Flexible multiple injection therapy education for adults with Type 1 diabetes: experience and innovation in the Australian setting.

Brigid Astrid Knight

BSc, Grad Dip Nutr & Diet, Grad Cert Diab Ed

A thesis submitted for the degree of Doctor of Philosophy at
The University of Queensland in 2017
Faculty of Medicine
Abstract
Management guidelines for Type 1 diabetes (T1DM) aim to improve outcomes by reducing the development of long term complications of diabetes. Management targets focus primarily on glycaemic control, but include other factors, such as control of blood lipids and maintenance of psychosocial well-being. Efforts to achieve diabetes targets should focus on patient centred care, making diabetes self-management education an important part of diabetes management. The introduction of the 5-day Dose Adjustment for Normal Eating (DAFNE) program in 2005 enabled Australians to access evidence-based structured education in intensive diabetes self-management, or flexible multiple daily injection (MDI) therapy, allowing greater dietary and lifestyle freedom. The introduction of this program raised some concerns among clinicians, namely, the potential for negative impact on dietary quality and the difficulty with access to a long duration program for some patients. In addition, there were concerns that the numeracy demands of flexible dose calculation may be beyond the capability of some patients.

Aims of the thesis were to:
• Examine the impact of a well established structured patient-based flexible MDI education program (The Dose Adjustment for Normal Eating program) which promotes increased dietary freedom, on dietary intake of energy and macronutrients and achievement of nutritional recommendations.
• Describe patient perspectives on the useability of a novel iphone application, designed to support flexible MDI therapy, with the aim of informing further development of this self-management tool
• Develop and pilot an abbreviated short-course format for structured flexible multiple injection therapy and evaluate patient experience and psychosocial outcomes.

Chapter 2 describes the impact on dietary intake following flexible MDI education that actively promotes dietary freedom. We were able to demonstrate that achievement of nutritional recommendations does not worsen when adults with T1DM are taught how to manage flexible insulin dosing with dietary freedom. We noted that individuals found it possible to reduce energy and carbohydrate intake, without increasing hypoglycaemia, which may offer benefits to weight control efforts.

Chapter 3 addresses patient perspectives of a novel iphone application designed to assist with dose calculation, record keeping and communication with health professionals for adults using flexible MDI therapy. We identified specific features of an iphone app that
users deemed useful to support patient-based management and this will go to inform further app development.

Chapter 4 describes patient experience and psychosocial outcomes of a structured flexible MDI education program, delivered in short-duration format. We found the short course education program was well tolerated by participants and improvements in psychosocial outcomes for this short program were consistent with that seen with the 5-day program.

In conclusion, this work adds to the knowledge base about the flexible MDI self-management education in terms of dietary implications, patient perspectives on phone-based devices to support self-management and preliminary exploration of alternative program delivery options for patient education. Further evaluation of the short-course program, specifically focusing on glycaemic outcomes, may shed light on alternative course options for those who are unable to attend a 5-day program.
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

I acknowledge that an electronic copy of my thesis must be lodged with the University Library and, subject to the policy and procedures of The University of Queensland, the thesis be made available for research and study in accordance with the Copyright Act 1968 unless a period of embargo has been approved by the Dean of the Graduate School.

I acknowledge that copyright of all material contained in my thesis resides with the copyright holder(s) of that material. Where appropriate I have obtained copyright permission from the copyright holder to reproduce material in this thesis.
Publications during candidature

Published peer-review articles


Publications included in this thesis


Incorporated as paper in Chapter 2

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knight BA</td>
<td>Designed experiments (90%)</td>
</tr>
<tr>
<td></td>
<td>Wrote the paper (100%)</td>
</tr>
<tr>
<td></td>
<td>Statistical analysis of data in table 2, 3 and Figure 1 (90%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (20%)</td>
</tr>
<tr>
<td>Hickman IJ</td>
<td>Designed experiments (5%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (30%)</td>
</tr>
<tr>
<td>Gibbons K</td>
<td>Statistical analysis of data in tables 2 and 3 (10%)</td>
</tr>
<tr>
<td>McIntyre HD</td>
<td>Designed experiments (5%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (30%)</td>
</tr>
</tbody>
</table>

Incorporated as paper in Chapter 3

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knight BA</td>
<td>Designed experiments (95%)</td>
</tr>
<tr>
<td></td>
<td>Wrote the paper (100%)</td>
</tr>
<tr>
<td></td>
<td>Qualitative analysis (70%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (20%)</td>
</tr>
<tr>
<td>McIntyre HD</td>
<td>Designed experiments (5%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (35%)</td>
</tr>
<tr>
<td>Hickman IJ</td>
<td>Edited paper (35%)</td>
</tr>
<tr>
<td>Noud M</td>
<td>Qualitative analysis (30%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (10%)</td>
</tr>
</tbody>
</table>

Incorporated as paper in Chapter 4

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Statement of contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knight BA</td>
<td>Designed experiments (80%)</td>
</tr>
<tr>
<td></td>
<td>Wrote the paper (100%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (10%)</td>
</tr>
<tr>
<td></td>
<td>Statistical analysis in tables 2 – 6 (100%)</td>
</tr>
<tr>
<td>McIntyre HD</td>
<td>Designed experiments (10%)</td>
</tr>
<tr>
<td></td>
<td>Edited paper (30%)</td>
</tr>
<tr>
<td>Hickman IJ</td>
<td>Edited paper (30%)</td>
</tr>
<tr>
<td>Gibbons K</td>
<td>Edited paper (15%)</td>
</tr>
<tr>
<td></td>
<td>Designed experiments (5%)</td>
</tr>
<tr>
<td>Taylor JT</td>
<td>Designed experiments (5%)</td>
</tr>
<tr>
<td></td>
<td>Edited the paper (10%)</td>
</tr>
<tr>
<td>Clare Bradley</td>
<td>Edited the paper (5%)</td>
</tr>
</tbody>
</table>
Contributions by others to the thesis

Professor Harold David McIntyre and Dr Ingrid Hickman: provided Advisor support and direction during the PhD process.

Associate Professor Anthony Russell and Dr Shelley Wilkinson: contributed their time and expertise at each stage of the milestone process.

Mr Ian Gillespie: invited us to collaborate in the development of the RapidCalc iphone app and contributed his expertise in patient training.

Statement of parts of the thesis submitted to qualify for the award of another degree

None
Acknowledgements

1. Supervisors
I would like to thank my Advisors Professor David McIntyre and Dr Ingrid Hickman for their unwavering support and endless patience. I am thankful for their confidence in my ability to complete this body of work, especially when my own confidence wavered. The support they provided was always encouraging and I will value that forever.

2. Collaborators
I would like to thank my Dietetic colleagues who helped with the diet history collection in the paper in chapter 1. The data collection for this study proved to be an onerous task and I am indebted to my colleagues for their assistance.

I would also like to thank Associate Professor Kristen Gibbons who provided expert advice on statistical design and gave very valuable input to statistical analyses for the papers in chapters 2 and 4. I am grateful for her patience in explaining statistical design and her ability to simplify statistical analysis in a meaningful way.

I would like to thank Claire Bradley for allowing us to use her patient assessment tools and for contributing her comments to the final manuscript in chapter 4.

3. Work Colleagues
I would like to thank Dr Andrew Cotterill and Professor David McIntyre who supported me in taking on new clinical initiatives in the diabetes service. Their ‘get it done’ attitude has made it possible for me to advance my skills in intensive management and go on to conduct the projects included in this PhD (chapters 2 – 4).
I’d also like to thank the OzDAFNE administration for allowing me to be involved in education and teaching in insulin management, which has provided the basis for my skill development in intensive insulin therapy.

4. Patients
I am grateful to the patients who contributed their time and input to the data collection for all of the papers (chapters 2 – 4). Their enthusiasm to contribute data to improve patient outcomes has enabled me to embark on this PhD, which would not be possible without this valuable contribution.
5. Family
Lastly, I would like to thank my family. They have been patient and supportive over a very long process, where they have made numerous sacrifices to enable me to complete this PhD.
Keywords
Type 1 diabetes, intensive insulin therapy, diabetes phone application, bolus calculator, dietary intake.

Australian and New Zealand Standard Research Classifications (ANZSRC)
ANZSRC code : 111199, Nutrition and Dietetics, 30%
ANZSRC code : 110606, Endocrinology, 70%

Fields of Research (FoR) Classification
FoR code: 1111, Nutrition and Dietetics, 30%
FoR code: 1103, Clinical Sciences, 70%
# Table of Contents

Abstract ..................................................................................................................................................... II  

Declaration by author ............................................................................................................................... IV  

Publications during candidature ............................................................................................................. V  
  Published peer-review articles .................................................................................................................. V  
  Publications included in this thesis ......................................................................................................... VI  

Statement of parts of the thesis submitted to qualify for the award of another degree ......................... IX  

Keywords .................................................................................................................................................. XII  

Table of Contents .................................................................................................................................. XIII  

List of Figures and Tables ....................................................................................................................... XIV  

Chapter 1  Introduction ........................................................................................................................... 1  

Chapter 2: Quantitative assessment of dietary intake in adults with Type 1 diabetes following flexible insulin therapy education with an active promotion of dietary freedom. ........................................ 8  
  Discussion and implications of findings Chapter 2 .............................................................................. 26  

Chapter 3: Qualitative assessment of user experiences of a novel smart phone application designed to support flexible intensive insulin therapy in type 1 diabetes. ................................................... 27  
  Discussion and implications of findings Chapter 3 .............................................................................. 51  

Chapter 4: Evaluation of psychosocial outcomes in adults with Type 1 diabetes following participation in a novel 'short course' structured flexible multiple daily injection (MDI) therapy ...... 53  
  self-management program ........................................................................................................................ 53  
  Discussion and implications of findings Chapter 4 .............................................................................. 69  

Chapter 5: Conclusion ............................................................................................................................. 71  

References .................................................................................................................................................. 74
List of Figures and Tables

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Table number</th>
<th>Table title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>Diabetes nutritional recommendation</td>
<td>18</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Baseline characteristics of those who attended 12 month follow up versus non-attenders</td>
<td>19</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>Pre and post course dietary analysis in 46 adults</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Participant characteristics</td>
<td>44</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>Short course outcomes</td>
<td>61</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Figure number</th>
<th>Figure title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>Key Criteria of a structured education program.</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>Percentage of participants achieving nutrition recommendations at baseline compared to 1 year post course.</td>
<td>21</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>Program and data collection schedule</td>
<td>59</td>
</tr>
</tbody>
</table>
## List of Abbreviations used in the thesis

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td>automated bolus calculator</td>
</tr>
<tr>
<td>BG</td>
<td>blood glucose</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
</tr>
<tr>
<td>CGMS</td>
<td>continuous glucose monitoring system</td>
</tr>
<tr>
<td>CP</td>
<td>carbohydrate portion</td>
</tr>
<tr>
<td>CVD</td>
<td>cardiovascular disease</td>
</tr>
<tr>
<td>DAFNE</td>
<td>dose Adjustment for Normal Eating</td>
</tr>
<tr>
<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
</tr>
<tr>
<td>DH</td>
<td>diet history</td>
</tr>
<tr>
<td>DKA</td>
<td>diabetic ketoacidosis</td>
</tr>
<tr>
<td>DTSQ</td>
<td>diabetes treatment satisfaction questionnaire</td>
</tr>
<tr>
<td>EASD</td>
<td>European Association for the Study of Diabetes</td>
</tr>
<tr>
<td>EDIC</td>
<td>Epidemiology of Diabetes Interventions and Complications</td>
</tr>
<tr>
<td>FIT</td>
<td>flexible insulin therapy</td>
</tr>
<tr>
<td>HbA1c</td>
<td>glycosylated haemoglobin</td>
</tr>
<tr>
<td>Hypo</td>
<td>hypoglycaemia</td>
</tr>
<tr>
<td>IDDM</td>
<td>insulin dependent diabetes mellitus</td>
</tr>
<tr>
<td>IOB</td>
<td>Insulin on board</td>
</tr>
<tr>
<td>MDI</td>
<td>multiple daily injection</td>
</tr>
<tr>
<td>NPH</td>
<td>neutral protamine hagedorn</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>PAID</td>
<td>problem areas in diabetes</td>
</tr>
<tr>
<td>SMBG</td>
<td>Self-monitoring of blood glucose</td>
</tr>
<tr>
<td>TDD</td>
<td>total daily dose</td>
</tr>
<tr>
<td>T1DM</td>
<td>type 1 diabetes</td>
</tr>
</tbody>
</table>
Chapter 1 Introduction

Type 1 diabetes (T1DM) management is driven by the focus on achievement of glycaemic targets to minimise the risk of long term diabetes complications. The landmark DCCT/EDIC (Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications) study conducted in the 1980s demonstrated that achievement of glycaemia as close to possible to the non-diabetic range reduces the risk of micro-vascular and macro-vascular complications of diabetes. DCCT intensive diabetes management, included standardised procedures across study centres, such as frequency of SMBG (≥4/day), frequency and type of insulin (≥3/day regular insulin and intermediate insulin or insulin pump therapy), use of specific glycaemic targets (pre meals, post meals and at 3 am) and intensive clinic follow up (monthly clinic visits and more frequent telephone contact). Compared to conventional treatment at the time, which involved limited urine or blood glucose monitoring (once/day), reduced frequency of injections (1-2/day), no specific glucose targets and quarterly clinic visits, intensive treatment significantly improved median glycosylated haemoglobin (HbA1c) (9.4% vs 7.2%). However, this improvement came at the cost of a 3-fold increase risk of severe hypoglycaemia and a 33% increased risk of becoming overweight. There was no impact on quality of life according to treatment modality. Following the DCCT, intensive therapy was offered at all centres and participants returned to care in their usual centre. The difference in HbA1c between former treatment groups reduced at 1 year and by the 5th year after the end of the formal trial, there was no difference between former treatment groups (8.1 vs 8.2%)\(^1\).

