential to improve glycaemic control (Markowitz et al., 2011). For example, Lorig et al. trialled a diabetes self-management intervention that included modules to assist users in coping with emotional challenges both related and unrelated to diabetes as well as relaxation audios (Lorig et al., 2010). While improvements were found in self-efficacy, patient activation and glycosylated haemoglobin (HbA1c) level at 6 months post-enrolment, there was no significant improvement in health behaviours including exercise participation. Emotional outcomes and effects on long-term glycaemia were not determined. Conversely, Glasgow and colleagues similarly reported that their internet-based diabetes education program (D-Net) did not significantly improve mood or glycaemic control, but the program was found to produce significant improvements in behavioural and psychosocial outcomes (Glasgow et al., 2003). Hence, current trials indicate promise for web-based programs to provide diabetes self-care intervention, whilst indicating a need to report on and further enrich their effects on both mood and glycaemia.

A mood-specific intervention is currently being trialled in the Netherlands and examines a cognitive-behaviour therapy (CBT), web-based program that targets depression symptoms and psychological distress in people with diabetes (van Bastelaar et al., 2011). A structured sequence of lessons is provided, following which participants are required to submit weekly homework tasks to a “coach” who provides feedback by e-mail. Participants can self-monitor mood within the program and are encouraged to relate this to their own offline blood glucose self-monitoring record. Guided programs of this nature may be tailored to meet the general needs of the diabetic population and have shown efficacy in improving the health outcomes that they specifically target. However, Type 2 diabetics must maintain consistent self-care in the context of unique daily challenges, which include psychosocial (Fisher, 2006) and emotional stressors (Alberti, 2002), which suggests that personalised, self-guided behavioural and emotional support may be optimally efficacious in improving overall wellbeing. Thus, there remains a need for research on the effects of web-based interventions with components that target improving both dysphoria and diabetes self-care (Markowitz et al., 2011). Personalised web interventions that utilise a holistically inclusive approach to diabetes self-management intervention can inform the refinement of current programs and enhance the development of future ones. Further, holistic web programs that combine diabetes self-care and mood intervention may be more appropriate in supporting users’ individual daily challenges, and have potential implications for addressing both short- and long-term disease management, psychological, and emotional issues.

This paper describes the study protocol for two randomised controlled trials of the OnTrack Diabetes program, an automated, web-based intervention aimed to achieve and maintain improvements in Type 2 diabetes self-management and dysphoria symptoms. Specifically, the program targets physical activity participation, nutrition, adherence to health routines, and mood disturbance (depression, anxiety and everyday stressors). Information resources and program content were in part guided by an initial study conducted by the first author, which involved qualitative interviews of people with Type 2 diabetes and General Practitioners (GPs; Figure 1). Participants were questioned about self-perceived barriers and enablers to effective Type 2 diabetes self-care, emotional challenges associated with managing diabetes, and requirements for additional support. Type 2 diabetic participants were asked if they would use an online diabetes self-management support program, and GPs were asked the circumstances in which they would refer their patients to such a program. Both groups were asked to provide suggestions for program content and diabetes self-care areas that should be addressed.

OnTrack Diabetes is based on SCT and incorporates CBT and motivational interviewing techniques. Specifically, the program includes informational resources; goal-setting, planning, creating routines for self-care behaviours, feeling confident and problem solving via interactive tools; goal attainment scaling via self-monitoring tools, quizzes, and automated feedback graphs; relaxation and mindfulness audios; and an electronic diary. Users are encouraged to increase their access to social support due to the fundamental role of psychosocial factors in facilitating behaviour change (Anderson-Bill et al., 2011). Increased access to health providers in their diabetes care team is also promoted. Whilst program sections appear in an ordered structure, users can choose to undertake segments in any order—a feature that is intended to foster user empowerment (Anderson et al., 1995). Both provided text and entered text is minimised, with extensive use of icons and pictures, simple sentences and vocabulary, so that reading requirements do not exceed Year 7 educational levels. OnTrack Diabetes builds upon previous work by Kavanagh and colleagues, with their OnTrack Alcohol and Depression program providing a basis for the OnTrack Diabetes layout and a majority of the information technology programming logic.

A pilot randomised controlled trial compares three conditions: an Immediate condition that accesses the full program straight after Baseline, a Delayed condition that accesses the full program after 3 months, and a Brief condition that accesses a modified program that only addresses physical activity. The main trial omits this last condition. Both trials evaluate the efficacy of the OnTrack Diabetes program in improving glycaemic control and mood, physical activity participation, diet, blood glucose self-monitoring, medication taking and dysphoria (depression, anxiety, and diabetes-specific distress) symptoms. User acceptability, ease of use, utility, program satisfaction, feasibility of implementation and cost-effectiveness are also assessed. It is hypothesised that at 3 months post-enrolment the Immediate condition will show the greatest improvements in glycaemic control (glycosylated haemoglobin A1C; HbA1c), symptoms of depression, anxiety and diabetes-specific distress, behavioural outcomes, diabetes self-efficacy and quality of life, compared with the Delayed condition (and in the case of the pilot, the Brief, modified intervention). In both the pilot and main trial, results of the Immediate and Delayed conditions are expected to be similar at 6 months, when both conditions will have received the full intervention. In the pilot, superior 6-month outcomes from both the Immediate and Delayed conditions are expected than from Brief intervention.

4.3 Methods

Design and Setting

The pilot and main trials both implement a randomised-controlled design with the participant as the unit of randomisation. The trial is conducted Australia-wide. Program implementation takes place wherever participants can obtain regular internet access. The researcher is based at the Wesley Research Institute in Brisbane. Flow diagrams for the pilot (Figure 1) and main (Figure 2) trials are shown below.

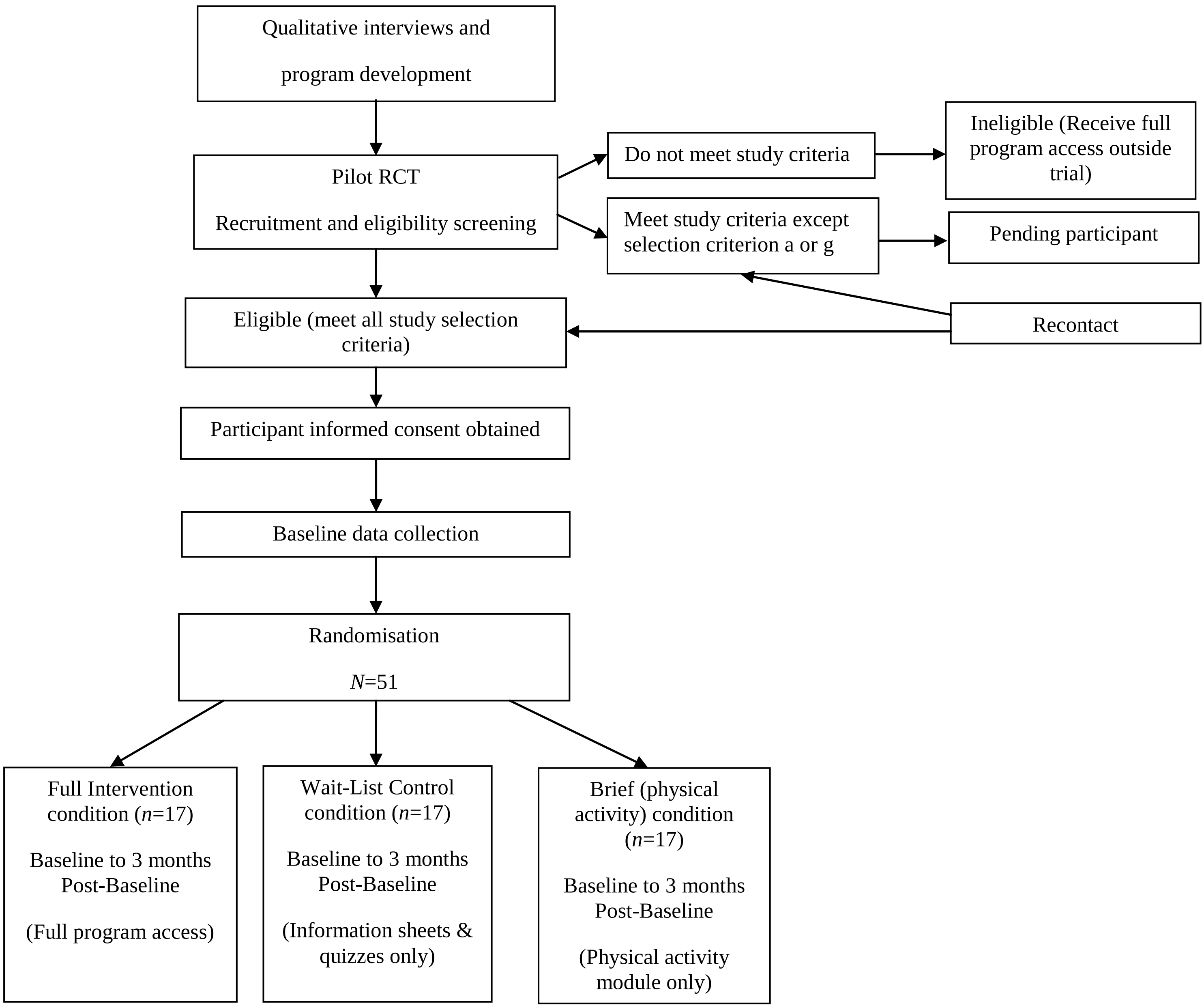

Figure 1. Consort diagram of OnTrack Diabetes pilot trial protocol.

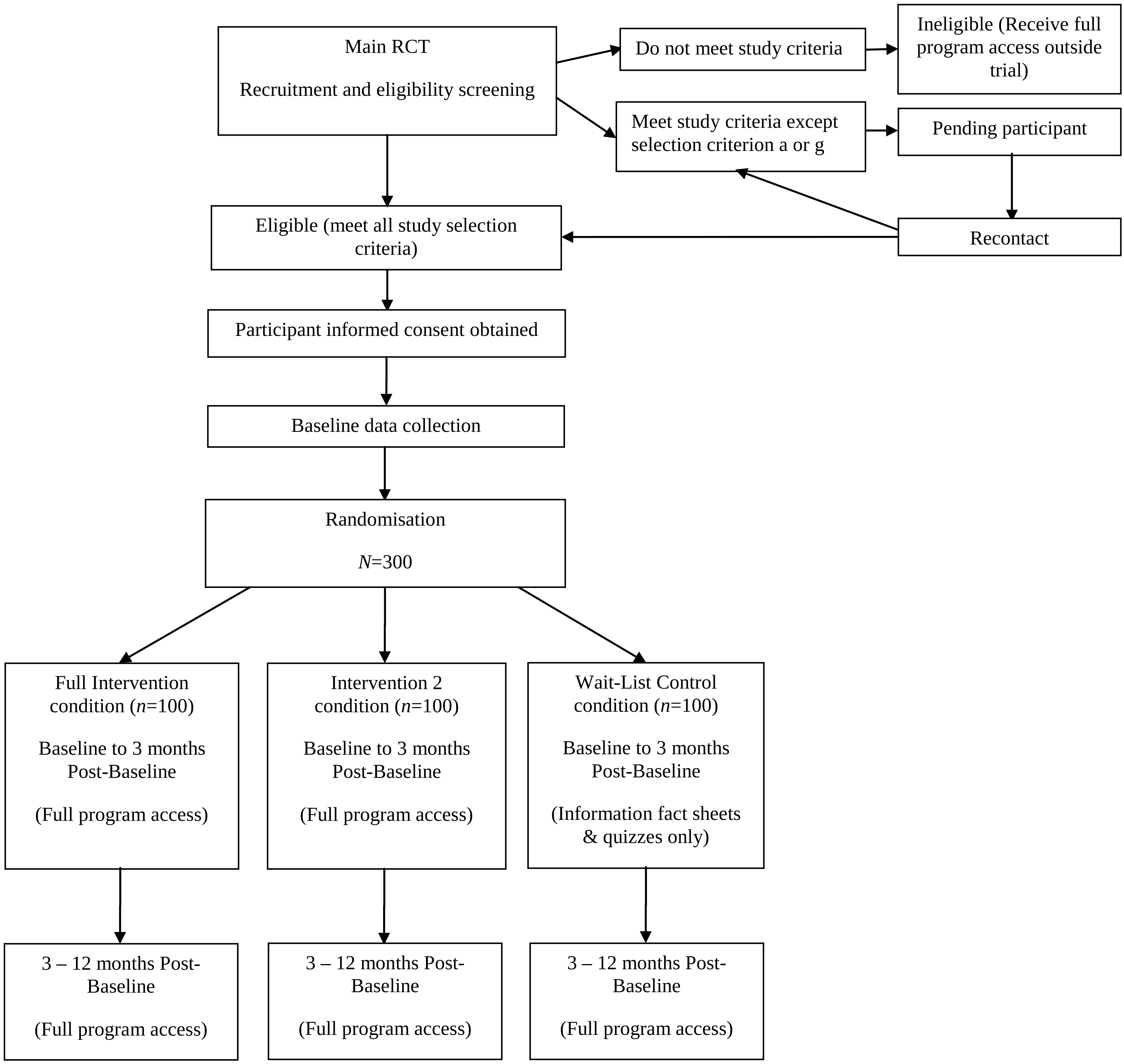

Figure 2. Consort diagram of OnTrack Diabetes main randomised controlled trial protocol.

Recruitment and sample

Recruitment strategies for the pilot and main trial are primarily community-based: newspaper advertisements, health organisation newsletters, radio broadcasts, notice board postings, bulletins, e-mails and online advertisements. Targeted methods include distributions of study flyers and posters to medical centres, letters to health institutions, pharmacies, and Health Professionals, and featuring the OnTrack Diabetes website URL on state-wide Diabetes Australia research web pages. Attendance at Diabetes expos and events allows in-person recruitment and further promotion of the project to Health Professionals.

A sample of 51 is aimed to be enrolled in the pilot trial. The main trial aims to enrol 300 participants. Selection criteria for both studies include: (a) Type 2 diabetes diagnosis (by medical physician/ according to WHO criteria) ≥ 3 months; (b) aged 18 – 75 years; (c) living in Australia without plans to leave within 12 months; (d) regular computer and internet access; (e) contactable by phone; (f) clear command of written English (at least year 5 education); and (g) stable diabetes pharmacotherapy (medication dose stable ≥ 4 weeks; medication type stable ≥ 3 months). Study exclusion criteria include: (a) current diagnosis of mental disorder other than depression or anxiety; (b) current suicidal risk; (c) significant cognitive disorder (e.g. from head trauma or dementia); (d) currently on steroid medication , or likely to commence these in the next 12 months; (e) pregnant or likely to become pregnant in the next 12 months. The pilot trial has an additional criterion of HbA1c ≥ 6.5% in order to provide a better chance of detecting between-group differences in HbA1c in the smaller sample.

All participants are asked to undertake a medical assessment by their General Practitioner prior to enrolment in the pilot or main trial. Individuals with physical limitations or concurrent physical disorders are advised of the need to exercise caution in setting physical activity goals according with their doctor's advice.

Study measures

Assessments for both the pilot and main trials are administered at baseline, 3-, 6-, and 12-month follow-up points.

Table 1. Measures used for OnTrack Diabetes program evaluation in pilot trial and main RCT.

Variable	Measure	Administration time point(s)	Administration method
Time-line follow-back		All	Phone interview
Clinical			
HbA1c (%)	Pathology sample at same laboratory		
Behavioural			
Physical activity	Active Australia Survey		- Time-line follow-back
Nutrition intake			
OnTrack Diabetes Questionnaire		All	Online
Demographics			
Clinical			
Weight (kg)	Same set of scales		
Waist circumference (cm)	Same measuring tape		
Psychological/emotional			
Depression, anxiety and distress	DASS-21		
Diabetes-specific distress	Diabetes Distress Scale (2 sub-scales)		
Self-efficacy for diabetes self-care	Diabetes Self-efficacy Scale		
Diabetes self-care behaviours	AusDiab study survey		
Alcohol consumption			
Smoking	TSQ		
Psychosocial			
Quality of Life	EQ-5D and SF-36		

Cost-effectiveness			
Health Service Utilisation	Health Service Utilisation Survey (includes cost data)		
OnTrack Diabetes Evaluation Questionnaire			
User satisfaction	10-point likert scale rating, from 0, “not at all” to 10, “totally”	3 months	Online & phone interview
Perceived ease of use	10-point likert scale rating from 0, “not at all” to 10, “extremely easy”		
Perceived program usefulness	10-point likert scale rating from 0, “not at all” to 10, “extremely”		
Implementation feasibility	10-point likert scale rating from 0, “not at all” to 10, “extremely”		

Study conditions

Procedures for participant recruitment, eligibility screening and enrolment are identical for the pilot and main trials. Participants register interest on the study website and select a time to undertake an eligibility screening appointment by phone. Eligible individuals undertake baseline measures by e-mail and phone interview at their selected appointment time. Individuals who satisfy all criteria except inclusion criterion (a)—time since diagnosis— or (g)—stable medication—are asked if they wish to be recontacted for future screening and if so, are categorised as “pending”. Individuals who are ineligible are allowed to use the program without being enrolled in the trial.

Following baseline measures, all eligible participants receive a secure username and password with which they log on to the program. Computer-generated randomisation occurs automatically. One week prior to the due date for follow-up study measures, participants receive an email notification with a link to the online survey and a pre-set time for the timeline follow-back phone interview. The email requests that participants email the researcher if the phone interview time does not suit them.

Study 1 (Pilot Trial) Conditions

Wait-list Control

Participants receive access to a blank screen and undertake their usual diabetes care. Following 3-month follow-up study measures, they receive access to the full OnTrack Diabetes program.

Brief, Modified Intervention – Physical Activity

Participants receive access to information resources about general diabetes self-care which include guidelines for physical activity, nutrition, blood glucose self-monitoring, and areas including foot and eye care. In addition, they can access the physical activity module, Keeping Active and Feeling Great. An example of a page from the Ideas about Fun Physical Activities tool is shown in Figure 3, below.

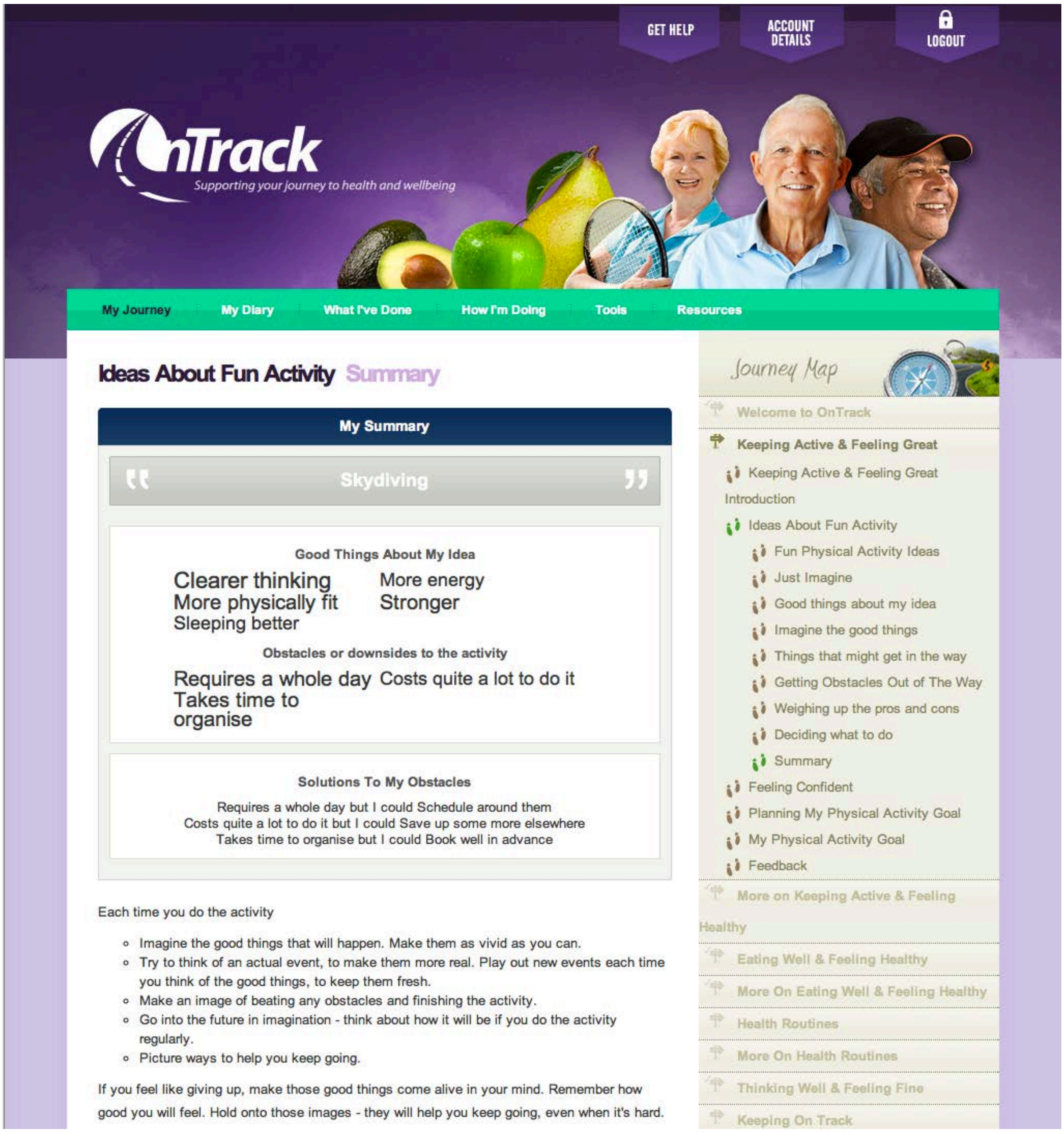

Figure 3. A summary page example from the Ideas about Fun Activity tool.

Full Intervention

Participants receive access to the full OnTrack Diabetes program. In addition to content received by the Brief, Modified Intervention condition, this includes access to a nutrition module (Eating Well and Feeling Healthy), a module focused on adherence to health regimes (Health Routines), an emotional well-being module (Thinking Well and Feeling Fine), and a maintenance module (Keeping On Track). The first section of each module includes a series of interactive tools that incorporate guided imagery, planning goal implementation, goal-setting, and confidence building. The planning tools guide participants in proceeding towards their own, personalised goals in incremental steps. A second section of each module is entitled "More On..." (e.g. More On Health Routines), and involves setting a weekly schedule to increase participation in desired health behaviours and pleasurable activities, and tools for problem-solving challenges. A printable summary is provided on completion of each interactive tool: These summaries can be accessed on future occasions, and participants can also complete tools or modules repeatedly if they wish. Self-monitoring tools allow daily monitoring of highest and lowest blood glucose levels, best and worst mood, and the degree that physical activity and nutrition goals were met. Automated feedback graphs on progress are provided for the past week, month, or 3 months. Mindfulness audios are playable on the computer, or can be downloaded to an MP3 player.

Study 2 (Main Trial) Conditions

Wait-list Control

Participants receive an email advising them to undertake their usual diabetes care. Following 3-month follow-up outcome measures, they receive access to the full OnTrack Diabetes program.

Full Intervention

Participants receive access to the full OnTrack Diabetes program from baseline onwards. The full program is identical to that received by the Pilot trial Intervention group. In addition, participants receive an automated reminder e-mail if they fail to log on to the program for 2 weeks or more.