The DCCT intensive treatment regimen was largely physician-led and a structured education curriculum was not used, resulting in varied approaches to patient education and management strategies. Dietary education for example, included 4 different options for meal planning and carbohydrate management education, from healthy food choices (no carbohydrate quantification) to total available glucose (where carbohydrate, fat and protein units are counted in the determination of insulin doses)\(^2\). When participants returned to usual centres, some centres were not involved in the DCCT and may not have had the expertise to optimally manage intensive therapy \(^1\). The rebound in HbA1c to 8% may be a result of this ‘dilution’ of specialised diabetes support or the reduction in support upon the return to quarterly clinic visits in patients who were accustomed to a physician-led approach to diabetes management.
In Germany around the same time, the Diabetes Teaching and Training Program (DTTP) was developed, which utilised an alternative approach to intensive diabetes management\(^3\). In contrast to the DCCT, the DTTP was delivered with a 5-day education program, with no extra follow up apart from usual care. The DTTP used a structured education curriculum, which ensured consistent diabetes management strategies across all centres. There was an active promotion of dietary and lifestyle flexibility and a patient-based approach to intensive diabetes management. The initial evaluation of the DTTP in 78 unselected adults with T1DM demonstrated a significant reduction in HbA1c (expressed as amount percent of total haemoglobin above the upper limit of normal range) from +2.6 (2) to +1.0 (1.7)\(^3\). This program has subsequently been taken up by other countries and is now the standard of care in Germany where it is linked with a national continuous quality–assurance program\(^4\). Samaan and colleagues reported on the audit data from this national program, which included 9583 patients for the period of 1992 – 2004.\(^4\) Twelve months post course, mean [SD] HbA1c improved (8.1 [2] to 7.3 [1.5]%), severe hypoglycaemia reduced (0.37 to 0.14 episodes/patient/year) compared to baseline and there was no weight gain. The DTTP program has since served as the basis for the Dose Adjustment for Normal Eating (DAFNE) in the UK (UKDAFNE) and Australia (OzDAFNE). Both programs use the DTTP program curriculum adapted for local conditions together with an active promotion the ‘freedom to eat’ approach. The Australian experience with DAFNE began in 2004 when five Australian centres were trained in the UK and courses began in 2005\(^5\). The first OzDAFNE audit, which reviewed data from Australian centres from 2005 to 2007 demonstrated an improvement in mean (sd) HbA1c at baseline of 8.2% (1.2) to 7.8% (1.3) 12 months post course, with the greatest HbA1c reduction seen in those with higher baseline HbA1c,\(^5\) which was also seen in a subsequent audit of the OzDAFNE (from 2007 to 2012).

Twelve month outcome data for structured flexible MDI education delivered as DTTP, UKDAFNE and OzDAFNE demonstrate similar trends in HbA1c, severe hypoglycaemia, weight, improvement in quality of life, treatment satisfaction and reduction in diabetes distress.\(^5\)-\(^8\) Longer term follow up of this ‘one off’ exposure to structured education has demonstrated ongoing significant improvements in HbA1c beyond 12 months post course, though with some rebound in HbA1c resulting in overall mean HbA1c reduction form baseline of approximately 0.3-0.5% HbA1c at 4 years \(^9,\(^{10}\) and 7 years.\(^11\) in contrast, the reduction in frequency of severe hypoglycaemia, is well maintained with no rebound from
12 months to 6 years\textsuperscript{12} and 12 years\textsuperscript{13}. Similarly, improvement in quality of life also is also well maintained with no rebound, up to 44 month post intervention.\textsuperscript{10}

In Australia, initial local support for the program was mixed, with some concerns about promoting dietary freedom and the potential negative impact that this would have on nutritional intake. Diabetes associations have published nutritional recommendations\textsuperscript{14,15} to address the risk factors for cardiovascular disease. These recommendations are consistent across countries, addressing macronutrient, saturated fat, fibre and alcohol intake, however poor achievement of these guidelines are commonplace, in those with T1DM as well as the general population\textsuperscript{16-19}. Historically, dietary prescription of macronutrients has been the mainstay of dietary management of diabetes, with a focus on controlling carbohydrate ‘portion’ intake to enable the ‘matching’ of dietary carbohydrate to insulin doses, and prescription of remaining dietary components to achieve recommended macronutrient intake\textsuperscript{20}. There were concerns that focusing on carbohydrate counting and introducing an active promotion of dietary freedom could potentially ‘worsen’ nutrient intake. Previous assessment of dietary intake has been conducted in the setting of flexible MDI education\textsuperscript{21,22} however quantitative assessment of energy and macronutrient intake in this setting where there is an active promotion of dietary freedom had not yet been performed. We felt that the concerns about potential dietary quality were valid, therefore we set out to conduct the first quantitative assessment of energy and nutrient intake following the introduction of the DAFNE program in Australia\textsuperscript{23}. Chapter 2 describes the nutritional intake of DAFNE participants in one centre over a two year period and specifically addresses 1) comparison of nutritional intake to recommendations and 2) impact of course participation on dietary intake of energy and macronutrients.

The duration of the 5-day DAFNE program has also raised some concerns relating to access to the program by both patients and health professionals. Many patients struggled to attend a program conducted over 5 consecutive days (40 hours) and some diabetes centres which were keen to deliver the program, were not able to commit personnel for 5 days. To address this issue, shorter duration programs have been developed, with some reporting significant improvements in glycaemic control\textsuperscript{24,25}. Intensive flexible MDI education programs in ‘short-course’ format differ in course design and delivery; however share common themes in course content. Oswald and colleagues\textsuperscript{25} reported significantly improved mean [SD] HbA1c (9.3 [1.5] to 8.3 [1.4]%) in sixty four adults with T1DM after participation in the Intensified Conventional Therapy (ICT) education program. This
program is based on carbohydrate counting and flexible insulin dose algorithms and is conducted in group sessions and individual consultations, with an average health professional contact time of 90 minutes per patient. Bendik and colleagues reported reduced frequency of severe hypoglycaemia, improved quality of life and increased autonomy after the Flexible Insulin Therapy (FIT) education program, which is conducted in 90 minute sessions, delivered weekly, for seven weeks. Both of these programs include education on carbohydrate counting, use of insulin dose algorithms and pattern based evaluation, which Grant and colleagues identified as ‘core’ curriculum components of structured flexible MDI self-management education, however a structured curriculum was not used.

There has been increased recognition of the importance of delivering patient-based flexible MDI education using a structured curriculum. Structured education programs are defined by the following criteria as outlined by Dineen and summarised in Figure 1.

Figure 1: Key Criteria of a structured education program

- A clear underlying philosophy on which the programme is based
- A structured written curriculum
- Trained educator familiar with the programme and its delivery
- A quality assurance system applied to the structure
- A process of audit of programme outcomes including biomedical, psychosocial, and patient experience

The use of the structured curriculum ensures that the education is evidence based, theory driven, delivered by experienced instructors and the delivered content is consistent and of high quality. Chapter 4 describes the development and outcomes following a short-duration structured patient-based flexible MDI education program based on OzDAFNE principles.

Promotion of insulin self-management requires the patient to manage a variety of mathematical calculations, including measuring and weighing foods, multiplying and dividing, using decimals, recognising and using fractions and working with ratios and percentages. Higher level numeracy skills are essential in day to day management of
flexible MDI and are related to achievement of glycaemic targets. Marden and colleagues assessed numeracy in 112 adults aged 18 – 65 years with T1DM attending a the Bournemouth Diabetes and Endocrine Centre and found that higher numeracy scores (those who scored above level 2 - equivalent to 14 – 16 years in the National Curriculum Framework in the UK) had significantly lower HbA1c than those scoring below level 2.\textsuperscript{31} Common numeracy problems were working with decimals, fractions, using percentages and converting units of measure – all skills which are essential to flexible MDI self-management\textsuperscript{30}. They identified that 47% of adults had numeracy scores below level 2, which is concerning in the setting of insulin self-management education, where numeracy skills up to, and at level 2 are considered essential.\textsuperscript{31}

In addition to influencing long term glycaemic control, poor numeracy may also carry a significant risk of short term adverse events. Sussman and colleagues\textsuperscript{32} assessed the accuracy of ‘on paper’ dose calculations for two glucose scenarios (low glucose and high glucose) in 205 adults with diabetes requiring insulin. They found that 63% of the calculations were incorrect. Even more concerning was the range of error seen, which was from -12 to +135 Units/dose. Not surprisingly, this degree of dose miscalculation represents a significant risk of hypoglycaemia. Hypoglycaemia associated with insulin administration error is one of the major contributors to emergency department admissions due to medication misuse\textsuperscript{33}.

To support safe and appropriate dose calculation, dose calculation tools have been developed, initially using a plastic dosing guide\textsuperscript{34}. Once the efficacy of bolus calculation was confirmed with such dosing guides, bolus calculator functionality was included in insulin pumps and then subsequently in bolus calculators for those using MDI\textsuperscript{32,35,36}. Bolus calculator functionality has also been incorporated into mobile phone applications. Given the present ubiquitous nature of mobile “smart” phones, access to bolus calculator functionality has significantly increased. In addition to dose calculation, mobile phone apps are also well suited to perform additional necessary functions to support flexible MDI management, namely diabetes diary recording and enabling data communication with health professionals. In chapter 3 we describe the qualitative assessment of user perspectives of the novel “Rapidcalc” mobile phone application that assists with bolus dose calculation, diary recording and communication with health professionals. This user perspective provides valuable insights into further development of mobile phone apps used to support patient-based flexible MDI.
Research questions and aims in this thesis
The purpose of these studies was to quantitatively assess the impact of a flexible MDI with an active promotion of dietary freedom on nutritional intake and to describe innovations aimed at improving access to safe and effective flexible MDI therapy.

Research Questions and aims of Chapter 2
Questions:
- What is the impact of flexible MDI therapy on energy and nutrient intake?
- What is the impact of flexible MDI therapy on the achievement of nutrition recommendations

Aims:
- To conduct a quantitative assessment of energy, macronutrient and fatty acid intake in adults with T1DM participating in the DAFNE program
- To examine the impact on achievement of nutritional recommendations in adults with T1DM following DAFNE education

Research Questions and aims of Chapter 3
Questions:
- What is the useability of a novel iphone application designed to support intensive flexible MDI self-management
- What existing and additional features users feel are important in a phone app to support self-management of flexible MDI therapy

Aims:
- To identify patient perspectives on the useability of a novel iphone application
- To identify additional features to improve useability and support patient-based management.

Research Questions and aims of Chapter 4
Question:
- What is patient experience following participation in a novel structured short-course intensive flexible MDI education program and how does this impact psychosocial outcomes?
- How do these psychosocial outcomes compare to the 5-day program?
Aims:

- To describe patient experience and evaluate the impact of a novel short-course structured intensive flexible MDI education program on treatment satisfaction, diabetes distress and wellbeing.
- To compare psychosocial outcomes to that seen with the 5-day DAFNE program.
Chapter 2: Quantitative assessment of dietary intake in adults with Type 1 diabetes following flexible insulin therapy education with an active promotion of dietary freedom.

Knight BA, Hickman IJ, Gibbons K, McIntyre HD.
Original Article: Quantitative assessment of dietary intake in adults with Type 1 diabetes following flexible insulin therapy education with an active promotion of dietary freedom. Brigid A Knight1,2, Ingrid J Hickman 3,4,5, Kristen Gibbons 4, and Harold D McIntyre 1,4,5

1 Queensland Diabetes Centre, Mater Health Services, Raymond Tce, South Brisbane, Australia
2 Lady Cilento Children’s Hospital, Stanley Street, South Brisbane Australia
3 Dept of Nutrition & Dietetics, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, Australia
4 Mater Research Institute, University of Queensland, Raymond Tce, South Brisbane, Australia
5 Mater Clinical School, University of Queensland, Raymond Tce, South Brisbane, Australia

Correspondence to: Brigid Knight, Lady Cilento Children’s Hospital, South Brisbane, Queensland, Australia. Phone: 61730685166
Email: bk24tips@tpg.com.au.

Word Count: 2416 (excluding references)

Funding: no funding was allocated for this research.

Conflict of Interest
Brigid Knight is a member of the OzDAFNE advisory board and involved in the delivery of DAFNE courses and training. H David McIntyre is a member of the OzDAFNE advisory board. Ingrid Hickman and Kristen Gibbons have no conflict of interest.
Abstract
Clinical practice guidelines for diabetes include dietary guidelines to address the increased risk of cardiovascular disease.

Aims: To identify impact of flexible insulin education with an active promotion of dietary freedom on energy and macronutrient intake and achievement of nutrient recommendations in adults with Type 1 diabetes.

Methods: Dietary assessment was performed prior to and 12 months following flexible insulin education. Nutrient intake and the proportion achieving the European Association for the Study of Diabetes (EASD) nutrient guidelines was compared at baseline and post course.

Results: Dietary data was available for 46 participants. Post course reductions were seen in median [ IQR ] energy kcal/d (1799 [1521 - 1931] to 1592 [1378 - 1940], $p = 0.002$), fibre g/1000kcal (14 [12-16] to 13 ([11-15], $p= 0.047)$, protein g/day (89 ([78-108] to 82 [74-93], $p = 0.001$) and carbohydrate g/day (198 [172-330] to 162 [143-204], $p = <0.001$). The proportion experiencing at least 1 severe hypoglycaemia event over 12 months was significantly reduced ($\chi^2 = 7.7$, $p = 0.006$) from baseline (n = 13, 26%) to post course (n = 3, 6%). Achievement of EASD guidelines was poor and did not change post course.

Conclusions: Flexible insulin education with an active promotion of dietary freedom does not appear to 'worsen' the achievement of EASD nutrition guidelines in adults with Type 1 diabetes. On the contrary, the dietary changes observed were reductions in energy, carbohydrate and protein intake. Flexible insulin education may offer benefits in enabling reduced energy intake without increasing hypoglycaemia.

Keywords: diabetes, flexible insulin, cardiovascular disease, nutrition, diet
Introduction

Despite improvements in diabetes care, cardiovascular disease remains the leading cause of death in type 1 diabetes mellitus (T1DM)\(^1\). Nutrient recommendations aim to address cardiovascular disease risk reduction, with restriction of dietary fat, saturated fat, trans fats and cholesterol and increased fibre intake. Dietary recommendations from the Diabetes Nutrition Group of the European Association for the Study of Diabetes and the World Health Organisation are summarised in Table 1\(^2,3\). Despite widespread acceptance of dietary recommendations aimed at reducing cardiovascular risk, low adherence to such guidelines has been a common observation in T1DM as well as the general population, across a number of countries \(^4-7\).

Historically, dietary prescription of macronutrients has been the mainstay of dietary management of diabetes, with a focus on controlling carbohydrate ‘portion’ intake to enable the ‘matching’ of dietary carbohydrate according to insulin doses, and prescription of remaining dietary components to achieve the recommended macronutrient profile\(^8\). Since the DCCT \(^9\), greater focus has been given to flexible approaches to insulin dosing, which enables a more flexible approach to carbohydrate intake, enabling a greater freedom in dietary intake in carbohydrate containing foods. This may direct focus solely to carbohydrate and away from a diet that conforms with dietary guidelines \(^2,8,10,11\).

The Dose Adjustment for Normal Eating (DAFNE) program is a flexible insulin therapy program, which actively promoted a ‘freedom to eat’ concept, with the motto, ‘Eat what you like, like what you eat’ when initially introduced to the United Kingdom and Australia. Education relating to healthy eating was included in the OzDAFNE structured curriculum, however the focus of the program was the acquisition of patient-based skills in insulin adjustment. Healthy eating was addressed only briefly and dietary prescription of macronutrient intake was not addressed. This overt promotion of dietary freedom is not associated with a detrimental impact on weight and blood lipids \(^10,12-14\), however the impact on macronutrient and energy intake has yet to be determined.

The impact of flexible insulin education and ‘modified’ dietary freedom has been previously assessed by Chantelau and colleagues\(^15\), who conducted a quantitative assessment of dietary intake in 48 adults with T1DM participating in the Diabetes Teaching and Treatment program (DTTP) where a ‘simplified carbohydrate prescriptive’ approach was used, allowing dietary freedom for protein, fat and energy, however carbohydrate intake
was prescribed. Following course participation, carbohydrate, fat, and protein were unchanged, as were blood lipids and body weight, though energy intake reduced significantly.

More recently, the effect of the DAFNE ‘freedom to eat’ approach has been examined in a qualitative study of eating patterns and food choices by Lawton and colleagues\textsuperscript{16}, who found food and eating patterns were relatively unchanged following DAFNE course participation. The reasons identified for the relative stability in food choices were dietary habituation, lack of interest in introducing new foods and the reluctance to engage in the extra effort involved in the determination of the carbohydrate count for ‘new’ foods.

In the management of T1DM, it is common practice for sucrose intake not to be prescribed and considered permissible providing the insulin dose caters for it \textsuperscript{17,18}. High sucrose foods are often also high in fat, saturated fat and energy, therefore increased dietary freedom in carbohydrate intake could also potentially raise fat, saturated fat and energy intake, thereby further reducing adherence to dietary guidelines. The aim of this study is to observe and quantify the impact of flexible insulin therapy education with an overt promotion of increased dietary freedom, on energy, macronutrient and fat intake in adults with T1DM and achievement of EASD nutrient recommendations.

**Material and Methods**
Participants agreed to the use of their non-identifiable data for audit purposes; however no formal consent form was used. The data collection procedures were reviewed by the Mater Health Services Human Research Ethics Committee and The University of Queensland Medical Research Ethics Committee and the study was exempted as a quality assurance activity, consistent with National Health and Medical Research Council guidelines\textsuperscript{19}.

Dietary assessment was performed alongside standard data collection procedures in all participants attending the DAFNE program at the Queensland Diabetes Centre, Mater Health Services, Brisbane, Australia for the first two years of course delivery. Eligibility criteria for DAFNE participation has previously been described \textsuperscript{13}. The following exclusion criteria were applied to the dietary data: pregnancy or clinically diagnosed eating disorder, either pre-existing or occurring within 12 months of course participation.
In addition to standard audit procedures for biomedical and patient reported data, dietary data was collected by a specialist diabetes dietitian using an open ended, interview administered diet history (DH) with a food frequency checklist and analysed using the Foodworks Professional program (Xyris Software, version 3.02.581). Energy kcal/d, carbohydrate g/d, fat g/d, saturated fat g/d, cholesterol mg/d and fibre g/1000 kcal/d were determined and Atwater factors were used to determine % contribution to total energy intake for protein, fat, carbohydrate, saturated fatty acid, polyunsaturated fatty acid and monounsaturated fatty acid. Weight loss intent was determined at baseline and defined as 'desire to lose weight', 'desire to gain weight', 'no desire to gain or lose weight'. Severe hypoglycaemia data was examined alongside dietary data to identify associations with dietary change.

Statistical analysis
Normally distributed variables were identified using the Shapiro-Wilk test and confirmed by examination of normal probability plots. Data are presented as mean (SD) if normally distributed, otherwise as median (interquartile range [IQR]). For pre and post course comparisons, variables were compared using paired t-tests in the event of the change variable being normally distributed and Wilcoxon signed rank test otherwise. Change variables are described as the mean change (95% CI) if normally distributed, otherwise as median change (IQR). The achievement of each EASD nutritional recommendation was compared at baseline and post course using McNemar’s test. Weight loss ‘intent’ was identified at baseline and weight loss post course was compared in those intending to lose weight versus those not intending to lose weight using the Student’s independent t test. Spearman’s Rank correlation coefficient was determined for change in frequency of severe hypoglycaemia versus change in energy and nutrient intake. Categorical analysis was performed, using McNemar’s test to compare the proportion of participants experiencing at least one event of severe hypoglycaemia pre course versus post course.

Results
Of the 75 participants eligible for 12 month data collection at the end of the audit period, paired pre course and 12 months post course dietary data were available for n = 46 (61%), with loss of follow up in n=29. The baseline characteristics of those who attended at 12 months post course compared to those who were lost to follow up is shown in table 2. There was no difference in age, HbA1c, BMI, frequency of BG monitoring or recording, frequency of severe hypoglycaemia or DKA, and dietary intake variables between these
two groups. Those who attended 12 month dietary assessment had longer diabetes duration (19.5 [11-26] years vs 9 [7-176], p= 0.002).

Pre and post course dietary intake is compared in Table 3. Statistically significant reductions were seen in energy (kcal/d), carbohydrate (g/d), protein (g/d) and fibre (g/1000kcal) intake. No significant change was detected in other nutrients. The percentage of participants achieving EASD recommendations at baseline and 12 months post course is shown in Figure 1. There was no difference in the proportion achieving nutrient recommendations at baseline and 12 months post course (McNemar testing shown in figure 1). Achievement of guidelines was lowest for fibre, saturated fat, protein and fat, and highest for cholesterol, monounsaturated fat and polyunsaturated fat.

Weight loss intent was available in 44 participants, with 24/44 (55%) intending to lose weight at baseline assessment. At baseline, mean [sd] BMI was higher in participants intending to lose weight (26.5 [3.3] kg/m^2), compared to those not intending to lose weight (24.0 [2.8] kg/m^2; p<0.001). In participants who intended to lose weight, mean weight loss was 0.8 [3.7] kg, compared to a mean [sd] weight gain of 2.1 [5.2] kg, though this failed to reach statistical significance (p =0.052).

The data on severe hypoglycaemia is not shown here as is consistent with what has been previously reported. The frequency of severe hypoglycaemia was heavily skewed, with approximately 70% of participants failing to experience a severe hypoglycaemic event in the 12 months pre-course or during the 12 months follow up period. Post course, there was a significant reduction in the number of severe hypoglycaemic events/12 months (p=0.014) and the proportion of participants experiencing at least 1 severe hypoglycaemic event/12 months (χ^2 = 7.7, p = 0.006). Correlation analysis failed to demonstrate a correlation between change in severe hypoglycaemia and change in any of the dietary variables (data not shown).

**Discussion**

The active promotion of dietary freedom alongside flexible insulin therapy education in adults with T1DM does not lead to increased dietary intake of energy or worsening of the nutrient profile.

Despite the active promotion of dietary freedom, significant reductions in energy intake were observed, which appear to be derived from reduced protein and carbohydrate intake. Increased use of intensive therapy followed the release of the DCCT findings, however the majority of participants attending this structured education program were not practicing flexible insulin therapy pre course. At baseline, participants often reported management
that was based on a prescribed carbohydrate portion meal plan, and many were advised to consume carbohydrate at all meals and snacks. Flexible therapy education facilitates a flexible carbohydrate intake, encouraging participants to be guided by appetite, rather than a specific carbohydrate portion meal plan. The flexible insulin therapy curriculum facilitates a reduction in carbohydrate intake by a number of means, including; participants learn to dose for lower carbohydrate or carbohydrate-free meals; basal titration eliminates the need for regular snacks; and strategies for physical activity encourage insulin reduction options where weight loss is desired, reducing the reliance on carbohydrate supplementation. The observed reduction in carbohydrate and energy may also be due to intentional energy restriction, given that more than half of the participants expressed a desire to lose weight. The small reduction in fibre is not surprising, given the reduction in carbohydrate intake, and though the magnitude of the reduction is not clinically relevant, the poor achievement of fibre recommendations is a concern that has been identified previously in other cohorts with T1DM. Dietary intake data from the Eurodiab IDDM Complications study found higher intakes of fibre to be independently related to beneficial trends in serum lipoprotein profiles in men and lower CVD risk in women. The small reduction in protein suggests a ‘whole food’ change rather than merely reduction in simple sugars and would be expected with reduced snacking (often with bread and cereal products) or deliberate energy restriction for weight control. The significant reduction in carbohydrate and energy intake, without increasing hypoglycaemia, indicates that the program has enabled participants to eat less, in a safe manner. Anecdotally, it was noted that for many participants, the ‘freedom to eat’ message has been interpreted as the freedom to ‘not eat’ or to ‘eat less’ or snack less, rather than eat more. Despite a statistically significant reduction in energy intake from baseline to 12 months, weight and BMI reductions were not detected in this cohort, however an audit of Australian DAFNE centres conducted by McIntyre and colleagues demonstrated a statistically significant weight loss (0.9 kg) in a larger cohort of 145 participants. In the setting of intensive insulin therapy and improved glycaemic control where studies such as the DCCT suggest the potential for weight gain, this is considered clinically relevant. The failure to detect weight loss in this cohort may be due to inadequate statistical power related to sample size.

Other studies that have examined dietary intake in the setting of flexible insulin therapy with a focus on carbohydrate counting, have also found dietary intake to be unaffected by increased insulin flexibility. Boulin and colleagues examined dietary intake in 72 children and found no difference in energy and macronutrient intake in children on fixed meal plans.
compared to carbohydrate counting and flexible MDI. Peters and colleagues observed dietary intake in 28 adolescents progressing from less intensively manage diabetes to insulin pump therapy and found that energy intake was reduced in the short term (3 – 6 months), but unchanged in long term follow up (18 months) and macronutrient intake was unchanged. The authors reported that commencement of insulin pump therapy was associated with reduced snacking. The low adherence to dietary guidelines appears to be widespread across fixed and flexible therapy, and comparison with control groups highlights that diet quality in those with T1DM is often poorer than in controls.

Despite the widespread difficulty in achieving dietary guidelines, education programs focusing on healthy diet education alongside carbohydrate counting and flexible insulin therapy have been shown to improve dietary intake, specifically in reducing energy, and fat and increasing fibre intake.

The main weakness of this study is the potential for diet history under-reporting. Underreporting of dietary intake is has been observed in women, and in those who are overweight or have previously exercised dietary restraint. Given that this cohort is predominantly (70%) female and that 52% of participants had a BMI in the overweight & obese range, some degree of underreporting is likely. More than half of the participants reported a weight loss intent, therefore it is difficult to separate under-reporting with deliberate dietary restriction. However the diet history interview enabled a trained dietitian to extend questioning to qualify the responses when dietary recall suggested implausible nutrient intakes. Validation studies of the diet history technique have demonstrated good agreement in energy intake using dietary history methodology, with only 4.6% under reporting when compared to double labelled water derived energy intake, supporting the validity of diet history methodology to assess energy intake. Short and long term reproducibility of the diet history method has been demonstrated by Schmidt and colleagues, who assessed mean intakes and correlation coefficients between diet history interviews, conducted 12 months apart, in 50 adults with T1DM. No difference was observed in energy or macronutrient intake between the 2 interviews and within subject correlations were 0.6 – 0.7 suggesting that any mis-reporting with DH methodology is likely to be systematic and supports use of the DH methodology in a pre-post study design to identify changes in nutrient intake.

Sample size is also a potential weakness of the audit and limits the ability to detect small changes in dietary intake. Post hoc analysis indicates that with 46 participants, changes in fat and saturated fat in the order of 2.9% and 1.5% respectively are able to be detected,
ruling out larger increases in fat intake in this setting. The high loss to follow up (39%) is also a concern, with the cohort lost to follow up characterized by shorter duration diabetes and poorer control. It possible that this study retained participants with improved compliance with diet, as dietary compliance has been seen to be associated with lower HbA1c. Participants who are non-compliant with dietary advice may demonstrate worsening dietary intake following advice on increasing dietary freedom, however given the observation of a small, but significant weight loss and neutral impact on blood lipids in the larger scale Australian audit, it doesn’t appear that dietary fat or energy intake worsen. The loss of those with higher HbA1c is expected to dilute impact of this education on improvement in HbA1c, given that greater reductions in HbA1c are seen in those with higher baseline values.

This report confirms that adults with T1DM attending flexible insulin therapy education have similar difficulties as other T1DM populations in achieving dietary guidelines. However, when flexible insulin education is delivered with an active promotion to eat freely, dietary intake does not appear to ‘worsen’. Instead, there is greater freedom to ‘eat less’ either at meals or snacks, resulting in a reduction in carbohydrate, protein and energy which may assist with weight loss efforts, without increasing hypoglycaemia. Given the heightened risk of cardiovascular disease in diabetes, efforts to achieve dietary guidelines should continue to be an important part of dietary education, and active promotion of the dietary guidelines alongside flexible insulin therapy education may be one way to address this widespread problem. As flexible therapy for the management of T1DM becomes more mainstream and there is a move away from dietary prescription, future research into dietary quality, including micronutrient and fibre intake may provide valuable insights to improving dietary quality and achievement of nutrient recommendations.
Tables and Figures

Table 1: Diabetes nutritional recommendations

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>EASD</th>
<th>WHO/FAO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein %</td>
<td>10 – 20*</td>
<td></td>
</tr>
<tr>
<td>Carbohydrate %</td>
<td>45 – 60</td>
<td></td>
</tr>
<tr>
<td>Fat %</td>
<td>≤ 35</td>
<td>&lt;35%</td>
</tr>
<tr>
<td></td>
<td>≤ 30 if overweight</td>
<td></td>
</tr>
<tr>
<td>Saturated fat % and</td>
<td>&lt; 10% saturated + trans fatty acids</td>
<td>&lt; 10%</td>
</tr>
<tr>
<td>trans fats</td>
<td></td>
<td>&lt; 7% high risk groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If high LDL cholesterol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;8% saturated fat + trans fats</td>
</tr>
<tr>
<td>Polyunsaturated fats %</td>
<td>≤ 10</td>
<td>6 – 10%</td>
</tr>
<tr>
<td>Monounsaturated fats %</td>
<td>10 – 20</td>
<td>15 – 30%</td>
</tr>
<tr>
<td>Cholesterol mg/d</td>
<td>&lt; 300</td>
<td></td>
</tr>
<tr>
<td>Fibre g</td>
<td>&gt; 40g/day or &gt;20g/1000kcal/d</td>
<td></td>
</tr>
<tr>
<td>Alcohol g/d</td>
<td>10† - 20‡</td>
<td></td>
</tr>
</tbody>
</table>

* Where there is nil evidence of nephropathy. Gender specific recommendation represented as † for women and ‡ for men. EASD = the Diabetes Nutrition Group of the European Association for the Study of Diabetes, WHO/FAO = joint World Health Organisation/Food and Agriculture Organisation expert consultation.
Table 2: Baseline characteristics of those who attended 12 month follow up versus non attenders.