Statistical Analyses

Preliminary analyses assess for baseline differences, and subsequent analyses control for any observed differences. The primary analyses will comprise multiple regressions, predicting post-treatment and follow-up results from Baseline measures and treatment contrasts, and multiple imputation will be used to predict missing data. Mixed models ANOVAs with repeated measures will also be applied, to confirm whether effects are still obtained without imputations. Both methods allow an intention-to-treat approach to the data.

Program Evaluation

User satisfaction, perceived ease of use, and usefulness and examined with ANOVAs. Program reach, acceptability, implementation feasibility and outreach are assessed using the RE-AIM framework.

Cost-effectiveness evaluation

Costs and outcomes for Delayed Intervention and Intervention conditions will be compared and the incremental cost-effectiveness ratio (ICER) calculated. Cost-effectiveness analysis (CEA) from a primary perspective of direct medical costs to the government is used. Standard costs are applied to Health Care Utilisation in both arms. Intervention costs are calculated including set-up costs that will be annualized and operating costs for the intervention. Out-of-pocket and time costs are also examined. Health outcome data recorded during the trial is used as the health outcome measures in the CEA. Utility weights are derived from EQ-5D using the Australian scoring algorithm (Viney et al., 2011) and SF-36 data transformed using the SF-6D derived from an Australian population. Detailed one-way sensitivity analyses will be undertaken on key parameters as well as a probabilistic sensitivity analysis.

Sample size and retention

Using multiple regression from Baseline, a sample of 50 in the pilot trial will have the power to detect a moderate effect size in outcomes at Post ($f = .17$) with power = .80, $\alpha = .05$, if planned contrasts are used to test the hypotheses that the full intervention is superior to the wait list, and that the physical activity module gives intermediate effects. The sample of 300 in the main trial has the power to detect a clinically and statistically significant effect in the primary clinical outcome of HbA1c level between the two conditions of wait-list and full intervention ($f = .027$) with power = .80, $\alpha = .05$, using a regression approach. This result is based on power calculations that were performed using the statistical software package *g-power*.

While studies use all allocated participants in the outcome analyses, efforts are made to maximise retention in the study, by developing rapport at the baseline assessment and collecting multiple means to contact participants, which include e-mail and landline and mobile phone contact details. With these strategies, the studies aim to have at least 70% retention at 12 months.

Ethics

Ethics approval to conduct this project was granted by the Uniting Care Health Human Research Ethics Committee (#Cassimatis 9111) and the Queensland University of Technology Human Research Ethics Committee (#1100000783).

4.4 Discussion

Results from this trial will provide insight into the efficacy, practicality and user perspectives on the effects of such a program and the success of its dissemination within the Australian context. A 12-month follow-up period will provide data on the maintenance of effects from the programs, as well as patterns of usage over time and the relationship of these variables to study outcomes.

Previous trials of diabetes self-management web-based programs indicate that a common limitation of such programs is a reduction in user engagement over time (Glasgow et al., 2003; Glasgow et al., 2011; Lorig et al., 2010). It is expected that ongoing access to interactive tools and self-monitoring that users can apply to issues with self-management and dysphoria as they arise will help to maximise engagement and retention. Fortnightly e-mail reminders may also assist users to keep on track of their program usage and prompt continued user engagement with the program (Wangberg, Bergmo, & Johnsen, 2008). Follow-up assessments in the trial will ask about usage of other treatments and website resources, but the validity of those reports cannot be guaranteed.

Findings will provide information about the effectiveness of using a self-guided approach to web-based Type 2 diabetes self-management intervention. Limitations to generalisability that affect studies conducted within specific clinical or experimental settings are avoided (Glasgow, McKay, Piette, & Reynolds, 2001) by provision of nation-wide access. As well as assessing whether the OnTrack Diabetes program will improve Type 2 diabetes self-management and dysphoria, this trial is intended to serve as a source of information about the successes and shortcomings entailed in implementing such a program. Results will provide information upon which future trials of web-based CBT interventions can build in terms of processes that enhance and those that impede the practicality and rigour of research in this domain.

4.5 Chapter Summary and Conclusions

This paper demonstrated the sequence of studies that comprise the OnTrack Diabetes project, which enables links to be made between study outcomes and the project methodology. The next chapter presents the second part of the research program's developmental stage.

CHAPTER 5

DEVELOPMENT OF THE ONTRACK DIABETES PROGRAM:

DESIGN OF A RANDOMISED CONTROLLED EVALUATION TRIAL

5.1 Notes

This manuscript was accepted with minor revisions by the international, peer-reviewed journal, *'Journal of Medical Internet Research'*.

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Authors' contributions to this paper:

The candidate is the first author, whose contributions included taking part in developing the written content and information technology program coding for the OnTrack Diabetes program, and drafting of this manuscript. The second author is the Principal Supervisor of the candidate, who co-developed written content for OnTrack Diabetes and guided program development. The second, third and fourth co-authors are also members of the candidate's supervisory team and provided edits to this manuscript. Further, each author had input into informing the design of the trial and making suggestions for program content. The final two co-authors were the information technology programmers who developed the programming logic and program database.

Overview of this paper:

Contributions of this paper to the scientific literature include its demonstration of the steps required in web-based intervention development. Furthermore, the paper emphasises differences in its developmental approach from other study interventions, due to the pre-established programming logic, amongst other variations.

“Program Development Paper”

Development of the OnTrack Diabetes Program: Design of a Randomized Controlled Evaluation Trial.

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Word count: 3179

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Abstract

Background. Type 2 diabetes affects an estimated 347 million people worldwide and often leads to serious complications including blindness, kidney disease, and limb amputation. Comorbid dysphoria is common and is an independent risk factor for poor glycaemic control. Professional support for diabetes self-management and dysphoria has limited availability and involves high costs, especially after hours and in rural and remote areas. Web-based cognitive behaviour therapy (CBT) interventions offer potentially acceptable and cost-effective support for people with diabetes and can be accessed from almost anywhere. This paper describes the development of the OnTrack Diabetes program, which is a self-guided, web-based program aimed to promote euthymia and improved disease self-management in people with Type 2 diabetes.

Method. Semi-structured interviews with 12 General Practitioners and 13 patients with Type 2 diabetes identified enablers of and barriers to effective diabetes self-management, requirements for additional support, and potential elements of a web-based support program. Existing information resources and research data informed the development of content, and consultants from relevant disciplines provided feedback on draft segments and reviewed the program before release. Costs were contained by using a self-guided delivery format and adapting program features and modules from an existing OnTrack program.

Conclusions. Development of the OnTrack Diabetes program demonstrates strategies to be employed to ensure that a program is acceptable to users and incorporates both authoritative information and evidence-based strategies. The next stages involve testing users' experiences and examining the program's effectiveness and cost-effectiveness in randomized controlled evaluations.

Keywords: Type 2 diabetes, depression, anxiety, self-management, internet, online, intervention, randomized, protocol

Abstract word count: 243

ANZCTR #: ACTRN12612000620820

5.2 Introduction

Type 2 diabetes is a burgeoning epidemic that affects an estimated 347 million people worldwide (WHO, 2011a), and is becoming one of the leading causes of global disease burden (WHO, 2011a). Inadequate diabetes self-care is strongly associated with poor glycaemic control, which increases the risk of diabetes complications including peripheral limb amputation, blindness and end-stage renal disease (WHO, 2011a), as well as cardiovascular disease and stroke (Holman et al., 2008). A 21% decrease in the incidence of diabetes complications occurs with each 1% improvement (reduction) in glycosylated haemoglobin A1c (HbA1c) level (UK Prospective Diabetes Study (UKPDS) Group, 1998), which indicates the utility of improving diabetes self-management. However, patients often struggle to meet recommended treatment targets and find it difficult to implement the behaviour changes required to achieve such improvements.

Diabetes patients are two to three times more likely than people without diabetes to experience depression, anxiety, stress and reduced wellbeing (Ali et al., 2006; Fisher et al., 2008; Funnell, 2006). Dysphoria appears to be both a consequence of Type 2 diabetes and to have a role in the condition's pathogenesis (Carnethon et al., 2007), impairing glycaemic control both directly via physiological mechanisms, and indirectly via reduced diabetes self-care (Gonzalez, Delahanty, et al., 2008; Gonzalez et al., 2007). As a result, dysphoric patients have an increased risk of diabetes complications (de Groot et al., 2001; Williams et al., 2010) and premature mortality (Lin et al., 2009). Optimal diabetes management therefore requires support for both mood and behavioural disease self-management.

Controlled trials of diabetes self-management interventions have shown that effective components include diabetes education (Duke et al., 2009; Norris, Engelgau, & Narayan, 2001), promotion of adherence to blood glucose self-monitoring (Durán et al., 2010; Kempf, Kruse, & Martin, 2012), physical activity (Richert et al., 2007; Sigal et al., 2004), dietary

(Dämon et al., 2011), and medication regimes (Haynes et al., 2008), and emotional support (Fisher et al., 2007). Interventions that incorporate only behavioural components have generally failed to produce robust and sustained improvements in psychological and emotional outcomes (Fisher et al., 2007). Similarly, interventions that specifically target depression or anxiety have typically failed to produce substantial improvements in diabetes self-management and physical outcomes (Wang et al., 2008). Even for high-functioning individuals the complexity of the Type 2 diabetes treatment regime exposes patients to a range of daily physical and emotional challenges (Funnell, 2006). A holistic intervention that incorporates both behavioural and psychological support may therefore offer optimum efficacy.

While some key components of effective support for Type 2 diabetes self-management have been identified, health system limitations prevent its reliable provision (Fisher et al., 2007), especially after hours or in more remote locations, where greater population spread and reduced practitioner to population ratios conspire to reduce access. Diabetes self-management support services that offer wide outreach and cost-effectiveness are needed.

Over recent years web-based interventions, and in particular those based on cognitive-behaviour therapy (CBT), have produced substantial improvements in emotional and behavioural outcomes in a range of problem areas (Hedman et al., 2012), with their effects similar in size to those of face-to-face treatments (Eland-de Kok, van Os-Medendorp, Vergouwe-Meijer, Bruijnzeel-Koomen, & Ros, 2011). CBT-based Type 2 diabetes interventions similarly have produced significant improvements in diabetes self-care (Ramadas et al., 2011), mood (Griffiths, Farrer, & Christensen, 2010), and psychosocial outcomes. These programs have also shown high user uptake, acceptability and usability, even in older users (Bond et al., 2007). Globally, web access is increasing rapidly, with the proliferation of cable and mobile networks increasingly bridging geographical and even socioeconomic divides (ABS, 2009). Web-based delivery of intervention programs may assist with meeting the need for improved access to additional disease self-management support by people with Type 2 diabetes (Fisher et al., 2007), conveying the advantages of 24-hour availability, broad access, privacy, lack of stigma and (particularly in the case of self-guided programs) steeply falling unit costs as user numbers increase.

Web programs based on empirically well-established theories have shown superior efficacy in improving diabetes self-management outcomes compared with programs that do not have a strong theoretical and empirical basis (Ramadas et al., 2011). In particular, chronic disease self-management programs that use Social Cognitive Theory (SCT; Bandura, 1986) as their theoretical underpinning have demonstrated efficacy (Bandura, 2004b). SCT is an appropriate theoretical basis for chronic disease self-management interventions, as it specifies predictors of human motivation and behaviour that can be targeted in self-management (Bandura, 2004b), including specific skills, self-efficacy, goals, and self-administered incentives (Bandura, 1986). SCT encourages patient empowerment, positing that humans actively make sense of the world and shape their own experiences, giving them the capacity to exercise choice and change their behaviour. The theory holds that environmental, interpersonal and intrapersonal variables are interlocked in processes of reciprocal determinism. Research that demonstrates that behavioural self-management (Hunt et al., 2012; Marks, Allegrante, & Lorig, 2005; Steinsbekk, Ø Rygg, Lisulo, Rise, & Fretheim, 2012; Strychar et al., 2012) and mood (Sacco & Bykowski, 2010; Sacco et al., 2007) have strong associations with cognitive and psychosocial factors is consistent with this view and lends support to diabetes self-management interventions being based on SCT principles.

SCT emphasises the importance of a person’s self-efficacy, or their current confidence in being able to successfully reach a performance target (e.g. to attain a specific adherence goal) (Bandura, 1977). When self-efficacy is strong, the individual is more likely to invest effort and to persist in the face of challenges considered to be the driving force behind initiating behaviour change. This is particularly important for people with Type 2 diabetes, who must learn to master a range of new skills for successful diabetes self-management as well as have the motivation to carry them out routinely. The primary driver of self-efficacy is the person's previous accomplishments, placing a strong emphasis on skill acquisition, successful performance, and the availability of recalled successes when making a self-efficacy judgment. In turn, skill acquisition is obtained by instruction, vicarious learning, and practice, which is refined by performance feedback.

Increased self-efficacy in chronic disease patients has demonstrated associations with improved health behaviours, including physical activity (Blanchard et al., 2007; Dutton et al., 2009), dietary adherence (Nouwen et al., 2011), and general diabetes self-care (Aljasem et al., 2001). Self-efficacy can significantly predict future adherence to the diabetes treatment regime, even after controlling for past levels of adherence (Kavanagh et al., 1993). The focus of SCT on autonomous cognitive and behavioural processes that encourage patient empowerment and target motivation supports its appropriateness as a theoretical basis for chronic disease self-care and psychological intervention (Fisher et al., 1982; Marks et al., 2005).

Outcome expectancies or incentives form a further key element of SCT (Fisher et al., 1982) and together with self-efficacy are critical to establishing motivation and investment of effort. In self-management, self-administered incentives, including self-evaluations against personal standards, are particularly important in the sustained self-regulation of behaviour (Bandura, 2004b). If self-efficacy is robust, falling short of a goal motivates increased effort. However, if self-efficacy is fragile or the experience triggers very negative emotion, falling short of personal standards undermines confidence and motivation, and the person may even relinquish the goal (Gist & Mitchell, 1992; Snoek, 2002). Accordingly, an intervention based on SCT encourages ambitious goal setting but tempers emotional responses to lesser attainments, focusing on success-related aspects and strategies to further improve performance, encouraging attributions of performance deficits to the difficulty of the task and goal rather than to immutable personal characteristics. Moderation of the goal to achieve stepwise increments in successful performance is sometimes required.

Web-based CBT has shown efficacy in reducing depression and anxiety symptoms in people who have diabetes (van Bastelaar et al., 2011). However, interventions primarily focused on targeting mood have yielded mixed results in terms of their effects on glycaemic control (Markowitz et al., 2011). Conversely, while behavioural-focused Type 2 diabetes interventions have demonstrated improved glycaemic control and behavioural outcomes, the majority have not evidenced improvements in psychological and emotional outcomes (Ramadas et al., 2011). Recently, a web-based CBT-style intervention that addressed diabetes-specific issues in the context of depression treatment was shown to be successful in producing significant mood improvements (van Bastelaar et al., 2011). However, similar to other mood-specific programs this intervention did not specifically incorporate behavioural diabetes self-management support. Evidence of the poor effects of such programs on glycaemia indicates that programs that simultaneously address behavioural aspects of Type 2 diabetes self-care are needed (Markowitz et al., 2011). Such interventions would be appropriate for implementation in the mainstream Type 2 diabetic population and may support those experiencing primarily psychosocial barriers to self-care, as well as those with co-occurring distress. Long-term relevance to each patient is also attainable using this approach, as individuals may move between phases of treatment adherence and less stable performance.

Most current web-based CBT interventions are guided programs that incorporate support from a health professional (Lorig et al., 2010; van Bastelaar, Pouwer, Cuijpers, Twisk, &

Snoek, 2008). However, studies that compare guided CBT-based programs with minimal support have similar impacts on clinical (Lorig et al., 2010; Lorig, Ritter, Villa, & Piette, 2008) and behavioural (Glasgow et al., 2010) outcomes as well as user engagement (Glasgow et al., 2011). Self-guided web-based interventions have shown equal effectiveness to guided interventions (Berger, Hämmerli, Gubser, Andersson, & Caspar, 2011) and offer the advantages of self-paced learning and skill acquisition, and higher perceived autonomy and privacy. Further, web-based programs encourage users to adopt an independent role in their disease management, which may enhance patient empowerment. There remains a need for further research on self-guided, web-based Type 2 diabetes self-management programs that incorporate mood support.

This paper describes the development of the OnTrack Diabetes program, which is a self-guided, web-based Type 2 diabetes self-management and dysphoria intervention. With a SCT (Bandura, 1986) foundation, OnTrack Diabetes is based on CBT and motivational interviewing techniques. The program is designed to improve Type 2 diabetes self-management, glycaemic control and dysphoria, including depression, anxiety and diabetes-specific distress symptoms. OnTrack Diabetes targets physical activity, diet, and adherence to health routines by providing informational and interactive behavioural, psychological and emotional support. The program promotes access to social and disease management support from family and friends as well as allied health professionals. It provides interactive tools designed to engage users in adopting personalised goals for each diabetes self-care area. Self-monitoring tools encourage users to record their daily progress with mood (best to worst), blood glucose levels (highest and lowest), physical activity and nutrition goal adherence (0 – 100%). Automated graphs give users feedback on progress in each area over the past week, month, and 3 months. The program is designed to provide a holistic approach to improving Type 2 diabetes self-management and mood and to endorse user empowerment by encouraging users to take an autonomous role in managing their condition.

5.3 Methods

Development of the OnTrack Diabetes program

Step 1. Qualitative research. Semi-structured interviews were conducted to explore enablers and barriers associated with effective Type 2 diabetes self-care, together with diabetes-related emotional challenges, requirements for additional disease management support and suggestions for online support program inclusions. The sample comprised 13 people with Type 2 diabetes and 12 General Practitioners (GPs). GPs were asked the circumstances in which they would refer patients to an online Type 2 diabetes self-management support program and the factors that may inhibit patient referral. Results revealed that patients and GPs shared most perspectives on diabetes self-management. Both the patients with diabetes and GPs identified a need for additional informational, motivational, emotional and social support. Suggestions for program content included self-monitoring tools, informational support, motivational assistance with improving and maintaining physical activity and diet, goal setting assistance, progress feedback, social support via a chat room and accessibility to health professionals. Detailed results are available in a separate paper.

Step 2. Basic structure and functionality. OnTrack Alcohol and Depression was previously developed by the second author and his colleagues as part of a suite of CBT-based web programs. OnTrack Alcohol and Depression was proposed as a basis for the layout of OnTrack Diabetes and the appropriateness of this was confirmed by a review of the Alcohol and Depression program structure. Motivational videos, mindfulness and relaxation audios and Information Technology coding from some of the self-monitoring and program tools were adapted for use in OnTrack Diabetes.

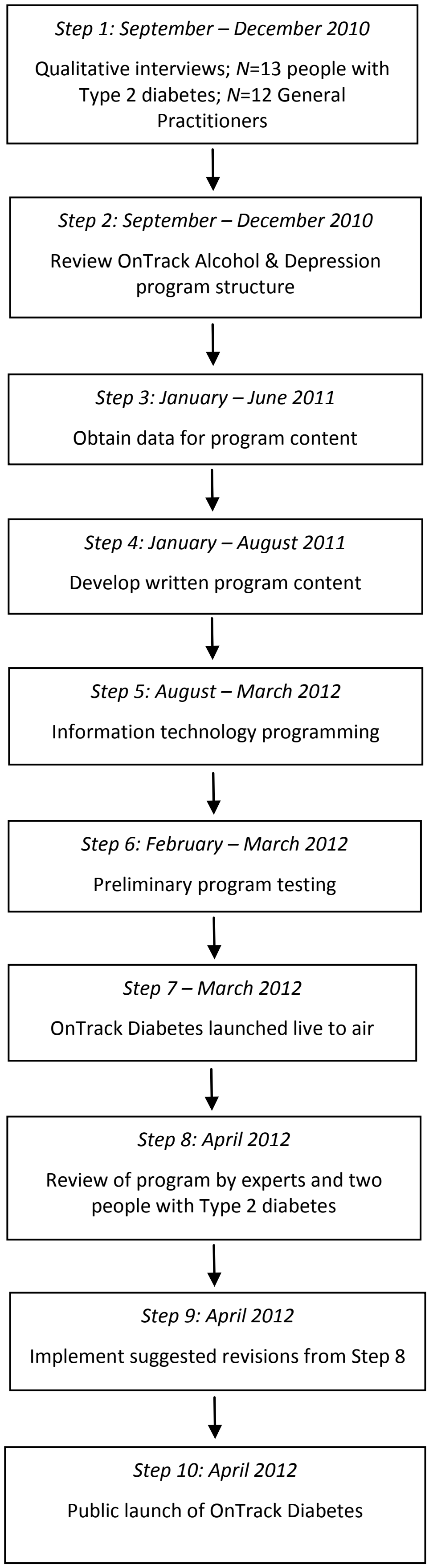

Figure 1. Steps involved in OnTrack Diabetes program development.

Step 3. Assembly of information resources. Sources that informed the development of OnTrack Diabetes information resources and tools included the Diabetes Australia Guidelines for Type 2 diabetes management (Australian Centre for Diabetes Strategies, 2010); National Health and Medical Research Council physical activity and nutrition guidelines for Australian adults (Department of Health and Aged Care, 2005); Optometrists Association Australia (Optometrists Association of Australia, 2011); Australasian Podiatry Council (Australasian Podiatry Council, 2009); Medicare Australia (Australian Government Department of Human Services, 2012), and relevant peer-reviewed empirical literature. A nutritionist, ophthalmologist and podiatrist were consulted to discuss proposed content.

Step 4. Content development. The first author compiled the obtained information and discussed proposed content inclusions with the second author. The program content addressed the barriers to Type 2 diabetes self-care identified in Study 1, and attempted to maximise enhancers. Information resources complement the program's interactive tools and provide the impetus for goal-setting and planning while providing resources that can be integrated into primary care. For example, the "My Feet Check Resource" contains a diagram of feet on which the date and any changes can be marked and a checklist to tick off symptoms that can be taken to Podiatry appointments.

Step 5. Programming. OnTrack Diabetes Information Technology programming logic is based on eXtensive Mark-up coding developed for OnTrack Alcohol and Depression by IT programmers (the last two authors). In collaboration with them, the first author coded tools and guidebook pages for the site. Programming modifications and the development of new features exclusive to OnTrack Diabetes was then undertaken. The administration site was built to include functions specific to this trial, including data recording and storage, access to study measures, and a schedule of follow-up study measure reminders. A graphic designer designed the website interface, inserted relevant images and formatted the program.

Step 6. Preliminary testing. OnTrack Diabetes was tested several times for bugs, errors in functionality and design issues by both the IT programmers and external observers.

Step 7. Test of the live program. OnTrack Diabetes was privately launched live to the web to enable further screening for bugs and tests for functionality.

Step 8. Expert review. An Endocrinologist, Diabetes Educator, AH, AS, PS, and two people with Type 2 diabetes reviewed OnTrack Diabetes and provided feedback.

Step 9. Program revision. The program content was revised in response to the reviews that were undertaken in Stage 8.

Step 10. Launch and efficacy trial. A randomized controlled trial was commenced with potential participants registering interest on the site's home page.

OnTrack Diabetes program content

The layout of OnTrack Diabetes is in the form of a "journey map" (Figure 2). *My Journey* contains five signposts, or modules, each of which comprises a series of interactive tools. Each tool is preceded by guidebook pages that inform users what the tool is about and a printable summary page is provided at the conclusion. Tool completion can be tracked in the section entitled *What I've Done*.

Social Support

Psychosocial factors including social support are highly influential to behavioural change and its maintenance (Bandura, 2004b). The *Building My Support Team* tool encourages users to form a social support network from the outset of the program that includes trustworthy family members, a partner, friends, and/or colleagues. Users are also encouraged to list the contact details of doctor/s and other health professionals, and can print a summary of these details.