<table>
<thead>
<tr>
<th>Baseline Variable</th>
<th>Attenders N=46</th>
<th>Non-attenders N=29</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Metabolic/Anthropometric</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women (number, %)</td>
<td>32 (70)</td>
<td>25 (86)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>40 (29-51)</td>
<td>37 (26 – 44)</td>
<td>0.366</td>
</tr>
<tr>
<td>Diabetes duration (years)</td>
<td>20 (11-26)</td>
<td>9 (7 – 17)</td>
<td>0.002</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25 (23-28)</td>
<td>26 (23-30)</td>
<td>0.147</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.8 (7.1-8.5)</td>
<td>8.5 (7.6-8.9)</td>
<td>0.147</td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>62 (54-69)</td>
<td>69 (60-74)</td>
<td></td>
</tr>
<tr>
<td>SH frequency</td>
<td>0 (0-1)</td>
<td>0 (0–2)</td>
<td>0.548</td>
</tr>
<tr>
<td>DKA frequency</td>
<td>0 (0-0)</td>
<td>0 (0-0)</td>
<td>0.592</td>
</tr>
<tr>
<td><strong>Dietary intake</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy (kcal/d)</td>
<td>1756 (1521-1931)</td>
<td>1893 (1515-2105)</td>
<td>0.638</td>
</tr>
<tr>
<td>Protein %</td>
<td>21 (± 3)</td>
<td>20 (± 4)</td>
<td>0.377†</td>
</tr>
<tr>
<td>Fat %</td>
<td>32 (± 7)</td>
<td>31 (± 6)</td>
<td>0.529†</td>
</tr>
<tr>
<td>Carb %</td>
<td>42 (± 7)</td>
<td>45 (± 7)</td>
<td>0.887†</td>
</tr>
<tr>
<td>SFA %</td>
<td>12 (10-14)</td>
<td>12 (7-14)</td>
<td>0.775</td>
</tr>
<tr>
<td>PUFA %</td>
<td>5 (4 – 5)</td>
<td>4 (3-6)</td>
<td>0.214</td>
</tr>
<tr>
<td>MUFA %</td>
<td>12 (11-14)</td>
<td>11 (10-13)</td>
<td>0.426</td>
</tr>
<tr>
<td>Chol (mg/d)</td>
<td>208 172-329)</td>
<td>233 (165-304)</td>
<td>0.816</td>
</tr>
<tr>
<td>Fibre (g/1000kcal)</td>
<td>13 (12-16)</td>
<td>12 (11-15)</td>
<td>0.085</td>
</tr>
</tbody>
</table>

BMI = Body mass index, HbA1c = glycosylated haemoglobin, SH = severe hypoglycaemia over 12 months, DKA = diabetes Ketoacidosis frequency over 12 months, Protein % = protein % of total energy intake (TEI), Fat % = fat % of TEI, Carb% = carbohydrate % of TEI, SFA = saturated fatty acid % of TEI, PUFA = Polyunsaturated fatty acid % of TEI; MUFA = monounsaturated fatty acid % of TEI, Chol = cholesterol.

†Normally distributed variables compared using independent t-test, otherwise Mann Whitney U test used. Normally distributed variables described as mean (± SD), otherwise as median (IQR).
Table 3. Pre and post course dietary analyses in 46 adults.

<table>
<thead>
<tr>
<th></th>
<th>Pre course</th>
<th>12 months post course</th>
<th>Change</th>
<th>95%CI or Median change IQR</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein (% TEI)</td>
<td>21 (± 3)</td>
<td>21 (± 4)</td>
<td>-0.2</td>
<td>-1 , 1</td>
<td>0.713</td>
</tr>
<tr>
<td>Carbohydrate (% TEI)</td>
<td>42 (± 7)</td>
<td>42 (± 7)</td>
<td>0.2</td>
<td>-2 , 3</td>
<td>0.892</td>
</tr>
<tr>
<td>Fat (% TEI)</td>
<td>32 (± 7)</td>
<td>34 (± 7)</td>
<td>2</td>
<td>-0.2 , 4</td>
<td>0.074</td>
</tr>
<tr>
<td>SFA (% TEI)</td>
<td>12 (10-14)</td>
<td>12 (10 – 15)</td>
<td>0.9</td>
<td>-1 - 3</td>
<td>0.286</td>
</tr>
<tr>
<td>PUFA (% TEI)</td>
<td>5 (4 – 5)</td>
<td>5 (4 – 6)</td>
<td>0.1</td>
<td>-1 - 1</td>
<td>0.323</td>
</tr>
<tr>
<td>MUFA (% TEI)</td>
<td>12 (11 – 14)</td>
<td>12 (11 – 15)</td>
<td>0.2</td>
<td>-2 - 2</td>
<td>0.136</td>
</tr>
<tr>
<td>Fat (g/d)</td>
<td>65 (49 –78)</td>
<td>62 (49 – 79)</td>
<td>3</td>
<td>-16 - 10</td>
<td>0.206</td>
</tr>
<tr>
<td>Cholesterol (mg/d) †</td>
<td>208 (172 –330)</td>
<td>211 (179 – 269)</td>
<td>-8</td>
<td>-68 - 37</td>
<td>0.159</td>
</tr>
<tr>
<td>Carbohydrate (g/d) †</td>
<td>198 (163 – 238)</td>
<td>162 (143 – 204)</td>
<td>-30</td>
<td>-48 - -19</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Energy (kcal/d)</td>
<td>1799 (1521 – 1931)</td>
<td>1592 (1378 – 1940)</td>
<td>-162</td>
<td>-459 - 57</td>
<td>0.002</td>
</tr>
<tr>
<td>Fibre (g/1000kcal) †</td>
<td>13 (12 – 16)</td>
<td>13 (11 – 15)</td>
<td>-1</td>
<td>-4 - 1</td>
<td>0.047</td>
</tr>
<tr>
<td>Alcohol (g) †‡</td>
<td>4 (0 – 11)</td>
<td>4 (0 – 14)</td>
<td>0</td>
<td>-1 - 4</td>
<td>0.251</td>
</tr>
</tbody>
</table>

%TEI = % total energy intake. SFA = saturated fatty acids. PUFA = polyunsaturated fatty acids. MUFA = monounsaturated fatty acids. Normally distributed data are presented as mean (±SD), and mean change variable and 95% confidence interval is shown, otherwise median (IQR), median change and median change IQR is shown. Paired baseline and 1 year data for primary outcome variables were compared using the paired t test for normally distributed change variables and †Wilcoxon Matched Pairs Test for the remainder. ‡Paired data available for 36 participants.
Figure 1: Percentage of participants achieving nutrition recommendations at baseline compared to 1 year post course.

Acknowledgements

This study was conducted as part of DAFNE audit activities and the authors would like to thank the Queensland Diabetes Centre, with special thanks to Helen d’Emden, Claire Waugh, Amanda Smith and Marina Noud for their support and assistance in data collection.

Nutrient abbreviations (and McNemar p values) are: protein = protein % TEI (0.763), fat = fat % TEI (0.655), SFA = saturated fat % TEI (0.999), PUFA = polyunsaturated fat % TEI (0.999), MUFA = monounsaturated fat % TEI (0.999), chol = cholesterol mg/d (0.134) and fibre = fibre g/1000kcal (0.656).
References


Discussion and implications of findings Chapter 2

This study describes the first quantitative assessment of energy and macronutrient intake in adults with T1DM following DAFNE education. We found that the ‘freedom to eat’ message was interpreted by many as a ‘freedom to eat less’, with reduced energy and carbohydrate intake and no increase in hypoglycaemia. The ability to eat less and snack less may be beneficial towards weight control efforts, without increasing the risk of hypoglycaemia. The predominance of females in the study sample may suggest a greater bias towards ‘eating less’, however it was observed that both males and females found the freedom to eat less to be a positive attribute, in terms of weight management, as well as lifestyle freedom (not having to eat meals or snacks at a predetermined time) and while exercising (not always having to eat before/during exercise, after learning about insulin reduction strategies).

The loss to follow up of 39% of the cohort is not unusual, given the ‘tendency’ for attrition seen in both the UK (with retention of 55% of participants 12 months post course) and Australian setting (with retention of 35 – 53%). This may be due to the ‘one off’ nature of the education program (delivered over 1 week) with structured follow up at 6 weeks and 6 months post course. This may not be adequate follow up to maintain ongoing contact with participants.

This study adds to one existing report that described the qualitative assessment of eating behaviour following DAFNE participation, demonstrating that eating behaviour is unchanged post course.

When this study was first conducted, nutrition guidelines had not been published for the Australian setting and local diabetes centres deferred to nutrition guidelines from the EASD or American Diabetes Association. In 2011 the NHMRC guidelines were released for Australian centres, with similar macronutrient recommendations as the EASD guidelines.

This study also confirms the poor achievement of nutritional recommendations and future studies incorporating flexible insulin self-management with promotion of healthy eating are warranted.
Chapter 3: Qualitative assessment of user experiences of a novel smart phone application designed to support flexible intensive insulin therapy in type 1 diabetes.

Brigid A Knight¹,²§, H David McIntyre¹,³,⁴,⁵ *, Ingrid J Hickman⁵,⁶ *, Marina Noud¹,² *

Qualitative assessment of user experiences of a novel smart phone application designed to support flexible intensive insulin therapy in type 1 diabetes.
Brigid A Knight1,2§, H David McIntyre 1,3,4,5 *, Ingrid J Hickman 5,6*, Marina Noud1,2*

1 Queensland Diabetes and Endocrine Centre, Mater Health Services, Brisbane, Australia
2 Lady Cilento Children’s Hospital, Brisbane Australia
3 School of Medicine, University of Queensland, Brisbane, Australia
4 Mothers and Babies Theme, Mater Research Institute – University of Queensland, Brisbane, Australia
5 Mater Research Institute, University of Queensland, Brisbane, Australia
6 Dept of Nutrition & Dietetics, Princess Alexandra Hospital, Brisbane, Australia

*These authors contributed equally to this work
§Corresponding author.

Email addresses:
    BK: Brigid.Knight@health.qld.gov.au
    HDM: David.McIntyre@mater.org.au
    IH: Ingrid.Hickman@health.qld.gov.au
    MN: Marina.Noud@health.qld.gov.au
Abstract

Background

Modern flexible multiple daily injection (MDI) therapy requires people with diabetes to manage complex mathematical calculations to determine insulin doses on a day to day basis. Automated bolus calculators assist with these calculations, add additional functionality to protect against hypoglycaemia and enhance the record keeping process, however uptake and use depends on the devices meeting the needs of the user. We aimed to obtain user feedback on the usability of a mobile phone bolus calculator application in adults with T1DM to inform future development of mobile phone diabetes support applications.

Methods

Adults with T1DM who had previously received education in flexible MDI therapy were invited to participate. Eligible respondents attended app education and one month later participated in a focus group to provide feedback on the features of the app in relation to usability for patient-based flexible MDI and future app development.

Results

Seven adults participated in the app training and follow up interview. App features that support dose adjustment to reduce hypoglycaemia risk and features that enable greater efficiency in dose calculation, record keeping and report generation were highly valued.

Conclusions

Adults who are self-managing flexible MDI found the Rapidcalc mobile phone app to be a useful self-management tool and additional features to further improve usability, such as connectivity with BG meter and food databases, shortcut options to economise data entry and web based storage of data, were identified. Further work is needed to ascertain specific features and benefit for those with lower health literacy.

Keywords: intensive management, diabetes technology, iphone, applications, self-management
Background

Self-management is the cornerstone of type 1 diabetes (T1DM) management and patient-based flexible multiple daily injection (MDI) therapy requires the individual to perform a number of (often complex) mathematical calculations. To calculate the prandial insulin dose, the carbohydrate count must first be calculated for a range of foods, requiring individuals to interpret carbohydrate data from food labels, nutrition databases and other published sources. Once the carbohydrate quantity is determined, the insulin:carbohydrate ratio is then applied, either by division or multiplication (depending on the method of carbohydrate counting). Subsequently, a dose correction is determined by subtracting target blood glucose (BG) from the prandial BG and dividing by the correction factor. Numeracy skills are essential for effective flexible MDI therapy and lower numeracy scores are associated with lower self-efficacy and higher glycosylated haemoglobin (HbA1c). Sussman and colleagues compared manual insulin dose calculations to an automated bolus calculator (ABC), and found 63% of dose determinations conducted manually were incorrect compared to 6% of calculations via an ABC.

Automated bolus calculators (ABCs) integrated with BG meters and insulin pumps have enabled safe and effective bolus determination as demonstrated by improvements in 1) glycaemic control, 2) treatment satisfaction, and 3) confidence in dose determination and reduction in 1) frequency and fear of hypoglycaemia, 2) dose calculation errors and 3) treatment burden associated with mathematical calculations and record keeping.

In addition to managing the prandial dose calculation, effective ongoing management of patient-based flexible MDI therapy requires the person with diabetes to undertake additional self-management tasks which add to the daily burden of diabetes management. These tasks include counting carbohydrates (which involves measuring foods, interpreting food labels, researching unfamiliar foods, performing an estimate of carbohydrate count when eating out), monitoring blood glucose levels (which involves washing hands prior to testing, taking care with meter and test strip handling, remembering to monitor prior to eating, pre bed, prior to driving and when feeling symptomatic with hypoglycaemia), learn the impact of physical activity and alcohol on blood glucose and make anticipatory adjustments, record BG and additional pertinent diabetes management information (such as carbohydrate, alcohol, activity, stress, illness) in a diabetes diary, and effectively collaborate with health professionals.
The BG or diabetes diary, which is often paper-based, is an essential component of flexible MDI, as it enables comparison to BG targets and enables BG trends to be analysed to inform proactive changes in insulin formula. Despite the importance of the BG diary, compliance with BG diary recording is often poor. Use of an electronic hand held diary has been shown to improve compliance with record keeping, compared to the ‘traditional’ paper-based diary and the combining of dose calculator and BG diary recording functionality may explain the satisfaction and preference for ABCs. Some ABCs enable users to record additional pertinent data (such as exercise and illness), usually in pre-determined text format. Free text data recording is not available in ABCs.

Integration of bolus calculator functionality into mobile phones has emerged, in some cases, with SMS messaging and telemedicine. In addition to the dose calculator and BG diary functionality of ABCs, mobile phones have added advantage of ‘connectivity’, enabling more efficient communication of data with health professionals providing self-management support. Improved motivation, self-management reflection and communication between patient and health professional has been observed with use of mobile phone diary apps, highlighting the benefits of this technology in self-management support.

In Australia, there are over 30 million mobile phones registered, which is more than one per person and approximately half (55%) use mobile phone apps. The ubiquitous nature of mobile phones ensures universal access to this technology, potentially enabling a greater number of individuals to access an ABC with BG diary features.

The RapidCalc mobile phone app was developed locally, as an adjunctive tool to support a specific subset of adults with T1DM – those who have been trained in flexible insulin self-management using carbohydrate counting and insulin:carbohydrate ratios. The app has been developed specifically to provide a phone-based platform to support the following self-management practices: bolus dose determination (based on individual insulin adjustment algorithms), diabetes diary recording, report generation and communication with health professionals. The app bolus calculation equation is consistent with ABCs, with the calculation for bolus doses determined from three calculations: 1) bolus for carbohydrate, based on insulin:carbohydrate ratio, 2) correction bolus based on prandial glucose, insulin sensitivity and target BG and 3) insulin on board (IOB) based on residual insulin from previous bolus dose(s). Rapidcalc also incorporates the following features,
which differentiates it from ABCs: 1) free text option for recording pertinent details relating to a specific events, 2) food photograph option, that enables the user to save a food photograph, time stamped with the relevant carbohydrate count in the diabetes diary, 3) variable options for bolus adjustment for exercise, 4) 'Reverse calculator' which calculates the carbohydrate required when BG is below target, 5) omission of correction bolus for high BG due to an antecedent hypoglycaemic event, or when consuming a significant quantity of alcohol and 6) data export capabilities via email.

To our knowledge, there are currently no other phone-based bolus calculator applications which incorporate these features.

The aim of this study was to obtain user feedback on the usability of the RapidCalc app in adults with T1DM already experienced in flexible MDI, with a view to informing further development of this application and identifying user preferences with this emerging technology. We sampled from graduates who had recently completed structured education in flexible insulin self-management education to explore the specific features that this specific type of insulin user would want from a phone based app to support day to day diabetes management.

Methods

Participants
The interview group consisted of 7 participants who had previously received flexible MDI education program by attending the Dose Adjustment for Normal Eating (DAFNE) program. The DAFNE program aims to equip graduates with evidence based insulin self-management skills based on carbohydrate counting and insulin algorithms, and includes insulin adjustment strategies for physical activity, illness and when consuming alcohol, and pattern evaluation of BG trends to inform ongoing insulin adjustment to achieve target glucose levels. Each DAFNE course is delivered in a group setting, over 5 consecutive days. DAFNE graduates were chosen, firstly, as they have received the same insulin self-management education and secondly, because they have had considerable experience contributing their opinion alongside others with T1DM in a group setting. Graduates who had completed DAFNE education in the most recent 13 months were invited by email to participate. The inclusion criteria were: age 18 – 65 years, access to an iphone or iPod touch, able to attend a 1-2 hr training session at study commencement and 1-2 hr group
interview at the end of the trial period, willingness to email RapidCalc results to the study centre once per week for the first four weeks of the study, using insulin Glargine (Lantus), Insulin Detemir (Levemir) or NPH (Humulin NPH, protaphane) insulin for basal insulin and Insulin Glulisine (Apidra), Insulin Lispro (Humalog) or Insulin Aspart (Novorapid) for bolus insulin, able to inject insulin for all meals and large snacks, able to test BG at least 4 - 6 times/day, HbA1c  53 - 86 mmol/mol (7 – 10%), absence of end stage diabetes complications or other serious medical condition except for well managed coeliac disease, thyroid disease or asthma (not requiring oral steroids) and able to read and speak English. Criteria for exclusion were: hypoglycaemia unawareness, major psychiatric illness that prevents interaction in a group setting, pregnancy or breast feeding and use of an insulin pump.

**Procedures**

Four weeks prior to the app education session, participants were instructed by phone or email how to load the app on their phone. Participants were asked to maintain a paper-based BG diary for 4 weeks, with weekly transmission to the study coordinator. The purpose of this was to support participants in optimising insulin algorithms prior to app use.

**App education session**

Education on the use of the app was conducted by the app developer in a group setting with all participants present. A diabetes educator (BK) was in attendance to support programming of the app with each user’s existing insulin dose algorithms. Participants started using the app following this session. Participants were invited to contact the diabetes educator (BK) for assistance with dose adjustment at any time until the focus group meeting. One month after app education session, all participants were invited to return for the focus group.

**The focus group**

The focus group was led by a diabetes educator (MN) who was not involved in development of the app or in the app education session. The open ended interaction of a group interview was chosen to stimulate thought and emotions, to reveal material which may not ordinarily be expressed in an individual interview. A semi-structured interview format was used, focusing on the attributes of usability, which include learnability, efficiency, memorability, errors and satisfaction. Interview prompts were devised within the research team, which was comprised of experienced clinicians and researchers and focus group questions are summarised in Appendix A. The aim was to develop themes to address the aims of the study without being deemed leading or judgemental.
At this visit, app data exports (data reports which show data entered by each user) were obtained for each participant to identify the duration of app use. The interview was audio recorded, then transcribed verbatim. Thematic analysis of the focus group followed the structured approach outlined by Braun & Clarke\textsuperscript{19} where themes were identified according to the group discussion and not limited to the usability attributes. Themes were coded according to specific app features to highlight the features that participants found useful or not. The transcript was reviewed by two reviewers (BK & MN) independently, who met to address discrepancies and agree on themes.

**Results**

Fifteen DAFNE graduates were sent an invitation to participate and nine graduates expressed interest, however 2 were unable to participate due to scheduling conflicts. Seven adults (5 female) with mean (SD) age of 36 (7) years and mean duration of diabetes 27 (7) years, attended app education and a 2 hour focus group. Participant characteristics are summarised in Table 1. Six of the seven participants used the app for the duration of the study period. The one participant who had not used the app for the duration of the study indicated that she had failed to sustain regular BG monitoring during the study, therefore ceased using the app.

Three main themes were identified from the focus group: 1) bolus calculator features and trust, 2) diabetes diary and report features and 3) satisfaction and control. Within each theme, sub-themes are described, with respondent quotes coded according to gender, number identifier, age category and diabetes duration: for example, F5 (A40-44, D20) refers to female number 5, aged 40 – 44 years, with 20 years diabetes duration.

**Bolus calculator features and trust**

Users programmed the app with their personal insulin algorithms with the help of the study team and none of the group reported difficulty in the set up process. Six participants reported that they trusted the accuracy of the dose calculation via the app, though five reported they like to ‘check the dose’ recommended by the app, against manual calculations. One participant (F1, A35-39, D27) rarely checked the dose, acknowledging that "I'm one of those people in the population that would go, 'I don't have to think, just tell me what to have.' " This person went on to add that she trusted the app more than her own calculations, claiming that “the app is a lot more consistent than I am” and “It's better
than guessing in the complete dark - it's less dark." She went on to acknowledge that her trust in the app meant that she didn't check her ratios (confirm suitability of current dosing algorithms), which she admitted did not enable 'fine tuning' and ongoing dose adjustment. F5 (A30-34, D25) described how the app made it easier for her to remember the insulin:carbohydrate ratio to use for specific meals, especially after a change in prescription for insulin:carbohydrate ratio.

Four participants described over-riding the dose, not because of a lack of trust, but for specific reasons, such as when physically active or when snacking. There was group agreement with F5 (A30-34, D 25), who reported "It's not that I don't trust it, it's just that I need to over-ride it." M1 (A30-34, D26) highlighted the problem with the pre-set time frames for dose algorithms in the app: "My ratios didn't fall into time frames provided by the app. I usually use the 1:1 ratio at lunch and a 2:1 ratio in the evening, so......if I had a snack in the afternoon, I usually use the 1:1.... but if I have the snack between 4 and 5 (pm) and that falls within the dinner... so I would be ignoring the dose that it was calculating because I thought no, that is twice as much as I want to be having." The 4 participants who had to override the app due to pre-set time frames for the insulin algorithms stated a preference for customisable time settings for insulin algorithms.

Three participants found the IOB feature useful in reducing the risk of hypoglycaemia. F1 (A35-39, D27) described this feature as "The best thing in the world." Though considered useful, many found that the IOB was misleading when meals and snacks were eaten in close proximity. The IOB is calculated based on total residual bolus insulin, therefore may overestimate the IOB in instances where meals/snacks are eaten in close proximity. Five participants agreed that they needed to over-ride the bolus suggestion when meals were consumed in close proximity.

The reverse calculator, which determines the carbohydrate to be consumed for BG below target, was used by 4 participants. Two users described specific instances where this feature protected against hypoglycaemia, or prevented over-treatment of hypoglycaemia. F3 (A30-34, D21) states, "What I love… was that it told me how much to have and I didn't overeat. The number of times that I overeat from hypos is ridiculous; it would be 99% of times." Four participants reported that the carbohydrate supplementation suggestion from the reverse calculator tended to be lower than their usual guidelines for hypoglycaemia management (15 g rapid acting carbohydrate). M2 (A30-34, D26) was particularly concerned when the app suggested dosing insulin for some of the hypo treatment: "Cause I found when I would be 3.4 or 3.3 (mmol/l), the DAFNE rules would say 1.5 CPs
(carbohydrate portions) and I'd put in 1.5 CPs and it would be telling me to take one unit of insulin, which I obviously wasn't going to do."

The exercise bolus adjustment feature, which can be programmed to reduce the bolus dose in the setting of physical activity, had been used by 4 participants. All agreed that adjusting insulin to manage BGLs around exercise was challenging. F4 (A30-34, D20) sums up her experience with the exercise feature, "I don't know how I'm reacting to exercise because I don't pay enough attention to it" and F2 (A35-39, D34), "I always muck it up somehow. I never seem to crack it." There was general agreement that exercise planning was difficult and that in order for “any app to work,” each user had to first understand their own exercise effect and develop management strategies with carbohydrate supplementation and/or insulin reduction. Two of the group reported that they used the exercise feature regularly: that it was beneficial and that the feature served as a prompt to think about changing bolus doses when they were more physically active than usual. Three participants agreed that a basal dose adjustment prompt for prolonged exercise would also be helpful in instances where exercise is of long duration.

The alcohol bolus adjustment feature, which withholds the correction bolus after alcohol consumption, was considered by the group as an important feature, however there was disparity in the quantity of alcohol that represents the threshold for when this feature should be chosen. All users agreed that being able to record alcohol consumption (even for small quantities, when no dose change was programmed) was important, to enable reflection on the effect of alcohol on BG levels.

Blood glucose data is entered manually into the app to determine the bolus dose. The entire group agreed that it would be beneficial to have a BG meter that could transmit glucose data directly to the app, eliminating the need to manually enter glucose data into the phone. Responses to this option were "That would be brilliant"; "I would do a dance about that one" and "That would be awesome" emphasize the overwhelming desire for this feature.

**Diary report features**

There was an overwhelming group consensus that the app was a 'great' record keeping device, due to 1) the convenience of entering data onto a smart phone and 2) the fact that
participants were rarely without their phone, enabling “better record keeping” compared to previous diary methods and other apps that participants had used. Participants expressed the desire to retrospectively edit data pertaining to their diabetes management or food consumed. M1 (A30-34, D26) described, "It drives me mad how you can't put an entry in after (an event) at any time of the day. Then I don't bother putting it in. You just wouldn't do it: (you) just forget about it." There was also a consensus that the ability to record a ‘true’ account of diabetes management history (using free text options) and record pertinent events was a valuable feature. Participants raised the idea of a ‘shortcut’ button to enable easy recording of a pre-determined list of events, in addition to the current free text option, to record what they considered to be pertinent and useful information, when later reviewing BG trends. To further individualise the app, many felt it would be useful to be able to personalise screen displays by allowing removal (or cloaking) of features to simplify the user interface.

Three participants found the Rapidcalc method for creating diabetes diary reports, using a macro to convert raw data into a diabetes report was difficult, and that not being able to easily generate this BG diary data for their treating clinician was a problem. The group agreed that web based storage of settings and BG diary data would be a more effective way to manage their diabetes diary, both for their own reflection and when consulting their health care provider. Some participants referred to web based storage of other phone data and that web based storage of the RapidCalc settings on the phone would also be useful to ensure data safety in the event of loss of device.

There was group agreement on the desire for food database connectivity, to assist with carbohydrate counting and enable foods consumed to be easily recorded in the diabetes diary. Some participants suggested that it would be helpful to ‘register’ favourite foods in the set up process, enabling favourite foods to be recorded in the diary via a shortcut menu. Participants also felt that it was important to capture specific information about food when reviewing BG trends and some had used the photograph feature for this purpose.

**Satisfaction and control**

There was group consensus that the app made bolus calculation easier and quicker, with one participant (F1, A35-39, D27) reporting that "the application worked for me in that there was less thinking involved" and that BG control improved from the start of app use. The group agreed that the app provided an improved means of diabetes record keeping
compared to previous methods. Two participants also reported improved BG control since using the app.

Three participants, reflected on improved satisfaction, compared to their experience with other apps. F1 (A35-39, D27) reported, “I was using another diabetic app and it wasn’t maintainable for me” and F5 (A30-34, D25), “I find (the app) so user friendly compared to other apps.” M1 (A30-34, D26) reported, “I quite enjoyed using it,” and F1 (A35-39, D27), “It has offered me something that nothing else in my busy-ness and my avoidance has offered me.” The entire group found the app to be a useful adjunct to their diabetes management and a number reported they enjoyed using it.

Discussion

Users of the Rapidcalc app developed a trust in the app calculation rapidly and described improved efficiency and efficacy of day to day insulin management compared to other methods of dose calculation and recording, and recommendations to further improve usability and reduce the burden of management were identified.

The attributes of usability for which the group were able to give feedback were errors, efficiency and satisfaction. Errors were not detected and trust in the app dose calculation was determined early due to ‘dose checking’ against manual calculations, which the users were accustomed to doing prior to app use. Early establishment of trust in the dose calculation may be due in part also to the way that the components of the bolus dose are displayed on the screen, enabling quick verification of bolus dose components and total dose. This is in contrast to Shepard and colleagues, who found that pump users did not trust an ABC (the Personalised Glucose Advisory System) when they could not determine how the dose was calculated. The issue of over-riding the app bolus calculator dose highlights the knowledge and experience in this cohort to understand other factors that impact on BG levels and reflects the active role these users take in the insulin dose adjustment process. Users who lack the knowledge and experience to confidently verify bolus insulin doses may not develop trust as readily.

Users commented on the quick and easy access to dose calculation and diary recording on a device that most people carry on their person, suggesting greater efficiency compared to alternative devices, and suggestions were offered to improve efficiency further. Features that could ‘save time’ and reduce hypoglycaemia risk were valued and
the specific app features identified as useful were IOB, reverse calculator, exercise and alcohol bolus modifiers and phone-based BG diary. Though this was not measured, improved glycaemic control was also reported by some participants.