OnTrack Diabetes Signposts

Users are encouraged to undertake the signpost modules and access the resources as they choose, although the program is structured in a logical sequence. The signposts are: *Keeping Active and Feeling Great*, *Eating Well and Feeling Healthy*, *Health Routines*, *Thinking Well and Feeling Fine*, and *Keeping OnTrack*. All but the last signpost are comprised of two sections, with the first comprised of tools that facilitate identifying the potential benefits of functional changes, goal formation, the recollection of relevant past successes, and creation of a detailed, stepwise plan.

The second section of each signpost (named *More on*...) contains tools that assist with planning a routine for the coming week. For example, users can plan to add incidental and short bursts of activity to their week as well as longer physical activity sessions, and specify the times and days that they will do them. Since the program is aimed to address dysphoria as well as health behaviours, the focus is on deriving pleasure from physical activity, healthy eating and health routines. The interactive tools encourage users to form a habit in implementing positive changes. Problem solving is an important skill for effective diabetes self-management (Steed, Cooke, & Newman, 2003). The second section of each signpost thus contains a problem solving tool to assist with overcoming challenges to reaching users' personalised goals. This tool can also be used to solve other problems, including threats to emotional wellbeing.

Users are asked to focus on practising the skills learned in each section for 1-2 weeks before moving forward in the program. In the meantime they are encouraged to log on to the site regularly to self-monitor, use resources, undertake and revisit tools as needed. The signpost *Keeping OnTrack* provides support whilst aiming to support the maintenance of progress. It focuses on moving on from past maladaptive behaviours and maintaining positive, new beginnings in the broader context of the individual's life. Users are asked to evaluate positive changes since starting the program without losing sight of other life goals (e.g. education, travel).

Self-Monitoring and Goal Attainment Scaling

'My Diary' provides an electronic self-monitoring record of: (a) daily goal attainments in relation to physical activity, eating and health routines (on a sliding scale from 0 to 100%); (b) highest and lowest blood glucose levels; and (c) mood (on a scale from best to worst). Entries are represented in feedback graphs that are shown in the "How I'm Doing" section of the program. The graphs display feedback for the previous month (average per day) and 3 months (average per week) for each self-monitoring area. Users are encouraged to compare results on different outcomes and are encouraged to recognise patterns between them. This function accords with the principles of self-evaluation and reinforcement.

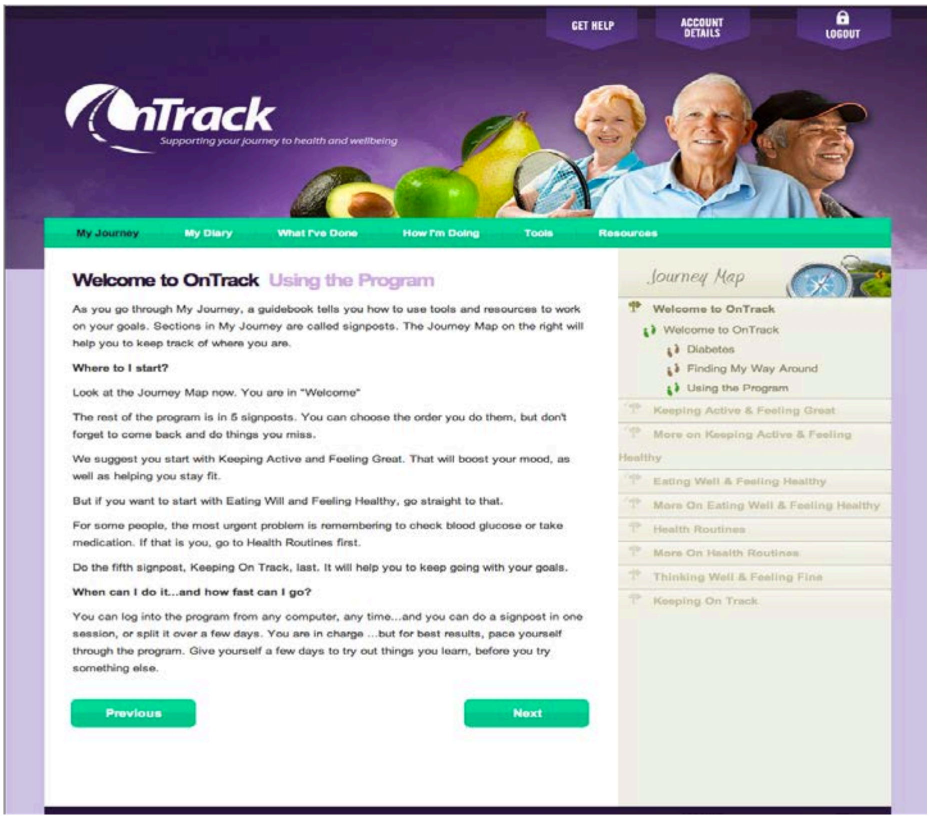

Figure 2. Screenshot of the OnTrack Diabetes program layout.

Self-Screening by Quizzes

Four self-administered quizzes enable users to evaluate their participation in diabetes self-care activities, mood, physical activity participation, and fat and fibre intake. Self-screening enhances early recognition of distress, which may lead to significant risk factors for major depressive disorder (Cuijpers et al., 2005; Karsten et al., 2011) and although requiring long-term assessment in diabetes patients (Fisher et al., 2008) commonly remains undiagnosed in primary care (Li et al., 2010).

OnTrack Diabetes Program Information Resources

Information resources on a number of Type 2 diabetes-related areas are included as printable fact sheets within the program. Specifically, information and resources are provided in the areas of: general Type 2 diabetes information; hyper- and hypo-glycaemia; weight management; physical activity guidelines and steps to increasing physical activity; nutritional guidance including reading nutrition labels, counting carbohydrates, sugars, the glycaemic index and glycaemic load, protein, fats, fibre, dairy, salt intake, and alcohol; eye care; foot care, and erectile dysfunction. Information sheets detail the roles of each primary care professional to diabetes management and include web URLs to relevant organisations that allow a search for primary care professionals within any area of Australia to be performed.

Additional Resources – Mindfulness Resources and Videos

The Resources section also contains mindfulness audios that provide spoken instructions on performing various forms of mindfulness (e.g. mindfulness meditation and mindfulness of pleasure). Users are encouraged to listen to the audios on their computer or download them to an MP3 player for use offline. Guidebook pages throughout the program refer users to the most relevant mindfulness resources to each area. Inclusion of these resources is based on evidence regarding the deleterious effects of stress on glycaemic control and its tendency to increase susceptibility to dysphoria and diabetes-specific distress. Users are trained to mitigate worrying thoughts by meditative practice.

Further, brief videos that feature role models on key health-related and behaviour change areas (e.g. alcohol modification, physical activity) are included, which provide vicarious experience.

5.4 Conclusions

This paper provides information on the processes involved in developing a self-guided, web, CBT-based intervention for Type 2 diabetes self-management and dypshoria. Providing details about web program development has implications for researchers with an interest in developing or refining current web interventions. Further, the effectiveness of the approach used to develop OnTrack Diabetes and its content can be evaluated by assessing links between the design methods, program components, and study outcomes.

5.5 Chapter Summary and Conclusions

This paper concludes the description of the developmental stage of the research program, and described the groundwork that was built upon in Stage 3 – the pilot randomised controlled trial of OnTrack Diabetes.

CHAPTER 6

EVALUATION OF THE ONTRACK DIABETES PROGRAM:

3-MONTH OUTCOMES OF A RANDOMISED CONTROLLED PILOT TRIAL

6.1 Notes

This paper is in submission to the international, peer-reviewed '*Journal of Medical Internet Research*'.

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Authors' contributions to this manuscript:

The candidate is the first author and was responsible for implementing all stages of the OnTrack Diabetes pilot trial, including the design of study measures, participant recruitment and data collection, data analyses and the write-up of results into this manuscript. The remaining authors were on the supervisory team for the candidate's PhD project. The second author was involved in collaborations regarding data analyses, and in co-developing and co-designing the OnTrack Diabetes program. All authors had a role in editing the manuscript and returning it to the candidate with feedback.

Overview of this paper:

This paper contributes to the scientific literature by communicating the strengths and shortcomings of web-based intervention when applied to this context. It provides a preliminary indication of the culmination of Stage 1 (exploration) and Stage 2 (development) of the project.

Evaluation of The OnTrack Diabetes Program: 3-Month Outcomes of A Randomised Controlled Pilot Trial.

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Abstract

Background. Type 2 diabetes is an urgent global health concern, with most patients not maintaining adequate self-management, which leads to increased risk of complications and premature mortality. Comorbid dysphoria is highly prevalent, and further impairs glycaemic control. Health systems are challenged to provide the extra support required to improve patient outcomes. Web-based support may offer a feasible solution. The OnTrack Diabetes program is a fully automated, web-based intervention designed to provide support for motivational self-management and psychological/ emotional issues. This paper describes 3-month outcomes of the OnTrack Diabetes pilot trial.

Method. This was a randomised controlled pilot trial. Participants: were aged 18-75, had type 2 diabetes ≥ 3 months, a glycosylated haemoglobin (HbA1c) level ≥ 6.5%, lived in Australia, and had computer and internet access. Study arms included: (i) *Wait-List Control*: usual care from Baseline, then full program access from 3 months Post-Baseline; (ii) *Brief/ Modified Intervention*: access to information and physical activity module from Baseline; (iii) *Full Intervention*: access to full program from Baseline. Measures were at Baseline and 3 months Post-Baseline. **Primary outcomes**: HbA1c level and mood. **Secondary outcomes**: diabetes self-care, diabetes self-efficacy, and quality of life. Qualitative evaluations of perceived program acceptability, utility, and usability and implementation feasibility were undertaken.

Results. The sample comprised 38 participants with a mean age of 60.42(*SD*=10.03), and a mean diabetes duration of 8.91(*SD*=7.77) years. Mixed Model Analysis revealed that there were no statistically significant changes in primary outcomes within or between groups, including HbA1c level ($F_{(1,32)}$= 3.85, p=.06), depression ($F_{(1,32)}$= .005, p=.95), or anxiety symptoms, ($F_{(1,32)}$= 2.28, p=.08). Analyses of secondary outcomes revealed that there was a significant reduction in the intake of sweet foods across groups over time ($F_{(1,32)}$= 6.50, p=.02), but no significant differences between groups were found. There were no significant differences across time for other secondary outcomes.

Qualitative outcomes revealed that users perceived the program to be highly acceptable, easy to use, and personally relevant. Both the brief/ modified and full intervention groups demonstrated poor engagement in the program according to number of log-ins (*M*=4.40, *SD*=4.36). Users commented that reminders to log on and/ or regular follow-up contact may improve their program engagement.

Discussion. Overall, results indicate that OnTrack Diabetes was positively perceived by users. The small sample size and poor user engagement were major limitations. Results suggest that reminders or reinforcement to log on to a web-based program regularly may improve user engagement. A larger sample size is aimed to be recruited to the main trial of OnTrack Diabetes, which will better indicate the program’s potential to significantly improve primary and secondary outcomes. This pilot has informed the feasibility of implementing web-based support in Australians with type 2 diabetes.

ANZCTR #: 362543

Keywords: diabetes self-management, depression, anxiety, diabetes-specific distress, web-based, online, intervention, comorbidity

6.2 Introduction

An estimated 371 million people are living with type 2 diabetes world-wide, and projections indicate that the condition is a dire challenge to health care systems, including those in developed countries (IDF, 2012b). Maintaining consistent type 2 diabetes self-management is essential to the effective control of clinical parameters including glycaemic control (I. M. Stratton et al., 2006), which is strongly associated with diabetes complications (The Diabetes Control and Complications Trial (DCCT) Research Group, 1995) and premature mortality (Barr et al., 2007). Comorbid dysphoria, referring to depression, anxiety, and diabetes-specific distress, is highly prevalent in diabetes patients (Anderson et al., 2001; Collins, Corcoran, & Perry, 2009) and is evidenced to be both an antecedent and a consequence of physical health conditions (Penninx & van Dyck, 2010). Dysphoria has been shown to reduce engagement in diabetes self-care (Gonzalez et al., 2008), worsen long-term health prognosis (Bruce, Davis, Starkstein, & Davis, 2005; Lin et al., 2009), and to contribute to severe emotional problems in diabetes patients, even at subclinical levels (Kokoszka, Pouwer, Jodko, Radzio, MuÄ‡ko et al., 2009). Diabetes-related morbidity and mortality cost an estimated $US 471 billion globally in 2012 (IDF, 2012b), with the effects of comorbid dysphoria likely to have contributed substantially to this burden. With health systems even in developed countries being at full capacity, the personal and economic burden is set to increase.

Regular, ongoing support for type 2 diabetes patients has been widely recognised as essential to maintaining psychological and emotional health and quality of life in the face of the demands imposed by diabetes (Fisher et al., 2007). A unique range of emotional, interpersonal and intrapersonal situations are experienced by patients (Alberti, 2002) that are strongly influenced by their ecological surroundings (Fisher et al., 2005). The role of psychosocial and environmental influences on diabetes self-care has been well-established in empirical research (Chida & Hamer, 2008; Glasgow & Toobert, 1988), which has demonstrated that using a holistic approach to provide intervention for diabetes self-management is important. The inter-related impacts of each aspect of the individual's experience necessitates that associated key barriers and facilitators to self-management be addressed. When it is not possible to target all key factors of self-management, encouraging chronic disease sufferers to feel empowered to manage their condition(s) (Capaldi, 2008) is of ultimate importance. Adequate coping and problem solving skills and self-efficacy are vital constituents to the maintenance of self-care behaviours, including exercise participation (Bandura, 1990) and chronic disease management (Bandura, 2004a). Chronic disease patients must persist with following their prescribed treatment regime in the context of a number of personal, psychosocial, and systemic barriers. Furthermore, emotional and psychological issues, which include anxiety (Adili et al., 2006) and depression (Snoek & Hogenelst, 2008), are common in those with diabetes (Collins et al., 2009; Snoek & Hogenelst, 2008) and present significant challenges to patients' motivation for self-care (Al-Hayek et al., 2012; Gonzalez et al., 2008), and impairments to their quality of life (Ali et al., 2010; Chyun et al., 2006).

Type 2 diabetes places substantial strains on health system resources and hence despite the strongly recognised need for extra diabetes self-management and emotional support, traditional approaches to address this issue remain limited. For example, in Australia, efforts have been at large to provide a framework for improving the outcomes of diabetes patients by encouraging access to an annual cycle of care comprised of consultations with allied health professionals, including psychologists. However, recent data indicates that just 18% of diabetes patients nationally utilised this service in 2012 (AIHW, 2012a).

Despite emphasis on the need for early recognition and screening of emotional issues and mood disorders in diabetes patients, under-diagnosis and under-treatment remain common. GPs are the primary care providers for the majority of type 2 diabetes patients, and are frequently required to fulfil a lifestyle and psychological counselling role (Britt et al., 2011). However, time limitations and role constraints prohibit thoroughness in this aspect of their care (Presseau et al., 2009). Furthermore, intermittent consultations do not provide sufficient regularity to support patients in maintaining motivation for implementing consistent self-care (Fisher et al., 2007). Interventions that can deliver consistent and regular patient support are needed to complement the care received by health professionals so that adequate diabetes self-management and psychological support are received by this population as required.

Web-based support has accrued substantial popularity in the chronic disease self-management field, with trials to date of web-based diabetes self-management interventions demonstrating that the web is an effective, reliable, and accessible mode of intervention delivery (Ramadas et al., 2011). Findings from trials of web-based interventions in samples of diabetes patients over 50 years of age have indicated their potential to produce lifestyle improvements, and that patients perceive these interventions to be highly acceptable and usable with satisfactory utility (Aalbers, Baars, & Rikkert, 2011). Furthermore, the web provides a promising modality via which to address geographical limitations to regular chronic disease self-management support, including access and health service availability issues. With use of the internet becoming increasingly wide-spread and cost-effective, the web offers a potentially feasible and acceptable means by which to supplement traditional forms of type 2 diabetes self-management support.

This paper presents 3-month pilot randomised controlled trial results of a web-based type 2 diabetes self-management and dysphoria intervention dubbed OnTrack Diabetes, which represents an Australian first. Details of the project protocol and program development are presented elsewhere. The OnTrack Diabetes program is based on social cognitive theory (Bandura, 1986), with interactive tools based on techniques from cognitive behaviour therapy and motivational interviewing. Extensive information resources on type 2 diabetes, diabetes self-care behaviours, and details about health professionals on the diabetes care team, amongst other topics, are provided. Self-monitoring tools to record daily blood glucose levels (highest and lowest), mood (best to worst), and physical activity and dietary goal adherence (from 0% not at all to 100% totally) enable participants to take part in goal-attainment scaling. Automated feedback graphs display progress with goal attainment in the past month and 3 months. The program was built on the results of qualitative interviews with type 2 diabetes patients and general practitioners (GPs) of self-perceived facilitators and barriers to effective type 2 diabetes self-management; emotional challenges associated with living with type 2 diabetes and suggestions for program inclusions. This has enabled the program to be developed in accordance with the ethos of patient empowerment in aiming to improve diabetes self-management, psychological and emotional health, and quality of life.

6.3 Methods

Design and Setting: A randomised controlled trial design with the participant as the unit of randomisation was used. The researcher was based at the Wesley Health and Medical Research Institute and the Queensland University of Technology in Brisbane, Australia. Enrolled individuals participated wherever they could access the program.

Recruitment and Enrolment: Expressions of interest were registered via the open access OnTrack Diabetes website page (www.ontrack.org.au/diabetes/). The site enabled individuals to select a preferred time to receive an eligibility screening call from the researcher. Recruitment methods included advertising in the Diabetes Australia – Queensland newsletter, and local regional newspapers in Australia. A link to the OnTrack Diabetes homepage was provided on the Diabetes Australia – Vic and Diabetes – SA websites. Study flyers and posters were provided to health professionals, including GPs and allied health professionals (Diabetes Educators, Podiatrists, Exercise Physiologists and Nutritionists) to display in their workplaces, or distribute to clients with type 2 diabetes.

Study selection criteria included: (a) type 2 diabetes diagnosis (by medical physician/ according to WHO criteria) ≥ 3 months; (b) aged 18 – 75 years; (c) HbA1c level ≥ 6.5%; (d) living in Australia without plans to leave within 12 months; (e) regular computer and internet access; (f) contactable by phone; (g) clear command of written English (at least year 5 education); and (h) stable diabetes pharmacotherapy (medication dose stable ≥ 4 weeks; medication type stable ≥ 3 months).

Study exclusion criteria included: (a) current diagnosis of mental disorder other than depression or anxiety; (b) current suicidal risk; (c) significant cognitive disorder (e.g. from head trauma or dementia); (d) use of steroid medication, or likely to commence in the next 12 months; and (e) pregnancy.

All individuals were asked to undertake medical clearance to confirm their suitability to participate in the program's physical activity module. Once enrolled in the trial, participants were further advised to seek medical approval before increasing their physical activity levels, and to respect their physical limitations when setting activity goals.

Study Measures

All enrolled participants undertook study measures at Baseline and at 3 months Post-Baseline. All measures were administered via online survey but for HbA1c level, physical activity participation and dietary intake, which were obtained by phone. Participants received an e-mail that contained the study survey link and which indicated an appointment time for the phone-based measures. Study measures are shown in Table 1, below.

Table 1. Psychometric instruments used to measure outcomes for OnTrack Diabetes pilot trial.

Measurement area	Outcomes assessed	Measure/s
Demographics	Age, gender, type 2 diabetes duration, education level, nationality, country of birth, relationship status, employment status, occupation, income, private health insurance	Short answer and multiple choice items
Clinical	Glycosylated haemoglobin (HbA1c) level	Venous blood sample
Emotional	Depression, anxiety, stress levels	Depression, Anxiety, Stress (brief version; DASS-21) scale (Handley, Shumway, & Schillinger, 2008)
	Diabetes-related emotional burden and interpersonal distress sub-scales	Diabetes Distress Scale (Fisher et al., 2008)
Psychological	Self-efficacy for diabetes self-care: blood glucose monitoring, physical activity, nutrition, medication-taking	Diabetes Self-Efficacy Scale (Kavanagh et al., 1993)

Measurement area	Outcomes assessed	Measure/s
Psychosocial	Health-related quality of life	EQ-5D (Shea, 2007)
Behavioural	Physical activity	Active Australia Survey (Armstrong, Bauman, & Davies, 2000) Time-Line Follow-Back method
	Dietary intake – number of serves of fruit, vegetables, sweet and fatty foods in the past week	Time-Line Follow-Back method
	Diabetes self-care – blood glucose self-monitoring, medication-taking, nutrition and physical activity	Diabetes Self-Care Activities Survey (Toobert, Hampson, & Glasgow, 2000)
User program evaluations	Users' internet usage, program usage, perceived utility and acceptability, ease of use, user interface, and satisfaction with program	OnTrack Diabetes Program Evaluation Survey

Study Procedures

Participants registered interest in the trial on the OnTrack Diabetes homepage following which they received an eligibility screening call. Individuals who were eligible to enrol received baseline study measures. Individuals who were ineligible for study enrolment were provided with ongoing program access.

Following baseline measures, enrolled participants received an email that specified a secure username and password with which to log on to the program. Randomisation to study conditions was performed via automated computer-generated random permutation. One week before the due date for 3-month Post-Baseline measures participants received an e-mail notification with a link to the online survey and an appointment time to undertake the timeline follow-back measure by phone and to provide their HbA1c result.

Pilot Trial Experimental Conditions

Wait-list Control

From enrolment, participants received access to a blank screen and undertook their usual diabetes care. Following 3-month Post-Baseline measures, they received access to the full OnTrack Diabetes program.

Brief, Modified Intervention – Physical Activity

From enrolment, participants received access to the program's information resources and the physical activity module, Keeping Active and Feeling Great. The module included a series of interactive tools that encouraged physical activity participation via goal-setting, working on increasing self-efficacy, problem-solving for obstacles, and setting a routine to incorporate desired changes into the coming week.

Full Intervention

From enrolment, participants received access to the full OnTrack Diabetes program. In addition to content received by the Brief, Modified Intervention condition, the full program included modules targeting dietary adherence (Eating Well and Feeling Healthy), health regime adherence (Health Routines), emotional wellbeing (Thinking Well and Feeling Fine), and maintaining positive changes (Keeping On Track). There were two sections to each module. The first section included tools incorporating guided imagery techniques, planning, goal-setting, and confidence building. The second section started with the words "More On..." (e.g. More On Health Routines). Included tools focused on setting routines to implement changes in the coming week, and problem-solving for obstacles to starting/ maintaining change. A printable summary page was shown on completion of each tool. Self-monitoring tools enabled the daily recording of best and worst mood, highest and lowest blood glucose levels, and adherence to physical activity and nutrition goals from 0% = *not at all*, to 100% = *totally*). Automated feedback graphs in the program displayed users' progress on recorded measures for the past month and 3 months. A range of mindfulness and meditation audio resources that could be downloaded to an MP3 player or computer were also available.

Statistical Analyses

Univariate Analysis of Variance (ANOVA) was used to assess for potential differences between study conditions on baseline variables. Main outcome analyses that predicted 3-month Post-Baseline outcomes were conducted using Mixed Model Analysis with repeated measures. An intention-to-treat approach was applied to the data. Differences between study conditions on quantitative user evaluations were assessed using Univariate ANOVA.

Ethics

This project received ethics approval from the Uniting Care Health Human Research Ethics Committee (*#Cassimatis9111*) and the Queensland University of Technology University Human Research Ethics Committee (*#1100000783*).