Users were able to give feedback on learnability in the setting of optimal access to health professional support. With appropriate training, users found the app easy to learn and use. First time users who do not have health professional support may struggle with learnability, especially if they are not familiar with flexible MDI strategies, such as carbohydrate counting and use of insulin dose algorithms, as the app requires the user to input specific insulin algorithms based on carbohydrate counting. Given that this app advises insulin dosing, it is expected that users would collaborate with their health professional in the programming and familiarisation process. Participants felt that they could not comment on memorability as they had not experienced resuming app use after a period of discontinuance.

Much of the discussion focused on app features that the group found useful and how the app could be further improved. The IOB feature is a novel concept for those who had not used an ABC previously and there was a positive response about the benefits of this feature in reducing hypoglycaemia risk. The reverse calculator was seen to be beneficial in controlling the tendency to ‘over treat’ hypoglycaemia. Over treatment of hypoglycaemia is a common practice and impacts negatively on HbA1c. The discrepancy between ‘usual’ hypoglycaemia management protocol and the calculation from the app is not surprising, given that the standard treatment for hypoglycaemia is based on a low glucose threshold (≤3.5 mmol/l) and fixed quantity of carbohydrate (15g), whereas the app mathematically calculates the relative carbohydrate quantity required to return the BG to target range. This issue is likely to be a concern with other users as well and highlights the importance of hypoglycaemia management education.

The bolus adjustment feature for exercise and alcohol were found to be helpful in reducing hypoglycaemia risk in those who used these features, though users felt that the threshold for bolus reduction in the setting of alcohol consumption needs to be individualised. Regarding bolus modifications for exercise, there was an overwhelming consensus that BG management around exercise was difficult and that individual requirements for exercise needed to be established before being confident to use the app to modify insulin doses for exercise. Users found that the exercise and alcohol bolus adjustment features
served as useful prompts to ‘consider’ dose adjustment in these settings. Fully adjustable
time frames were also preferred, to enable dose algorithms to be tailored to individual
requirements for meals and snacks. Pre-set time frames for insulin algorithm settings
appeared to increase the burden of dose determination in individuals who use varied
algorithms through the day.

The idea of connectivity between the app and food composition databases, to enable
carbohydrate data to be sourced and recorded, was favoured by the group: a preference
that has been demonstrated in other reports\textsuperscript{15,20}. Connectivity with the internet was also
favoured by the group, as a means to enable the diabetes diary data to be ‘securely’
stored and potentially able to be accessed remotely by health professionals.

Users placed high value on the diabetes diary and felt that it should reflect a full and true
account (including retrospective data edit capability) of diabetes management, confirming
that users consider a comprehensive diary to be a valuable tool in their diabetes
management. This desire to retrospectively edit diabetes diary data has also been
reported by Arsand and colleagues\textsuperscript{22}. Users felt it was important to record all data they
perceive to be pertinent, either by free text or with ‘personalised’ buttons to ‘economise’
data entry. Users of the Personalised Glucose Advisory system\textsuperscript{20} also reported that the
bolus calculator should take into account and record a broad range of factors affecting BG
levels, such as physical activity duration and intensity, consumption of higher protein and
higher fat meals, hormonal changes relating to the menstrual cycle, breastfeeding, stress,
shift work and alcohol consumption. The concerns about data safety and having easy
access to diary data lends further support to the importance that users place on diabetes
diary data and the sharing of this information with health care professionals.

Lawton & colleagues\textsuperscript{11} voiced the concern that some users of ABCs will fail to verify bolus
doses or reflect on glycaemic outcomes to inform ongoing insulin dose titration. This is a
valid concern. ‘Dose checking’ did drop off in this cohort, as seen in the Lawton cohort,
however one would expect this attrition, given that users have confirmed that the
calculations can be trusted. In this cohort as well as Lawton’s, individuals were identified
who exhibited either a ‘blind trust’ in the bolus calculator, or did not know how to adjust the
insulin algorithms, which is a concern if the algorithms are not optimised. Lawton’s
concern that dependency on the bolus calculator may lead to deskilling, abandoning
diabetes diary reflection and proactive titration of insulin doses and reliance on the bolus
calculator, leaving users potentially unable to determine doses in the event of meter failure is also valid and highlights the importance of ongoing education and support, before and after the introduction of ABC’s.

A recurring theme across a number of features was the desire for functionality that reduces the burden of day to day management: in diabetes diary recording and carbohydrate counting, with shortcut buttons and BG meter and food database connectivity, personalisation of user screens and easier access to BG diary data. This highlights that role that ABCs can play to reduce the burden of day to day management, however care should be taken to ensure that ABCs are not offered in place of structured education in insulin self-management, a process that is difficult to ‘short cut’. Others have stressed that when ABCs are used, comprehensive education in flexible MDI should remain the key focus of self–management \textsuperscript{11,23}, with education and support on ABC use delivered by health professionals familiar with ABC functionality. Structured education and ongoing support for flexible MDI using an ABC should include, at the very least, the following: 1) appropriate education on patient-based flexible MDI, including carbohydrate counting , 2) comprehensive education on programming and use of the dose calculator, delivered by health professionals experienced with these devices, 3) pattern evaluation education using the bolus calculator diary and graphs and 4) regular and ongoing insulin optimisation support from health professionals experienced in use of ABCs and a meter failure plan.

Limitations
The main limitation of this study is the small number of participants and one focus group. We deliberately targeted adults with T1DM who were managing their diabetes in a specific way, using advanced skills that require a certain degree of health literacy and self-directed care. Using DAFNE graduates ensured that all participants had received similar flexible MDI education, enabling us to focus on the patient experience with the app in those who have received flexible MDI self-management education. All DAFNE graduates have experienced nearly 40 hours of group interaction and hence we were confident of the ability of focus group participants to not be ‘led’ by others in the group, or for the group to be dominated by any individual. Despite the small number of participants, we feel feedback from this focus group has yielded valuable user experiences on specific app features in individuals self-managing flexible MDI. We are not able to comment on the
usability of this app for other patient groups, where flexible MDI education has not been provided, or in those with low health literacy.

The recruitment of DAFNE graduates yielded a cohort that is more confident with carbohydrate counting and patient-based insulin adjustment and the trust in the app calculation and willingness to over-ride the bolus suggestion for special circumstances observed in this cohort is most likely enhanced by a familiarity with insulin adjustment terminology and patient-based insulin dose adjustment strategies. The process of confirming the dose calculation and over-riding a dose based on prior experience may not apply to users who are not confident with insulin dose adjustment strategies and this may have an eroding effect on confidence and willingness to use the app in instances where adequate education and support are not available.

The focus group participants all had long standing diabetes (average 27 years, range 20 – 38 years), however, this selection bias is not expected to impact on how the app may be perceived or used. Those newly diagnosed with T1DM are taught similar concepts in patient-based insulin optimisation from diagnosis, hence are also expected to be able to successfully use the app, providing insulin algorithms are adjusted as insulin requirements change during the honeymoon phase.

The short duration of follow up limits the ability to comment about retention or efficacy of this device when it is no longer novel or resumption of app use after a period of discontinuance. Given that the app performs the dual function of dose calculation and diabetes diary recording and has the potential to reduce the burden of diabetes management, we feel that users who are motivated to self-manage patient-based flexible MDI and maintain a diabetes diary will continue to use this app in preference to paper-based approaches and other mobile phone apps currently available. For those resuming app use after a period of discontinuance, the ‘help’ screens within the app may assist with memorability. The inclusion of pattern recognition software has been suggested 11 and this may reduce attrition associated suboptimal control due to inappropriate insulin algorithms.

Flexible MDI therapy is also taught outside of the DAFNE program24-26, and though there are differences between programs in terms of mode of delivery and course duration, these programs all address what are considered to be the ‘core’ elements of insulin self-
management education, namely, carbohydrate counting, insulin dose algorithms, adjustment for illness and exercise and proactive dose adjustment of insulin algorithms, and programs generally require users to manage dose calculations manually\textsuperscript{27}. We feel that the insights from this focus group can be extrapolated to other patients who have received flexible MDI education outside of the DAFNE program.

Insulin users with low health literacy may gain as much, or greater benefit from using a phone app for dose calculation, to reduce risks associated with dose calculation errors and improve communication of data with health professionals. As with this study cohort, care would need to be taken to ensure that the appropriate carbohydrate counting education is provided, however modifications to the app, such as pattern recognition and prompts to contact health professionals are potential exciting directions for future research with a broader user group.

Conclusions

Overall, users were satisfied and enjoyed using the app to manage their diabetes and trust in the bolus calculator was developed relatively quickly. The ability to maintain a true and complete diabetes diary that enables users to record a range of factors in daily management is important to adults with T1DM who are actively engaged in their insulin self-management. Features such as personalised user screens, shortcut buttons for data entry, and food database and meter connectivity, were highly valued for their potential to reduce the burden of day to day management. Also favoured were options to increase accessibility to a full and accurate account of diabetes management in the diabetes diary that is easily accessible to users and their health professionals. The importance of comprehensive education, both in terms of patient-based insulin dose determination, as well as ongoing dose titration is not diminished or substituted by use of a bolus calculator. These devices should be considered as tools to reduce the burden of flexible MDI and should supplement sound flexible MDI education.

This focus group has provided valuable insights into the features of a smart phone-based app that adults with T1DM feel are important to support effective patient-based flexible MDI. Longer term follow up of patient experience and clinical efficacy of mobile phone apps incorporating these features warrants further investigation.
Tables and Appendices

Table 1: Participant characteristics

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Diabetes duration (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30-34</td>
<td>F</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>30-34</td>
<td>M</td>
<td>26</td>
</tr>
<tr>
<td>3</td>
<td>30-34</td>
<td>F</td>
<td>21</td>
</tr>
<tr>
<td>4</td>
<td>30-34</td>
<td>M</td>
<td>25</td>
</tr>
<tr>
<td>5</td>
<td>30-34</td>
<td>F</td>
<td>27</td>
</tr>
<tr>
<td>6</td>
<td>35-39</td>
<td>F</td>
<td>34</td>
</tr>
<tr>
<td>7</td>
<td>50-54</td>
<td>F</td>
<td>38</td>
</tr>
</tbody>
</table>
Appendix A: Focus Group Questions

<table>
<thead>
<tr>
<th>Questions</th>
<th>Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tell me about your experiences using the rapidcalc app</td>
<td>Satisfaction</td>
</tr>
<tr>
<td>Prompts if needed:</td>
<td></td>
</tr>
<tr>
<td>• Challenges</td>
<td></td>
</tr>
<tr>
<td>• Benefits of app</td>
<td></td>
</tr>
<tr>
<td>Describe your experience with learning how to use the app (general question first, then more specifically,...) Prompts if needed:</td>
<td>Learnability</td>
</tr>
<tr>
<td>• Inputting settings</td>
<td></td>
</tr>
<tr>
<td>• Use of help screens</td>
<td></td>
</tr>
<tr>
<td>• Using dose calculator</td>
<td></td>
</tr>
<tr>
<td>Did you feel you could trust the bolus calculator?</td>
<td>Errors</td>
</tr>
<tr>
<td>Prompts if needed:</td>
<td></td>
</tr>
<tr>
<td>• How closely does the application suggested dose compare with your usual bolus calculations?</td>
<td></td>
</tr>
<tr>
<td>• For meals</td>
<td></td>
</tr>
<tr>
<td>• For snacks</td>
<td></td>
</tr>
<tr>
<td>How does the app influence your efficiency in:</td>
<td>Efficiency</td>
</tr>
<tr>
<td>• Dosage calculation?</td>
<td></td>
</tr>
<tr>
<td>• BGL diary recording?</td>
<td></td>
</tr>
<tr>
<td>• Exercise adjustments?</td>
<td></td>
</tr>
<tr>
<td>• BGL diary reflection?</td>
<td></td>
</tr>
<tr>
<td>• Communication of your diary with another person (eg. your health professional)</td>
<td></td>
</tr>
<tr>
<td>Specific features- what is your experience with specific app features:</td>
<td>Efficiency</td>
</tr>
<tr>
<td>• IOB</td>
<td>Satisfaction</td>
</tr>
<tr>
<td>• Reverse calculator</td>
<td></td>
</tr>
<tr>
<td>• exercise feature</td>
<td></td>
</tr>
<tr>
<td>• history page</td>
<td></td>
</tr>
<tr>
<td>• graphs</td>
<td></td>
</tr>
<tr>
<td>If you were to have a period of not using the app, do you think that you can easily pick it up again and remember how to use it?</td>
<td>Memorability</td>
</tr>
<tr>
<td>What would you ask the developers to change? Given the opportunity to build a new application from scratch, what would you put in to make it better?</td>
<td>Future improvements</td>
</tr>
<tr>
<td>Do you plan to continue to use rapidcalc?</td>
<td>Satisfaction</td>
</tr>
</tbody>
</table>

List of abbreviations

ABC automated bolus calculator
BG blood glucose
CP carbohydrate portion
Declarations

Ethics approval and consent to participate
All participants were informed of aims of the study and gave their written consent. The study was approved by the Mater Health Services Human Research Ethics Committee.

Consent to publish
All authors have confirmed approval of the final manuscript and provided consent to publish.

Availability of data and materials
The authors do not wish to make the data available as it contains information that could identify specific individuals.

Competing interests

BK contributed to the app development specifically with respect to the clinical features, with the aim of developing a tool to assist clients using flexible MDI. There is no financial benefit to the authors in the app development or its promotion. The App developer did not contribute financially to the project, nor were they involved with the data analysis, interpretation or publication.

Funding
No funding was allocated to this study

Authors’ contributions
HDM and IH contributed to the study conception, design, manuscript revision and final approval. MN contributed to the study conception, design, conducted participant interviews and independently reviewed interview transcripts. BK conceived the study, managed ethics approval and study coordination, analysed participant interview transcripts and drafted the manuscript. All authors read and approved the final manuscript.

Acknowledgements

This trial has received no funding, and we are thankful to DAFNE graduates who have contributed to this study.

Authors’ information

BK: Brigid.Knight@health.qld.gov.au
Queensland Diabetes and Endocrine Centre, Mater Health Services, Brisbane, Australia;
Lady Cilento Children’s Hospital, Brisbane Australia.

HDM: David.McIntyre@mater.org.au
School of Medicine, University of Queensland, Brisbane, Australia;
Queensland Diabetes and Endocrine Centre, Mater Health Services, Brisbane, Australia;
Mothers and Babies Theme, Mater Research Institute – University of Queensland, Brisbane, Australia;
Mater Research Institute, University of Queensland, Brisbane, Australia.

IH: Ingrid.Hickman@health.qld.gov.au
Dept of Nutrition & Dietetics, Princess Alexandra Hospital, Brisbane, Australia;
Mater Research Institute, University of Queensland, Brisbane, Australia.

MN: Marina.Noud@health.qld.gov.au
Queensland Diabetes and Endocrine Centre, Mater Health Services, Brisbane, Australia;
Lady Cilento Children’s Hospital, Brisbane Australia.
References


10. Ramotowska A, Szypowska A. Bolus calculator and wirelessly communicated blood glucose measurement effectively reduce hypoglycaemia in type 1 diabetic children -


Discussion and implications of findings Chapter 3

The rapidcalc iphone app was developed by Gilport Enterprises (http://www.gilport.com/rapidcalc/index.html) in collaboration with myself, with the specific aim of providing a multi-purpose phone-based app to assist people using flexible MDI therapy. The DAFNE cohort was identified as a patient group who would be ‘optimally’ trained in using flexible MDI strategies, hence the collaboration with myself as a DAFNE facilitator in developing the clinical parameters of this app.

This study sought to identify the specific features of a novel iphone app that would support adults in managing the myriad of tasks required to successfully self-manage intensive MDI therapy. We found that users who were self-managing MDI therapy were highly engaged in their diabetes management and valued app features that enabled safe dose calculation, accurate and comprehensive diary recording and diabetes diary reporting that was secure and able to be communicated with health professionals. App features unique to this device, which users found useful were, the reverse calculator, insulin reduction advice following alcohol consumption or after hypoglycaemia and free text options for data entry. Users preferred using the app to other phone-based diabetes apps, and further customisation to reduce the burden of record keeping, and functionality to improve data safety and connectivity with other apps were identified for future app development.

Additional directions for future development include evaluation of this app in insulin-users with limited numeracy. Connectivity with BG meter and food database would reduce the burden of data entry by the patient, as well as reduce the undue risk of medication errors in individuals with reduced numeracy. This device has the potential to support patient-based management of insulin therapy in individuals who may have previously relied on health-professional-centred direction for insulin management and the improved communication with the diabetes diary opens up viable alternatives to patient support, outside of the traditional clinic visit.

Outside of the DAFNE setting, the app may also be useful to support flexible MDI therapy, however care must be taken in patient selection to ensure that users have some basic understanding of carbohydrate counting and insulin action and algorithms. This app is not considered as a ‘stand-alone’ tool to be used ‘in place’ of basic diabetes education, as errors in either carbohydrate count or accidental mistakes in app programming may result in insulin dose errors.
Planning is currently underway to evaluate the app in a clinical trial with a larger patient group, taking into account additional outcome measures, including glycaemia. This will also enable assessment of the app in users who have not received the structured/extensive diabetes education that is the hallmark of DAFNE course.
Chapter 4: Evaluation of psychosocial outcomes in adults with Type 1 diabetes following participation in a novel ‘short course’ structured flexible multiple daily injection (MDI) therapy self-management program

Brigid A Knight¹,²,⁶, Ingrid J Hickman ³,⁴,⁵, Kristen Gibbons ⁴, Janet Taylor ¹,⁶
Harold D McIntyre¹,⁴,⁵

Practical Diabetes. 2017; 34 (7): 235-239a
Evaluation of psychosocial outcomes in adults with Type 1 diabetes following participation in a novel ‘short course’ structured flexible multiple daily injection (MDI) therapy self-management program.

Brigid A Knight1,2,6, Ingrid J Hickman3,4,5, Kristen Gibbons4, Janet Taylor1,6 Harold D McIntyre1,4,5

1 Queensland Diabetes Centre, Mater Health Services, Raymond Tce, South Brisbane, Australia
2 Lady Cilento Children’s Hospital, Stanley Street, South Brisbane Australia
3 Dept of Nutrition & Dietetics, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, Australia
4 Mater Research Institute, University of Queensland, Raymond Tce, South Brisbane, Australia
5 Mater Clinical School, University of Queensland, Raymond Tce, South Brisbane, Australia
6 TIPS for Diabetes, Level 5, 201 Wickham Tce, Brisbane, Australia

Keywords: multiple injection therapy, education, type 1 diabetes, structured education

Funding: No funding was provided.

Conflict of Interest:

Brigid Knight is a member of the OzDAFNE advisory board and involved in the delivery of DAFNE courses and training. Janet Taylor is an accredited DAFNE facilitator. H David McIntyre is a member of the OzDAFNE advisory board. Ingrid Hickman and Kristen Gibbons have no conflict of interest.
Title Evaluation of psychosocial outcomes in adults with Type 1 diabetes following participation in a novel 'short course’ structured flexible multiple daily injection (MDI) therapy self-management program.

Abstract

Objectives
To evaluate the psychosocial impact of a novel education program, comprised of an abbreviated curriculum based on the ‘core elements’ of insulin self-management education, with a view of identifying education options for those unable to attend a 5-day Dose Adjustment for Normal Eating (DAFNE) program.

Methods
The program was developed by DAFNE course facilitators and trialled using participants naive to flexible MDI education. Post course treatment satisfaction, wellbeing and diabetes distress were compared to baseline.

Results
Twenty one adults attended the program and sixteen participants returned 3 months post course. Significant improvements were seen in W-BQ12 total score, PAID score and DTSQ, equivalent to that observed following participation in the 5-day program.

Conclusions
Short-course flexible MDI education is well tolerated by adults with T1DM with improvements in treatment satisfaction and psychosocial outcome that are consistent with the 5-day DAFNE program. Further investigation of the glycaemic impact of this novel curriculum is warranted.
1. Introduction
Since the Diabetes Control and Complications Trial (DCCT), where insulin management was mostly 'physician led' with fixed insulin dose prescription, there has been a move toward patient-based insulin management using flexible multiple daily injection (MDI) therapy. There has also been greater recognition of the value of a structured curriculum in patient self-management education. Structured flexible MDI education programs have demonstrated improvements in HbA1C\textsuperscript{1-13}, reductions in hypoglycaemia\textsuperscript{4,6,7,9,10,13,14} and improvements in quality of life\textsuperscript{1,5,12,15} and patient reported outcome measures (such as treatment satisfaction, diabetes distress and wellbeing).\textsuperscript{1,4,5,7,13} Structured education programs are characterized by: a clear underlying philosophy, a structured written curriculum, a quality assurance process in program development and outcome assessment, and delivery by trained facilitators.\textsuperscript{16} This ensures that education is guided by an established curriculum and all patients receive the same teaching, regardless of participant variables (eg, previous education or diabetes duration) and facilitator variables.

Flexible MDI education programs differ in design and delivery. Most programs focus on: carbohydrate counting, flexible insulin dosing according to carbohydrate content of meals, corrective insulin to return blood glucose towards target range and management strategies based on daily activities that impact blood glucose levels, such as physical activity, alcohol consumption and illness. Programs address day to day dose determination as well as ongoing proactive insulin dose optimisation and may include a psychosocial component\textsuperscript{3} and individual goal setting.\textsuperscript{17} Many programs are based on adult learning principles and support skills based teaching including learning from experience and observation. The complex nature of such programs results in a lengthy time commitment with some programs conducted over 4 - 5 days.\textsuperscript{1,5,6,10,17} Many programs deliver this education in a group format which, in addition to potentially being more resource efficient, has been shown to enhance learning opportunities, as group members are able to contribute varied individual experiences and strategies in diabetes management.\textsuperscript{18}

Five-day structured education programs for flexible MDI, which include the Dose Adjustment for Normal Eating (DAFNE) program\textsuperscript{1} and the Diabetes Teaching and Treatment Program (DTTP),\textsuperscript{8} have consistently demonstrated beneficial clinical outcomes across different countries,\textsuperscript{7,8,10,13} however there are barriers to access and delivery of a 5-day program, which include the impact on work/home life, loss of income and increased demand for hospital resources. Short duration flexible MDI education programs include a
program reported by Oswald and colleagues, where improvements in glycaemic control were seen following participation in a program consisting of group and 1:1 consultations, with a mean of 90 minutes of professional contact per patient. Bendik and colleagues report reduced frequency of severe hypoglycaemia, improved quality of life and increased autonomy in a program delivered in weekly 90 minute sessions over seven weeks.

Successful flexible MDI self-management requires the patient to: 1) understand day to day insulin dose adjustment according to a variety of factors, such as carbohydrate intake, blood glucose (BG), physical activity and illness and 2) identify the requirement for proactive optimisation of basal insulin doses and bolus insulin algorithms. The curriculum topics that address these skills are carbohydrate counting, insulin dose algorithms and pattern based evaluation, which have been identified by Grant and colleagues as ‘core’ curriculum items for structured flexible MDI self-management education. Participants in the 5-day program manage the daily dose calculation with little difficulty, but struggle to perform proactive insulin optimisation despite practising this on a daily basis in the 5-day program. Many 5-day program participants stated a preference to rely on trained health professionals to manage this flexible MDI task. Offering proactive insulin optimisation education and support post course may enable the day to day insulin determinations to be taught in a short course format, with proactive insulin optimisation tailored to individual requirements post course.

We developed the curriculum with the aim of combining the following attributes of flexible insulin self-management education in a novel program, which to the author’s knowledge currently doesn’t exist: short course format focusing primarily on skills of carb counting and flexible insulin algorithms, use of established insulin algorithms (from DAFNE), use of a structured curriculum and with proactive insulin support offered by experienced facilitators on a 1:1 basis, post course. Compared to the 5-day program, the shortened program is less time consuming (40 vs 10 hours) and includes only the ‘basic’ components involved in daily determination of insulin doses in the setting of flexible MDI therapy. It doesn’t include a number of (5-day program) curriculum components aimed at improving overall knowledge (such as diabetes physiology, exercise physiology, ketone development, pregnancy diabetes and travelling with diabetes) and motivation (goal setting). The risk shortening this education is that participants may struggle to learn often complex calculations over this time frame and that it may lead to distress or dissatisfaction.
We sought to pilot the program in adults with T1DM and evaluate:
1) the impact on treatment satisfaction, diabetes distress and wellbeing
2) the frequency that participants contacted facilitators for assistance with 'proactive insulin optimisation' support
3) participant feedback on the curriculum items that were deemed useful

2. Methods:
Two specialised DAFNE facilitators (diabetes specialist nurse and diabetes specialist dietitian) with experience in DAFNE dosing strategies and adult learning principals developed the curriculum to be delivered in two, 5 hour sessions, 1 week apart. The curriculum topics were: carbohydrate counting, BG targets, hypoglycaemia management and basal insulin titration strategies (session 1), and bolus insulin dosing algorithms, snack dosing, adjustment for exercise, alcohol and sick days and brief introduction to proactive insulin optimisation (session 2). Patients were encouraged to email between session 1 and 2 for carbohydrate counting support. Proactive insulin optimisation was briefly addressed in session 2 to ensure that participants understood that this was also an important part of insulin self-management and would be conducted post course. Post course proactive insulin optimisation support was offered in the form of email/phone contact, which was encouraged on a weekly basis for 4 weeks after session 2. A structured curriculum was used and participants were provided with learning materials (worksheets, carbohydrate counting resources, BG diary, insulin adjustment rules and BG targets). End of study data collection was conducted three months post course. At this time, participants were asked to identify topics they found useful and not useful in a shortened curriculum. Figure 1 outlines the schedule of course delivery, follow up and data collection.
Adults with T1DM were recruited from this study centre and referrals from local endocrinologists. Participants who met the study criteria were sequentially recruited into one of four group programs, with up to 8 participants per group. This ‘patient only’ program did not include partners or other family members. Inclusion criteria for the program and study were consistent with the 5-day DAFNE program with the following exceptions: HbA1C 7 – 10% (53 – 86 mmol/mol), using rapid acting analogue insulin for meals and long acting analogue insulin once or twice/day and agree to test blood glucose 4 - 6 times/day. Exclusion criteria were: illness preventing group participation, inaccessibility to email or fax, pregnancy or breast feeding and previous attendance at 5-day DAFNE course.

At baseline, the following data were collected: age, gender, duration of diabetes and history of diabetes complications, and at baseline and study end data collected were HbA1C, body mass index, number of severe hypoglycaemic episodes in previous three months, number of BG tests performed (over the previous two weeks), number of BG tests recorded (over the previous two weeks), Problem Area in Diabetes (PAID questionnaire, available from garry@silverfernhealthcare.com), Wellbeing questionnaire (W-BQ12, available from www.healthpsychologyresearch.com) and Diabetes Treatment Satisfaction Questionnaire (DTSQs, available from www.healthpsychologyresearch.com). DTSQs total score comprises the composite score from six items and total score ranges from 0 to a maximum score of 36, with higher scores indicating greater treatment satisfaction. The W-BQ12 instrument is a measure of depressed mood and anxiety (negative well-being subscale), energy and positive well-
being, however none of the sub-scales are diabetes-specific. Each of the three subscales has four items scored 0 to 3 and a total scoring range of 1 – 12, which contribute to the total score (range 0 – 36) with higher scores indicating better well-being. The PAID questionnaire comprises 20 questions that address a range of emotions frequently expressed in diabetes and the total score (range 0 – 100) is a measure of diabetes related distress, with higher scores indicating greater distress.

Baseline data and change variables were tested for normality using the Shapiro-Wilk test. Variables were compared at baseline and post course using the paired t-test for normally distributed change variables and the Wilcoxon matched pairs test for the remainder. For categorical data, Fisher’s exact test was used. Statistical calculations were performed using STATISTICA (data analysis software system), version 12.0 (StatSoft, Inc.).

All participants gave their written consent. The study was approved by the Mater Health Services Human Research Ethics Committee.

3. Results
Twenty one participants were recruited to 4 groups, with 6 participants per group for 2 groups, 5 in one group and 4 in one group. Sixteen of the twenty one participants (76%) returned for three month follow up. There was loss to follow up in 3 groups, 1 participant in two groups and 3 participants in one group. Baseline characteristics of participants who failed to return for follow-up were similar to those who attended follow up, with the exception of the W-BQ12 energy subscale. Participants who failed to return had a lower baseline mean [SD] W-BQ12 energy score (4.2 [1.9]), indicating less energy, compared to those who attended follow up (6.8 [2.3], p = 0.039).

Table 1 summarises the short-course outcome data . The novel program demonstrated significant improvements in all psychosocial scores: mean (SD) W-BQ12 from 25 (5) to 28 (7), mean (SD) DTSQ from 25 (4) to 31(5) and median (IQR) PAID 19 (14-36) to 8 (5-14).

No statistically significant change was seen post course for HbA1C, either on a whole cohort basis or when participants with baseline HbA1C < 7.5% (7/21 participants) were excluded from the analysis. Weight and body mass index were also unchanged. Participants failed to conduct SMBG as recommended (4/day, or 56 performed over 2 weeks) at baseline and post course. There was no change in the frequency of SMBG or SMBG recording or in BMI. Severe hypoglycaemia was reported by 3 (14%) participants.
at baseline three months prior to baseline assessment, compared nil post course (data not shown). Post course, two participants sent 3 – 4 emails over the 4 weeks post course, two participants sent two emails and six participants sent one email. Seven participants made no contact with the facilitator for assistance for post course proactive insulin optimisation.

Table 1: Short course outcomes

<table>
<thead>
<tr>
<th></th>
<th>Pre course</th>
<th>Post course</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1C - %</td>
<td>8.0 (0.7)</td>
<td>8.0 (0.9)</td>
<td>0.969</td>
</tr>
<tr>
<td>- mmol/mol</td>
<td>64 (8)</td>
<td>64 (10)</td>
<td>0.943</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.6 (70.2 – 82.5)</td>
<td>74.1 (69.1 – 81.9)</td>
<td>0.127</td>
</tr>
<tr>
<td>Body Mass Index (kg/m2)</td>
<td>26.9 (2.9)</td>
<td>26.5 (3.1)</td>
<td>0.202</td>
</tr>
<tr>
<td>No. of BG tests performed over 2 weeks</td>
<td>49.5 (27.1)</td>
<td>51.9 (20.9)</td>
<td>0.783</td>
</tr>
<tr>
<td>No. of BG tests recorded over 2 weeks</td>
<td>0 (0 – 52)</td>
<td>56 (0 – 56)</td>
<td>0.208</td>
</tr>
<tr>
<td>Rapid insulin TDD (U/d)</td>
<td>29.1 (11.7)</td>
<td>24.5 (8.3)</td>
<td>0.132</td>
</tr>
<tr>
<td>Basal insulin TDD (U/d)</td>
<td>28.4 (8.9)</td>
<td>30.3 (9.9)</td>
<td>0.184</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.9 (2.9)</td>
<td>26.5 (3.1)</td>
<td>0.202</td>
</tr>
<tr>
<td>W-BQ12 total score</td>
<td>25 (5)</td>
<td>28 (7)</td>
<td>0.038</td>
</tr>
<tr>
<td>DTSQ overall score</td>
<td>25 (4)</td>
<td>31 (5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PAID overall score</td>
<td>19 (14 - 36)</td>
<td>8 (5 - 14)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

N = 16. Normally distributed variables described as mean (SD), otherwise as median (IQR). Normally distributed baseline variables compared using independent t test, otherwise Mann-Whitney U Test was used. BMI = Body mass index (kg/m²). HbA1C = glycosylated haemoglobin. TDD = Total daily dose (U/d). DTSQ = Diabetes Treatment Satisfaction Questionnaire. PAID = Problem Areas in Diabetes. W-BQ12 = 12 item Wellbeing Questionnaire.

Of the sixteen participants who returned for the three month follow up assessment, fifteen were using carbohydrate counting and ratio dosing with insulin algorithms, compared to
none at baseline. Participants identified the following curriculum topics as most useful: carbohydrate counting, using insulin:carbohydrate ratios and learning the process of insulin adjustment. Two participants nominated “learn how to evaluate own insulin doses” as useful.

4. Discussion and conclusion
4.1 Discussion
Treatment satisfaction, wellbeing and diabetes distress improves in adults with T1DM following participation in a novel ‘short course’ structured flexible MDI education program.

This cohort were similar to the 5-day DAFNE participants in terms of mean [SD]: HbA1C (8.0 [1]%; 65 [11] mmol/mol), diabetes duration (18 [11] years), BMI (27 [3] kg/m²) and frequency of severe hypoglycaemia (29%), however they were slightly younger (34.8 [10.7] vs 43.3 [14.3] years), and fewer had retinopathy (14 vs 29%) and neuropathy (0 vs 10%). The first Australian audit of the 5-day DAFNE program demonstrated a ‘clinically relevant’ median (IQR) drop in PAID from 25 (15-45) to 16 (10-30) (p<0.0001), which is consistent with the mean (SD) drop for the UK audit of 25 (17) to 17 (14) (p<0.001). A more recent Australian audit of the 5-day program also demonstrated a 10-point drop in the PAID score post course. The 10-point reduction in PAID in the current study suggests the short course has an equivalent positive impact on diabetes distress as the 5-day program despite lower PAID scores for this cohort at baseline.

The increase in treatment satisfaction in this cohort is also clinically relevant, although the magnitude of improvement was slightly less than that seen in the 5-day program, where mean (SD) DTSQ increased from 23 (6) to 32 (4) at 6 months, the post course scores were similar. The higher treatment satisfaction at baseline for this cohort compared to the comparison 5-day course, may limit the ability to detect an improvement due to the ‘ceiling effect’ of this tool, where ‘close to maximum’ scores at baseline limit the ability to see a change or improvement post course. We chose the DTSCs (status version) which is known to be limited by the ceiling effect, to enable comparison to the 5-day DAFNE program.

The improvement in total wellbeing score of 4 points was similar to that seen in the 5-day program, where mean (SD) total wellbeing score increased from 21 (6) to 24 (6), six months post course. The lower mean ‘energy’ well being scores in those who failed to return for follow up may have limited the improvement seen post course as the greatest...
gains in quality of life measures are seen with ‘poorer’ measures of quality of life at baseline\textsuperscript{30}.

As with the 5-day program, participants in this study were not confident with the process of proactive dose optimisation and there was a heavy reliance on the facilitators to direct proactive dose decisions. The limited use of the BG diary (an essential tool in proactive insulin optimisation) and the low numbers of participants (n =2) suggesting inclusion of the topic, “learn how to evaluate your own insulin doses” in the short-course format, supports the notion that participants in this cohort were also reluctant to take on the role of proactive insulin optimisation. The use of email/phone proactive insulin optimisation support in less than 50% of participants, suggests either an unwillingness to take on this activity, or that the mode of delivery of this support was not suitable, or both. Most participants (15/16 [94%]) were carbohydrate counting and using insulin algorithms by the end of the course.

The short course program failed to influence SMBG frequency and many participants failed to conduct SMBG as recommended. Despite the majority of participants making changes to their daily diabetes management (carbohydrate counting and dosing with insulin algorithms) change in management did not translate to increasing SMBG frequency. Such a change may represent a greater degree of behaviour modification than changing how the insulin is calculated at each meal. This highlights the limitation of this short course curriculum, which does not address behaviour modification. In addition, the duration of the group interaction may not provide adequate opportunities for participants to observe the value of regular SMBG. More selective inclusion criteria that require participants to be demonstrating appropriate SMBG frequency prior to course enrolment may be required for those participating in the short course program.

The failure to see an improvement in HbA1c with the short course program may be due to limited power to detect a change in HbA1c associated with study size. Given that the majority of participants were conducting intensive management at the end of the course, we would hope to see this translate to improvements in glycaemic control, however a more rigorous evaluation of glycaemic outcome is warranted.

\textbf{Limitations}

Compared to 5-day DAFNE participants, this cohort was slightly younger with fewer diabetes complications. However, given the similar baseline characteristics and the
enrolment of only adults, we do not expect this difference to contribute any bias in our study. The predominance of female participants is consistent with general experience at this site for the 5-day DAFNE course and the clinical implications of this bias are expected to be minimal.

The comparison of psychosocial data in this cohort (after briefer 3 month follow up) with the 5-day DAFNE program (after 6 and 12 months) may introduce some bias. However given that the magnitude in change in PAID, W-BQ12 and DTSQ scores was equivalent to that seen at 6 and 12 months with the 5-day program, and the relative stability in these quality of life from 6 to 12 months in the 5-day program\textsuperscript{12} we consider it most likely that these changes are seen relatively promptly post course and sustained up to 6 and 12 months, enabling comparison with these longer term studies.

4.2 Conclusion
Short-course flexible MDI self-management education is well received by adults with T1DM and may be an alternative or adjunctive option for those who are unable to access a 5-day program. The poor utilisation of post course proactive insulin optimisation support reflects the previously observed reluctance to take on this aspect of flexible MDI therapy and alternative approaches to supporting proactive insulin optimisation both in the 5-day as well as short course format are required. Evaluation of longer term impact on psychosocial as well as glycaemic outcome for this novel program are also warranted.

Acknowledgements
The authors thank the participants who contributed their time in providing valuable feedback on this novel program.
References


10. Sämann A, Mühlhauser I, Bender R, Kloos C, Müller UA. Glycaemic control and severe hypoglycaemia following training in flexible, intensive insulin therapy to


Discussion and implications of findings Chapter 4

This study describes the development of novel short course structured curriculum using similar dose algorithms as the DAFNE 5-day curriculum and the impact on patient reported outcome measures. This program was developed by DAFNE facilitators, using DAFNE insulin dose algorithms as these were consistent with common practice at the time, however the short course program is not part of the OzDAFNE collaborative.

Given the short duration of the program and ‘skills ‘based' focus on carbohydrate counting and insulin dose algorithms, it was acknowledged that the program would not be able to address behaviour change and thus aimed to recruit individuals who were already conducting some specific important management behaviours of multiple injection therapy. As such, the additional inclusion criteria which were added to the standard DAFNE criteria were: baseline HbA1c 7 – 10%, already using basal bolus insulin therapy and self-monitoring of blood glucose 4 – 6 times/day. The standard DAFNE criteria were also used, which were: T1DM, no longer in honeymoon, > 18 years of age, able to read and write English, absence of psychiatric illness, not pregnant and able to interact in a group setting.

We found adults with T1DM were able to learn how to manage the daily dose calculations for flexible MDI following short course participation. Significant improvements in diabetes distress, treatment satisfaction and wellbeing were observed. The magnitude of improvement in these measures appears to be consistent with that seen in the 5-day program. This study confirms that a shortened structured flexible MDI education program based on carbohydrate counting and insulin dose algorithms from the 5-day program is well accepted in adults with T1DM and improves psychological parameters to the same degree as the 5-day program.

For a short-course program to be effective, we believe that it is important to select appropriate patients who are already practicing some basic elements of multiple injection therapy, as the short course curriculum is likely to be ineffective in changing multiple behaviours. As such, we feel that the full 5-day program will continue to be suitable for many patients, but the option for a short-course program is also important, for those who may benefit from abbreviated education in the specific skills in use of insulin algorithms. Having a short-course option for education will enable health care professionals to deliver
targeted education to specific patients over two ½ day sessions (potentially requiring health professional input of 2 full days when emails are taken into account) in the place of 5-full days, which represents a time and cost effective approach. 

Further evaluation of the impact of this short-course format on glycaemic outcomes and with a larger cohort is warranted.
Chapter 5: Conclusion

This thesis explores both the dietary behaviours and the patient experience with structured flexible MDI education using the OzDAFNE program, and presents novel and original data regarding dietary intake and alternative approaches to supporting self-management of flexible MDI outside of a 5-day program. The work has addressed the research questions and aims outlined in chapter 1. In this final chapter, I summarise the main contributions that this thesis has made to the field of T1DM intensive management education and include suggestions for future research directions.

Main contributions and future research

The first manuscript addressed the quantitative assessment of the impact of intensive flexible MDI therapy education with an active promotion of dietary freedom on energy and nutrient intake. This is the first quantitative study of the dietary impact of this educational program and supports existing qualitative data, demonstrating that despite an active promotion of increased dietary freedom, rather than eat more simple sugar and saturated fat containing foods, adults with T1DM took the opportunity to eat less and were able to self-manage insulin doses to minimise the risk of hypoglycaemia. This has implications for weight management in insulin users, who are potentially at increased risk of hypoglycaemia when choosing to eat less without flexible insulin strategies. This study also confirms few adults with T1DM achieve nutritional recommendations, consistent with national and international trends.

The questions that are raised by this study include:

- Would the active inclusion of advice directed at achievement of nutritional guidelines, alongside flexible MDI education improve achievement of nutritional recommendations?
- Is this education superior to standard management for the management of weight in overweight or obese individuals with T1DM or those with T2DM using insulin?

Patient-based flexible MDI therapy requires patients to manage often complex mathematical calculations on a daily basis, with increased risk of adverse outcome with errors in calculation. In addition, patient-centred management requires effective communication between patients and health professionals to enable timely and relevant
support to the patient. The second manuscript investigated the user perspectives of a novel iphone application designed to support patient-based intensive flexible MDI management. Users found the dose calculator app to be a beneficial adjunct to patient-based flexible MDI management and reported increased satisfaction and control with this device compared to other dose calculators. Users desired functionality that enabled a reduction in the burden of day to day management, such as connectivity with BG meters and food databases, shortcut data entry buttons and customisable user interfaces. Food database connectivity potentially creates the link between dietary intake recording and dietary assessment creating the potential for the app to interact with the user to feedback diet advice to improve diet quality. This qualitative study has resulted in further modification in the Rapidcalc app and plans are currently underway to conduct a clinical trial of the app, to evaluate glycaemic outcomes in a larger cohort who have not been previously trained in the DAFNE program.

The questions that are raised from this study include:

- Will users continue to use this app after it is no longer novel and what is the longer term impact on glycaemic control?
- Is there a role for this app in those with low health literacy, who are more at risk of making dose calculation errors?
- What is the impact on diabetes outcomes, include user satisfaction, with further development of the app, incorporating features suggested by users?
- Is there potential to improve dietary intake with this app with the incorporation of automatic response messages based on patient-entered diet history and food database data?

The third manuscript described the development and delivery of a novel short-course flexible MDI self-management education program that focuses solely on carbohydrate counting and algorithms for insulin dose determination, with proactive insulin optimisation offered post course. Short course flexible MDI therapy enables greater numbers of patients and health care centres to access high quality structured education in flexible MDI. Well established insulin dose algorithms from the 5-day OzDAFNE program, together with carbohydrate counting formed the core elements of the short program. We were able to confirm that short-course education in flexible MDI is able to reproduce improvements to psychosocial outcomes equivalent to a 5-day program. We also found
that short-course education failed to modify the frequency of blood glucose monitoring and the implications for glycaemic outcome are yet to be determined.

**The questions that are raised from this study include:**

- What is the impact on glycaemic control?
- Are there other modes of support to teach proactive insulin optimisation?
- Are there some individuals who will ‘never’ self-manage proactive insulin optimisation and is there a role for an alternative ‘physician-led’ approach in some patients?
- How do we identify patients willing to self-manage proactive insulin optimisation, to enable more tailored education?
- How does this short-course program fit into the DAFNE landscape? Is there scope for short-course education first, to enable immediate access to flexible MDI education in daily dose determination, then patients move on to DAFNE education?
- What is the impact of improved access to patient-centred flexible MDI education within the health care setting in terms of costs and access to services?
References