6.4 Results

Recruitment and enrolment processes are displayed in Figure 1, which outlines the distribution of expressions of interest and details participant attrition. Over one-third (37.68%) of expressions of interest were excluded from participation based on selection criteria, with the main criterion being failure to meet the HbA1c threshold of ≥ 6.5%. The participant retention rate at the 3-month Post-Baseline follow-up was 89.47%.

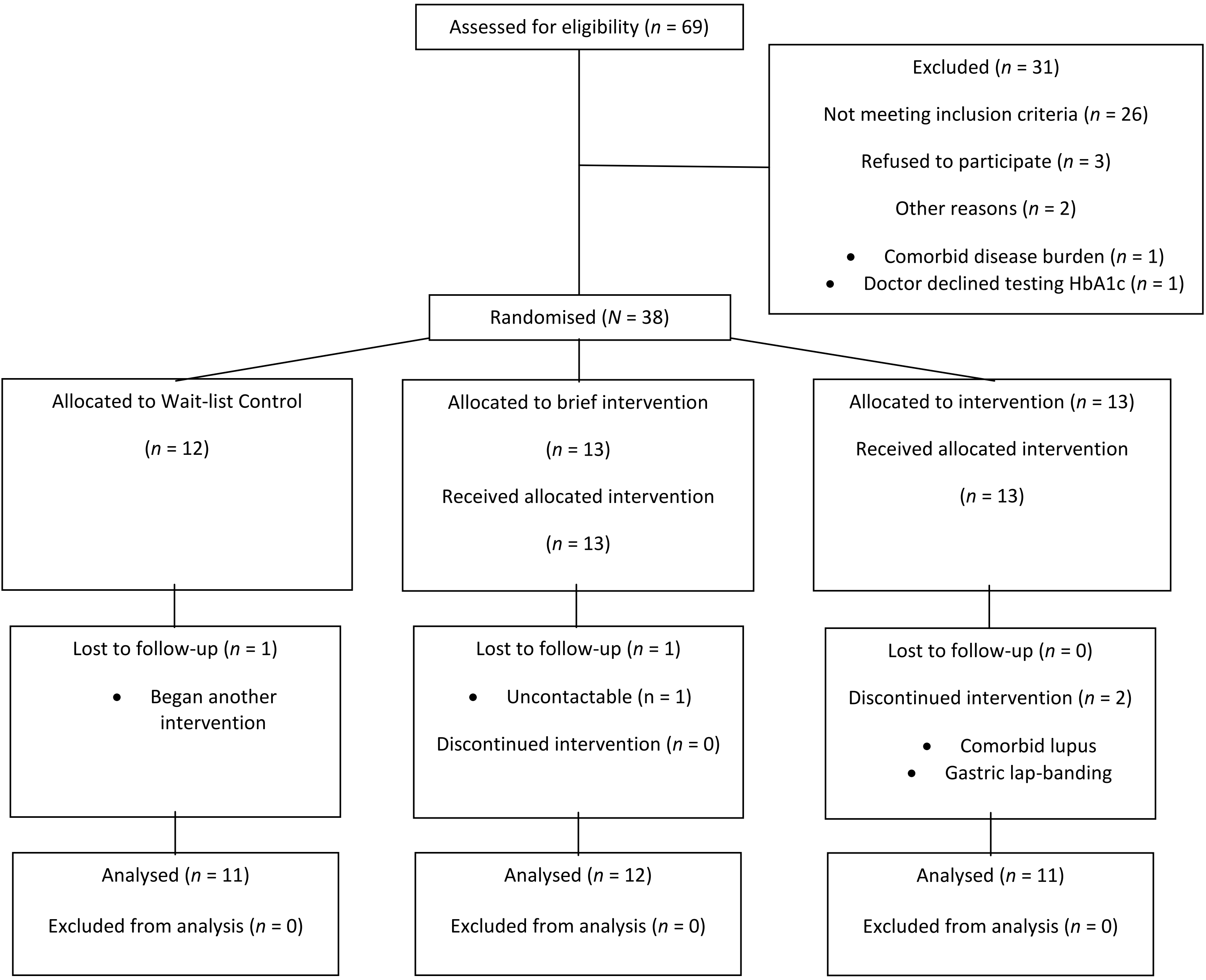

Figure 1. Consort diagram of OnTrack Diabetes pilot randomised controlled trial recruitment and enrolment processes.

A sample of 38 participants (13 males, 37.14%) was enrolled in the trial and included in data analyses, as shown in Figure 1. The sample had a mean age of 60.42 (*SD*=10.03; range=23 – 75), a mean type 2 diabetes duration of 8.91 (*SD*=7.77; range=1 – 27) years, and an average HbA1c level of 7.09% (*SD*=1.08, range=6.5 – 10.8%). Most of the sample was overweight, with an average body mass of 96.71 (*SD*=22.41; range=56 – 173.5) kg and a mean waist circumference of 109.59 (*SD*=13.76; range=85 – 137) cm. Most had at least one comorbid condition with type 2 diabetes, which primarily included hypertension (*n*=14), followed by asthma (*n*=7) and arthritis (*n*=7). The majority were employed in professional roles (40.7%, *n*=13), with 21.8% (*n*=7) working in senior/ managerial positions, and the same proportion being unemployed. There were no statistically significant differences between experimental conditions on any participant baseline characteristics, which are displayed in Table 2, below.

Table 2. Participant baseline characteristics according to experimental condition.

(*N*=38) Characteristic	Wait-list control (*n*=11)	Full intervention (*n*=13)	Brief intervention (*n*=11)
Age(yrs), *M*(*SD*)	*62.27(5.98)*	56.2(13.58)	62.6(9.06)
Gender (%)			
Males	7	2	4
Females	4	11	7
Weight(kg), *M*(*SD*)	95.79 (0.79)	96.42 (26.79)	97.95 (20.55)
Waist(cm), *M*(*SD*)	111.22 (13.22)	105.76 (10.62)	113.06 (17.83)
T2D duration(yrs), *M*(*SD*)	9.0(7.37)	9.22(8.82)	8.43(7.98)
HbA1c level(%), *M*(*SD*)	7.94 (1.15)	7.52 (0.79)	7.99 (1.34)
Income level(per yr)	*$50 – 75 000	$50 – 75 000	$50 – 75 000
Employed (%)	81.82	76.92	62.5

Note: *Income is in Australian dollars

Quantitative Data Analyses

There were no significant differences between experimental conditions on any baseline outcomes. As shown in Table 3, there were no statistically significant differences between experimental conditions from Baseline to 3 months Post-Baseline on primary outcomes. Analyses revealed a significant improvement from Baseline to 3-months Post-Baseline across experimental conditions on the secondary outcome number of serves of sweet foods consumed in the past week, as shown. However, there was no significant difference found in sweet food consumption according to experimental condition, over time ($F_{(2, 30)}$=1.19, p=.32). No further statistically significant differences were revealed in secondary outcomes between Baseline and 3 months Post-baseline.

Table 3. Results of Analyses Comparing Outcomes from Baseline and 3-months Post-Baseline.

Outcome	Baseline *M* (*SE*)	3 months Post-Baseline *M* (*SE*)	*df*	Overall sample *F*	*p*	Between-groups *F*	*p*
HbA1c level	7.82(.19)	7.47(.17)	31.02	3.85	.06	.67	.52
Anxiety	5.24(.96)	4.24(.95)	31.14	2.28	.14	2.6	.09
Depression	7.03(1.23)	6.96(1.17)	31.14	.005	.95	.57	.57
Stress	10.13(1.16)	9.81(1.28)	31.16	.07	.79	.32	.73
DD emotional burden	2.26(.21)	1.98(.17)	31.54	3.85	.06	2.1	.14
DD social support	1.97(.20)	1.93(.18)	31.05	.13	.73	.73	.50
Incidental activity	34.19(8.85)	24.17(6.72)	32.26	1.44	.24	.87	.40
Walking	100.26(18.87)	123.57(20.57)	30.73	1.02	.32	1.5	.24
Moderate activity	72.97(15.64)	75.99(17.39)	30.45	.03	.86	1.0	.37
Vigorous activity	27.49(12.12)	29.20(13.28)	31.61	.01	.91	.35	.71
Fruit serves	14.58(1.38)	13.89(1.11)	32.36	.27	.61	.57	.57
Vegetable serves	19.49(1.78)	18.42(1.68)	29.11	.35	.56	.03	.97
Sweet food serves	7.17(1.45)	4.50(1.28)	29.98	6.5	.02	1.2	.32
Fatty food serves	4.55(1.07)	2.95(.72)	31.98	1.76	.19	.75	.48
HR-QOL	.27	.30	32	.61	.20	.20	.82

Note. *df* = degrees of freedom; DD = diabetes distress; HRQOL = health-related quality of life

Analyses of Exposure to Intervention & User Feedback

Overall, participants in the full intervention condition reported that the OnTrack Diabetes program had high acceptability, useability, and utility, as shown in Table 3.

Table 4. Quantitative User Evaluations of the OnTrack Diabetes Program at 3 months Post-Baseline According to Experimental Condition.

Variable	Full Intervention (*n*=12) *M*(*SD*)	Brief/modified Intervention (*n*=11) *M*(*SD*)	Between-groups differences *F*	*p*
Number of log-ins	4.62(6.56)	4.18(2.14)	3.9	.06
Time online/week(h)	2.3(1.5)	2.5(1.6)	.64	.44
Problems with online access	2.3(.95)	2.33(1.03)	.08	.79
User-friendly	3.4(.52)	4.17(.98)	8.59	.01
Easy to understand	3.8(.79)	4(.89)	.01	.90
Trustworthy	4(.94)	4.33(.82)	.05	.80
Confident in suggestions	3.78(.67)	3.17(.41)	1.8	.20
Useful (program)	3.3(.95)	3.5(1.05)	.08	.79
Useful (information resources)	3.5(.85)	3.67(1.03)	.10	.76
Easily applicable to self	3.1(1.66)	3.33(1.03)	6.7	.02
Addressed exercise well	3.33(.87)	3(1.26)	0	1.0
Addressed diet well	3.1(1.1)	3(1.41)	.02	.90
Addressed health routines well	3.67(1.12)	3.2(1.48)	.05	.84
Addressed emotional challenges well	2.63(.92)	2.8(1.1)	0	.10
Attractive pages	3.22(.97)	3.83(.98)	1.5	.70
Text/graphics easy to read	3.78(.97)	3.83(.75)	2.46	.14
Engaging to use	2.89(.93)	3.5(1.05)	.46	.51
Boring	2.6(1	1.83(.98)	.59	.46

Note. Values represent mean ratings on a scale from 1 (*Not at all*) to 5 (*Extremely*).

Participants indicated that the program was easy to understand, engaging and easy to use. They also indicated that they trusted using the program's suggestions and found it to be personally relevant. On average, participants reported that they found the program at least moderately useful for their purposes in addressing physical activity, healthy eating, and in particular health routines. However, they perceived that the program was slightly less useful in addressing their emotional challenges. Most claimed that they would be likely to refer someone they knew with type 2 diabetes to the program.

Qualitative Program Feedback at 3-Months Post-Baseline

Some aspects of the program that participants reported liking most included, "...its one-on-one involvement", the information fact sheets, its personalised nature, the self-monitoring tools, and its presentation. Participants commented that the program "...provided me with the opportunity to discuss my particular problems with a professional, and made me aware that I could also do this with my GP and diabetes nurse." Additionally, OnTrack Diabetes was regarded to be "...well prepared and sectioned not to overwhelm. It provided realistic goals". Another user indicated liking that "...everything (in the program) is interconnected and you can go from one to another part. It is all there in front of you." Further comments by participants about the most useful aspects of the program included:

> The one (tool) that tracks your mood, blood glucose levels, nutrition and exercise goals. I like seeing the trends especially if there is an improvement in my control. I don't like when the dots don't connect.
>
> (*Female, 58 years, full intervention condition*)
>
> Provided a program that I could access for information and motivation. It was available when I needed to clarify something and I did not have to leave home or spend time in waiting rooms
>
> (*Female, 44 years, full intervention condition*)
>
> (I most liked)...just having a single online place to store the daily records.

(*Female, 62 years, full intervention condition*)

Participants commented that remembering to visit the program regularly was problematic at times. Suggestions were made to implement reminders to log on. Further suggestions for improvements included converting the web program into an application that could be accessed via a smart phone or tablet to increase its accessibility. Furthermore, participants suggested including a blog or page from which health professionals or support persons could be contacted from within the program. Some users who had access only to the brief, physical activity intervention commented that they were dissatisfied at having been randomised to this condition. For example, two participants indicated that they already undertook regular physical activity, and were hence frustrated about only receiving access to this module.

6.5 Discussion

This pilot trial represents the first of an automated, interactive web-based support intervention for type 2 diabetes self-management and dysphoria. Results reflect the feasibility, acceptability and perceived utility of the OnTrack Diabetes program in an Australian type 2 diabetic population. Failure to detect statistically significant differences between experimental conditions is largely reflective of the small sample size. Indeed, utilising a small sample size for the pilot trial must be acknowledged as a limitation to achieving adequate statistical power to detect real differences in study outcomes. This shortcoming was primarily due to the time constraints imposed on the pilot trial due to budgeting and resource limitations. Nonetheless, this pilot trial has shown to be useful in informing the research team about the feasibility of the study protocol and testing the program's functionality and user evaluations, as this specific form of intervention is novel in the Australian context.

Our finding that anxiety produced a downward trend across time concurs with that of a meta-analysis of web-based, cognitive behavioural therapy interventions for mood, which indicated that effect sizes of interventions for anxiety symptoms were generally larger than those for depressive symptoms (Spek et al., 2007). However, the difference in the amount of therapist-based support included in these interventions was suggested to be a potentially contributing factor. The reduction in the consumption of sweet foods may be indicative of participants' desire to improve their diabetes control, and hence enrol in a research trial. Related to this is the fact that the mean HbA1c level for participants in all conditions was just above 7%, which indicates that despite substantial power issues due to the small sample size, especially within a 3-month time period, the result is close to reaching clinical significance. This suggests that the program has the potential to produce clinically and statistically significant improvements, and that this may be determined using a larger sample size.

Most importantly, it is necessary to reflect on the fact that the majority of participants in the brief and full intervention conditions demonstrated poor engagement in the program, with many acknowledging that they wished they had used the program more often. Participants in the brief intervention condition were not satisfied with the perceived paucity of resources and tools that they received, indicating that they considered receiving only a brief module to be insufficient. In particular this was an issue for those individuals who did not wish to work on improving their physical activity. Results from the full intervention condition indicated that even if users had a choice about which program module to access, they are unlikely to have experienced improvements in primary or secondary outcomes due to poor engagement.

Participants who received the full intervention reported being pleased about the personalised aspects of the program, which they could relate to their own issues and experiences with type 2 diabetes self-management. This feedback is parallel with previous research that indicates the importance of an individualised approach to diabetes treatment and self-management intervention (Kaufman, 2010). The program was reported by this group to be highly acceptable and easy to use, with an acceptable graphical presentation and lay-out. Users in this group also reported that the program helped them to feel more comfortable discussing issues with their health care providers.

Suggestions made by users will be used to inform refinements of the OnTrack Diabetes program for the main randomised controlled trial. Reminder e-mails or SMS's will be sent to participants at regular intervals to encourage them to log on more frequently. User engagement has been reported as a common issue in previous web-based trials of intervention support programs (Glasgow et al., 2011; Lorig et al., 2010). This issue suggests that the implementation of therapist support and/ or reminders may be instrumental to encourage user engagement in web-based interventions, at least until a routine is established and/ or users are at a maintenance stage of self-care, which may require less regular access. Overall, results from this initial pilot trial of OnTrack Diabetes have indicated that, whilst the program gains users' trust and is perceived to be acceptable and easy to use with a range of features that they consider to have utility, techniques to improve user engagement are needed. These issues will be worked upon prior to recruiting a large sample to the main randomised controlled trial of the program, which will provide greater power to reasonably assess clinical, mood, and behavioural outcomes.

6.6 Chapter Summary and Conclusions

This paper reported a number of strengths, limitations, and areas for improvement in the OnTrack Diabetes program implementation that will be extended upon in the main randomised controlled trial of the program.

CHAPTER 7

DISCUSSION, SUMMARY AND CONCLUSIONS

7.1 Abstract

This PhD project was comprised of three stages that fulfilled its overarching objective, which was the development and evaluation of an automated, web-based type 2 diabetes self-management and dysphoria intervention. Specific aims of the project were associated with each stage, with provided a foundation for the progression of consecutive stages and formed the basis for contributions to the scientific literature via journal publications. Stages comprised: (1) Exploration – (i) investigation of telehealth as a means of intervention delivery by systematic review (Paper 1) and (ii) qualitative interviews on patients' and physicians' perceptions of living with type 2 diabetes (Paper 2); (2) OnTrack Development – (i) consolidation of project protocol (Paper 3); (ii) development of the OnTrack Diabetes program (Paper 4); and (3) Evaluation – pilot trial evaluation of the OnTrack Diabetes program (Paper 5). Overall, this project can thus be seen to have resulted in valuable scholarly contributions that will assist with shaping the future of web-based diabetes self-management research. This chapter discusses how the project findings and their resulting papers link with the project aims at each stage. Project outcomes are then discussed in the context of Social Cognitive Theory. Finally, strengths and limitations, practical implications and future directions are presented followed by concluding remarks.

7.2 Overall Discussion

The overarching objective of this PhD project was to develop and evaluate a web-based intervention for type 2 diabetes self-management and dysphoria, which was fulfilled. Each stage of this project formed a foundation for the later ones. Information on the effects of behavioural telehealth interventions on glycaemic control and diabetes self-care (Paper 1) provided information on the potential efficacy of this form of intervention. Due to the paucity of well-reported research, defined by the quality and validity of its reporting, and the heterogeneity of included studies, it was difficult to draw firm conclusions. However, it appeared that behaviourally-based telehealth interventions are generally not effective at producing significant improvements on diabetes self-care outcomes.

The qualitative responses of patients and physicians on experiences of living with type 2 diabetes (Paper 2) provided evidence of the need for additional self-management support for people with type 2 diabetes, and emphasised the need for emotional and psychological support in particular. The subsequent development of the program was an iterative process that was described in two papers; the procedures used in the project (Paper 3), and the steps involved in developing the web-based support program (Paper 4).

The final stage comprised the randomised controlled pilot trial of the OnTrack Diabetes program (Paper 5). There was no significantly differential effect for the web intervention on any outcome over the initial 3 months, which was largely due to the limited sample size which prevented adequate statistical power from being achieved to detect statistical differences amongst outcomes. This limitation was largely the result of restrictions in project resources which prevented the recruitment of research staff to undertake assessments and implement the program. In this context, the time constraints of the PhD program made for a tight timeline in terms of program development, testing, and implementation, which substantially limited the pilot trial recruitment period. Nonetheless the result for anxiety approached significance, suggesting that an effect may be obtained with a larger sample. Program evaluations indicated that users had high levels of satisfaction with the program, and it had moderate to high acceptability, utility, and ease of use. Users also reported that the program provided trustworthy information, and that they liked its graphical presentation and lay-out. Overall, the project provided an important contribution to understanding the unmet needs of people with type 2 diabetes and the role that a web-based program may have in meeting these. It created a self-management intervention for both type 2 diabetes and dysphoria that for the first time could be delivered with or without coaching support. It also offered a preliminary trial of this program's efficacy.

7.3 Discussion of Papers in Relation To Project Aims

The initial aim of this research was to build a remotely accessible intervention via which type 2 diabetes self-management and mood support could effectively be delivered. Telehealth was at first explored as a possibility for this intervention. Although there is a plethora of scientific literature reporting on telehealth studies, there is a paucity of evidence on the effects of telehealth interventions on both diabetes self-management and mood. Further, it was difficult to distinguish the effectiveness of particular components of multi-faceted interventions, and this is particularly useful in the case of informing diabetes self-management interventions, which typically have a range of behavioural self-management components to address. Therefore, we wished to ascertain a general idea about what the current status of telehealth research could offer type 2 diabetes patients in terms of behavioural and clinical improvements, and thus conducted a systematic literature review (Paper 1).

Specifically, behavioural components of diabetes self-management interventions were the focus of the review to evaluate their effectiveness. Results indicated that much improvement is required in the efficacy of behavioural telehealth interventions that aim to address glycaemic control and at least one diabetes self-care area. In addition, it was decided that we may not be able to offer much more than previous telehealth interventions already have in terms of producing an original intervention with superior efficacy. Thus, it was decided to explore the more novel, web-based approach to diabetes self-management intervention. Paper 1 adds to the health psychology and diabetes self-management arena by emphasising the need for improvements in telehealth interventions. Results also make clear the inconsistencies and poor quality and validity of study reporting in this area, which made it difficult to draw conclusions based on the available research. The review was also useful for providing an overview of the theoretical approaches that are commonly used in primarily behavioural telehealth interventions for diabetes self-management, and in doing so, provided support for using Social Cognitive Theory as a theoretical foundation. Furthermore, the importance of addressing psychosocial issues in diabetes self-management support interventions was demonstrated by included studies. Essentially, findings reported in Paper 1 assisted with our decision to implement web-based, as opposed to telephone-based intervention, and presented a novel view to the scientific literature that may prompt consideration of the efficacy of particular behavioural components in telehealth.

An overview of the literature on qualitative studies that explored the views of patients with type 2 diabetes and health care professionals (Section 1.4) provided some scope on key facilitators and barriers to type 2 diabetes self-management, and further information could be derived from quantitative research. The aim of the qualitative exploration (Stage 1) reported in Paper 2, or Chapter 3, was to determine issues that specifically relate to Australian people with type 2 diabetes that was as recent as possible. This provided a substantial foundation for the development of a type 2 diabetes self-management and dysphoria intervention. Findings from the qualitative interviews revealed the depth to which type 2 diabetes patients experience emotional losses in response to their condition; the impacts of type 2 diabetes on their lives, and gave insight into their lived experiences with managing the condition. Physicians' perceptions indicated that they wished to support patients, but that motivational issues were key barriers to their effectiveness in delivering appropriate type 2 diabetes care as advised by recommendations. Physicians also highlighted that although patients have individual experiences of their diabetes, their concerns and emotional difficulties come from some common sources, which doctors were mostly able to identify with sufficiently. However, there were also some discrepancies between patients' and physicians' perceptions, with physicians taking a more practical perspective of patients' self-management issues. Overall, findings indicated that patients require further support with their day-to-day diabetes self-management, and that emotional support is also very much needed, and would be well received. Further, both patients and physicians indicated perceiving that web-based support was an acceptable means by which to receive this support, and both samples offered many suggestions for program content.

Stage 2 involved the development of the OnTrack Diabetes program. Paper 3 (in Chapter 4), which describes the project protocol, was aimed to report on the overall study processes involved in the OnTrack Diabetes project. The purpose of this was to elucidate these processes in the scientific literature so that they could be linked to final outcomes of the research, and used as a basis for replication or improvement in future trials. This paper makes a contribution to the literature by demonstrating important links between the qualitative interviews (Stage 1; Paper 2), and Stages 2 (program development) and 3 (pilot trial implementation) of the project. Therefore, project procedures and sequence can be analysed and critiqued by others. This lends to the scientific literature by providing information on what was involved in the development and evaluation of the first program of its kind in the context of type 2 diabetes self-management and dysphoria intervention in Australia.

As this research project involved the development of a novel form of technological intervention in the context of type 2 diabetes self-management and mood, the aim of the program development paper (Paper 4, or Chapter 5) was to outline the scientific community on the processes involved in its development. In doing so, we made explicit the sequence of steps that were involved in the content, graphical, and technological design of the OnTrack Diabetes program. The paper can thus be used as a point of comparison for researchers who wish to or who have developed web-based chronic disease self-management and/ or mood interventions. The paper provides an indication of the typical time requirements involved in such a venture, although the time to develop OnTrack Diabetes was significantly reduced by the availability of pre-established web lay-out and some program tool features, as well as technological functionalities. Paper 4 further provides a useful vantage point to refer to in future, as the expansion of technological interventions is in rapid development. When methods of program development that are included in the paper become superseded, this paper will indicate the typical processes that were used in the early 2010’s to develop web-based interventions.

Stage 3 was defined by the randomised controlled pilot trial of OnTrack Diabetes, and had two aims. The first was to gain a preliminary indication of its effectiveness in improving clinical, behavioural, psychological/ emotional, and quality of life outcomes in people with type 2 diabetes. It is noted that some of the measures listed in the project protocol paper are not mentioned in the paper on the pilot trial evaluation. This is for the reason that the pilot evaluation paper aimed to present findings of primary significance out of the outcomes which were measured. This was in the context that clinically/ statistically significant outcomes were deemed unlikely with such limited statistical power, which was found to be the case. The information that was collected will be used to inform the main randomised controlled trial, when the increased power will enable possible associations between these lifestyle factors and outcomes to be assessed. The second aim was to evaluate users' perceived acceptability, utility, and ease of use of the program, and the feasibility of its implementation. This pilot trial also enabled the study protocol to undergo assessment, to inform any necessary refinements before going on to the larger, randomised controlled main trial of the program. Overall, these aims were successfully fulfilled. Paper 5 (in Chapter 6) reported on the pilot trial results and demonstrated that the program was useful in incorporating suggestions from participants who took part in the qualitative interviews in Stage 1 (Paper 2), as the program evidenced in producing high user evaluations. This paper highlights the successes and difficulties associated with implementing automated web-based type 2 diabetes self-management and dysphoria support. Results are discussed and suggestions for potential improvements to program implementation are considered. This paper is the first scientific dissemination of research on an intervention of this kind within the Australian context, and hence it makes a substantially valuable contribution to the scientific literature in both its indication of study outcomes and user evaluations.

7.4 Discussion of Findings in Relation to Social Cognitive Theory

Social Cognitive Theory (SCT) proved to be a well suited approach to the overarching aims of this research project. The systematic review on telehealth interventions (Paper 1) showed that SCT is commonly used in remotely accessible interventions for diabetes self-management. The theory is particularly applicable to the purpose of this project, as it aimed to address concomitant psychological and emotional issues, which are accounted for in SCT. The qualitative exploration of patients' experiences with managing type 2 diabetes (Paper 2) validated the use of SCT, as in their responses participants revealed that type 2 diabetes ultimately affects all aspects of their lives, including their social environments, their interpersonal relationships, and their psychological and emotional well-being. Participants' accounts also indicated that when these factors were conducive to supporting them in their diabetes self-management, they were more successful in implementing recommended self-care, which indicated that there is scope for interventions that align with the principles of SCT. Further, SCT provided a logical and practical framework with which to structure an automated support program (Paper 4). The specific ways in which SCT was incorporated into the OnTrack Diabetes program are outlined below. The OnTrack Diabetes pilot trial (Paper 5) produced results that reflect on the incorporation of patients' responses from the qualitative interviews (Paper 2) into the program. In general, the high ratings obtained on user evaluations indicated that a web-based intervention that uses SCT as its primary theoretical foundation can create positive user impressions. However, motivational and other issues, which are also discussed below, potentially impacted on user engagement.

7.5 Application of Social Cognitive Theory to the OnTrack Diabetes Program

SCT was successfully incorporated into the OnTrack Diabetes program as a theoretical foundation, which demonstrated that the principles of this theory are well suited as a basis for web-based chronic disease self-management intervention. Specific aspects of SCT were applied to particular program features that promoted the principles of behavioural self-management and emotional regulation denoted by the theory.

My Journey Map describes the program's background lay-out, which enables users to view the journey on which they will embark in the program and to view their lists of options to undertake any particular sections of the program that they wish to at any time. This aspect encourages user autonomy and program personalisation. As a whole, using the various aspects of My Journey aims to take users on a path towards higher self-efficacy, self-awareness, skill acquisition, and stress relaxation. This is applied with the provision of cognitive guidance to implement behavioural changes, interactive self-efficacy promoting tools, self-monitoring functions and feedback, encouragement of performance accomplishments, vicarious learning, and building social supports. A brief description of how the OnTrack Diabetes program fulfilled the requirements of SCT for motivating and potentially maintaining changes in the behavioural self-management of users with type 2 diabetes is outlined below.

Skill and ability enhancement for type 2 diabetes self-management – Extensive diabetes education resources on general type 2 diabetes information, self-care, information about the purpose and requirements for accessing allied health professionals, and support services can be accessed under the “resources” tab. This informational support provided the basis for skill acquisition of self-management behaviours and a strong knowledge base that informs users on the value of performing adequate self-care. Hence, the program fulfilled the need for ability to enact desired behaviours, which is vital to making progress with behaviour change (Bandura, 1986).

Self-monitoring – My Diary is a section of the program that contains self-monitoring tools for daily blood glucose levels (highest and lowest), mood (best to worst), physical activity and nutrition goal adherence (0% = *not at all*, to 100% = *totally*). These tools encouraged self-observation and self-evaluation, which are important to goal-setting and creating motivation for self-care by creating a negative feedback control loop that motivates individuals to reduce discrepancies between current and desired performance accomplishments (Bandura, 1991). Regular self-monitoring and goal-setting tools enable participants to more readily develop and maintain self-awareness of their progress, and re-set their goals accordingly. Printable and foldable self-monitoring cards enable them to undertake self-monitoring when they are not logged in to the program. This encourages proximal self-evaluation of progress towards their goals, which is considered important in SCT (Bandura, 1989), as distal self-reflection is not as effective at producing motivation for improvement in performance attainments.

Feedback control – Automated feedback graphs are produced from information entered into My Diary, and display goal progress in the past month and 3 months. The function of feedback control is another essential constituent that is implicated in the process of self-evaluation (Bandura, 1989). Using the feedback graphs, participants can regularly assess their effectiveness in producing positive outcomes in their glycaemic control and diet and physical activity goals. SCT proposes that failure to meet personal internal standards should create a negative feedback loop that promotes higher goal striving. However, individuals with low self-efficacy may experience adverse emotional effects and reduced motivation when they fail to meet their standards. The program aims to buffer possible detrimental effects of negative feedback on mood by providing interactive tools that encourage user self-efficacy (e.g. the Feeling Confident tool). However, if users did not use or complete these particular tools they may have experienced a negative emotional reaction and/ or reduced motivation from observing regressions in progress. This potential for a negative effect of self-monitoring on behaviour emphasises the importance of using at least the tools that are primarily aimed to impact self-efficacy beliefs in conjunction with the self-monitoring tools and graphs.

Goal-Setting – Users were encouraged to set personalised goals. Therefore, these goals should have had personal valence and been set at a level that was perceived to be appropriately challenging by each user. Further, viewing goal progress using the feedback graphs enabled participants to perform goal attainment scaling which, as discussed, can lead to increased motivation when discrepancy between actual and desired outcomes is detected. SCT proposes that these two aspects of goal-setting are necessary to produce the incentive to increase performance accomplishments. However, poor user engagement in the program means that this process is unlikely to have occurred in most pilot trial participants. Once again, although the program included guidelines via interactive tools that advised on setting goals in small, incremental steps (e.g. “My Physical Activity Goal Plan”), if users had not accessed these tools they may have set easy goals for themselves, which failed to enhance their motivation and led to inaction.

Problem Solving – Interactive tools on problem solving strengthen participants' self-efficacy by enhancing their beliefs in their capabilities to cope with challenges, including behavioural set-backs from treatment regime non-adherence. Making an effort to overcome barriers to change which results in success leads to more positive expectancies when similar difficulties are faced in future. Therefore, these tools encourage the strengthening of cognitive guidance to endure through challenges as well as motivation to do so via practice effects.

Mastery of performance accomplishments – Interactive tools (e.g. "My Physical Activity Plan" and "My Health Actions Routine") encouraged participants to create a plan to master personally set performance accomplishments. This is consistent with the SCT notion of mastery achievements motivating performance and thereby leading to increased self-efficacy and goal pursuits (Bandura, 1977). Mastering desired performance attainments are also associated with positive effects on mood. Hence, these tools serve the purpose of aiming to improve type 2 diabetes self-care behaviours and mood.

Vicarious learning – Videos in the program demonstrate scenarios in which actors discuss their strategies for overcoming low mood; gaining motivation to participate in physical activity; overcoming problems with alcohol, and communicating more effectively to improve their intimate relationships. The actors are average Australians who are likely to be similar in age (middle-aged) to most participants, and to report experiencing similar behaviour change and mood issues as participants. Therefore they are people with whom participants in the project would be thought to have identified with. Viewing the videos is a source of efficacy by enabling symbolic modelling to be performed, wherein even though videos of people with type 2 diabetes were not included due to budgeting issues, participants could have generated applications of the rules extracted from the examples and applied them to diabetes self-management. For example, the video of overcoming issues with alcohol could have been applied to personal dietary issues. People with dial-up internet access and/ or slow internet connection speeds may have had difficulties uploading the videos so verbatim transcripts of video content were also available. Viewing the transcripts changes the vicarious reinforcement effect, however, in that it does not use modelling.

Verbal persuasion – Interactive tools are based on verbal persuasion regarding providing users with instructions on diet, physical activity, health behaviours, emotional well-being, and maintaining change. This is the weakest source of efficacy beliefs (Bandura, 1977). However, it is the basis of most psychotherapeutic and web-based interventions, and combined with the other sources of efficacy incorporated in the program, is sufficiently enriched. Participants are not provided with instructions per se, but rather are encouraged to exercise their own judgement in deciding the course of action that they wish to take. This should encourage patient empowerment and autonomy in making decisions about implementing personalised changes. The program then merely provides guidance to facilitate this process.

Physiological state – Stress relaxation has demonstrated efficacy in mitigating the negative effects of aversive physiological arousal on behaviour, including on defensive or avoidance behaviours (Bandura, 1989). Furthermore, perceived inefficacy to cope with potential threats tends to result in avoidance behaviour regardless of whether aversive arousal is present. Meditation and mindfulness-based audio files in the program train users to relax, which according to SCT, has the effect of increasing their perceived efficacy to cope with potential threats and physiological arousal (Bandura, 1989). Hence, the audios are potentially useful for reducing negative physiological symptoms and affective disturbance, and may have longer-term effects on diabetes self-care avoidance behaviours.

Forethought/ Cognitive guidance – SCT denotes that initially, calculated judgements are required for the implementation of novel desired behaviours. However, after repeated practices, the behaviour becomes less cognitively effortful, which is represented neurologically by a change from the activation of top-down processing to that of lower level neural processing in response to behavioural activation. OnTrack Diabetes implements guided imagery techniques that work on this function to train users to implement their desired behaviours using cognitive guidance to establish cognitive behavioural patterns in their thought processing. For example, one of the first interactive tools contained in each program module (e.g. "Ideas About Fun Physical Activity") asks participants for suggestions about a physical activity that they would like to participate in during the following week. Specification that the activity should be implemented in a short-term time frame represents is consistent with the importance of proximal temporality in exercising cognitive forethought to increase motivation. Further, printable summaries enable users to apply program-based cognitive guidance in even closer proximal temporality to the event.

Social support – Social support is an essential factor in successful type 2 diabetes self-management, and accords with the importance of psychosocial interactions to health and wellbeing that is outlined in SCT (Bandura, 2004b). Accordingly, "Building My Support Team" is an interactive tool in which users are taken through steps to create a list of people who can support them as they work through the program. Supports can include family members, friends, or anyone from their wider support network, for example work colleagues and community members. "Building My Support Team" includes a section wherein users can complete a support page that lists the health professionals that comprise their diabetes self-management team, including allied health professionals (e.g. diabetes educator, podiatrist, dietitian, optometrist, etcetera), as well as their primary care provider. Along with the information resources on accessing each member of the diabetes care team, this section aims to encourage ease of access to contact details and to remind participants that there is both personal and medical social support available nearby. SCT proposes that social support can buffer against the negative effects of depression on self-care behaviours (Bandura, 1998). Once again, the utility of this effect largely depends upon utilisation of this tool.

In sum, SCT can be seen as a suitable theoretical approach to have used as a foundation for the OnTrack Diabetes intervention. SCT can also be used to understand the successes and shortcomings of the current research project.

7.6 Understanding the Results of This Research in the Context of SCT

It is interesting to note that the very motivational issues that were aimed to be improved in the pilot trial of the program may have borne the same issues for user engagement in the program as they did for engagement in type 2 diabetes self-management. As discussed earlier, the issue of participant attrition and poor user engagement is common to a number of prior research studies on web-based interventions, including those for diabetes self-management.

OnTrack Diabetes incorporated a socio-ecological approach to self-management, and therefore encouraged participants to establish their own environments for creating behaviour change, for example by increasing social support and making plans for desired changes. However, it is possible that participants needed some assistance with implementing these changes initially, or at least required assistance with the motivation to do so. Some may have experienced behavioural avoidance which resulted in their failure to implement change. Presenting participants with extensive informational support and tools for self-management makes salient their need to improve their self-care and, in accordance with motivational interviewing, emphasises the discrepancies between their current and desired situations. Consistent with SCT, participants may then have avoided using the program due to their perceived inefficacy to cope with the self-management regimen.

Qualitative interviews indicated that most people experienced substantial emotional challenges but did not consider themselves to be depressed. A similar issue may have been responsible for poor user engagement in the pilot trial, as participants were possibly reluctant to admit that they had emotional issues due to their perceived inefficacy to cope with them. This suggests the need for more support to at least get started with the intervention, and probably also intermediate additional health professional/ research team support to encourage the maintenance of program use. The program includes quizzes that participants can undertake to do quick assessments of their dysphoria and diabetes self-management. These quizzes are incorporated into the program with the intention that participants can develop greater self-awareness of dysphoria symptoms, and upon their recognition of problems seek help as required. However, low program engagement indicates that these quizzes were not used as intended.

7.7 Practical Implications of Findings

The Stages of this project and the scientific papers that resulted from each have a variety of implications. The systematic review on behavioural telehealth interventions (Paper 1) illuminated the uncertainties that remain inherent in determining a thoroughly efficacious approach in the field. The paper builds a foundation for empirical inquiry into the efficacy of providing primarily behavioural support for diabetes self-management, and gave scope as to how telehealth can be expanded to improve upon current findings.

Qualitative interview findings (Paper 2) may assist with health professionals' understanding of the experiences of type 2 diabetes patients, and that dysphoria, though rarely presented in the clinic room, is commonplace for many throughout the course of the condition. As such, this paper may contribute to closing the gaps in communication between health professionals and patients. The paper may also serve as a foundation for other studies that wish to further explore dysphoria in type 2 diabetes patients, or as the basis for development of other interventions.

The protocol (Paper 3) and development papers (Paper 4) are useful in assisting researchers to identify the typical processes involved in implementing a randomised controlled trial of a web-based intervention, and what is involved in program development. Dissemination of these papers is particularly foundational due to the novel nature of OnTrack Diabetes. Further, these papers elucidate what could have been improved upon, or where new techniques could replace superseded ones in the development of future programs.

Pilot trial results (Paper 5) contribute important information on user perceptions of automated, web-based interventions, which indicate that there is promise for expansion in this area. Hence, results may form the impetus for further studies that seek to build upon the foundation that this trial has provided.

7.8 Strengths and Limitations of this Project

This research project has a number of strengths that are in part associated with using SCT as a theoretical foundation, and also some that are associated with the project design. A mixed models approach was used throughout this study, in terms of implementing both qualitative and quantitative techniques. The use of both approaches adds strength to the methodological design, as this approach is commonly regarded to be the gold standard of conventional research.

The qualitative interviews first and foremost opened the researcher’s eyes to the issues experienced by type 2 diabetes patients in managing their condition. It is difficult to step into the shoes of people and understand their lived experiences without having explored this meaningfully. Hence, using mixed methodology was highly facilitative to the development of a patient-empowered program for people with type 2 diabetes. Furthermore, the qualitative study provided the chance to tailor the intervention to a range of patients’ needs, whilst it provided a standardised, hence more cost-effective (Radhakrishnan, 2012) intervention approach. Stage 1 also provided scope as to some of the potential reasons for poor user engagement in the pilot trial, such as the issue of the avoidance of emotional issues possibly prompting participants’ needs for more follow-up support.

Having a pre-designed web-based program lay-out was helpful in providing structure to the OnTrack Diabetes program interface from the outset, which would otherwise have taken considerable time in designing. Further, it was cost effective to have had some of the information technology content; the mood self-monitoring tool; the mindfulness and meditation audios and videos, and some of the tool structures established. The major contribution of the PhD candidate to the content input and eXtensive Markup Language (XML) programming also resulted in considerable savings in intervention production costs.

A number of strengths are associated with the pilot trial of OnTrack Diabetes. The randomised controlled trial design is methodologically robust in controlling for issues associated with participant randomisation and the effects of individual differences and inequalities between research groups. Additionally, random allocation of participants to research groups via computerised random permutations enabled participant allocation concealment from the researcher. Advice to participants not to reveal their experimental condition upon 3-month Post-Baseline assessments meant that the researcher was also blinded to participants' experimental conditions. Both of these criteria assist with ensuring the quality and validity of study methodology according to the Cochrane tool for assessing risk of bias.

The pilot trial evaluation measures were valid and reliable instruments that are typically used in diabetes research. Adding the timeline follow-back method for assessing dietary intake and physical activity adherence had the potential advantage of greater accuracy for cueing participants' recall of their behaviours in the previous week (Sobell & Sobell, 1992). User evaluation measures provided a comprehensive indication of participants' experiences with using the program, and incorporated the use of both qualitative and quantitative measures.

Particular strengths of the OnTrack Diabetes program included users' high evaluations, which in general indicated that they are satisfied with the program and perceive it to be highly acceptable, accessible, and user-friendly. Patients reported valuing the option to personalise the program according to their needs. As well as the positive evaluations, responses also provided scope for improvements on particular aspects of intervention delivery.

Online administration of the OnTrack Diabetes Baseline and 3-month study surveys enabled greater accuracy, and may have assisted with the relatively high participant retention rate (89.47%), due to convenience. Using an automated web-based intervention required relatively minimal person support, as one researcher was able to conduct a randomised controlled trial when the intervention. Finally, the pilot trial provided a preliminary indication of the program's potential for real-world implementation and reach, with analyses to follow this up with analyses on the larger sample that will be recruited to a main randomised controlled trial of the program.

There were also a number of limitations to various aspects of the project of which it is important to make mention. In terms of the Stage 1 qualitative interviews, including a sample of people with type 2 diabetes and physicians from regional and rural areas would have assisted with better tailoring of the program to the needs of rural and regional residents with type 2 diabetes. OnTrack Diabetes accommodates the needs of a variety of people to a large degree, as users are able to personalise the program by selecting personally appropriate options amongst the interactive tools and undertaking personally relevant areas of the program. However, there would have been foreseeable value in nonetheless gaining the perspective of those in regional populations to evaluate whether there were any substantial differences in their perspectives on type 2 diabetes self-management and emotional challenges. The reason for not doing so was that it was important to take notes of non-verbal communication from patients with type 2 diabetes, and hence the face-to-face format of the interviews was an integral factor in deriving themes from the data. There were also limitations to the researcher travelling to remote locations alone to conduct interviews.

Program development in Stage 2 raised a number of unexpected hurdles in progressing with the project. The common issue of learning to understand information technology rules and limitations made some stages of program development difficult to work through. It can be difficult for researchers to adapt to the limitations of information technology programming, in which case what would seem to have been a simple request to implement a seemingly simple feature of program functionality was revealed to take much longer than had been supposed. Further, at various points in the development stage, bugs were discovered in the system even after initial testing of the functionality and pages had been conducted. Such is the issue of combining psychological and behavioural research with the field of technology.

The pilot trial may have been improved in some aspects, including that few participants were from rural or regional areas, which limited the thorough assessment of implementation feasibility to these populations. However, aims to recruit a much larger, more geographically diverse sample to the main trial will advance from this limitation. A major issue that contributed to the failure to find significant outcomes on primary and secondary outcomes was the relatively small sample size that was enrolled, which limited the power to detect significant differences between study conditions. Part of this issue was associated with delays in programming, as discussed, which limited recruitment time. The small sample size also limited the ability to undertake analyses of the variety of factors that can influence the improvement of diabetes self-management, which include educational attainment (Sacco, Bykowski, Mayhew, & White, 2012), demographic (McCabe, 2004) and psychosocial characteristics (Akimoto et al., 2004; Chida & Hamer, 2008).

Furthermore, some participants commented that the 3-month follow-up timeline follow-back phone call may have motivated improvements in their self-management in the week prior, although randomised allocation would have controlled for differential impacts between experimental conditions. This suggests the potential for therapist-based support or coaching to enhance the effects of an automated intervention. It also indicates the difficulties in maintaining treatment fidelity in research on automated interventions, for example due to the potentially reinforcing effects of contact with the researcher.

A final limitation relates to issues associated with user engagement in the program. However, the literature indicates that participant attrition is common in web-based interventions, including for diabetes self-management. For example, a trial of the Diabetes Network (D-Net) intervention in 270 diabetes patients indicated that user engagement decreased over a 4-month implementation period, from 70% of participants visiting at least weekly during the first 6 weeks to 47% during weeks 7 to 16 (Glasgow et al., 2011). This was the case despite the website having included features to enhance user engagement that included “Ask an Expert” to enhance dietary, physical activity, and medication adherence. Additionally, Heinrich and colleagues (2012) trialled the web-based Diabetes Interactive Education Program (DIEP) in 99 people with type 2 diabetes, and found that only a minority of participants used the included self-management tools and functionalities as the researchers had intended (Heinrich et al., 2012). They concluded that health care professionals must play an active role in program implementation to achieve improved user engagement and outcomes.

7.9 Future Directions for This Research

This research project was instrumental in planting the seeds for future outcome-related developments. A main randomised controlled trial of the OnTrack Diabetes program is planned for implementation in the near future which will extend upon findings from this PhD project. A larger sample size will provide more statistical power to enable the detection of statistically significant differences in study outcomes. In addition, the resulting increased statistical power will allow analyses of program effects according to various participant sub- groups to be performed, such as higher and lower HbA1c level, and mood cohorts.

The pilot trial clearly indicated the need to increase user engagement in the program. Suggestions to do so include supplementing the automated intervention with reminders or reinforcements to log in to the program, such as automated e-mails, Short Message Service texts, and/ or therapist coaching. Web-based support programs for affective disorders have demonstrated efficacy when combined with enhanced health provider care over and above the effects of enhanced provider care (Hickie et al., 2010). Therefore, automated interventions may add benefits to the effects of consulting with a primary care provider alone, but there is potentially greater strength in integrating the health care system into their delivery.

Other trials of web-based diabetes self-management interventions have demonstrated that no additional benefit is derived from implementing moderate versus minimal support in interventions (Glasgow et al., 2010). However, studies have not compared the effects of a fully automated web-based program with those obtained by a minimal and/ or moderate support web-based program. Evidence on pharmacological and psychotherapeutic treatments for diabetes self-management and mood demonstrate that combining treatment approaches obtains the best outcomes. This may also be the case in terms of web-based intervention.

Health professional integration into technological intervention delivery is a rapidly emerging field, and hence further suggestions for project advancement include integrating OnTrack Diabetes with e-mails from health professionals, or creating an interface via which electronic medical health records could be shared with patients, and health professionals could access patients' self-monitoring progress graphs, blood glucose levels, mood ratings, dietary and physical activity records within the program.

An additional suggestion is the incorporation of enhanced social support features, such as a blog, forum, or chat rooms, so that users can contact other program users and/ or health professionals from within the program. This form of social support was suggested by patients in qualitative interviews for web-based program content. However, limitations to implementing this form of support include the need for monitoring contacts between users, and increased financial costs, and it was not practical to do so with the time and personnel constraints of the current project.

Aside from enhancing user engagement and current aspects of OnTrack Diabetes is the possibility of advancing the program's technological scope. For example, pilot trial participants suggested translating the program to tablet form so that it could be accessed via an ipad or iphone for increased portability. Another suggestion was made to convert various program features such as the self-monitoring tools, into a smart phone application. Australia has substantial access to mobile phone coverage, and the use of apps for monitoring and diary-keeping, as well as for health adherence have become the norm. However, many health-related monitoring apps are available and are often not used regularly. Adding OnTrack Diabetes program features could be successful in increasing user engagement in an app. Smart phone apps have already demonstrated implementation feasibility in people with type 2 diabetes for self-monitoring and feedback purposes (Nes et al., 2012).

Adding a smart phone application to a web-based program may assist with strengthening the program. For example, reminders could be sent to the mobile phone to encourage users to log in or perform self-monitoring. In relation to SCT, the temporal proximity of cognitive guidance may be increased using an app, and this would eliminate users' need to print out self-monitoring cards from the program to undertake self-monitoring and guided imagery exercises. Finally, smart phones can be used to provide an Ecological Momentary Assessment function that enables situational constituents to be recorded with present behaviours so that users can gain even greater self-awareness of their need to correct their behaviour or progress.

A final suggestion for future developments of OnTrack Diabetes is the development and evaluation of OnTrack Juvenile Diabetes for children and adolescents with type 1 diabetes. Type 1 diabetes prevalence is rapidly increasing in juveniles and self-management and dysphoria are also major issues in this cohort (WHO, 2011b). Targeting issues in the younger population can strengthen self-management efficacy and emotional coping skills before problems arise. Potential for working on child-parent collaborations by including a shared interface with the parent is a possibility.

Overall, suggestions for future directions related to this research are overflowing, with many exciting potentials to build upon the experiences and findings of this PhD project.

7.10 Concluding Remarks

Overall, this research project has resulted in the fulfilment of its overarching objective to develop and trial a unique, web-based type 2 diabetes self-management and dysphoria intervention. Results from Paper 1 informed the potential for behavioural diabetes self-management intervention using telehealth methods. Paper 2 informed the basis for web-based program development. Patients' struggles with managing type 2 diabetes and strategies for effective self-care and coping were uncovered. Paper 3 has provided scope regarding the processes used to develop and implement OnTrack Diabetes. This paper may be used to establish protocols, and/ or as a basis for research design improvement. Paper 4 outlined processes involved in creating a web-based support program. Finally, Paper 5 presented preliminary results of the pilot trial of OnTrack Diabetes. Results indicate that users are satisfied with the program and gave it moderate to high evaluation ratings. However, user engagement and restricted sample size presented limitations. Scope has been provided to enhance the efficacy of OnTrack Diabetes in the upcoming main randomised controlled trial. Overall, this research project has been successful in crossing previously unchartered territories regarding type 2 diabetes self-management and dysphoria intervention and, in doing so, has paved the way for future developments.

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Appendix A

Queensland University of Technology
Brisbane Australia

PARTICIPANT INFORMATION for QUT RESEARCH PROJECT

Exploration of the Impact of Type 2 Diabetes on Self-Care Towards Development of An Innovative Online Support Program

Research Team Contacts	
Ms Mandy Cassimatis – Student	Professor David Kavanagh – Supervisor
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Description

This project is being undertaken as part of a postgraduate research project for Mandy Cassimatis. The project is funded by Queensland University of Technology. The source of all information obtained during the project will remain confidential.

The purpose of this project is to explore the experiences of people who are living with Type 2 diabetes in terms of their participation in physical activity, nutrition and medication-taking and experience with emotional challenges.

The research team requests your assistance as a representative of those in the population group of interest.

Participation

Your participation in this project is voluntary. If you do agree to participate, you can withdraw from participation at any time during the project without comment or penalty. Your decision to participate will in no way impact upon your current or future relationship with QUT or with any other external body. Furthermore, the details of your participation including the results obtained or your withdrawal from the project at any stage remain confidential.

Please note that you may withdraw from participating at any time before, during, or directly after the interview. However, due to the anonymous coding of information for confidentiality purposes thereafter, you may not withdraw information which was procured during the study at a later stage.

Your participation will involve an initial session which includes a 30 – 40-minute interview with the researcher in which you will be asked questions relating to your experience of living with Type 2 diabetes and your participation in relevant self-care behaviors, including physical activity, nutrition, and medication-taking as well as the impact of any emotional challenges.

Interviews will take place in a quiet room at either the Wesley Research Institute, located at the Wesley Hospital, Brisbane, or in the IHBI building at QUT Kelvin Grove. You will further have the opportunity to provide your opinions on the inclusion of particular components for an internet program which will be designed based on information obtained from interviews conducted in this preliminary research. You will be reimbursed for any parking and/ or travel costs associated with your participation in the project.

Expected benefits

This project is expected to provide you with the opportunity to share your experiences of living with type 2 diabetes so that this can be used to develop a unique and effective form of support for people in their day-to-day diabetes management.

Risks

There is a chance that participants may experience some discomfort discussing issues relating to their diabetes management. Please see the questions that are provided with this form to see if you are likely to experience this and if so, you may wish not to take part or to inform the researcher at any stage of the interview that you would not like to continue participating.

All participants will be provided with links to resources for emotional support which can be accessed by telephone or online. In the event that you experience psychological distress as a result of your participation in the study, QUT offers independent counselling services.

QUT provides limited free counseling for research participants of QUT projects, who may experience some distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on 3138 0999. Please indicate to the receptionist that you are a research participant.

Confidentiality

Whilst your name is required for the purpose of the interview appointment, data obtained will be coded using an anonymous identification number following your participation. All information provided will remain strictly confidential. Following the study, all data will be filed in a highly secure archive at QUT facilities.

Consent to Participate

We would like to ask you to sign a written consent form (provided by the researcher) to confirm your agreement to participate. Alternatively, you may indicate your wish to participate via telephone or e-mail, in which case a verbal or alternative written consent mechanism will be used.

Questions / further information about the project

Please contact the research team members named above to have any questions answered or if you require further information about the project.

Concerns / complaints regarding the conduct of the project

QUT is committed to researcher integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Unit on 3138 5123 or ethicscontact@qut.edu.au. The Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep this sheet for your information.

Queensland University of Technology Brisbane Australia	**CONSENT FORM for QUT RESEARCH PROJECT**

Exploration of the Impact of Type 2 Diabetes on Self-Care Towards Development of An Innovative Online Support Program

Research Team Contacts	
Ms Mandy Cassimatis – Student	Professor David Kavanagh – Supervisor
Phone: 0488 666 760	Phone: 3184 6143
E-mail: m1.cassimatis@qut.edu.au	E-mail: david.kavanagh@qut.edu.au

Statement of consent

By signing below, you are indicating that you:

- have read and understood the information document regarding this project
- have had any questions answered to your satisfaction
- understand that if you have any additional questions you can contact the research team
- understand that you are free to withdraw at any time, without comment or penalty
- understand that you can contact the Research Ethics Unit on 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project
- agree to participate in the project

Name ____

Signature ____

Date ______________________

Please return this sheet to the investigator.

QUT Queensland University of Technology Brisbane Australia

PARTICIPANT INFORMATION for QUT RESEARCH PROJECT

Exploration of the Impact of Type 2 Diabetes on Self-Care Towards Development of An Innovative Online Support Program

Research Team Contacts	
Ms Mandy Cassimatis – Student	Professor David Kavanagh – Supervisor
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E-mail: m1.cassimatis@qut.edu.au	E-mail: david.kavanagh@qut.edu.au

Description

This project is being undertaken as part of a postgraduate research project for Mandy Cassimatis. The project is funded by Queensland University of Technology. The source of all information obtained during the project will remain confidential.

The purpose of this study is to explore the views of General Practitioners who treat patients with Type 2 diabetes, particularly in terms of the helpful factors and challenges involved in meeting self-management targets and the impact of emotional challenges.

The research team requests your assistance as a representative of those in the population group of interest.

Participation

Your participation in this project is voluntary. If you do agree to participate, you can withdraw from participation at any time during the project without comment or penalty. Your decision to participate will in no way impact upon your current or future relationship with QUT or with any other external body. Furthermore, the details of your participation including the results obtained or your withdrawal from the project at any stage remain confidential.

Please note that you may withdraw from participating at any time before, during or directly after the interview. However, due to the anonymous coding of information for confidentiality purposes, you may not withdraw information which was procured during the study at a later stage.

Your participation will involve an initial session which includes a 10 – 15 minute interview with the researcher in which you will be asked questions relating to patients living with Type 2 diabetes and common enablers of and barriers to meeting recommended self-management targets. In particular, the areas of physical activity, nutrition, and medication-taking and the impact of emotional challenges will be addressed. Further, you will be asked to provide your professional opinion on component areas for inclusion in an online support program.

Interviews will take place at a time of greatest convenience to you. An appointment will be arranged whereby the interviewer will attend the General Practice in which you work. Alternatively, arrangements can be made to conduct the interview in a private interview room at the Wesley Research Institute, Auchenflower, or in the IHBI building at QUT

Kelvin Grove. You will be reimbursed for any parking and/ or travel costs associated with your participation in the project.

Expected benefits

This project is expected to provide you with the opportunity to indicate your experiences of the issues faced by patients living with Type 2 diabetes so that this can be used to develop a unique and effective form of support for people in their day-to-day Type 2 diabetes self-management.

Risks

You are highly unlikely to experience discomfort as a result of your participation in the interview. However, if you wish not to take part at any stage, please inform the researcher and the interview will be ceased.

QUT provides limited free counseling for research participants of QUT projects, who may experience some distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on 3138 0999. Please indicate to the receptionist that you are a research participant.

Confidentiality

Whilst your name is required for the purpose of the interview appointment, data obtained will be coded using an anonymous identification number following your participation. All information provided will remain strictly confidential. Following the study, all data will be filed in a highly secure archive at QUT facilities.

Consent to Participate

We would like to ask you to sign a written consent form (provided by the researcher) to confirm your agreement to participate. Alternatively, you may indicate your wish to participate via telephone or e-mail, in which case a verbal or alternative written consent mechanism will be used.

Questions / further information about the project

Please contact the research team members named above to have any questions answered or if you require further information about the project.

Concerns / complaints regarding the conduct of the project

QUT is committed to researcher integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Unit on 3138 5123 or ethicscontact@qut.edu.au. The Research Ethics Unit is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep this sheet for your information.

<u>*Study 1a*. Qualitative Interview for Participants</u>

1. What things are helpful in supporting you to manage your diabetes?

   (*Unless clarified already*)... What makes this helpful?

2. *Many people find that there are ups-and-downs in controlling their diabetes.*

   What things make it particularly challenging for you to follow your treatment plan, or keep your diabetes well-controlled?

   (*Unless clarified already*) In what way is that challenging?

3. Are there any particular times when it is easiest to be physically active and eat healthy foods?

   a. What kinds of things make it difficult to do these things?

4. In your experience, what has been most emotionally challenging about having diabetes?

5. *We are currently developing an online program to support diabetes self-management, to complement usual health care.*

   What things do you think we should include in an online program to support people like yourself to manage diabetes?

6. Under what circumstances would you use an online program on diabetes?

   a. Are there any (other) program features that would give you greater confidence in using it?

Demographics Survey

This survey provides us with some details about the sample of people who are taking part in the interviews. Please do not write your name on this form as all information provided here and in the interview will be coded so that it is anonymous.

1. **Age**: _______ years

2. **Occupation**: ___________________

3. **Relationship status**: ☐ Single ☐ Married ☐ In a relationship

4. **Time period since Type 2 diabetes diagnosis**: _________________

5. **Current treatment regimen**:

☐ Diet & exercise only (no medication)

☐ + Tablets for diabetes (e.g. Metformin, Diabex, Januvia...)

☐ + Insulin

6. **Which health professional/s do you consult for your diabetes management?**

☐ General Practitioner

☐ Endocrinologist

☐ Allied health professional/s (e.g. Dietitian, diabetes educator...)

Please list ____

____

7. **Do you receive any additional form/s of regular support for your diabetes management?** (e.g. diabetes support group, counselling...)
If so, please list.

____
____
____

8. **On average, my diabetes control in the past 6 months has been:**

☐ Excellent ☐ Good ☐ Fairly stable ☐ Fairly unstable ☐ Mostly unstable

Kessler-10 Scale

1. In the past 30 days, about how often did you feel tired out for no good reason?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

2. In the past 30 days, about how often did you feel nervous?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

3. Do not answer this question if you answered “none of the time” to question 2.

In the past 30 days, about how often did you feel so nervous that nothing could calm you down?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

4. In the past 30 days, about how often did you feel hopeless?

- None of the time

- A little of the time
- Some of the time
- Most of the time
- All of the time

5. In the past 30 days, about how often did you feel restless or fidgety?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

6. Do not answer this question if you answered "none of the time" to question 5. In the past 30 days, about how often did you feel so restless you could not sit still?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

7. In the past 30 days, about how often did you feel depressed?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

8. In the past 30 days, about how often did you feel that everything was an effort?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

9. In the past 30 days, about how often did you feel so sad that nothing could cheer you up?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

10. In the past 30 days, about how often did you feel worthless?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time

Thank you

Pre-Interview Script

Thank you for coming in today to take part in an interview. First, I'll provide you with an Informed Consent form. This contains details about the study and the rules and regulations related to conducting research at QUT. Anything discussed in the interview today is strictly confidential and you will remain anonymous.

If you don't wish to proceed with taking part at any stage at all, it is perfectly ok. Even if it's just before or during the interview, just let me know, ok?

[Provide PIS and allow to sign]

There is a quick, one-page survey to complete. This is so that we have some details about who is taking part in the research. This information will also be confidential. It's just so that we can describe our sample of participants in writing up the study.

[Provide Demographics Survey, & allow to complete]

While we call it an interview, this is really a discussion about your own experience with managing Type 2 diabetes. I will ask you some questions to guide the discussion, but please feel free to give answers that are as detailed as you like. If I ask you anything which you would prefer not to discuss, then please let me know and we can either move onto the next question or stop the interview. If you'd like a short break at any stage, please let me know.

[RECORDER]

I am recording the interviews so that information can be transcribed from them. So, if you don't mind, I'll just press record now. I actually become a little audio-shy, so it's probably best to forget that the recorder is in the room.

[Press RECORD]

Begin interview

Queensland University of Technology Brisbane Australia	CONSENT FORM for QUT RESEARCH PROJECT

Exploration of the Impact of Type 2 Diabetes on Self-Care Towards Development of An Innovative Online Support Program

Research Team Contacts	
Ms Mandy Cassimatis – Student	Professor David Kavanagh – Supervisor
Phone: 0488 666 760	Phone: 3184 6143
E-mail: m1.cassimatis@qut.edu.au	E-mail: david.kavanagh@qut.edu.au

Statement of consent

By signing below, you are indicating that you:

- have read and understood the information document regarding this project
- have had any questions answered to your satisfaction
- understand that if you have any additional questions you can contact the research team
- understand that you are free to withdraw at any time, without comment or penalty
- understand that you can contact the Research Ethics Unit on 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project
- agree to participate in the project

Name ____________________________________

Signature ____________________________________

Date ____________________

Please return this sheet to the investigator.

Study 1b. Qualitative Interview for General Practioners

1. What things do your patients find helpful in supporting them to manage to their diabetes?

2. What things make it particularly challenging for your patients to follow their treatment plan, or keep their diabetes well-controlled?

3. In your experience, what do patients most commonly find emotionally challenging about having diabetes?

4. Are there any particular times when you think patients tend to find it easiest to be physically active and eat healthy foods?

a. What major barriers do you associate with making these things difficult?

5. *We are currently developing an online program to support diabetes self-management to complement usual health care.*

What things do you think we should include in an online program to support people to manage diabetes?

6. Under what circumstances would you refer patients to an online program on diabetes?

a. Are there any (other) program features that would give you greater confidence in referring patients to the program?

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PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

Online Type 2 Diabetes Trial

Evaluation of OnTrack Diabetes:

An Online Type 2 Diabetes Self-Care and Emotional Support Program

UnitingCare Queensland Approval Number Cassimatis9111

QUT Ethics Approval Number 1100000

RESEARCH TEAM

Lead Investigator:	Ms Mandy Cassimatis, Lead Investigator
Principal Investigator:	Prof David Kavanagh, Principal Investigator

DESCRIPTION

This project is undertaken as part of a PhD for Mandy Cassimatis.

The purpose of this project is to test the effectiveness of the OnTrack Diabetes program. This is an online program aimed to support people with Type 2 diabetes to improve their self-care and day-to-day stress/emotional coping. The project team is interested in finding out if people with Type 2 diabetes find the program useful, and whether it can help them with their diabetes management and mood. You don't need to have problems with your mood to take part. It's about seeing if the program helps anyone with Type 2 diabetes enjoy life to the full and have improved diabetes outcomes.

You are invited to participate in this project if you: have had Type 2 diabetes for at least 3 months, are aged 18-75 years, live in Australia, have regular access to a computer with the internet, are contactable by telephone, and have at least grade 5-level written English. Please contact the Lead Investigator by phone or e-mail (details below), who will go through some further criteria with you. Or, you can go online to see if you are eligible to participate using this link: *(Provide link to online screening tool)*

PARTICIPATION

Participation in this project is entirely voluntary. If you do agree to participate, you can withdraw from the project without comment or penalty. Your decision to participate or not participate will in no way affect your current or future relationship with the Queensland University of Technology or the Wesley Research Institute.

Participation involves receiving access to the OnTrack Diabetes program. As we are testing which parts of the program improve specific areas of diabetes and emotional outcomes, participants may receive access to some content for the first 3 months. Then, all participants have access to the full program for the next 3 months. Participants are given a secure username and password with which they can access the program from any computer or smartphone with the internet.

Participants are asked to complete study measures which include online surveys about Type 2 diabetes self-care and mood, and some interview questions by telephone about nutrition and physical activity. This is done at the start of participation and at 3, 6 and 12 months. Most measures are online and take approximately 1 hour to complete. The interview may take 30-45 minutes.

Participants' most recent glycosylated haemoglobin (HbA1c) result (if it was taken less than 4 weeks ago), weight, height and waist measurements, are requested. With their consent, we can get the HbA1c level from their doctor if this is easier. If it has been longer than 4 weeks since an HbA1c test was done, we ask that another test is taken so that the result is recent. Following this, the participant is given a secure username and password and can access the OnTrack Diabetes program. At 12 months, the research team contact participants to see how they are going after using the program, and ask them to undertake final measures which are the same as the ones they have done.

EXPECTED BENEFITS

It is expected that this project will benefit you by providing information and support for your Type 2 diabetes management and mood. The research team expects that you will enjoy taking part in the OnTrack Diabetes program and that it may be of benefit to your mood and assist you with your diabetes management. However, your participation in this project is part of testing the program, so we cannot be certain of these benefits.

RISKS

There are minimal risks associated with your participation in this project. These include the possibility that disclosing sensitive information about your Type 2 diabetes control/ mood may be uncomfortable for you. However, as most measures are undertaken online anonymously, we expect that there would be minimal, if any, impact. Participation remains anonymous throughout and following the trial, so participants can be assured that their privacy is maintained.

Should you wish to access additional support services for any discomfort or distress experienced during the trial, there will be information about relevant support services on the OnTrack Diabetes program site. You are also encouraged to contact the researcher to enquire about additional support services, if required.

QUT provides for limited free counselling for research participants of QUT projects who may experience discomfort or distress as a result of their participation in the research. Should you wish to access this service please contact the Clinic Receptionist of the QUT Psychology Clinic on (07) 3138 0999. Please indicate to the receptionist that you are a research participant.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially. Your information will be coded anonymously in the study's database so that there is no risk of your personal details being revealed to any person outside the research team. This database is only accessible by secure username and password by authorised research personnel. There is extremely minimal risk that privately disclosed information which you provide during the study could be accessed by unauthorised personnel.

The project is funded by the Wesley Research Institute (WRI). The WRI will not have access to the data obtained during the project.

Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

CONSENT TO PARTICIPATE

We would like to ask you to confirm your agreement to participate by either signing a written consent form provided by the researcher; online following online eligibility screening; or via a verbal consent mechanism. Due to the nature of the project, any of these methods are sufficient to obtain your consent to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If have any questions or require any further information about the project please contact one of the research team members below.

Mandy Cassimatis – Lead Investigator   Prof David Kavanagh – Principal Investigator

Wesley Research Institute

The Wesley Hospital, Brisbane

Phone (07) 3721 1703

Email m1.cassimatis@qut.edu.au

School of Psychology & Counselling, Faculty of Health

Institute of Biomedical Health and Innovation, QUT

Phone (07) 3138 6143

Email david.kavanagh@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

UnitingCare Queensland and QUT are committed to research integrity and the ethical conduct of research projects.

This research has received ethics approval from the UnitingCare Health Human Research Ethics Committee. However, in the case of any concerns that you have about your participation in this research or its conduct, please contact the UCQ HREC Coordinator, Ms Pat Patterson, on (07) 3025-2000 or email uc.ucare@ucareqld.com.au. Alternatively you may contact the QUT Research Ethics Unit on (07) 3138 5123 or email ethicscontact@qut.edu.au.

Uniting Care Queensland and QUT Research Ethics Unit are not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep this sheet for your information.

Queensland University of Technology

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UnitingCare Health

CONSENT FORM FOR QUT RESEARCH PROJECT

Online Type 2 Diabetes Trial

Evaluation of OnTrack Diabetes:

An Online Type 2 Diabetes Self-Care and Emotional Support Program

UnitingCare Queensland Approval Number Cassimatis9111

QUT Ethics Approval Number 1100000

RESEARCH TEAM CONTACTS

Mandy Cassimatis – Lead Investigator	Prof David Kavanagh – Principal Investigator
Wesley Research Institute	School of Psychology & Counselling, Faculty of Health
The Wesley Hospital, Brisbane	Institute of Biomedical Health and Innovation, QUT
Phone (07) 3721 1703	Phone (07) 3138 6143
Email m1.cassimatis@qut.edu.au	Email david.kavanagh@qut.edu.au

STATEMENT OF CONSENT

By signing below, you are indicating that you:

- have read and understood the information document regarding this project
- have had any questions answered to your satisfaction
- understand that if you have any additional questions you can contact the research team
- understand that you are free to withdraw at any time, without comment or penalty
- understand that you can contact either UCQ HREC Coordinator, Ms Pat Patterson, on (07) 3025-2000 or email uc.ucare@ucareqld.com.au or the Research Ethics Unit on (07) 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the project
- understand that non-identifiable data collected in this project may be used as comparative data in future projects
- agree to participate in the project

Name ____

Signature ____

Date ________________________

MEDIA RELEASE PROMOTIONS

From time to time, we may like to promote our research to the general public through, for example, newspaper articles. Would you be willing to be contacted by QUT Media and Communications for possible inclusion in such stories? By ticking this box, it only means you are choosing to be contacted – you can still decide at the time not to be involved in any promotions.

☐ Yes, you may contact me about inclusion in promotions

☐ No, I do not wish to be contacted about inclusion in promotions

Please return this sheet to the investigator.

Queensland University of Technology

UnitingCare Health

The Wesley Research Institute
Making a difference today

Authorised Consent to Release Pathology Result

[*Ethics approval ref: Cassimatis9111*]

As part of my pending/ current participation in the OnTrack Diabetes Project, I, _____NAME____ hereby consent to my doctor providing the project's researcher, Mandy Cassimatis, with my HbA1c pathology result.

I understand that this result will only be used for the purpose of this research, and that it is important to help determine the effects of the program. As such, I consent to the release of this result to the researcher under the condition that this information will remain confidential to those outside the research team. I acknowledge that, while at first this result will be identifiable as my own, once entered into the system, it will be anonymously coded.

Signature: ____________________________________ Date: __________________________

Doctor's name: _________________________

Contact details

Phone: _______________________

Fax: ________________________

[Please note that in the majority of circumstances, the participant will be e-mailed this form and given the option to provide oral consent for their convenience.]

The OnTrack Diabetes Survey

Today's Date ☐☐ / ☐☐ / ☐☐

Age ☐☐

Date of Birth ☐☐ / ☐☐ / ☐☐

Sex ◯ Male ◯ Female

What treatment are you currently receiving for Type 2 diabetes?

Diet only ◯

Tablets ◯

Insulin ◯

Insulin and tablets ◯

Other ◯

HbA1c Result (within past 4 weeks) ☐☐.☐☐ %

Waist and Hip

1.Waist (cm) ☐☐.☐ 2.Waist (cm) ☐☐.☐ 3.Waist (cm) ☐☐.☐

Hip (cm) ☐☐.☐ Hip (cm) ☐☐.☐ Hip (cm) ☐☐.☐

Height (cm) ☐☐.☐

Demographic Information

1. What is your highest level of education completed?
   - ☐ Never attended school
   - ☐ Primary school
   - ☐ Some high school
   - ☐ Completed high school (Yr 12 or equivalent)
   - ☐ University, TAFE etc
2. Are you of Aboriginal or Torres Strait Islander origin?
   - ☐ No
   - ☐ Aboriginal
   - ☐ Torres Strait Islander
   - ☐ Both
3. In which country were you born?
   - ☐ Overseas

☐Australia

4. What is your marital status?
   ☐Married
   ☐De facto
   ☐Separated
   ☐Divorced
   ☐Widowed
   ☐Never married

5. Which of the following best describes your household type?
   ☐Person living ALONE
   ☐Married or de facto couple ONLY
   ☐Married or de facto couple living with children
   ☐One person living with children
   ☐Shared household
   ☐All other households

6. What language do you usually speak in this household?
   ☐English
   ☐Italian
   ☐Greek
   ☐Cantonese
   ☐Mandarin
   ☐Other (specify) ________________

The following questions are about your health

7. Have you ever been told by a doctor or nurse that you have high blood pressure or hypertension?
   ☐Yes ☐ No ☐ Don't know

8. Are you currently taking tablets for high blood pressure?
   ☐Yes ☐ No ☐ Don't know

9. Have you ever been told by a doctor or other health professional that your blood cholesterol or triglycerides are high?
   ☐Yes ☐ No ☐ Don't know

The following questions are about drinking alcohol

10. In terms of drinking alcohol, which category would you generally put yourself in?
    ☐I have never drunk alcohol (Go to Question 16)

☐I used to drink but gave it up
☐I'm a heavy drinker
☐I'm a moderate drinker
☐I'm a light drinker

11. Have you ever felt that you should cut down on your drinking?
☐Yes ☐ No

12. Have people ever annoyed you by criticizing your drinking?
☐Yes ☐ No

13. Have you ever felt bad or guilty about drinking?
☐Yes ☐ No

14. Have you ever taken a drink first thing in the morning to steady your nerves or get rid of a hangover?
☐Yes ☐ No

15. Have you ever been treated for alcoholism or a drinking problem?
☐Yes ☐ No

The following questions are about smoking.

16. Do you currently smoke cigarettes, cigars, pipes or any other tobacco product?
☐Daily
☐At least weekly (not daily)
☐Less often than weekly
☐Not at all

17. Over your lifetime, would you have smoked at least 100 cigarettes or a similar amount of tobacco?
☐Yes (Go to Question 18) ☐No (Go to Question 21)

18. In the past, have you ever been a daily smoker?
☐Yes (Go to Question 19) ☐No (Go to Question 20)

19. Did you stop smoking in the last 5 years?
☐Yes (Go to Question 20) ☐No (Go to Question 21)

20. In what year did you stop smoking?
☐2005

☐2006
☐2007
☐2008
☐2009
☐2010
☐2011

The next questions are about income and employment

21. Which number best describes your total household income **before** tax?
☐$1 500 or more per week ($78 000 or more per year)
☐$800 - $1 499 per week ($41 600 - $77 999 per year)
☐$600 - $799 per week ($31 200 - $41 599 per year)
☐$400 - $599 per week ($20 800 - $31 199 per year)
☐$200 - $399 per week ($10 400 - $20 799 per year)
☐$80 - $199 per week ($4 160 - $10 399 per year)
☐$1 - $79 per week ($52 - $4 159 per year)
☐no income
☐I do not wish to answer this question

22. Are you the main income earner in your household?
☐Yes
☐No
☐Joint income earners
☐Don't know

23. Do you have a full time job or part time job of any kind?
☐Yes
☐No (Go to Question 36)

24. Which of the following categories best describes your areas of employment?
☐ **Managers and Administrators**
(Magistrate, Farm Manager, General Manager, Director of Nursing, School School Principal)
☐ **Professionals**
(Scientist, Doctor, Registered Nurse, Allied Health Professional, Teacher, Artist, Engineer, Accountant)
☐ **Associate Professionals**
(Technician, Manager, Youth Worker, Police Officer, Program Administrator)
☐ **Tradespersons and Related Workers**
(Hairdresser, Gardener, Florist, Mechanic, Machinist, Cook)
☐ **Clerical and Service Workers I**

(Secretary, Personal Assistant, Flight Attendant, Law Clerk)

☐ **Clerical, Sales and Service Workers II**
(Typist, Word Processing/ Data Entry Operator, Receptionist, Child Care Worker, Nursing Assistant, Hospitality Worker, Sales Clerk)

☐ **Clerical, Sales and Service Workers III**
(Filing/Mail Clerk, Parking Inspector, Sales Assistant, Telemarketer, Housekeeper)

☐ **Intermediate Production and Transport Workers**
(Sewing Machinist, Machine Operator, Bus Driver)

☐ **Labourers and Related Workers**
(Cleaner, Factory Worker, General Farm Hand, Fast Food Cook)

25. Which of the following describe your current employment status? You can pick more than one.
☐ Working full-time
☐ Working part-time
☐ Not working (but not retired)
☐ Home duties
☐ Full-time student
☐ Part-time student
☐ Retired
☐ Permanently unable to work/ ill
☐ Other

These questions are about your health.

26. In the last 12 months, how well do you think your diabetes has been controlled?
☐ Very well controlled
☐ Well controlled
☐ Average control
☐ Poorly controlled
☐ Very poorly controlled
☐ Very variable control
☐ Don’t know

27. In the last week how well do you think your diabetes has been controlled?
☐ Very well controlled
☐ Well controlled
☐ Average control
☐ Poorly controlled
☐ Very poorly controlled
☐ Very variable control
☐ Don’t know

28. Have you ever been shown how to test your blood sugar level?
    ☐ Yes ☐ No ☐ Don't know

29. Have you ever been shown how to test your urine for sugar?
    ☐ Yes ☐ No ☐ Don't know

30. What method do you mainly use for testing your own sugar level?
    ☐ Monitor glucose at the doctor's office only
    ☐ Blood glucose test strips read by eye at home
    ☐ Blood glucose test strips read by meter at home
    ☐ Urine glucose test strips at home
    ☐ None

31. Have you ever tested for sugar in either your blood or urine?
    ☐ Yes ☐ No

32. How often have you tested your sugar levels in the last month (4 weeks)?
    ☐ Never
    ☐ Once a week or less
    ☐ About 2 – 6 times a week
    ☐ Once a day
    ☐ 2 or more times a day

33. Do you write down your test results?
    (If you use a blood glucose meter, and check through the results but you do not write them down, answer how often you check through the meter memory).
    ☐ Never
    ☐ Occasionally
    ☐ Often
    ☐ Always

34. Which test do you use most often to monitor your diabetes?
    Answer one response only.
    ☐ Urine test for sugar (Go to Question 47)
    ☐ Blood test for sugar (Go to Question 48)

35. Over the past month your urine tests have been mostly:
    ☐ 0
    ☐ Trace

☐ +
☐ ++
☐ +++
☐ ++++
☐ Can’t recall

36. Over the past month your blood tests have been mostly:
☐ Less than 4
☐ 4 – 10 mmol/L
☐ 10 – 15 mmol/L
☐ 15 – 20 mmol/L
☐ Over 20 mmol/L
☐ Can’t recall

37. In the last month, approximately how many times have you experienced the symptoms of hypoglycaemia (low blood sugar)?

☐☐ times (write “0” if none)

38. Before this research trial, had you ever heard of glycosylated haemoglobin A1c (HbA1c) or haemoglobin “A one C”? This is often referred to as the “long term sugar test”.
☐ Yes ☐ No (Go to Q51) ☐ Don’t know (Go to Q51)

39. About how many times in the last year has a doctor, nurse or other health professional checked your haemoglobin “A one C”?
☐ None
☐ Once
☐ Twice
☐ Three or more times
☐ Don’t know

40. Have you ever been treated for or suffered from any of these conditions?

	Yes	No	Don’t know
Trouble with the back of your eyes or retinopathy	☐	☐	☐
Kidney disease	☐	☐	☐
Nerve damage	☐	☐	☐
Gangrene	☐	☐	☐
Heart disease (e.g. angina, heart attack)	☐	☐	☐
Stroke	☐	☐	☐
(Men) Impotence (difficulty getting or Sustaining an erection)	☐	☐	☐
Poor circulation to the feet or legs	☐	☐	☐

41. How many times have you ever been admitted to hospital because of any of the above conditions?
    - ☐ None
    - ☐ Once
    - ☐ 2 to 5 times
    - ☐ More than 5 times
    - ☐ I don't know
42. Have you ever been told by a doctor or nurse that you have any of the following conditions? If you answer 'yes' to any of these questions, write what age you were when you were first diagnosed with that condition in the box.

	Yes	No	Age of diagnosis
Asthma	☐	☐	☐☐
COPD, chronic bronchitis or emphysema	☐	☐	☐☐
Kidney disease or renal disease	☐	☐	☐☐
Angina, heart disease, a heart attack, an Irregular heart rhythm, missed heart beats, or a blocked artery in the heart	☐	☐	☐☐
Stroke or TIA ("mini stroke")	☐	☐	☐☐
Arthritis (including osteoarthritis, rheumatoid arthritis)	☐	☐	☐☐
Hypertension (High Blood Pressure)	☐	☐	☐☐
Osteoporosis	☐	☐	☐☐
Lung cancer	☐	☐	☐☐
Malignant Melanoma	☐	☐	☐☐
Prostate cancer	☐	☐	☐☐
Breast cancer	☐	☐	☐☐
Other types of cancer (malignancy)	☐	☐	☐☐
Alzheimer's disease	☐	☐	☐☐
Dementia	☐	☐	☐☐
Schizophrenia or psychosis	☐	☐	☐☐
Depression	☐	☐	☐☐
Bipolar disorder/ manic depression	☐	☐	☐☐
Anxiety disorder or Nervous Disorder (e.g. panic disorder or post-traumatic stress disorder)	☐	☐	☐☐
Substance use disorder (abuse of or dependence on alcohol or other drugs)	☐	☐	☐☐

43. Have you ever had a foot ulcer (defined as – full thickness skin breaks below the malleoli for more than 1 week)?

☐Yes ☐ No ☐ Don't know

44. If yes, what was the cause (e.g. shoes)?

    ____

45. How long ago did you have the ulcer?
    ☐ In the last month
    ☐ In the last year
    ☐ In the last 3 years
    ☐ More than 3 years ago

46. Do you get any pain or discomfort in your legs or feet?
    ☐Yes ☐ No ☐ Don't know

    If no, go on to Question 66.

47. How would you describe the pain or discomfort? (Mark all types of pain)
    ☐ Burning/ numb/ tingling
    ☐ Aching/ cramp-like/ tired
    ☐ Other

48. When is the pain the worst?
    ☐ During the night
    ☐ Day and night the same
    ☐ During the day

49. Does the pain ever wake you at night?
    ☐Yes ☐ No

50. Do any of the following help or reduce the pain?
    ☐Walking
    ☐ Standing
    ☐ Sitting down or lying down
    ☐ Other (including medication)

51. Where do you get this pain or discomfort? (Click on the box which says the most painful site).
    ☐ Feet
    ☐ Knee to ankle
    ☐ Anywhere else

52. Do you ever get a pain or discomfort in your leg(s) when you walk?

☐ Yes
☐ No (Go to Question 67)
☐ I am unable to walk

53. Does this pain ever begin when you are standing still or sitting?
☐Yes ☐ No ☐ Don't know

54. Do you get this pain if you walk uphill or hurry?
☐Yes ☐ No ☐ Don't know

55. What happens to this pain if you stand still?
☐ Usually continues for more than 10 minutes
☐ Usually disappears in 10 minutes or less

56. Is a foot ulcer present?
☐Yes ☐ No

57. If yes, where is the ulcer located? ____

58. The normal range for blood glucose is:
☐ 4 – 8 mmol/L
☐ 7 – 15 mmol/L
☐ 2 – 10 mmol/L

[SF-12 items]

These questions are about how you feel and how well you are able to do your usual activities. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:
☐Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling or playing golf:
☐ Yes, Limited A Lot

☐ Yes, Limited A Little
☐ No, Not Limited At All

3. Climbing SEVERAL flights of stairs:
   ☐ Yes, Limited A Lot
   ☐ Yes, Limited A Little
   ☐ No, Not Limited At All

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
   ☐Yes ☐ No

5. Were limited in the KIND of work or other activities:
   ☐Yes ☐ No

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS such as feeling depressed or anxious?

6. ACCOMPLISED LESS than you would like:
   ☐Yes ☐ No

7. Didn't do work or other activities as CAREFULLY as usual:
   ☐Yes ☐ No
8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work including both work outside the home and housework?
   ☐ All of the Time
   ☐ Most of the Time
   ☐ A Good Bit of the Time
   ☐ Some of the Time
   ☐ A Little of the Time
   ☐ None of the Time

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
   ☐ All of the Time
   ☐ Most of the Time
   ☐ A Good Bit of the Time
   ☐ Some of the Time

☐ A Little of the Time
☐ None of the Time

10. Did you have a lot of energy?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

11. Have you felt downhearted and blue?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc)?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

[EQ-5D items]

Under each heading, please check the box that best describes your health TODAY

1. Mobility
   ☐ I have no problems walking around
   ☐ I have slight problems walking around
   ☐ I have moderate problems walking around
   ☐ I have severe problems walking around
   ☐ I am unable to walk around

2. Self-Care
   ☐ I have no problems washing or dressing myself
   ☐ I have slight problems washing or dressing myself

☐ I have moderate problems washing or dressing myself
☐ I have severe problems washing or dressing myself
☐ I am unable to wash or dress myself

3. Usual Activities (e.g. work, study, housework, family or leisure activities)
   ☐ I have no problems doing my usual activities
   ☐ I have slight problems doing my usual activities
   ☐ I have moderate problems doing my usual activities
   ☐ I have severe problems doing my usual activities
   ☐ I am unable to do my usual activities

4. Pain/ Discomfort
   ☐ I have no pain or discomfort
   ☐ I have slight pain or discomfort
   ☐ I have moderate pain or discomfort
   ☐ I have severe pain or discomfort
   ☐ I have extreme pain or discomfort

5. Anxiety/ Depression
   ☐ I am not anxious or depressed
   ☐ I am slightly anxious or depressed
   ☐ I am moderately anxious or depressed
   ☐ I am severely anxious or depressed
   ☐ I am extremely anxious or depressed

[Diabetes Self-Care]

These questions are designed to find out about how you have managed your diabetes over the last 7 days. If you were sick during the last 7 days, please think back to the last 7 days you were not sick.

1. On how many of the last 7 days did you eat 5 or more servings of fruit and vegetables?
   ☐ 0
   ☐ 1
   ☐ 2
   ☐ 3
   ☐ 4
   ☐ 5
   ☐ 6
   ☐ 7

2. How many days during the past week did you eat high-fat foods, such as full-fat

   dairy products, full-fat pastries or other desserts?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

3. How many days during the past week did you participate in at least 30 minutes total (one session, or several smaller sessions) of physical activity?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

4. On how many of the last 7 days did you test your blood sugar?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

5. On how many of the last 7 days did you check your feet?

- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7

[Medication Adherence]

1. Do you ever forget to take your diabetes medicine?
☐Yes ☐ No

2. Are you careless at times about taking your diabetes medicine?
☐Yes ☐ No

3. When you feel better, do you sometimes stop taking your diabetes medicine?
☐Yes ☐ No

4. Sometimes, if you feel worse when you take the diabetes medicine, do you stop taking it?
☐Yes ☐ No

[Diabetes Distress Scale-17]

Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problems that people with diabetes may experience. Consider the degree to which each of the items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking to indicate the degree to which each item may be bothering you in your life NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would click on the box "1". If it is very bothersome to you, you might click on "6".

Problem	Not a Problem		Moderate Problem		Serious Problem	
	1	2	3	4	5	6
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	☐	☐	☐	☐	☐	☐
2. Feeling angry, scared and/or depressed when I think about living with diabetes.	☐	☐	☐	☐	☐	☐
3. Feeling that diabetes controls my life.	☐	☐	☐	☐	☐	☐
4. Feeling that I will end up with serious long-term	☐	☐	☐	☐	☐	☐

complications, no matter what I do.

5. Feeling overwhelmed by the demands of living with diabetes. ☐ ☐ ☐ ☐ ☐ ☐

6. Feeling that friends or family are not supportive enough of my self-care efforts (eg planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods). ☐ ☐ ☐ ☐ ☐ ☐

7. Feeling that friends or family don't appreciate how difficult living with diabetes can be. ☐ ☐ ☐ ☐ ☐ ☐

8. Feeling that friends or family don't give me the emotional support that I would like. ☐ ☐ ☐ ☐ ☐ ☐

[Self-efficacy for overcoming depression/negative thoughts. Kavanagh et al., 1993]

These scales are about your ability to make your time enjoyable and satisfying and control unpleasant thoughts. We want to know what you can do without any professional help, so please imagine you are not coming to us when you make your ratings.

Moderately enjoyable time

Look at the first scale below. Over the next 12 months, can you make a total of 30 minutes each day at least moderately enjoyable?

1. Rate the **percentage of occasions** that you followed your blood glucose testing as recommended (e.g. by your Doctor or Diabetes Educator) **over the past 8 weeks**.

0 ———————————————————————— **100**

10 20 30 40 50 60 70 80 90

Not at all **Moderately** **Totally**

2. Rate **how many days each week**, on average, that you followed your recommended eating plan **over the past 8 weeks**.

0 ———————————————————————— **7**

½ 1 2 3 4 5 6

Number of days I followed my eating plan

3. Rate the **percentage of occasions** that you followed your exercise program **over the past 8 weeks**.

0 ——————————————————————— **100**

10 20 30 40 50 60 70 80 90

Not at all **Moderately** **Totally**

The next questions are about **<u>how confident</u>** you are in doing certain activities. For each of the following questions, please slide the rating scale to the number which corresponds with your confidence that you can do the tasks as recommended, **over the <u>next</u> 8 weeks**.

1. Rate the **percentage of occasions** that you feel confident that you can test your blood glucose level as recommended (e.g. by your Doctor or Diabetes Educator) **over the next 8 weeks**.

0 ——————————————————————— **100**

10 20 30 40 50 60 70 80 90

Can't do it **Moderately certain can do it** **Certain can do it**

2. Rate **how many days each week** you feel confident that you can follow your recommended diet **over the next 8 weeks**.

0 ——————————————————————— **7**

½ 1 2 3 4 5 6

Number of days I can do it

3. Rate the **percentage of occasions** you feel confident that you can follow your exercise program **over the next 8 weeks**.

0 ——————————————————————— **100**

10 20 30 40 50 60 70 80 90

Can't do it **Moderately certain can do it** **Certain can do it**

[DASS-21]

Please read each statement and click on the box for the number 0, 1, 2, or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

1. I found myself getting upset by quite trivial things
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

2. I was aware of dryness of my mouth
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

3. I couldn't seem to experience any positive feeling at all
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

4. I experienced breathing difficulty (eg. excessively rapid breathing, breathlessness in the absence of physical exertion)
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

5. I just couldn't seem to get going
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

6. I tended to over-react to situations
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

7. I had a feeling of shakiness (eg. legs going to give way)
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time

☐ 3 Applied to me very much, or most of the time

8. I found it difficult to relax
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

9. I found myself in situations that made me so anxious I was most relieved when they ended
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

10. I felt that I had nothing to look forward to
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

11. I found myself getting upset rather easily
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

12. I felt that I was using a lot of nervous energy
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

13. I felt sad and depressed
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

14. I found myself getting impatient when I was delayed in any way (eg. lifts, traffic lights, being kept waiting)
   ☐ 0 Did not apply to me at all

☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

15. I had a feeling of faintness
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

16. I felt that I had lost interest in just about everything
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

17. I felt I wasn’t worth much as a person
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

18. I felt that I was rather touchy
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

19. I perspired noticeably (eg. hands sweaty) in the absence of high temperatures or physical exertion
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

20. I felt scared without any good reason
   ☐ 0 Did not apply to me at all
   ☐ 1 Applied to me to some degree, or some of the time
   ☐ 2 Applied to me to a considerable degree, or a good part of time
   ☐ 3 Applied to me very much, or most of the time

21. I felt that life wasn't worthwhile
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time
    [Health Service Utilisation]

The following questions relate to your use of a variety of health services **over the past 6 months**.

1. Have you visited a doctor (General Practitioner) in the last 6 months?
   ☐ Yes ☐ No

   If yes, please complete the table below for each doctor you have visited ***over the last 6 months****. If you do not know the exact date of your appointment, please provide an estimate of the number of appointments over the last 6 months.*

Doctor	Practice	Suburb	Appointment date/s (or number of appointments)	Cost for each visit*
Dr. Brown	***Kelpie Medical Centre***	***Ipswich***	***07/05/2011***	***$60***

*This is how much it cost you out of pocket. If you were bulk-billed, you would write '$0' OR Please write how much you payed and the cost covered by your health insurance.

2. Have you had an appointment with any other health professionals over the past 6 months?

   This does not include health professionals you have seen while you have been admitted to hospital, but does include health professionals you have had an appointment with at the hospital as an outpatient.

   Examples of health professionals include specialists such as a cardiologist or an endocrinologist, a dietician, a physiotherapist, a counsellor/psychologist, a diabetes educator, etc.

☐ Yes ☐ No (Go to Question xx)

If yes, please complete the table below for each health professional you have visited over the past 6 months (remembering that this ***does not*** *include any health professionals you may have seen while you were admitted to hospital). If you do not know the exact date of your appointment, please provide an estimate or the number of appointments over the last 6 months.*

Type of health professional	Appointment date/s **(or number of appointments)**	Cost for each visit*
Examples: *Endocrinologist*	*05/01/2011, 10/06/2011*	
Dietician	*5 appointments – 01/02/2011 to 05/06/2011*	

*This is how much it cost you out of pocket. If you were bulk-billed, you would write '$0' OR Please write how much you payed and the cost covered by your health insurance.

3. Have you been admitted to hospital during the last 6 months?

   ☐ Yes ☐ No

   If yes, please provide details in the table below. If you do not know the exact date of submission, please provide an estimate or the number of admissions over the last 6 months.

Hospital	Date of admission/s (or number of admissions)	Cost
Example: Wesley Hospital	*02/04/2011 and 08/06/2011*	

*This is how much it cost you out of pocket. If you were bulk-billed, you would write '$0' OR Please write how much you payed and the cost covered by your health insurance.

4. Other hospital utilisation

   Have you utilised any other hospital service over the past 6 months other than hospital based specialists (such as a cardiologist) or hospital admissions?

   ☐ Yes ☐ No (Go to Section x)

   If yes, please provide details in the table below. If you do not know the exact date you accessed the service, please provide an estimate or the number of times you accessed the service over the last 6 months.

Hospital service	Name of hospital	Date service accessed **(or number of times accessed)**	Cost for this service
Emergency clinic			
Day procedure at a hospital that did not involve admission, e.g. angioplasty			
Cardiac rehabilitation program			
Others?			

*This is how much it cost you out of pocket. If you were bulk-billed, you would write '$0' OR Please write how much you payed and the cost covered by your health insurance.

5. How much time did you take off work due to your health (e.g. feeling sick, having a medical procedure done, unable to work), over the past 6 months?

   ☐ weeks ☐ days ☐ hours

6. Have you been on any medications over the past 6 months which were prescribed by your doctor?

   ☐ Yes ☐ No

If yes, please write the brand names of medications, strength (e.g. milligrams, grams, or millilitres), and how much you take of this medication each day in the table below.

1. Brand name of medication	2. Unit strength as shown on the pack (e.g. milligrams, grams, millilitres)	3. Amount taken each day (e.g. 2 tablets, 2 times a day)
Example: Coversyl	*5 mg*	*1 tablet, 2 times/day*

The OnTrack Diabetes

3-month Follow-up Survey

2.0

Today's Date ☐☐ / ☐☐ / ☐☐

Section 1. *My Details*

Age ☐☐ Date of Birth ☐☐ / ☐☐ / ☐☐

Sex ◯ Male ◯ Female

What treatment are you currently receiving for Type 2 diabetes?

Diet only ◯

Tablets ◯

Insulin ◯

Insulin and tablets ◯

Other ◯

HbA1c Result (within past 4 weeks) ☐☐.☐☐ %

Waist and Hip

1. Waist (cm) ☐☐.☐ 2. Waist (cm) ☐☐.☐ 3.Waist (cm) ☐☐ ☐
   .

   Weight (kg) ☐☐.☐

Section 2. *My Health*

1. Have you ever been told by a doctor or nurse that you have any of the following conditions? If you answer 'yes' to any of these questions, write what age you were when you were first diagnosed with that condition in the box.

	Yes	Age of diagnosis	No	
Don't know				
Asthma	☐	☐☐	☐	☐
COPD, chronic bronchitis or emphysema	☐	☐☐	☐	☐
Kidney disease or renal disease	☐	☐☐	☐	☐
Angina, heart disease, a heart attack, an				

irregular heart rhythm, missed heart beats, or a blocked artery in the heart	☐	☐☐	☐	☐
Stroke or TIA ("mini stroke")	☐	☐☐	☐	☐
Arthritis (including osteoarthritis, rheumatoid arthritis)	☐	☐☐	☐	☐
Hypertension (High Blood Pressure)	☐	☐☐	☐	☐
Osteoporosis	☐	☐☐	☐	☐
Malignant Melanoma	☐	☐☐	☐	☐
Prostate cancer	☐	☐☐	☐	☐
Breast cancer	☐	☐☐	☐	☐
Other types of cancer (malignancy)	☐	☐☐	☐	☐
Depression	☐	☐☐	☐	☐
Anxiety disorder or Nervous Disorder (e.g. panic disorder or post-traumatic stress disorder)	☐	☐☐ ☐☐	☐ ☐	☐ ☐
Substance use disorder (abuse of or dependence on alcohol or other drugs)	☐	☐☐	☐	☐
Trouble with the back of your eyes or retinopathy	☐	☐☐	☐	☐
Nerve damage	☐	☐☐	☐	☐
Gangrene	☐	☐☐	☐	☐
Men: Impotence (difficulty getting or sustaining an erection)	☐	☐☐	☐	☐
Poor circulation to the feet or legs	☐	☐☐	☐	☐

2. How many times have you ever been admitted to hospital because of any of the above conditions?
   ☐ None
   ☐ Once
   ☐ 2 to 5 times
   ☐ More than 5 times
   ☐ I don't know

Alcohol

3. In terms of drinking alcohol, which category would you generally put yourself in?
   ☐I have never drunk alcohol (Go to Question 6)
   ☐I used to drink but gave it up
   ☐I'm a heavy drinker
   ☐I'm a moderate drinker
   ☐I'm a light drinker

4. Have you ever felt that you should cut down on your drinking?
   ☐Yes ☐ No

5. Have you ever felt bad or guilty about drinking?
   ☐Yes ☐ No

6. Have you ever been treated for alcoholism or a drinking problem?
   ☐Yes ☐ No

Smoking

7. Do you currently smoke cigarettes, cigars, pipes or any other tobacco product?
   ☐Daily
   ☐At least weekly (not daily)
   ☐Less often than weekly
   ☐Not at all

8. Over your lifetime, would you have smoked at least 100 cigarettes or a similar amount of tobacco?
   ☐Yes (Go to Question 18) ☐No (Go to Question 5)

9. In the past, have you ever been a daily smoker?
   ☐Yes (Go to Question 19) ☐No (Go to Question 20)

10. Did you stop smoking in the last 5 years?
    ☐Yes (Go to Question 20) ☐No (Go to)

11. In what year did you stop smoking?
    ☐2005
    ☐2006
    ☐2007
    ☐2008
    ☐2009
    ☐2010
    ☐2011
    ☐2012

Type 2 Diabetes

12. In the **last 3 months**, how well do you think your diabetes has been controlled?
    ☐ Very well controlled
    ☐ Well controlled
    ☐ Average control

☐ Poorly controlled
☐ Very poorly controlled
☐ Very variable control
☐ Don't know

13. In the **last week** how well do you think your diabetes has been controlled?
    ☐ Very well controlled
    ☐ Well controlled
    ☐ Average control
    ☐ Poorly controlled
    ☐ Very poorly controlled
    ☐ Very variable control
    ☐ Don't know

14. What method do you mainly use for testing your own sugar level?
    ☐ Monitor glucose at the doctor's office only
    ☐ Blood glucose test strips read by eye at home
    ☐ Blood glucose test strips read by meter at home
    ☐ Urine glucose test strips at home
    ☐ None

15. How often have you tested your sugar levels in the **last month (4 weeks)**?
    ☐ Never
    ☐ Once a week or less
    ☐ About 2 – 6 times a week
    ☐ Once a day
    ☐ 2 or more times a day

16. Do you write down your test results?
    (If you use a blood glucose meter, and check through the results but you do not write them down, answer how often you check through the meter memory).
    ☐ Never
    ☐ Occasionally
    ☐ Often
    ☐ Always

17. Over the past month your urine tests have been mostly:
    ☐ 0
    ☐ Trace
    ☐ +
    ☐ ++

☐ +++
☐ ++++
☐ Can't recall

18. Over the past month your blood glucose tests have been mostly:
☐ Less than 4
☐ 4 – 10 mmol/L
☐ 10 – 15 mmol/L
☐ 15 – 20 mmol/L
☐ Over 20 mmol/L
☐ Can't recall

Mobility

[SF-12 items]

These questions are about how you feel and how well you are able to do your usual activities. If you are unsure about how to answer a question, please check the box which describes the best answer you can give.

2. In general, would you say your health is:
☐Excellent
☐ Very good
☐ Good
☐ Fair
☐ Poor

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

13. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling or playing golf:
☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

14. Climbing SEVERAL flights of stairs:
☐ Yes, Limited A Lot
☐ Yes, Limited A Little
☐ No, Not Limited At All

During the **PAST 4 WEEKS** have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

15. ACCOMPLISHED LESS than you would like:
    ☐Yes ☐ No

16. Were limited in the KIND of work or other activities:
    ☐Yes ☐ No

During the **PAST 4 WEEKS**, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS such as feeling depressed or anxious?

17. ACCOMPLISED LESS than you would like:
    ☐Yes ☐ No

18. Didn't do work or other activities as CAREFULLY as usual:
    ☐Yes ☐ No

19. During the **PAST 4 WEEKS**, how much did PAIN interfere with your normal work including both work outside the home and housework?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

The next three questions are about how you feel and how things have been DURING **THE PAST 4 WEEKS**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **PAST 4 WEEKS** –

20. Have you felt calm and peaceful?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

21. Did you have a lot of energy?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time

☐ None of the Time

22. Have you felt downhearted and blue?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

23. During the **PAST 4 WEEKS**, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc)?
    ☐ All of the Time
    ☐ Most of the Time
    ☐ A Good Bit of the Time
    ☐ Some of the Time
    ☐ A Little of the Time
    ☐ None of the Time

Quality of Life

[EQ-5D items]

Under each heading, please check the box that best describes your health **TODAY**

6. Mobility
   ☐ I have no problems walking around
   ☐ I have slight problems walking around
   ☐ I have moderate problems walking around
   ☐ I have severe problems walking around
   ☐ I am unable to walk around

7. Self-Care
   ☐ I have no problems washing or dressing myself
   ☐ I have slight problems washing or dressing myself
   ☐ I have moderate problems washing or dressing myself
   ☐ I have severe problems washing or dressing myself
   ☐ I am unable to wash or dress myself

8. Usual Activities (e.g. work, study, housework, family or leisure activities)
   ☐ I have no problems doing my usual activities
   ☐ I have slight problems doing my usual activities

☐ I have moderate problems doing my usual activities
☐ I have severe problems doing my usual activities
☐ I am unable to do my usual activities

9. Pain/ Discomfort
   ☐ I have no pain or discomfort
   ☐ I have slight pain or discomfort
   ☐ I have moderate pain or discomfort
   ☐ I have severe pain or discomfort
   ☐ I have extreme pain or discomfort

10. Anxiety/ Depression
   ☐ I am not anxious or depressed
   ☐ I am slightly anxious or depressed
   ☐ I am moderately anxious or depressed
   ☐ I am severely anxious or depressed
   ☐ I am extremely anxious or depressed

Section 4. *My Diabetes Self-Care*

[Diabetes Self-Care]

These questions are about how you have managed your diabetes over the **last 7 days**. (If you were sick during the last 7 days, please think back to *the last 7 days you were **NOT** sick*).

Blood Sugar Testing

2. a) Approximately how many **days per week** has your doctor/diabetes care team recommended that you <u>test your blood sugar levels</u>? (Select “0” if this has *not* been recommended)

   0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

   b) On how many of the last 7 days did you actually test your blood sugar?

   0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

Diabetes Medication

3. a) Has your doctor/diabetes care team recommended that you take diabetes medications **every day**?

   ☐ Yes ☐ No

   b) On how many of the **last 7 days** did you <u>take your diabetes medications exactly as recommended</u> by your doctor/diabetes care team?

   0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

[Medication Adherence]

4. Do you ever forget to take your diabetes medicine?
☐Yes ☐ No

5. Are you careless at times about taking your diabetes medicine?
☐Yes ☐ No

6. When you feel better, do you sometimes stop taking your diabetes medicine?
☐Yes ☐ No

7. Sometimes, if you feel worse when you take the diabetes medicine, do you stop taking it?
☐Yes ☐ No

Foot Care

8. a) Approximately how many **days per week** has your doctor/diabetes care team recommended you <u>check your feet</u>? (Select "0" if this has *not* been recommended)
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

   b) On how many of the **last 7 days** did you actually check your feet?
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

9. Have you ever had a foot ulcer (defined as – full thickness skin breaks below the malleoli for more than 1 week)?
☐Yes ☐ No ☐ Don't know

10. How long ago did you have the ulcer?
☐ In the last month
☐ In the last year
☐ In the last 3 years
☐ More than 3 years ago

11. Do you get any pain or discomfort in your legs or feet?
☐Yes ☐ No ☐ Don't know

If no, go on to Question

12. How would you describe the pain or discomfort?
☐ Burning/ numb/ tingling
☐ Aching/ cramp-like/ tired

☐ Other

13. Do you ever get a pain or discomfort in your leg(s) when you walk?
    ☐ Yes
    ☐ No
    ☐ I am unable to walk

14. Is a foot ulcer present?
    ☐Yes ☐ No

[Diabetes Self-Efficacy Scale. Kavanagh et al.]

These questions are about <u>how much you followed</u> your recommended treatment plan **over the <u>past</u> 8 weeks**.

Please slide each rating scale to the number that best describes how much you followed your treatment regimen in each of these areas **over the past 8 weeks**.

4. Rate the **percentage of occasions** that you followed your blood glucose testing as recommended (e.g. by your Doctor or Diabetes Educator) **over the past 8 weeks**.

0 ——————————————————————————— **100**

10 20 30 40 50 60 70 80 90

Not at all Moderately

Totally

5. Rate **how many days each week**, on average, that you followed your recommended eating plan **over the past 8 weeks**.

0 ——————————————————————————— **7**

½ 1 2 3 4 5 6

Number of days I followed my eating plan

6. Rate the **percentage of occasions** that you followed your exercise program **over the past 8 weeks**.

0 ——————————————————————————— **100**

10 20 30 40 50 60 70 80 90

Not at all Moderately Totally

The next questions are about **<u>how confident</u>** you are in doing certain activities. For each of the following questions, please slide the rating scale to the number which corresponds with your confidence that you can do the tasks as recommended, **over the <u>next</u> 8 weeks**.

4. Rate the **percentage of occasions** that you feel confident that you can test your blood glucose level as recommended (e.g. by your Doctor or Diabetes Educator) **over the next 8 weeks**.

0 ——————————————————————— **100**

10 20 30 40 50 60 70 80 90

Can't do it **Moderately certain can do it** **Certain can do it**

5. Rate **how many days each week** you feel confident that you can follow your recommended diet **over the next 8 weeks**.

0 ——————————————————————— **7**

½ 1 2 3 4 5 6

Number of days I can do it

6. Rate the **percentage of occasions** you feel confident that you can follow your exercise program **over the next 8 weeks**.

0 ——————————————————————— **100**

10 20 30 40 50 60 70 80 90

Can't do it **Moderately certain can do it** **Certain can do it**

Section 5. *My Feelings*

[Diabetes Distress Scale-17]

Listed below are some problems that people with diabetes may experience. Consider the degree to which each of the items may have distressed or bothered you **DURING THE PAST MONTH** and click on the box under the appropriate number.

Please note that we are asking to indicate the degree to which each item may be bothering you in your life *NOT* whether the item is merely true for you. If you feel that a particular item is NOT a bother or a problem for you, you would click on the box "1". If it is very bothersome to you, you might click on "6".

Problem	Not a Problem		Moderate Problem		Serious Problem	
	1	**2**	**3**	**4**	**5**	**6**
9. Feeling that diabetes is taking up too much of my mental and physical energy every day.	☐	☐	☐	☐	☐	☐
10. Feeling angry, scared and/or depressed when I think about living with diabetes.	☐	☐	☐	☐	☐	☐
11. Feeling that diabetes controls my life.	☐	☐	☐	☐	☐	☐
12. Feeling that I will end up with serious long-term complications, no matter what I do.	☐	☐	☐	☐	☐	☐
13. Feeling overwhelmed by the demands of living with diabetes.	☐	☐	☐	☐	☐	☐
14. Feeling that friends or family are not supportive enough of my self-care efforts (eg planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	☐	☐	☐	☐	☐	☐
15. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	☐	☐	☐	☐	☐	☐
16. Feeling that friends or family don't give me the emotional support that I would like.	☐	☐	☐	☐	☐	☐

[DASS-21]

Please read each statement and click on the box for the answer which indicates how much the statement applied to you ***over the past week***. There are no right or wrong answers. Do not spend too much time on any statement.

22. I found myself getting upset by quite trivial things

    ☐ 0 Did not apply to me at all

    ☐ 1 Applied to me to some degree, or some of the time

☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

23. I was aware of dryness of my mouth
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

24. I couldn't seem to experience any positive feeling at all
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

25. I experienced breathing difficulty (eg. excessively rapid breathing, breathlessness in the absence of physical exertion)
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

26. I just couldn't seem to get going
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

27. I tended to over-react to situations
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

28. I had a feeling of shakiness (eg. legs going to give way)
☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

29. I found it difficult to relax

☐ 0 Did not apply to me at all
☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

30. I found myself in situations that made me so anxious I was most relieved when they ended
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

31. I felt that I had nothing to look forward to
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

32. I found myself getting upset rather easily
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

33. I felt that I was using a lot of nervous energy
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

34. I felt sad and depressed
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

35. I found myself getting impatient when I was delayed in any way (eg. lifts, traffic lights, being kept waiting)
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time

☐ 3 Applied to me very much, or most of the time

36. I had a feeling of faintness
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

37. I felt that I had lost interest in just about everything
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

38. I felt I wasn't worth much as a person
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

39. I felt that I was rather touchy
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

40. I perspired noticeably (eg. hands sweaty) in the absence of high temperatures or physical exertion
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

41. I felt scared without any good reason
    ☐ 0 Did not apply to me at all
    ☐ 1 Applied to me to some degree, or some of the time
    ☐ 2 Applied to me to a considerable degree, or a good part of time
    ☐ 3 Applied to me very much, or most of the time

42. I felt that life wasn't worthwhile
    ☐ 0 Did not apply to me at all

☐ 1 Applied to me to some degree, or some of the time
☐ 2 Applied to me to a considerable degree, or a good part of time
☐ 3 Applied to me very much, or most of the time

Section 6. *My Health Service Use*

[Health Service Utilisation]

The following questions relate to your use of a variety of health services **over the past 3 months**.

7. What health insurance cover do you have?
   ☐ Hospital and extras cover
   ☐ Hospital cover only
   ☐ Extras cover only
   ☐ None
   ☐ Don't know

8. a) How many times have you seen a General Practitioner (GP) in the **last 3 months**?
   ☐ times

   b) How much do you pay to see your GP (after Medicare rebates)? $ ☐
   c) Approximately how many times have you seen the following health professionals in the **last 3 months**?

Health Professional	Number of visits	Cost for each visit (before health insurance claim)
Diabetes Specialist, Endocrinologist, or Physician		
Podiatrist or Chiropodist		
Opthalmologist or Optometrist		
Other medical specialist (e.g. cardiac specialist, nephrologist)		
Diabetes Educator or Diabetes Nurse (including		

home visits)		
Nutritionist or Dietician		
Psychologist or Counsellor		
Physiotherapist or Exercise Physiologist		
Dentist		
Other health professional (Please specify)		

d) How many times have you been admitted to hospital during the last 3 months?

Hospital	Number of admissions	Cost to you (before any health insurance claim)
Example: Wesley Hospital	*1*	*$320*

e) Other hospital utilisation

How many times have you utilised any other hospital service **over the past 3 months** *other than hospital based specialists (such as a cardiologist) or hospital admissions*?

Hospital service	Name of hospital	Number of times accessed	Cost to you (before any health insurance claim)
Emergency clinic			
Day procedure at a hospital that did not involve admission, e.g. angioplasty			
Cardiac rehabilitation program			
Others?			

f) How much time did you take off work due to your health (e.g. feeling sick, having a medical procedure done, unable to work), **over the past 3 months**?
☐☐ full days ☐☐ part days

g) Please list all medications you have been on **over the past 3 months** which were prescribed by your doctor.

Please write the names of medications, strength (e.g. milligrams, grams, or millilitres), and how much you take of this medication **each day** in the table below.

4. Name of medication	5. Unit strength as shown on the pack (e.g. milligrams, grams, millilitres)	6. Amount taken each day (e.g. 2 tablets, 2 times a day)
Example: Coversyl	*5 mg*	*1 tablet, 2 times/day*

OnTrack Diabetes 3-month Evaluation Survey

PARTICIPANT #: ___

Extent of computer use (Experience with computers)

1) Over the LAST 3 MONTHS, how many hours per week, on average, did you spend online?

a) Less than 2.5
b) 2.5 – 5
c) 5 – 8
d) 8 +

2) I accessed OnTrack Diabetes most often from...

a) Home
b) Work
c) Friend or family member's computer
d) Library
e) Internet cafe, or public kiosk
f) Other (please comment)

3) On average, I accessed OnTrack Diabetes...

a) Once
b) A few times
c) Once a fortnight
d) Once a week
e) 2 – 3 times a week
f) Every day

Appreciation/ Acceptability

1) Please slide the bar to show how much you would you recommend the OnTrack Diabetes program to other people with Type 2 diabetes (Not at all to extremely)?

2) I felt safe entering personal information into the program (Not at all to extremely)

Usability

Please slide the bar (least to most) to show how much you agree with the following items:

I found that the OnTrack Diabetes program...

1) Was user friendly
   Comments?

2) Let me tailor it to get what I wanted
   Comments

3) Was easy to understand
   Comments

4) Had information I could trust
   Comments

5) Focused on things I wanted to work on
   Comments

Engagement & Graphics

6) Had attractive pages
   Comments

7) Was engaging to use
   Comments

8) Was boring
   Comments

9) The text and graphics were easy to read
   Comments

10) The program's web pages opened quickly
    Comments

11) There were problems getting enough online access to do the program
    Comments

12) It was hard to find time to use the program
    Comments

Ease of Use

1) The program was easy to use

Comments

2) I could easily work out what to write or select in the tools
   Comments

3) I felt confident using the program's suggestions
   Comments

Perceived Utility/ Usefulness

1) I found the information resources useful
   Comments

2) I found the program useful
   Comments

4) I could easily apply the program to myself
   Comments

How well did the program address each of the following areas?

13) Physical activity
    Comments

14) Healthy eating
    Comments

15) Following health routines e.g. blood glucose monitoring
    Comments

16) Emotional challenges
    Comments

17) Please comment on what you think the most useful component of the program was for you:

Qualitative comments

1) What did you like most about the OnTrack Diabetes program?

   Please give some feedback about why you liked this part of the program most:

2) What did you like least about the OnTrack Diabetes program?

Please give some feedback about why you liked this part of the program least.

3) Please comment on any suggestions you have that would help us improve the program for future users.

Ease of Use

1) Please rate, from 1 to 5, being least to most, how easy you found your way around in the program:
   Comments?

2) From 1 to 5, how confident would you feel using the program's suggestions?
   Comments?

Perceived usefulness/ utility

1) How well do you think the program addresses:

a) Physical activity (from 1 – 5)?

   Comments?

b) Healthy eating (1 – 5)?

   Comments?

c) Following health routines, for example blood glucose monitoring (1 – 5)?

   Comments?

d) Emotional challenges (1 – 5)?

   Comments?

Qualitative Comments

1) What did you like most about the OnTrack Diabetes program?

Please give some feedback about why you liked this part of the program the most:

2) What did you like least about the OnTrack Diabetes program?

Please give some feedback about why you liked this part of the program least:

3) Please comment on any suggestions you have that would help us to improve the program for future users: