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FUNDING AND SUPPORT

The development and pilot of SMS4BG was funded by a grant from the Waitemata District Health Board. The SMS4BG trial was funded by a grant from the Health Research Council of New Zealand in partnership with Waitemata and Auckland District Health Boards (through the Research Partnerships for New Zealand Health Delivery initiative) (grant number: HRC 14/724), and a grant from the New Zealand Ministry of Health. Both the trial and pilot study were designed, conducted, analysed, and interpreted independently of the funders.

Other research expenses associated with the completion of the research for this thesis were funded by the candidate's University of Auckland Doctoral PReSS (Postgraduate Research Student Support) account and the Elizabeth Ewing Memorial Scholarship in Adolescent and Young Adult Health.

Grants for travel were provided by the New Zealand Society for the Study of Diabetes for the candidate to attend and present findings from this thesis at the following meetings:

- New Zealand Society for the Study of Diabetes Annual Scientific Meeting, May 6-8, 2015. Wellington, New Zealand
- New Zealand Society for the Study of Diabetes Annual Scientific Meeting, May 7-9, 2014. Queenstown, New Zealand

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CONTRIBUTION FROM STUDY INVESTIGATORS

Professor Ralph Maddison and Associate Professor Robyn Whittaker supervised this thesis, and provided guidance throughout. Under their guidance, the candidate contributed to the design and implementation for all included studies. Robyn Whittaker was responsible for the funding and overall vision of SMS4BG.

Chapter 1-2: The candidate wrote these chapters with supervisory support.

Chapter 3: The candidate designed the review with input from her supervisors. The candidate screened articles, extracted and analysed the data, and drafted the manuscript with input from all authors. Decisions regarding eligibility for inclusion, risk of bias and data extraction were verified independently by Robyn Whittaker and Leila Pfaeffli Dale. All authors read and approved the final manuscript.

Chapter 4: The candidate developed the study concept, design, and procedures with input from all co-authors. She obtained ethical approval, collected the data, analysed the results, and drafted the manuscript. Rinki Murphy, Manish Khanolkar, Steven Miller, and Jo Naylor identified potential participants for the study. All authors read and approved the final manuscript.

Chapter 5: The candidate wrote this chapter with supervisory support

Chapter 6: The candidate along with Robyn Whittaker, Karen Carter, Richard Cutfield, Catherine McNamara, Rinki Murphy, Matt Shepherd and Richard Hulme were responsible for the study design and procedures. Karen Carter obtained ethical approval. The candidate with support from Robyn Whittaker, Johan Strydom, Karen Carter, Matt Shepherd and Ashley Hulme developed the intervention. The candidate, Karen Carter and Robyn Whittaker were responsible for data collection, and the candidate was responsible for data analysis and interpretation with support from Karen Carter, Robyn Whittaker, Matt Shepherd, Rick Cutfield and Catherine McNamara. The candidate wrote the manuscript. All authors provided critical feedback on the manuscript.

Chapter 7: The candidate along with co-authors contributed to the study concept, design, and procedures. She gained ethical approval for the study. She created the statistical analysis plan with assistance from co-author Yannan Jiang. The candidate, with input from the co-authors, wrote the manuscript.

Chapter 8: The candidate along with co-authors contributed to the study concept, design, and procedures. The randomisation sequence was completed by Yannan Jiang. The candidate was responsible for the study management and co-ordination of all trial procedures including delivery of the SMS4BG intervention. The candidate cleaned the data and analysed the engagement data and feedback on the intervention. The analysis of primary and secondary outcomes was performed by Yannan Jiang. The candidate, with input from the co-authors, wrote the manuscript. The candidate contributed to the preparation of the successful grant that funded this trial.

Chapter 9: The candidate wrote this chapter with supervisory support.

CO-AUTHORSHIP FORMS

Chapter 3: Systematic review

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and the title and publication details or details of submission of the co-authored work. Chapter 3: The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review. Dobson R, Whittaker R, Pfaeffli Dale L, Maddison R. The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review. Submitted to Digital Health.

Nature of contribution by PhD candidate	Rosie was responsible for the study design, search strategy, selection of studies, data extraction, interpretation of results and wrote the manuscript
Extent of contribution by PhD candidate (%)	90

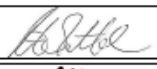
CO-AUTHORS

Name	Nature of Contribution
Robyn Whittaker	Assisted with the study design, article selection, interpretation of findings, and provided editorial support
Leila Pfaeffli Dale	Assisted with article selection, data extraction, and provided editorial support
Ralph Maddison	Assisted with the study design and provided editorial support

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- the PhD candidate was the lead author of the work and wrote the text.

Name	Signature	Date
Robyn Whittaker		15/08/2017
Leila Pfaeffli Dale		10/08/2017
Ralph Maddison		10/08/2017

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Chapter 4: The use of mobile health to deliver self-management support to young people with type 1 diabetes: A cross-sectional survey.

Dobson R, Whittaker R, Murphy R, Khanolkar M, Miller S, Naylor J, Maddison R. (2017). The use of mobile health to deliver self-management support to young people with type 1 diabetes: A cross-sectional survey. JMIR Diabetes 2(1): e4.

Nature of contribution by PhD candidate	Rosie was responsible for the study design, procedures, data collection and data analysis, obtained ethical approval, and wrote the manuscript
Extent of contribution by PhD candidate (%)	90

CO-AUTHORS

Name	Nature of Contribution
Robyn Whittaker	Assisted with study design and provided editorial support
Rinki Murphy	Assisted with study design and procedures, and provided editorial support
Manish Khanolkar	Assisted with study design and procedures, and provided editorial support
Steven Miller	Assisted with study design and procedures, and provided editorial support
Joanna Naylor	Assisted with study design and procedures, and provided editorial support
Ralph Maddison	Assisted with study design and provided editorial support

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- the PhD candidate was the lead author of the work and wrote the text.

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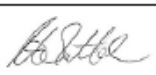
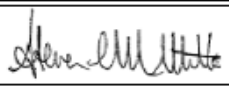
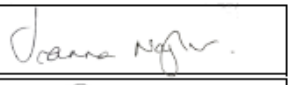
Robyn Whittaker		15/08/2017
Rinki Murphy		29/07/2017
Manish Khanolkar		31/07/2017
Steven Miller		28/07/2017

Jo Naylor		23/08/2017
Ralph Maddison		10/08/2017

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Chapter 6: Diabetes text-message self-management support programme (SMS4BG): A pilot study

Dobson R, Carter K, Cutfield R, Hulme A, Hulme R, McNamara C, Maddison R, Murphy R, Shepherd M, Strydom J, Whittaker R. Diabetes text-message self-management support program (SMS4BG): A pilot study. JMIR mHealth uHealth 2015;3(1):e32

Nature of contribution by PhD candidate	Rosie provided input into study design, procedures, and data collection. She developed the intervention, analysed and interpreted the data, and wrote the manuscript with input from co-authors.
Extent of contribution by PhD candidate (%)	65%

CO-AUTHORS

Name	Nature of Contribution
Karen Carter	Assisted with study design, obtained ethical approval, oversaw study procedures, provided guidance on intervention development and data collection, and provided editorial support
Richard Cutfield	Assisted with study design and procedures, data analysis and interpretation, and provided editorial support
Ashley Hulme	Provided input into intervention development and assisted with data collection
Richard Hulme	Assisted with study design and procedures, and provided editorial support
Catherine McNamara	Assisted with study design and procedures, data analysis and interpretation, and provided editorial support
Ralph Maddison	Assisted with study design and provided editorial support
Rinki Murphy	Assisted with study design and provided editorial support
Mathew Shepherd	Assisted with study design and procedures, intervention development, data analysis and interpretation, and provided editorial support
Johan Strydom	Developed the content management system, and provided editorial support
Robyn Whittaker	Assisted with study design and procedures, intervention development, data collection, data analysis and interpretation, and provided editorial support

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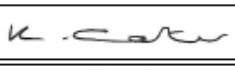
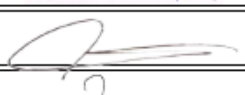
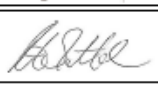
The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- the PhD candidate was the lead author of the work and wrote the text.

Name	Signature	Date
Karen Carter		02/08/2017
Richard Cutfield		02/08/2017
Ashley Hulme		05/09/2017
Richard Hulme		22/08/2017
Catherine McNamara		11/9/17
Ralph Maddison		10/08/2017
Rinki Murphy		29/07/2017
Mathew Shepherd		09/08/2017
Johan Strydom		28/07/2017
Robyn Whittaker		15/08/2017

Chapter 7: Protocol

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Chapter 7: Text message-based diabetes self-management support (SMS4BG): Study protocol for a randomized controlled trial

Dobson R, Whittaker, R. Jiang, Y. Shepherd, M. Maddison, R. Carter, K. Cutfield, R. McNamara, C. Khanolkar, M. Murphy, R. Text message-based diabetes self-management support (SMS4BG): Study protocol for a randomized controlled trial. Trials 2016 17:179.

Nature of contribution by PhD candidate	Rosie designed the study protocol, obtained ethical approval, developed the intervention, and wrote the manuscript
Extent of contribution by PhD candidate (%)	80

CO-AUTHORS

Name	Nature of Contribution
Robyn Whittaker	Was the recipient of funding for the study, assisted with study design and intervention development, and provided editorial support
Yannan Jiang	Assisted with study design, statistical analysis plan, carried out the randomisation sequence, and provided editorial support
Mathew Shepherd	Assisted with study design and intervention development, and provided editorial support
Ralph Maddison	Assisted with study design and provided editorial support
Karen Carter	Assisted with study design and provided editorial support
Richard Cutfield	Assisted with study design and provided editorial support
Catherine McNamara	Assisted with study design and provided editorial support
Manish Khanolkar	Assisted with study design and provided editorial support
Rinki Murphy	Assisted with study design and intervention development, and provided editorial support

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The undersigned hereby certify that:

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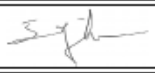
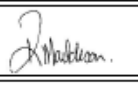
- the PhD candidate was the lead author of the work and wrote the text.

Name	Signature	Date
Robyn Whittaker		15/08/2017
Yannan Jiang		02/08/2017
Mathew Shepherd		09/08/2017
Ralph Maddison		10/08/2017
Karen Carter		02/08/2017
Richard Cutfield		02/08/2017
Catherine McNamara		11/9/17
Manish Khanolkar		31/07/2017
Rinki Murphy		29/07/2017

Chapter 8: Randomised controlled trial

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Nature of contribution by PhD candidate	Rosie designed the study protocol, developed the intervention, oversaw the day-to-day running of the study, recruited participants, collected data, analyzed the acceptability and engagement results, and wrote the manuscript
Extent of contribution by PhD candidate (%)	75

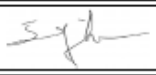
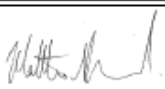
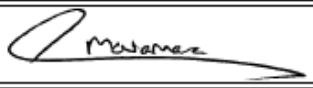
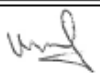
CO-AUTHORS

Name	Nature of Contribution
Robyn Whittaker	Was the recipient of funding for the study, assisted with study design, intervention development and data collection, and provided feedback on the manuscript
Yannan Jiang	Assisted with study design, statistical analysis plan, carried out the randomisation sequence, analysed the main results, and provided feedback on the manuscript
Matthew Shepherd	Assisted with study design and intervention development, and provided feedback on the manuscript
Ralph Maddison	Assisted with study design and provided feedback on the manuscript
Catherine McNamara	Assisted with study design and provided feedback on the manuscript
Richard Cutfield	Assisted with study design and provided feedback on the manuscript
Manish Khanolkar	Assisted with study design and provided feedback on the manuscript
Rinki Murphy	Assisted with study design and intervention development, and provided feedback on the manuscript

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- the PhD candidate was the lead author of the work and wrote the text.

Name	Signature	Date
Robyn Whittaker		25/09/2017
Yannan Jiang		21/09/2017
Matthew Shepherd		21/09/2017
Ralph Maddison		21/09/2017
Richard Cutfield		22/09/2017
Catherine McNamara		25/09/2017
Manish Khanolkar		25/09/2017
Rinki Murphy		21/09/2017

PUBLICATIONS, PRESENTATIONS AND AWARDS

Publications included in thesis

Published peer-reviewed scientific journal articles

1. **Dobson R,** Whittaker R, Pfaeffli Dale L, Maddison R. The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review. Digital Health. 2017 Nov;3, 1-12.
2. **Dobson R**, Whittaker R, Murphy R, Khanolkar M, Miller S, Naylor J, Maddison R. The Use of Mobile Health to Deliver Self-Management Support to Young People With Type 1 Diabetes: A Cross-Sectional Survey. JMIR Diabetes 2017 2(1): e4.
3. **Dobson R,** Whittaker, R. Jiang, Y. Shepherd, M. Maddison, R. Carter, K. Cutfield, R. McNamara, C. Khanolkar, M. Murphy, R. Text message-based diabetes self-management support (SMS4BG): Study protocol for a randomized controlled trial. Trials 2016 17:179.
4. **Dobson R**, Carter K, Cutfield R, Hulme A, Hulme R, McNamara C, Maddison R, Murphy R, Shepherd M, Strydom J, Whittaker R. Diabetes Text-Message Self-Management Support Program (SMS4BG): A Pilot Study. JMIR mHealth uHealth 2015;3(1):e32

Articles submitted to peer-reviewed scientific journals

1. **Dobson R,** Whittaker, R. Jiang, Y. Shepherd, M. Maddison, R. McNamara, C. Cutfield, R. Khanolkar, M. Murphy, R. A randomised controlled trial of a text message-based diabetes self-management support programme (SMS4BG). *Submitted to BMJ.*

Publishers' approvals

1. **Dobson R,** Whittaker R, Pfaeffli Dale L, Maddison R. The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review. Digital Health. 2017 Nov;3, 1-12

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2. **Dobson R**, Whittaker R, Murphy R, Khanolkar M, Miller S, Naylor J, Maddison R. (2017). The Use of Mobile Health to Deliver Self-Management Support to Young People With Type 1 Diabetes: A Cross-Sectional Survey. JMIR Diabetes 2(1): e4.

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3. **Dobson R**, Carter K, Cutfield R, Hulme A, Hulme R, McNamara C, Maddison R, Murphy R, Shepherd M, Strydom J, Whittaker R. Diabetes Text-Message Self-Management Support Program (SMS4BG): A Pilot Study. JMIR mHealth uHealth 2015;3(1):e32

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4. **Dobson R,** Whittaker, R. Jiang, Y. Shepherd, M. Maddison, R. Carter, K. Cutfield, R. McNamara, C. Khanolkar, M. Murphy, R. Text message-based diabetes self-management support (SMS4BG): Study protocol for a randomized controlled trial. Trials 2016 17:179.

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Other publications during candidature[1]

1. **Dobson R**, Whittaker R, Bartley H, Connor A, Chen R, Ross M, McCool J. Development of a culturally tailored text message maternal health program: TextMATCH. JMIR Mhealth Uhealth 2017; 5(4):e49.
2. Eyles, H, Jull, A, **Dobson, R**, Firestone, R, Whittaker, R, Te Morenga, L, Goodwin, D, Mhurchu, CN. Co-design of mHealth Delivered Interventions: A Systematic Review to Assess Key Methods and Processes. Current Nutrition Reports. 2016;5(3):160-7.
3. Pfaeffli Dale L, **Dobson R**, Whittaker R, Maddison R. The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: A systematic review. European journal of preventive cardiology. 2016;23(8):801-17.
4. Direito, A., Dale, L. P., Shields, E., **Dobson, R**., Whittaker, R., & Maddison, R. (2014). Do physical activity and dietary smartphone applications incorporate evidence-based behaviour change techniques? BMC Public Health, 14(1), 646.

Conference presentations

1. **Dobson, R**., Whittaker, R. SMS4BG: Text messaging self-management support for people with diabetes. HINZ: Health Informatics New Zealand Conference, 1-3 November 2017, Rotorua, New Zealand (Oral presentation)
2. **Dobson, R**., Whittaker, R. Using text messaging to extend diabetes self-management support outside the clinic environment. 14th International Congress of Behavioural Medicine, 1-10 December 2016. Melbourne, Australia (Oral presentation)
3. **Dobson, R**., Maddison, R., Whittaker, R., Murphy, R., Khanolkar, M., & Naylor, J. An opportunity for mHealth: Results from a cross-sectional survey of young adults with type 1 diabetes. New Zealand Society for the Study of Diabetes Annual Scientific Meeting, May 6-8, 2015. Wellington, New Zealand (Oral presentation).
4. **Dobson, R**., Whittaker, R., Carter, K., Cutfield, R., McNamara, C., Murphy, R., Shepherd, M., Hulme, R., Skipper, C., Pomfret, J., Moodabe, K., Patel, K., & Naidoo, M. A text message based diabetes self-management programme (SMS4BG): A pilot study. New Zealand Society for the Study of Diabetes Annual Scientific Meeting, May 7-9, 2014. Queenstown, New Zealand (Oral presentation).
5. **Dobson, R.,** Whittaker, R., Carter, K., Shepherd, M., Hulme, R., McNamara, C. & Pomfret, J. A pilot of a text message based diabetes self-management programme (SMS4BG). Australasian Society of Behavioural Health and Medicine, 11th Scientific Conference, February 12–14, 2014. Auckland, New Zealand (Oral presentation).
6. Whittaker R, Bramley D, Carter K, Cutfield R, **Dobson R**, Dorey E, et al. A comprehensive approach to self-management support for diabetic patients and clinicians. Health Informatics New Zealand Conference, November 27–29, 2013, Rotorua, New Zealand.

[1] Where the candidate is listed as the primary author, her contribution comprised full responsibility for writing, submission, and revision of the manuscript. Where the candidate is listed as a co-author, she contributed to the development of methods, interpretation, and revision of the manuscript.

Other presentations

1. **Dobson, R**., Whittaker, R. SMS4BG: Text message based diabetes self-management support. mHealth Symposium at University of Southern California. 3 November 2017. Los Angeles, US. (Oral Presentation)
2. **Dobson, R.** Using text messaging to extend diabetes self-management support outside the clinic environment. Health Psychology Seminar Series (Semester 2, 2016). Department of Psychological Medicine, School of Medicine, University of Auckland, September 27th, 2016. Auckland, New Zealand (Seminar).
3. **Dobson, R.**, Whittaker, R., Maddison, R. Using text messaging to extend diabetes self-management support outside the clinic environment. School of Population Health Research Showcase, December 14-16, 2015. Auckland, New Zealand (Poster & oral presentation).
4. **Dobson, R**. SMS programmes for maternal health and diabetes management. NIHI Symposium: From mHealth to Future Tech: Future Wellness for all, October 22-23, 2015. Auckland, New Zealand (Oral presentation).
5. **Dobson, R**. mHealth in supporting diabetes self-management. Diabetes Regional Study Day, October 22, 2014, Auckland New Zealand. (Oral presentation)
6. **Dobson, R**., Whittaker, R., Maddison, R., A pilot study of a text message based diabetes self-management support programme (SMS4BG). EXPOSURE Conference, October 13, 2014. Auckland, New Zealand (Oral presentation).
7. **Dobson, R**., Whittaker, R., Maddison, R., A pilot study of a text message based diabetes self-management support programme (SMS4BG). HealtheX Conference, September 12, 2014. Auckland, New Zealand (Oral presentation).

Awards during candidature

2015

The University of Auckland School of Population Health Research Showcase, **Best Postgraduate Student Poster**, Auckland, New Zealand, December 14-16 2015

> "Using text messaging to extend diabetes self-management support outside the clinic environment"

2014

Australasian Society of Behavioural Health and Medicine, 11th Scientific Conference, **Best Student Oral Presentation,** Auckland, New Zealand, Feb 12–14, 2014.

> "A pilot of a text message based diabetes self-management programme (SMS4BG)"

Elizabeth Ewing Memorial Scholarship in Adolescent and Young Adult Health

ABBREVIATIONS

BCT	Behaviour change technique
BG	Blood glucose
BIPQ	Brief illness perception questionnaire
BP	Blood pressure
CDSS	Clinical decision support system
CG	Control group
CHERRIES	Checklist for reporting results of internet e-surveys
CI	Confidence interval
CONSORT	Consolidated standards of reporting trials
CSM	Common-sense model
DCCT	Diabetes control and complications trial
DDS2	Diabetes distress scale – 2-item
DHB	District health board
DSME	Diabetes self-management education
EDIC	Epidemiology of diabetes interventions and complications
EMI	Ecological momentary interventions
GCP	Good clinical practice
GP	General Practitioner
HbA1c	Haemoglobin A1c
IG	Intervention group
ITT	Intention-to-treat
mHealth	Mobile health
MMS	Multimedia message
MOH	Ministry of Health
NIHI	National Institute for Health Innovation
NZ	New Zealand
OECD	Organisation for economic co-operation and development
QALY	Quality-adjusted life year
QOL	Quality of life
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
RCT	Randomised controlled trial
SCT	Social cognitive theory
SD	Standard deviation
SDSC	Summary of diabetes self-care activities
SEDM	Self-efficacy in diabetes management scale
SMS	Short message service
SMS4BG	Self-management support for blood glucose
T1D	Type 1 diabetes
T2D	Type 2 diabetes
US	United States

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VAS	Visual analogue scale

CHAPTER 1. THESIS INTRODUCTION

The increasing prevalence of diabetes and costly long-term complications associated with poor glycaemic control are issues facing health services internationally. For people with diabetes, engagement with self-management is critical for successful outcomes particularly in those with poor control. There is a need for innovative tools to deliver self-management interventions, and there is growing evidence for the use of mobile health (mHealth) for this purpose. Short messaging services (SMS) or text messages have the advantage of universal use, instant transmission at low cost and, given the ubiquity of mobile phones, may be the ideal platform for the delivery of diabetes self-management support to people in their day-to-day lives. This thesis investigates the use of SMS to deliver self-management support to people with poorly controlled diabetes.

1.1. Thesis aim and objectives

This thesis aims to develop and evaluate an mHealth diabetes self-management support programme. The specific objectives were to:

1. Investigate what is currently known about the use of SMS to support self-management in people with poorly controlled diabetes, and identify gaps in the literature.
2. Investigate current engagement in already available mHealth and explore perceived roles of mHealth in supporting diabetes management
3. Develop an mHealth tool for the delivery of self-management support to people with poorly controlled diabetes.
4. Assess the acceptability and effectiveness of an mHealth self-management support intervention.
5. Discuss the thesis findings in relation to the current literature and identify implications for clinical practice and areas for future research.

It is hypothesised that text messaging will be both acceptable for the delivery of diabetes self-management support, and effective in improving glycaemic control.

1.2. Thesis structure

This thesis is organised into four parts.

Part 1 introduces the problem, the burden of poorly controlled diabetes, and introduces a potential solution, mHealth:

- Chapter 2 presents a literature review outlining the burden of diabetes and discusses the potential of mHealth to support the management of diabetes.
- Chapter 3 includes a submitted paper presenting a systematic review of SMS based diabetes self-management interventions
- Chapter 4 includes a published paper investigating current engagement, and preferences for, mHealth in young adults with diabetes

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Part 2 describes the development and pilot of an mHealth diabetes self-management support intervention for adults with poorly controlled diabetes (SMS4BG; Self-Management Support for Blood Glucose):

- Chapter 5 describes the development of SMS4BG including the theoretical framework and evidence base that informed it
- Chapter 6 includes a published paper of a pilot study of SMS4BG assessing its usability and acceptability

Part 3 describes the evaluation of the effectiveness of SMS4BG:

- Chapter 7 includes a published paper of the protocol for a randomised controlled trial to assess the effectiveness of SMS4BG
- Chapter 8 presents a submitted paper presenting the results of the randomised controlled trial.

And Part 4 explores the thesis findings, implications for clinical practice, and areas for future research, and comprises Chapter 9.

Part 1: The problem and a potential solution

This section of the thesis outlines the problem of poorly controlled diabetes, introduces mHealth and explores its potential to improve diabetes management. Firstly, Chapter 2 provides a summary of the literature outlining the burden of diabetes particularly for minority populations, and the importance of self-management in improving outcomes. It then discusses the potential of mHealth in the management of diabetes, highlighting how SMS can provide a tool for delivering diabetes self-management support without increasing health disparities seen with other forms of technology. To explore what is already known about the use of SMS to deliver self-management interventions to people with poorly controlled diabetes, Chapter 3 presents a systematic review of SMS based diabetes self-management interventions. Finally to understand current use of readily available mHealth Chapter 4 presents a survey of current engagement with mHealth in young adults with diabetes, and explorers the potential role of mHealth in supporting diabetes management in this population.

CHAPTER 2. DIABETES: BURDEN AND MANAGEMENT

2.1. Overview

This following chapter summarises the problem of poorly controlled diabetes and the potential of mHealth in providing a solution. Specifically, it reviews the literature on the burden of diabetes and its management. It then reviews the literature around the use of mobile phone technology for health behaviour change and disease management support, identifying how mobile phones can play a part in providing diabetes self-management support for people with poorly controlled diabetes.

2.2. The burden of diabetes

Diabetes mellitus is a chronic condition characterised by increased levels of blood glucose (hyperglycaemia), which can lead to an array of microvascular and macrovascular complications. Diabetes mellitus is categorised into different forms with the most common being type 1 diabetes and type 2 diabetes. Type 1 diabetes is an autoimmune disorder in which insulin producing beta cells in the pancreas are destroyed resulting in insulin deficiency and raised levels of glucose.(1) Diagnosis is typically during childhood although can occur at any age. The cause of type 1 diabetes, although not fully understood, is believed to be multifactorial with a number of environmental factors thought to play a part as well as genetic susceptibility.(2) To date no treatment has been found to either prevent or cure type 1 diabetes, therefore the goal is management including control of blood glucose and prevention of long term complications.

In contrast type 2 diabetes is the result of insulin resistance and deficient insulin secretion. Type 2 diabetes is the most common form, comprising over 90% of adults with diabetes internationally.(1) An unhealthy lifestyle leading to obesity, as well family history, can contribute to the development of type 2 diabetes, and the condition can go undiagnosed for years due to the gradual onset of hyperglycaemia. Insulin resistance can be improved through lifestyle modification and pharmacological treatment. Although type 1 and type 2 diabetes are heterogeneous diseases with considerable variation in clinical presentation and disease progression, both are characterised by progressive loss of β-cell mass/function manifesting clinically as hypoglycaemia. Once hypoglycaemia occurs people across both types are at risk of developing the same complications.(3)

When a person's blood glucose levels are consistently high it can lead to serious damage to key organs including the kidneys, heart, eyes, blood vessels, and nerves.(1) The leading cause of mortality and morbidity in people with diabetes is cardiovascular disease including stroke, myocardial infarction, peripheral artery disease, angina, and congestive heart failure.(4) Cardiovascular disease is also the largest contributor to healthcare costs associated with diabetes. Individuals with diabetes are also at increased risk for the development of diabetic retinopathy leading to vision problems and blindness, as well as kidney disease (nephropathy). Nerve damage leading to peripheral neuropathy is also a common complication of diabetes resulting in pain, loss

of sensation and in severe cases amputation.(5) Diabetes complications can be prevented or delayed with good blood glucose control, and screening allows for early detection and treatment to halt or slow their progression. The Diabetes Control and Complications Trial (DCCT),(6, 7) the Epidemiology of Diabetes Interventions and Complications (EDIC) observational follow-up study,(8) and the UK Prospective Diabetes Study,(9) contribute to substantial evidence that good control of diabetes translates into significant reduction to the risk of diabetic complications. Prevention of diabetic complications by better glycaemic control is not only advantageous for the person's quality of life but will substantially decrease healthcare costs associated with treating or managing the complications.(5, 10-13)

In 2012 the national cost of diabetes in the United States (US) was nearly $250 billion, with approximately three quarters of this cost attributable to direct health care expenditure and the remaining representing the loss of productivity resulting from absenteeism in the workplace and unemployment due to disability or premature mortality.(14) In the US, it has been estimated that medical care associated with people with diabetes accounts for one fifth of all healthcare costs, highlighting the substantial burden of the condition on healthcare systems.(14)

The growing prevalence of diabetes is considered to be one of the biggest global health issues facing society. It is estimated that there are over 400 million adults currently living with diabetes around the world and an additional 300 million are at risk for developing diabetes.(15) The New Zealand Health Survey annual update of key results for 2015/16 reported the prevalence of diabetes in adults (aged 15 years and over) as 5.8% (95% CI: 5.4 - 6.2) - estimating that 217,000 (95%CI; 201,000-234,000) New Zealand adults live with diabetes.(16) In New Zealand a higher prevalence is seen in Pacific and Māori (indigenous) ethnic groups, and those living in most deprived areas.(16, 17) Approximately 29% of people with diabetes in New Zealand (including 43% of Māori and 50% of Pacific people with diabetes) have HbA1c levels indicative of poor control (≥65mmol/mol) putting them at risk for the development of complications.(18) Ethnic minorities are particularly vulnerable to the development of diabetes, typically develop the condition earlier, and experience poorer control and increased rates of complications.(19-23) Factors such as language barriers, cultural practices and beliefs, knowledge of diabetes, beliefs about medication, and inaccurate illness perceptions may be contributing factors.(24-26) There is considerable evidence that poorer health outcomes are seen in vulnerable populations such as ethnic minorities as well as people living rurally, elderly populations, those of lower socioeconomic status and those with lower education.(27) Addressing these health disparities is a priority in the care of people with diabetes. Services need to meet the needs of vulnerable groups such as Māori and Pacific while addressing the barriers contributing to these disparities. Interventions need to be culturally appropriate and provide education on how to access care and support, as well as increase the person's ability to participate in the management of their health.

2.3. Diabetes management

Stabilising blood glucose levels or achieving good glycaemic control is the primary goal of diabetes management. Glycosylated haemoglobin (HbA1c) is the most commonly used measure of control in individuals with diabetes. It measures average blood glucose levels over several months with the

target for individuals with diabetes being <53mmol/mol (<7%) indicating good control of the condition.(28). To achieve good control, significant engagement from patients and healthcare providers is needed with diabetes being one of the most demanding chronic conditions both behaviourally and psychologically. In contrast to many other chronic conditions, treatment of diabetes is largely carried out through self-care, with one estimate suggesting that 95% of diabetes care is provided by the patient and/or their family.(29) Healthcare professionals provide the patient with the knowledge, guidance and treatments but the patients must then translate this into self-management of their condition in their everyday lives. Juggling the demands of diabetes self-management with the demands of work and family can be particularly challenging compounded by factors such as motivation, language barriers, health literacy, socio-economic status, and beliefs resulting in poor compliance for many people.

Successful diabetes management involves managing medical responsibilities including blood glucose monitoring, medication adherence, and insulin administration alongside engaging in health behaviours around diet and physical activity. There are a wide range of interventions designed to support people with diabetes to self-manage; from passive interventions (e.g. provision of information) to more active interventions (e.g. interventions to change behaviour).(30) Supporting a person's self-management of their condition involves providing encouragement, information and support to help that person obtain greater control of their condition. This may be done by increasing their understanding of their condition, encouraging them to be active participants in the decision making around their condition and motivating them to engage in healthy behaviours such as blood glucose monitoring, healthy eating and physical activity.

Providing a person with information around successful diabetes management alone is rarely adequate to improve their diabetes management behaviours and outcomes.(31) A person's beliefs about their diabetes, their motivations, as well as how they feel about their condition is known to have a big impact on their engagement with self-management. Psychological theories and models provide frameworks for understanding the factors contributing to a person's engagement in health behaviours. The concept of self-efficacy (a person's situational confidence in their ability to perform a specific behaviour), a construct of the Social Cognitive Theory, is considered fundamental to a person carrying out self-care behaviours.(32) People demonstrating high levels of self-efficacy have been shown to be better able to manage their diabetes and engage in self-management behaviours,(33) with this relationship seen across diverse ethnicities and levels of health literacy.(34) Social Cognitive Theory offers a theoretical framework to understand the relationship between self-efficacy and diabetes self-care behaviours.(33) When self-management interventions aim to target the sources of self-efficacy through techniques such as modelling, skills mastery and social persuasion, they increase the participant's confidence in their ability to self-manage their diabetes and therefore make successful engagement in self-management behaviours more likely. Another model that has influenced diabetes self-management interventions includes the Common Sense Model (or Self-Regulation Model).(35) This model proposes that a person's illness perceptions and emotional representations are drivers for their coping strategies and their self-management behaviours. Self-management interventions can support people to form accurate and

constructive illness perceptions and coping strategies which in turn can increase their likelihood of engaging in diabetes self-management.

Providing education about diabetes and how to effectively manage it, including information about blood glucose monitoring, diet and exercise, is an essential component in supporting a person to manage their diabetes. Internationally, self-management education is acknowledged as a crucial component of diabetes care. In New Zealand the Quality Standards for Diabetes Care state that "People with diabetes should receive high quality structured self-management education that is tailored to their individual and cultural needs".(36) This can be provided individually or through group programmes such as Diabetes Self-Management Education (DSME) Programmes. DSME aims to target key diabetes self-care behaviours including physical activity, eating, medication taking, blood glucose monitoring, problem solving, reducing the risks of complications, and psychosocial adaptation to diabetes.(37) DSME programmes have been shown to improve diabetes self-management behaviours, clinical outcomes, quality of life, and health service use, but ongoing support appears key for benefits associated with DSME to be sustained long term.(38-40) Ongoing self-management support following DSME programmes is not always feasible due to limited resources and clinician time. There is currently no superior approach to the delivery of diabetes self-management education but it is recommended that programmes be tailored, culturally appropriate, flexible, and theoretically based.(41) In New Zealand there are a range of self-management programmes delivered to people with diabetes, which are typically delivered in group environments through secondary care, primary care or community organisations, but these vary considerably across the country resulting in inconsistent access and support.(42) Although the majority of people with diabetes in New Zealand will have the opportunity to attend formal diabetes education, it is estimated that only approximately 5-10% of people with diabetes attend structured diabetes self-management programmes.(43, 44)

2.4. Mobile phones as a tool for behaviour change and disease management

Mobiles phones are ubiquitous worldwide with 95% of the global population residing in areas covered by mobile networks.(45) In New Zealand there are more mobile phone connections than people – 121 active mobile connections per 100 population in 2015.(46) Smartphone (mobile phone with a computer operating system) ownership is continuing to increase with approximately 70% of New Zealand adults reporting smartphone ownership although rates vary across population groups (from 91% of those aged 18-34 to 45% of those aged 55+; and from 57% of those earning less than $40,000 per year to 83% of those earning more than $90,000 per year).(47) Over 90% of smartphone owners report using their device daily and use of these devices is increasing each year.(47) Although smartphone ownership is increasing, and with it the use of mobile-internet related activities, SMS volumes have remained steady with around 12 million SMS messages sent in New Zealand per year.(46) Pay-as-you-go (Prepay) remains the dominant mobile phone subscription type for New Zealand consumers over contract based plans.(46) Due to the pervasiveness of mobile phones and high integration into our daily lives, this platform appears ideal for the delivery of health interventions.

Mobile health (mHealth), is the use of mobile devices, including mobile phones, to deliver health services and information.(48) To date mHealth have utilised tools such as text messaging, video messaging, phone calls, mobile internet, mobile applications (apps), and sensors, in areas such as chronic disease monitoring, medication and treatment adherence, appointment reminders, patient-provider communication, delivery of health information, and behaviour change intervention. Due to the universal adoption and adaptability of mHealth it has potential to reach population groups whose needs are not being met by traditional health services.(49) It provides a unique tool to access individuals at opportune times in any environment.(50-54) The delivery of health behaviour interventions within a person's natural environment allows for treatment to be extended beyond clinic settings and supports the application of knowledge, behaviour, and skills within an individual's real life experiences.

Short messaging service (SMS) or text messaging, the real-time exchange of alphanumeric messages of up to 160 characters, is one of the most frequently used mobile communication tools internationally.(51) They are an appealing method of communication,(55) and it has been said that 99% of text messages are opened, and 90% are read within a few minutes of being delivered.(56) They are well suited for public health interventions due to their low cost, vast reach, frequent use, and ability to be tailored and personalised. To date SMS has been the most extensively researched form of mHealth with the majority of text message based behaviour change interventions for disease prevention and management showing evidence for short term positive impacts on behavioural or clinical outcomes.(57-61) They have so far been used successfully for medication adherence,(62) smoking cessation,(63) diabetes management,(64) physical activity,(52) and weight loss.(54) Additionally, the value of SMS in providing extended contact following initial intervention has been shown,(65, 66) providing support for the use of text messaging in extended contact interventions for the maintenance of behaviour change.

2.4.1 mHealth and diabetes

The flexibility of mobile phones and their adoption into everyday life mean they are an ideal tool in supporting people with diabetes whose condition requires constant management. mHealth can provide essential elements of diabetes support including calculators for insulin adjustments, reminders to test blood glucose and take medication, a medium for recording results, education, support and encouragement, as well as an avenue for patient/provider communication. There is growing evidence for the use of mHealth to deliver diabetes interventions to support medication adherence, monitoring, provide information, and support behaviour change.(64, 67-71) Research has shown that diabetes interventions delivered via SMS can result in statistically significant reductions in glycaemic control,(72-76) increased satisfaction with healthcare,(72) reductions in healthcare costs,(72) increased self-efficacy,(76) and improved self-management behaviours e.g. adherence and blood glucose monitoring.(76-78) Although promising, many previous studies utilising SMS have lacked sufficient sample sizes, were of insufficient duration, or interventions lacked theoretical grounding.

With the growing prevalence of smartphones the number of applications (apps) for diabetes management has grown exponentially in recent years. Research has shown potential for apps to

improve glycaemic control and self-management behaviours,(70, 71) and thousands of apps designed to support people with diabetes are readily available through the app stores for smartphone users. This proliferation of apps has allowed greater access to self-management support to people in their everyday lives. Unfortunately with increasing availability of diabetes related apps there is concern regarding the accuracy and evidence base of many of these, as well as the privacy of personal data.(79, 80) Furthermore many of the available apps today rely on access to the Internet as well as technology literacy to maximise their functionality which poses potential barriers to their use.

Although there is growing support for the use of mHealth in diabetes and evidence for high technology access across cultural and societal groups,(81, 82) there is increasing evidence of a digital divide with lower use of technologies in those that have low health literacy, low income and members of ethnic minorities.(83-88) In particular research has shown that those with lower education and those from ethnic minorities are less likely to engage with health tools utilising the internet.(87) Contributing factors include low technology literacy, mismatch between individual needs and the available tools, lack of local information, literacy and language barriers, and lack of cultural appropriateness.(89) To ensure uptake of mHealth tools in groups that are in most need, these factors need to be addressed as well as barriers such as knowledge, access, cost, and time. Research into the development of diabetes related mHealth tools needs to consider factors related to the digital divide in vulnerable populations to ensure these interventions do not increase health disparities.

2.4.2 The use of theoretical frameworks in mHealth

Theoretical frameworks can provide a basis for guiding intervention development by helping to conceptualise, measure and identify the factors which affect the target behaviour. The majority of health behaviour research does not utilise theory. Of studies that do utilise theory, many use theory to inform the research but few rigorously apply it.(90) There have been few theoretically based mHealth interventions and even fewer targeting disease management.(91) The effectiveness of digital/internet interventions has been shown to be associated with more extensive use of theory,(92) and it is therefore likely that this is also the case for mHealth interventions. mHealth interventions, and in particular text message based interventions, are an ideal method for delivering theoretically based intervention components based on constructs of models.(57) This is because the technology allows for in-the-moment intervention, across geographical locations, and can be easily personally tailored. Text messaging therefore has potential as an alternative approach to individual or group behaviour change programmes. As well as being an ideal medium to deliver theoretically based interventions, the process of delivering interventions via SMS aligns with theoretical constructs in that it can provide behavioural reinforcement, cues to action, accountability and social support.

2.5. Summary

Addressing the individual and system burden of poorly controlled diabetes is vital. There is strong evidence that supporting a person to self-manage their diabetes improves their behaviours, clinical

outcomes and engagement with the healthcare system. But ensuring that self-management education and support is appropriate and accessible is key to its success. Mobile phones are an ideal platform for delivering diabetes self-management interventions due to salience and flexibility of this type of device. With a plethora of apps already available to support diabetes management, assessment of current engagement is important, specifically in population groups where smartphone ownership is prolific such as young adults. There is increasing evidence for mHealth interventions being effective in improving outcomes in people with diabetes but ensuring they meet the needs of the population they are designed to target is essential. The mHealth modality is also crucial to ensure they do not increase health disparities with minority groups already experiencing poorer outcomes from diabetes. Understanding of the impact of mHealth interventions on glycaemic control in people with poorly controlled diabetes is needed, arguably the group most in need of intervention to reduce the costly and debilitating complications of the condition.

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CHAPTER 3. THE EFFECTIVENESS OF TEXT MESSAGE-BASED SELF-MANAGEMENT INTERVENTIONS FOR POORLY-CONTROLLED DIABETES: A SYSTEMATIC REVIEW

3.1. Preface to the publication

To explore the effectiveness of SMS to deliver self-management interventions to people with poorly controlled diabetes this chapter presents a published manuscript of a systematic review of the literature. It addresses the following thesis objective:

1. Investigate what is currently known about the use of SMS to support self-management in people with poorly controlled diabetes and identify gaps in the literature.

Changes to the formatting of the published manuscript have been made to ensure consistency across the thesis.

Supporting documents associated with this chapter can be found in Appendix 1 including a copy of the PRISMA checklist and the risk of bias table.

Why was this work needed?

Chapter 2 described the potential for SMS to deliver diabetes self-management support without increasing health disparities seen with other forms of technology. Although there is increasing evidence for SMS in supporting diabetes management the evidence for those specifically with poorly controlled diabetes is yet to be reviewed.

What was undertaken?

A systematic review of randomised controlled trials investigating the use of SMS based self-management interventions on HbA1c for patients with poorly controlled diabetes was carried out.

Publication citation:

Dobson R, Whittaker R, Pfaeffli Dale L, Maddison R. The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review. Digital Health. 2017 Nov;3, 1-12.

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Contribution by the candidate

The aim of the systematic review was developed by the candidate with guidance from her supervisors. The candidate designed and carried out the methods including generating the review criteria, conducting the search and extracting the data. The candidate, with input from the co-authors formulated the results and wrote the manuscript.

The effectiveness of text message-based self-management interventions for poorly-controlled diabetes: A systematic review

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3.2. Abstract

Background: Poorly controlled diabetes leads to debilitating complications at a significant cost to health systems. Text messaging (SMS) is an ideal platform for the delivery of self-management interventions to patients with poorly controlled diabetes due to the ubiquity of mobile phones, and the ability of SMS to reach people in their everyday lives when self-management of the condition is vital. This systematic review aimed to assess the effectiveness of SMS based diabetes self-management interventions on glycaemic control in adults with poorly controlled diabetes.

Methods/design: MEDLINE, PubMed, EMBASE, The Cochrane Library and PsychINFO were searched from inception through 23 January 2017 for randomised controlled trials investigating the use of SMS based self-management interventions on Haemoglobin A1c (HbA1c) for patients with poorly controlled diabetes.

Results: Seven studies met the inclusion criteria and were included in the review. Three of the studies reported a significant decrease in HbA1c from baseline to follow up in the intervention group compared to the control group. No clear relationship between positive outcomes and intervention dose, content, and functionality was seen.

Discussion: Evidence supporting SMS for improvements in glycaemic control in people with poorly controlled diabetes is mixed. Previous reviews have reported positive impacts on glycaemic control for SMS interventions in patients with diabetes; however, when limited to those with poorly controlled diabetes the evidence is less clear. Large scale studies with robust methodology and longer-term follow-up are needed to further understand the impact of SMS based self-management interventions for people with poorly controlled diabetes.

3.3. Introduction

Addressing the growing global burden of diabetes is a priority for health services. There is considerable evidence that good glycaemic control in patients with both type 1 or type 2 diabetes results in significant reductions in the risk of developing complications, such as renal failure, diabetic retinopathy, lower limb amputation, stroke, and heart disease.(6, 7, 9, 93-96) These complications not only have an detrimental impact on a patient's quality of life, but the clinical management of these is a significant source of health service expenditure.(5) A haemoglobin A1c (HbA1c) target of <7% (<53 mmol/mol) is the widely recommended target for good control.(28, 36) When glycaemic control is sub-optimal (>7%; 53 mmol/mol) or poor (>8%; 64mmol/mol) increased intervention is recommended.(97) Estimates indicate that approximately 25-30% of people with diabetes have HbA1c's over 8% (64mmol/mol) indicating poor control and higher rates are seen in ethnic minorities,(18, 98). Given the costly and debilitating nature of both the microvascular and macrovascular complications of poorly controlled diabetes, considerable support and input is needed to achieve and maintain this target of good glycaemic control.

Individual behaviours play an integral role in diabetes control including blood glucose monitoring, medication adherence, healthy eating, and physical activity, and therefore diabetes self-management education and support is a fundamental part of diabetes care. There are a wide range of interventions designed to support people to self-manage their diabetes; from passive interventions (e.g. provision of information) to more active interventions (e.g. interventions to change behaviour or increase self-efficacy).(30) Supporting a person's self-management of their condition may involve providing encouragement and information to help that person obtain greater control of their condition. Support may increase a person's understanding of their condition, encouraging them to be active participants in the decision making around their condition and motivating them to engage in healthy behaviours.(30) Interventions designed to support diabetes management have traditionally been delivered via written materials or in face to face or group sessions such as Diabetes Self-Management Education (DSME) Programmes. DSME is designed to address the seven key self-management behaviours identified by the Association of American Diabetes Education; 1) healthy eating, 2) being active, 3) monitoring, 4) taking medication, 5) problem solving, 6) reducing risks, and 7) healthy coping.(41) For patients with poor control; however, support may need to extend beyond traditional healthcare settings to sustain the behaviours needed to manage diabetes in the context of a patient's daily life. There is growing evidence for the use of mobile phones for this purpose.

Short message services (SMS) or text messages have the advantage of instant transmission at a low cost to end users and, given the ubiquity of mobile phones, could be an ideal platform for the delivery of diabetes self-management support. Previous systematic reviews have provided support for the effectiveness of mHealth (mobile health) for diabetes self-management,(64, 68, 99) although these reviews have included studies of patients without specifying a level of glycaemic control (i.e. including those who are already maintaining good control of their diabetes). It is our understanding that no previous review has specifically looked at the use of SMS in patients with the greatest need (i.e. not meeting the recommended HbA1c target). The purpose of this systematic review was to evaluate the current evidence for the use of SMS to deliver diabetes self-

management interventions to improve glycaemic control in adults with poorly controlled diabetes. Specific aims included; 1) to examine the effectiveness of SMS-based diabetes self-management interventions on change in HbA1c, 2) to explore the theoretical basis of these interventions and commonly utilised behaviour change techniques (BCT's)(100), and 3) to understand the features/components of these SMS interventions that are associated with better outcomes in this population.

3.4. Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.(101) See Appendix 1 for the completed checklist. The protocol was not published.

3.4.1 Eligibility criteria

Eligible studies were randomised controlled trials (RCTs) utilising SMS to deliver diabetes self-management interventions to adults with poorly controlled diabetes. Participants of eligible studies were adults aged 16 years and over with poorly controlled diabetes (type 1 or 2), defined as HbA1c over 7% (53 mmol/mol). Although the definition of poor control is generally considered to be >8% (64 mmol/mol) few studies have specifically targeted this group. Therefore for the purpose of this review it was decided that studies targeting only those patients not meeting the widely accepted standard for good diabetes control be included.(28, 36) Studies that examined mixed chronic disease populations, or pregnant patients were excluded.

Studies in which SMS was the platform for delivering diabetes self-management intervention (education, reminders, monitoring, self-care i.e. nutrition, exercise) were included. Studies with multifaceted interventions where SMS was just one component of the intervention were included in the review if SMS was a primary component that all intervention participants received. Studies were excluded if they examined the use of messages created by a clinician/investigator based on individual clinical judgement or where SMS was used only as a means of real-time communication between provider and patient (i.e. not an automated programme). Studies were included if the comparator or control group involved either no intervention (usual care) or an intervention variant that did not include SMS. Included studies needed to report HbA1c as a measure of diabetic control as a primary or secondary outcome.

The review was restricted to full-text articles published in peer review journals. Studies were excluded if published in languages other than English or were published only in the form of conference abstracts.

3.4.2 Search strategy

Comprehensive searches were conducted from inception through 23 January 2017 using MEDLINE, PubMED, EMBASE, The Cochrane Library and PsychINFO. Details of the MEDLINE search strategy can be seen in Table 1(amended for other databases). Reference lists of relevant previous reviews and included studies were searched for additional papers.

Table 1: MEDLINE Search Strategy

#	Search	Results
1	mobile phone/	7613
2	(((mobile or smart) and phone*) or smartphone*).tw.	10704
3	(cell* and (phone* or telephone*)).tw.	4543
4	(mhealth or m-health or mobile-health).tw.	2297
5	((text or sms or short or instant) and messag*).tw.	5906
6	(texting or texted).tw.	612
7	1 or 2 or 3 or 4 or 5 or 6	22042
8	diabetes mellitus/	114517
9	diabet*.tw.	565564
10	(IDDM or NIDDM or MODY or T1DM or T2DM or T1D or T2D).tw.	41514
11	8 or 9 or 10	591081
12	7 and 11	1007

3.4.3 Selection of Studies

The searches were carried out by the first author and results merged into EndNote X7 Referencing Software where duplicates were removed. Titles and abstracts were screened and unrelated articles excluded. Articles identified for full text review were reviewed against the criteria above by the first author and any uncertainty around inclusion was resolved by consensus with the other authors. Reasons for exclusion were recorded.

3.4.4 Data extraction

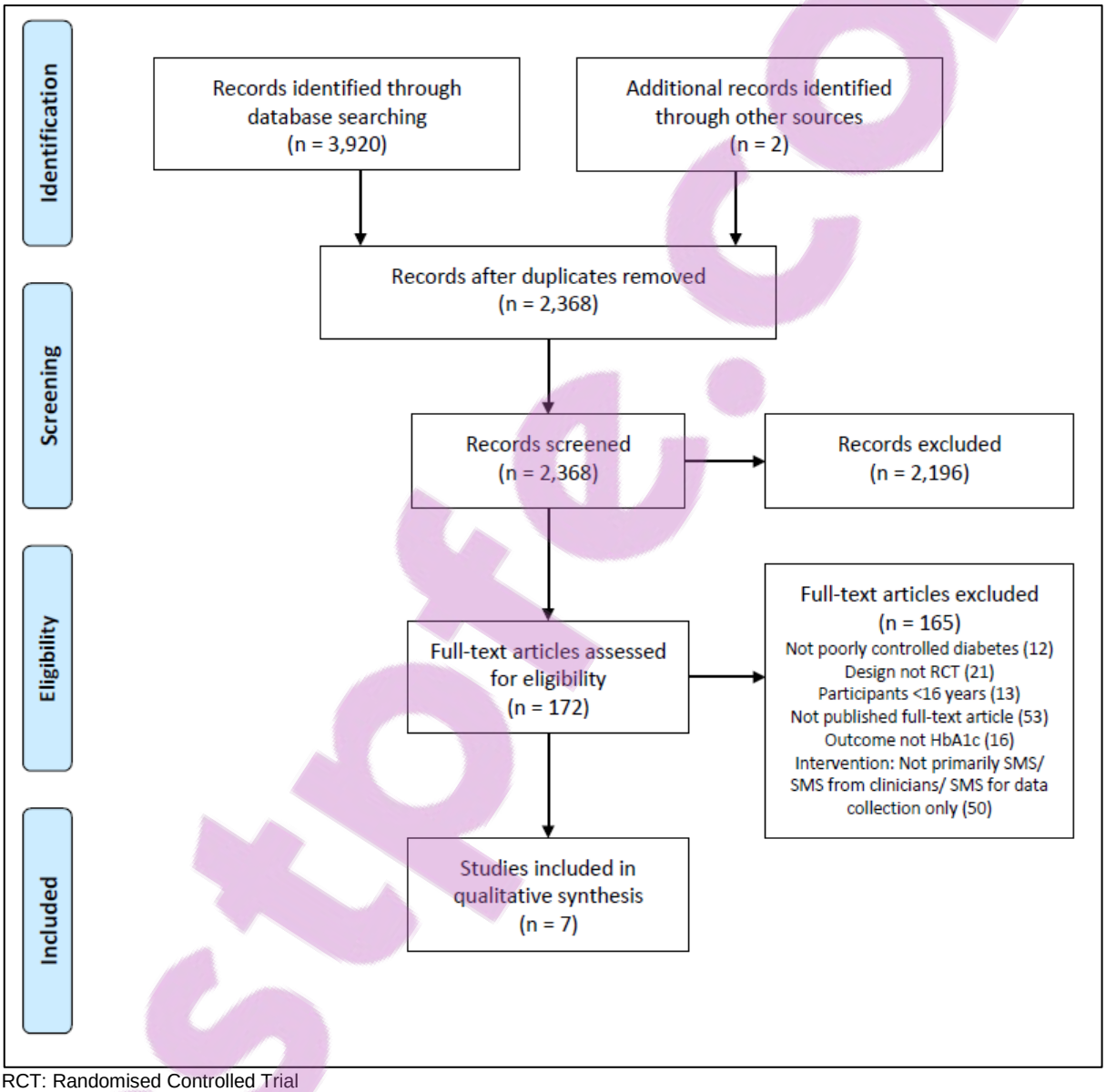
Data were extracted using structured forms informed by the PRISMA checklist(101) and Cochrane Systematic Review Handbook(102), including; study design (design, duration), population characteristics (sample size, diabetes type, age, country), intervention (description, tailoring), comparator (description), theoretical model, and outcomes. In addition, each study was assessed for use of BCTs and the diabetes self-management behaviours targeted. BCTs were coded using the BCT Taxonomy (v1) of 93 hierarchically clustered techniques.(100) During data extraction, it was also evaluated whether the authors reported on an adequate randomisation process, allocation concealment, whether outcomes assessors were blinded, attrition rate, and whether there was evidence of selective reporting. Data extraction was performed by the first author and any uncertainty resolved by consensus following independent assessment by other authors. A narrative synthesis methodology was used to synthesise the data extracted.

3.4.5 Risk of bias assessment

Risk of bias was assessed using methods outlined in the Cochrane Handbook for Systematic Reviews of Interventions for assessing the risk of bias(102) for the following domains: selection bias (including method of randomisation and allocation concealment), detection bias, attrition bias and reporting bias. If available, published study protocols and trial registry data were accessed to inform risk of bias assessment. Trial registry sites were searched if trial registration was not stated in manuscript. Risk was judged as high, low, or unclear. Unclear risk was given if there was a lack of information or uncertainty.

3.5. Results

A total of 3,922 records were identified from the combined database searches and other sources. Once duplicates were removed 2,368 records were screened for eligibility using title and abstract. One hundred and seventy two full-text articles were assessed for eligibility of which seven studies met the inclusion criteria and are included in this review. Figure 1 shows the data collection process.



RCT: Randomised Controlled Trial

Figure 1: PRISMA flow diagram of study selection

3.5.1 Assessment of risk of bias

Figure 2 presents the risk of bias summary and graph (see Appendix 2 for further detail of the judgements for risk of bias in the included studies). Inadequate reporting meant that presence of bias was unclear in all but one of the studies and therefore it could not be judged that any study was free of bias. Two studies were low risk for selection bias (low risk for sequence allocation and allocation concealment).(103, 104) Due to the nature of mHealth interventions, meaning participant

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blinding is not feasible, detection bias was determined on blinding of the outcome assessors only. Blinding was not described in six of the studies, with one study considered high risk due to the absence of blinding.(103) Two studies were considered high risk for attrition bias with the remaining five studies considered low risk.(74, 75, 77, 103, 104) No study referenced a published protocol but all were registered with a clinical trials registry with the exception of one.(105) For those registered, three studies were considered low risk for reporting bias.(74, 103, 106)

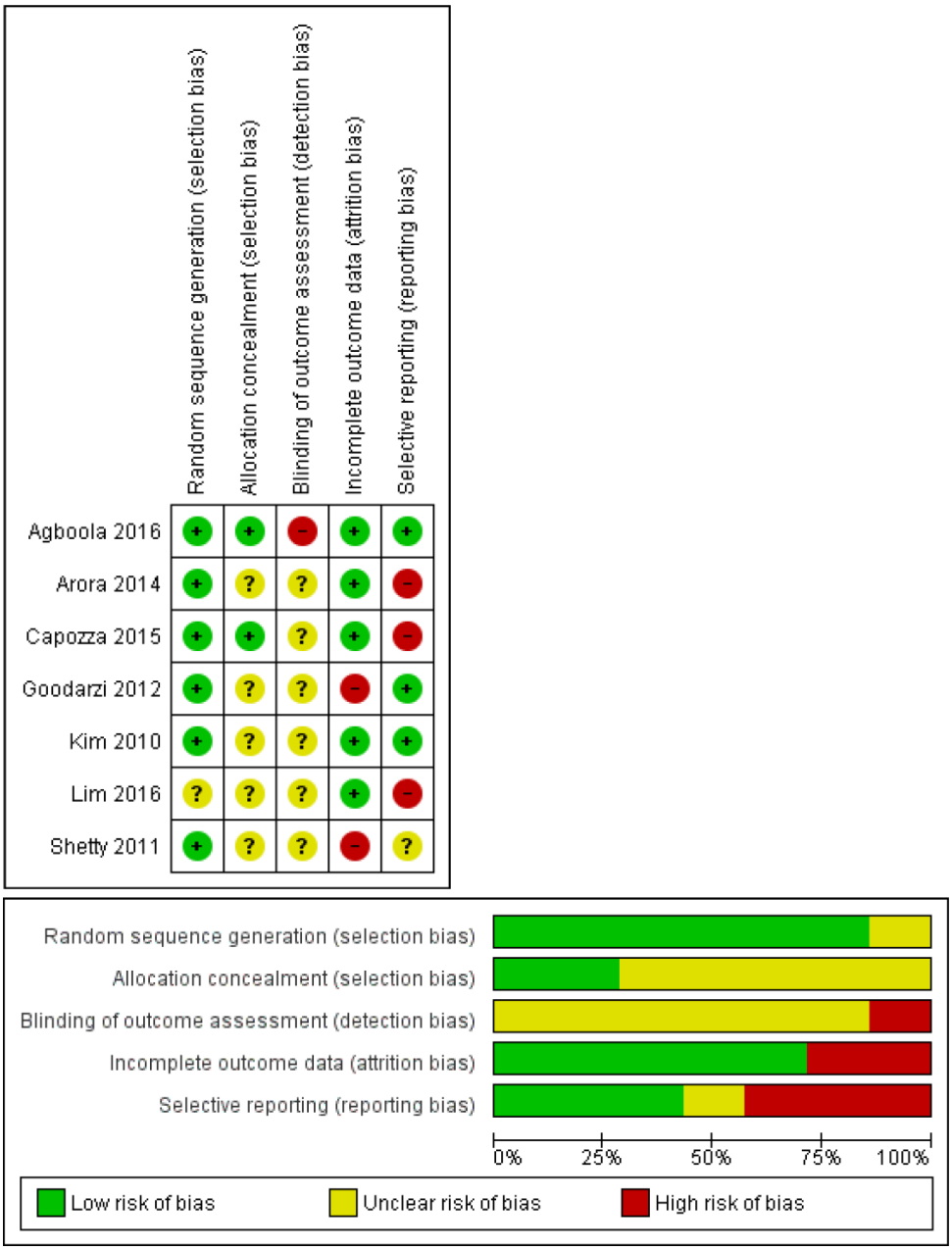

Figure 2: Risk of bias summary and graph: review authors' judgements about each risk of bias item for each included study and presented as percentages across all included studies.

3.5.2 Characteristics of studies

The characteristics of the included studies can be seen in Table 2.(74, 75, 77, 103-106)

Table 2: Characteristics of included studies

Study	Study design	Participants: Sample size (baseline/follow up); Age (mean(SD)); Country	Intervention		Comparison group	Theoretical model
			Description	Tailoring		
Agboola (2016)(103)	RCT Parallel 2 arms 6 months	126/95 adults with T2D (HbA1c>7%) Age: IG=50.3years (10.5); CG=52.6years (12.6) Country: USA	'Text to Move (TTM)' – SMS and pedometer. 2 SMS per day at set times; one providing coaching/feedback based on daily step counts received via pedometer and pre-set goals; and the other support, health education, motivation, and reminders to engage in healthy behaviours. Data stored on a web-based portal viewable by participants. Versions in English and Spanish	Stage of behaviour change and language	Usual care and pedometer	Transtheoretical model
Arora (2014)(77)	RCT Parallel 2 arms 6 months	128/92 adults with T2D (HbA1c ≥8%); Age: IG=50.5years (10.3); CG=51.0years (10.2) Country: USA	'TExT-MED' – 2 SMS per day at set times providing education/ motivation, medication reminders, healthy living challenges & diabetes trivia. Versions in English and Spanish	Language	Usual care	Health belief model
Capozza (2015)(104)	RCT Parallel 2 arms 6 months	156/93 adults with T2D (HbA1c>8%) Age: IC=52.0years (11.2); CG=54.5years (10.7) Country: USA	'Care4Life' – Bidirectional SMS with web-based portal for viewing response trends from reply SMS. Between 1-7 SMS per day including 1 diabetes education SMS each day. Optional SMS including medication reminders, glucose testing reminders, BP monitoring reminders, & tracking & encouragement toward weight loss & exercise goals. Versions in English or Spanish	Message types, frequency and language.	Usual care	None reported
Goodarzi (2012)(106)	RCT Parallel 2 arms 3 months	100/81 adults with T2D (HbA1c>7%); Age: IG=51.0years (10.3); CG=57.0years (9.8) Country: Iran	4 SMS per week with Information about exercise, diet, diabetic medication, and self-monitoring of blood glucose	None reported	Usual care	None reported
Kim (2010)(74)	RCT Parallel 2 arms 3 months	100/92 adults with T2D (HbA1c 7-12%) Age: IG=47.8years (9.6); CG=49.0years (10.7) Country: Korea	Web based system which receives data from glucometer and sends automatic adjustments of insulin dose via unidirectional SMS each day at 5pm	Insulin adjustments based on patient-specific data	Usual care and glucometer	None reported
Lim (2016)(75)	RCT Parallel 2 arms 6 months	100/85 adults with T2D (HbA1c 7-10.5%) Age: IG=64.3years(5.2) CG=65.8years (4.7) Country: Korea	CDSS-based U-Health Service which receives data from activity monitor and glucometer, and then CDSS rule engine sends SMS feedback and instructions including lifestyle changes and medication adjustments. In addition a website for recording diet and receiving dietary feedback.	Messages based on patient-specific data	Usual care, glucometer and pedometer	None reported
Shetty (2011)(105)	RCT Parallel 2 arms 12months	225/144 adults with T2D (HbA1c 7-10%) Age: IG=50.1years (9.9) CG=50.5years (8.3) Country: India	2-4 SMS per 3 days providing instructions on nutrition, physical activity, healthy living and reminders to follow medication prescription	Content and frequency	Usual care	None reported

RCT: Randomised controlled trial; SD: Standard deviation; SMS: Short message service; CDSS: Clinical decision support system; IG: Intervention group; CG: Control group; HbA1c: Haemoglobin A1c; BP: Blood pressure

3.5.3 Study design and participants:

All of the included studies were 2-arm parallel group randomised controlled trials. The study durations were 3 months,(74, 106) 6 months,(75, 77, 103, 104) or 12 months.(105) In four studies the comparator was usual care alone,(77, 104-106) and in the remaining studies usual care with the addition of either a glucometer,(74) pedometer,(103) or both.(75) Three of the studies took place in the United States,(77, 103, 104) two in Korea, (74, 75) one in India,(105) and one in Iran.(106)

All of the studies included adults with type 2 diabetes. In majority of the studies participants were required to have a baseline HbA1c level over 7%,(74, 75, 103, 105, 106) with only two stating that they were targeting those with poorly controlled diabetes requiring HbA1c over 8% (64 mmol/mol).(77, 104) Baseline sample sizes ranged from 100 to 225 and included a total of 935 participants. Participants were relatively homogenous in terms of mean age (late-40s to mid-50s) with the exception of one study whose target population was older adults 60 years and over.(75) High attrition was seen in four of the seven studies.(77, 103-105)

3.5.4 Intervention

Only three of the studies utilised SMS as the sole intervention,(77, 105, 106) the remaining studies included pedometers/activity monitors,(75, 103) glucometers,(74, 75) web-based tools,(74, 75, 103, 104) and home gateway systems.(75) All but one of the interventions were tailored to the participant to some degree. In two studies the message content and frequency was tailored by individual preferences, (104, 105) three allowed participants to choose the language of the messages,(77, 103, 104) and three provided feedback on patient specific data received from devices (glucometer or pedometer).(74, 75, 103) One study tailored the content based on the participant's stage of change (transtheoretical model of behaviour change).(103)

SMS functionality varied in the studies. In two studies SMS was used for providing education/information only,(105, 106) and in another two feedback and treatment instructions only.(74, 75). In the one SMS functioned as a tool to provide feedback, motivation and education,(103) in another the SMS delivered education and reminders,(77) and in the final study SMS functionality included education, reminders, data collection and feedback.(104)

The dose of SMS in the studies varied with two delivering less than one SMS per day,(105, 106) one study delivering one SMS per day,(74) and two studies delivering two SMS per day.(77, 103) The dose was variable in two studies. In one, SMS were sent in response to incoming data which was requested a minimum of eight times per week, (75) and in the other study participants selected the dose and could receive between one and seven messages per day.(104)

There was considerable variation in the content of the SMS. Table 3 shows the frequency of studies addressing specific self-management behaviours identified by the Association of American Diabetes Educators.(41) Two studies targeted single behaviours - physical activity,(103) or medication adherence.(74) One study targeted three behaviours, two studies four behaviours and two studies five behaviours (see Table 3).

Table 3: Diabetes self-management behaviours targeted by interventions

Self-management behaviours	Number of studies targeting behaviour
Healthy eating	5 (75, 77, 104-106)
Physical activity	6 (75, 77, 103-106)
Blood glucose monitoring	4 (75, 77, 104, 106)
Taking medication	6 (74, 75, 77, 104-106)
Problem solving	0
Reducing risks	1 (77)
Healthy coping	1 (104)

[1] Self-management behaviours identified by the Association of American Diabetes Education(41)

Only two of the seven studies explicitly stated that they had a theoretical basis: the transtheoretical model,(103) and Health Belief Model.(77) The most commonly utilised BCT's in the interventions were '4.1. Instruction on how to perform the behaviour' and '5.1. Information about health consequences'. Other commonly utilised techniques included '2.4. Self-monitoring of outcome(s) of behaviour', '2.7. Feedback on outcome(s) of behaviour', and '7.1 Prompts/cues'. A summary of the frequency of BCT utilised in the interventions can be seen in Table 4. In two of the studies the control group were asked to perform self-monitoring of the outcome(s) of behaviour (BCT2.4) but were not provided any feedback on this. The control arms of all other studies did not incorporate BCTs.

Table 4: Behaviour change techniques utilised

Behaviour change technique(100)	Number of studies incorporating technique in the intervention
1.1 Goal setting (behaviour)	1 (104)
1.5 Review behavioural goal(s)	1 (103)
2.4. Self-monitoring of outcome(s) of behaviour	4 (74, 75, 103, 104)
2.7. Feedback on outcome(s) of behaviour	4 (74, 75, 103, 104)
4.1. Instruction on how to perform the behaviour	5 (74, 75, 77, 105, 106)
5.1. Information about health consequences	5 (77, 103-106)
7.1 Prompts/cues	4 (75, 77, 103, 104)
8.1 Behavioural practice/rehearsal	3 (77, 103, 104)

3.5.5 Outcomes

A significant decrease in HbA1c from baseline to follow up in the intervention group compared to the control group was seen in only three of the seven studies.(74, 75, 106) The remaining studies all showed a decrease in mean HbA1c in the intervention group from baseline to follow up and this difference was significant in one study but not when compared to the control group.(103)

A summary of the key findings of the included studies can be seen in Table 5. There was very little consistency in other outcome measures reported in the studies. Four studies (75, 77, 103, 105) reported on changes in physical activity with only one study reporting a significant increase in the frequency of activity in the intervention group.(75) Three studies reported on changes to diet, with one study reporting no significant changes in adherence to diet prescription,(105) one study reported no significant change in diet behaviours,(77) and the other showed a significant decrease in the mean caloric intake of the intervention group.(75) Two studies (77, 106) reported on changes in diabetes related self-efficacy, with both showing improvements in the intervention group but only one reporting a significant change in this construct in the intervention group compared with the control group.(106) Diabetes knowledge was also reported in these two studies, again both showed

improvements in the intervention group but with only one reporting a significant change compared with the control group.(106) Two studies reported improvements in blood glucose monitoring in the intervention group,(74, 77) but in only one of these studies the difference was significant.(74) Satisfaction and acceptability with the interventions was reported in four of the studies - all reported high satisfaction levels and acceptability of the interventions.(77, 103-105)

Table 5: Main findings of the included studies

Study	HbA1c Outcomes	Self-management outcomes	Satisfaction/ Acceptability
Agboola (2016)(103)	Significant decrease in HbA1c the IG by –0.43% (95% CI –0.75 to –0.12, p=.01), non-significant decrease in the CG. No significant difference in the change in HbA1c from baseline to follow up in the IG when compared to the CG. (0.07%; 95% CI –0.47 to 0.34, p=.75)	No statistically significant difference in overall **monthly step counts** between the IG and CG at follow up.	High ratings of usefulness, 94% would recommend it, and 72% wanted to continue the programme.
Arora (2014)(77)	Non-significant decreased in HbA1c by 1.05% in the IG compared with 0.60% in the CG (D0.45; 95% CI –0.27 to 1.17).	Non-statistically significant improvements in **medication adherence, knowledge, self-efficacy,** and **self-care activities (healthy eating, BG monitoring, foot care, exercise)** in IG compared to CG	Very high satisfaction, 100% would recommend it and 79% wanted to continue the programme.
Capozza (2015)(104)	Both groups average HbA1C decreased from baseline to follow up. No statistically significant difference between the IC and CG in terms of change in HbA1C at follow up (p >0.05).	Not reported	High satisfaction. 94% would recommend the programme to others.
Goodarzi (2012)(106)	The IG compared with CG improved significantly in HbA1C (p = 0.02).	Statistically significant improvements in **diet**, **physical activity, self-efficacy, practice** and **knowledge** in the IG. No significant improvement in **attitudes**.	Not reported.
Kim (2010)(74)	A significantly greater decrease in HbA1c from baseline to follow up was seen in the IG compared to the CG (p=0.02).	Significantly higher BG **monitoring** during the study period in the IG group compared to the CG.	Not reported
Lim (2016)(75)	A significant decrease in HbA1c from baseline to follow up was seen in the IG compared to the CG (P<0.01).	Significantly greater decrease in **caloric intake** and increase in **exercise** episodes in the IG compared to CG.	Not reported
Shetty (2011)(105)	There was no significant difference in the mean HbA1C values in both groups. The percentage of patients with an HbA1c <8% at one year increased significantly in the IG.	No significant improvement in **diet** or **physical activity**.	High acceptability based on the requested message frequency by participants.

CI: Confidence interval; IG: Intervention group; CG: Control group; HbA1c: Haemoglobin A1c; BG = Blood glucose

3.6. Discussion

To our knowledge, this is the first systematic review to examine the use of SMS for delivery of diabetes self-management interventions specifically to those with poorly controlled diabetes. Seven

RCTs met our criteria and were included in the review, with three of the studies reporting a significant decrease in HbA1c from baseline to follow up in the intervention group compared with the control group.

Due to the small number and heterogeneity of the included studies, as well as the variable methodological quality of the trials a meta-analysis of the data was not conducted and it is difficult to draw conclusions on the effectiveness of SMS interventions on glycaemic control in poorly controlled diabetes. Similarly, it is not possible to tease out the features/components of the SMS interventions that are associated with better outcomes. Unlike previous reviews reporting consistently positive impacts on glycaemic control for SMS interventions in patients with diabetes, when this is limited to those with poorly controlled diabetes the evidence appears to be mixed. This review was also limited to the use of SMS that was automated rather than including SMS sent individually by a researcher or clinician. Use of individually sent (non-automated) SMS requires considerable cost and time, limiting its applicability for the wider population, and it could be argued that this is no different to individual clinician guidance provided via other mediums. As our review found mixed results, it could be further investigated whether individual clinician/researcher written feedback messages added to automated SMS interventions are needed to increase the effectiveness of the interventions for those with poorly controlled diabetes.

It has been reported that internet and mobile based interventions with a theoretical basis are more effective than those that have no theoretical basis(57, 92). Two of the included studies reported a theoretical basis and neither of these studies found significant effects on their primary outcomes. Although the majority of studies did not explicitly state a theoretical basis, BCTs were utilised in all of the studies.

Interestingly, all four studies that reported no significant difference in the change in HbA1c between groups did report decreases in HbA1c in the intervention group over the study period. In addition all four of these studies reported high acceptability and satisfaction with the interventions. This may indicate that this type of intervention is well received in the target population and provides some rationale for further development and investigation of SMS interventions in this group.

3.6.1 Characteristics of effective interventions

The three interventions that found a significant decrease in HbA1c from baseline to follow up were heterogeneous in their design. The first provided education and utilised SMS only, the second provided insulin adjustments based on patient specific data gathered using a glucometer, and the final study provided medication and lifestyle guidance based on patient specific data gathered using a glucometer and pedometer. A key similarity between two of the successful interventions was the use of devices to gather data to provide automated clinical guidance/feedback through SMS utilising BCTs, 2.4. Self-monitoring of outcome(s) of behaviour, and 2.7. Feedback on outcome(s) of behaviour. This monitoring functionality as well as individual feedback could be a key factor for success of mHealth interventions in this area.(107, 108) Although the inclusion of additional devices used for monitoring (e.g. glucometers and pedometers) adds further cost to the intervention which needs to be considered.

Dosages in the effective interventions varied from four messages per week through to eight messages per week. The self-management behaviours targeted also varied - one study only targeted taking medication whereas as the other two both targeted taking medication, healthy eating, physical activity and monitoring. The effective interventions were all of short duration (3 months or 6 months) with none providing longer term follow up. Longer studies in this review did not show significant results, leading to questions about the sustainability of any significant findings.

With a lack of similarity between the three successful interventions, similarities between ineffective interventions was also explored. All four studies saw some degree of improvement in HbA1c in the intervention group. These studies were of longer duration, tailored, and had higher dose SMS. Interestingly, although the interventions in these studies were all well received, all four studies had high rates of attrition which could be a contributing factor to the results. High attrition is common in mHealth studies,(58, 109) and ways to address this need to be considered.

3.6.2 Limitations of review

This review has several limitations which must be considered. Key limitations include the small number of eligible studies and methodological limitations of many of these studies. In addition only published full-text papers in English were included resulting in potential for publication and language bias.

For this review, poorly controlled was defined as above the recommended target of 7% (53 mmol/mol). It is generally considered that a higher cut-off should be adopted for the definition of poorly controlled such as 8% (64 mmol/mol), therefore the findings in relation to ‘poor control’ must be interpreted with caution. However, if a higher cut-off had been utilised, only two studies would have met the criteria for the review hence the benefit of the lower threshold.

A strength of this review is that it synthesises evidence from studies with RCT design. Unfortunately, although all of the included studies were published from 2010 onwards (and four in the last three years), many of the articles failed to report key methodological features and detailed descriptions of the interventions. This is disappointing considering widely available guidance such as the CONSORT statement on how RCTs should be published.(110) Therefore assessment of some types of bias in the included studies was unclear.

3.6.3 Implications for future research

The findings from this review show potential for the utilisation of SMS in improving glycaemic control for those with poorly controlled diabetes, although more research is needed before recommendations can be made regarding adoption by healthcare services. Improving glycaemic control in those with poorly controlled diabetes is challenging but the benefits to success in this group are potentially greater, both at an individual level and at a health system level. From this review it is unclear what characteristics and components of SMS interventions are more efficacious. This aligns with previous reviews highlighting that more work is needed to understand the successful components of this type of intervention.(51, 111, 112) There is a need for better quality trials and robust reporting on longer term follow up.

Although this review excluded paediatric populations younger than 16 years (due to the unique characteristics of this group in managing diabetes) there was a lack of studies involving young adults (16 to 24 years). With both increasing prevalence of type 2 diabetes in young adults and the period of adolescence a critical time for the formation of life long habits around diabetes self-management in type 1 diabetes, there appears to be a need for more investigation of the use of mHealth in this group.

The content of the text messaging interventions is key to their success;(52, 113) mobile phones provide a platform, and SMS a delivery mechanism, for behaviour change interventions but this platform and mechanism are not a solution in themselves. This review was unable to demonstrate a relationship between positive outcomes and intervention content and functionality, and so more investigation needs to be made into what content and features are likely to be helpful. This should include consideration of specific characteristics of people with poor control to ensure they are personalised and tailored appropriately. Making them more relevant may also help to decrease attrition, common in mHealth studies.

3.7. Conclusions

The findings from the seven studies included in this review demonstrated that the evidence for improvements of SMS on glycaemic control in people with poorly controlled diabetes is mixed. Contrary to previous reviews reporting positive impacts on glycaemic control for SMS interventions in patients with diabetes, when this is limited to those with poorly controlled diabetes the evidence is less clear. The review is limited by the small number of trials. Considering that diabetes management is one of the most investigated areas for the use of mHealth, this highlights the lack of focus on those with poorly controlled diabetes, a group most in need of intervention.

3.8. Declarations

Conflicting interests: The Authors declare that there is no conflict of interest

Funding: The Authors received no funding for this research or publication of the article.

Ethical approval: None

Guarantor: RD

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CHAPTER 4. THE USE OF MOBILE HEALTH TO DELIVER SELF-MANAGEMENT SUPPORT TO YOUNG PEOPLE WITH TYPE 1 DIABETES: A CROSS-SECTIONAL SURVEY

4.1. Preface to the publication

The following chapter comprises a published manuscript describing a cross-sectional survey designed to investigate the current and perceived roles of mHealth in supporting young people to manage their diabetes. It addresses the following thesis objective:

2. Investigate current engagement in already available mHealth and explore perceived roles of mHealth in supporting diabetes management

Minor changes to formatting have been made to the published manuscript to ensure consistency across the thesis.

Supporting documents associated with this chapter can be found in Appendix 2 including a copy of the ethics approval letter, CHERRIES checklist, participant information sheet, consent form, and survey questions.

Why was this study needed?

Evidence shows that young adulthood is a period of particular challenge for people diagnosed with diabetes. It is a transitional period in a person's life during which they assume greater responsibility for their self-care and disease management. Not only is this period a critical time for diabetes self-management, it is a time of typical decline in glycaemic control.(114) This decline in control is not surprising in the context of hormone changes, developmental changes, increasing independence, and in the context of transitions within the healthcare system. Poor engagement with diabetes self-management in this period is likely to continue with poor self-management behaviours in adulthood.(115) This makes this a vital period for the establishment of good self-management to reduce the costly and debilitating long term complications of the disease. This period therefore an ideal target for self-management interventions.

As described in Chapter 1 mobile phones appear to be an ideal platform for the delivery of diabetes self-management interventions. There is increasing smartphone ownership, particularly in young people, and a proliferation of apps already available to people with diabetes. It is therefore important to understand current engagement with this type of tool and whether the needs of young people with diabetes are being adequately met by apps. As was seen in Chapter 3, there has been a lack of studies investigating the use of text messages (SMS) to deliver self-management interventions to this population and so the potential of this modality in this group is unclear. An investigation of the characteristics and preferences of this group will determine whether these are unique and there is a need of mHealth interventions to be developed specifically for this group or if broader diabetes support interventions can meet their needs. Furthermore, when developing

mHealth tools, a necessary step to enhance effectiveness is to understand the population's preferences for this mode of delivery.

What was undertaken?

A descriptive cross-sectional survey was conducted with young adults with type 1 diabetes across the Auckland region. The survey incorporated both closed and open-ended questions to investigate current and perceived roles of mHealth in supporting diabetes self-management. It investigated current technology access and use of technology to manage diabetes, usefulness of currently available apps, interest in SMS based diabetes support, and preferences for mHealth content.

Publication citation:

> Dobson R, Whittaker R, Murphy R, Khanolkar M, Miller S, Naylor J, Maddison R. (2017). The Use of Mobile Health to Deliver Self-Management Support to Young People with Type 1 Diabetes: A Cross-Sectional Survey. JMIR Diabetes 2(1): e4.

Link to original publication: https://diabetes.jmir.org/2017/1/e4/

Contribution by the candidate:

The candidate came up with the study concept, design, and procedures, with guidance from her supervisors. The candidate obtained ethical approval, collected the data and analysed the results. The candidate wrote the manuscript, receiving input and feedback from co-authors.

A cross-sectional survey investigating the use of mobile health to deliver self-management support in young people with type 1 diabetes

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List of research project topics and materials

4.2. Abstract

Background: Young people living with type 1 diabetes face not only the challenges typical of adolescence, but also the challenges of daily management of their health and evolving understanding of the impact of their diagnosis on their future. Adolescence is a critical time for diabetes self-management, with a typical decline in glycaemic control increasing risk for microvascular diabetes complications. To improve glycaemic control, there is a need for evidence-based self-management support interventions that address the issues pertinent to this population, utilising platforms that engage them. Increasingly, mobile health (mHealth) interventions are being developed and evaluated for this purpose with some evidence supporting improved glycaemic control. A necessary step to enhance effectiveness of such approaches is to understand young people's preferences for this mode of delivery.

Objective: A cross-sectional survey was conducted to investigate the current and perceived roles of mHealth in supporting young people to manage their diabetes.

Methods: Young adults (16-24 years) with type 1 diabetes in Auckland, New Zealand, were invited to take part in a survey via letter from their diabetes specialist.

Results: A total of 115 young adults completed the survey (mean age 19.5 years; male 52/115, 45%; European 89/115, 77%), with all reporting they owned a mobile phone and 96% (110/115) of those were smartphones. However, smartphone apps for diabetes management had been used by only 33% (38/115) of respondents. The most commonly reported reason for not using apps was a lack of awareness that they existed. Although the majority felt they managed their diabetes well, 63% (72/115) reported wanting to learn more about diabetes and how to manage it. A total of 64% (74/115) respondents reported that they would be interested in receiving diabetes self-management support via text message (short message service, SMS).

Conclusions: Current engagement with mHealth in this population appears low, although the findings from this study provide support for the use of mHealth in this group because of the ubiquity and convenience of mobile devices. mHealth has potential to provide information and support to this population, utilising mediums commonplace for this group and with greater reach than traditional methods.

4.3. Introduction

Rates of type 1 diabetes are increasing both in New Zealand and internationally.(2, 21, 116, 117) Good diabetes control at an early age is integral in delaying the onset and slowing the progression of long-term complications of the disease such as renal failure, blindness, and lower limb microvascular disease.(8, 93, 118, 119) Type 1 diabetes is one of the most demanding chronic conditions, both psychologically and behaviourally, requiring considerable daily management throughout the individual's life for optimal outcome. Successful diabetes management involves managing medical responsibilities (including blood glucose monitoring and insulin administration) alongside behaviours around diet and physical activity.(120) There is evidence of a positive relationship between diabetes self-management behaviours and metabolic control, particularly in adolescence.(121-126) Poor engagement with diabetes self-management in adolescence is likely to continue to poor self-management behaviours in adulthood,(115) making this a vital period for the establishment of good self-management and prevention of debilitating long-term complications.

There is a wide range of interventions designed to support young people to self-manage their diabetes that tend to involve providing encouragement, information, and motivation to obtain greater control of their condition. This may be done by increasing their understanding of diabetes, encouraging them to be active participants in decision making around their condition, and motivating them to engage in healthy behaviours.(30) The importance of a combination of approaches for self-management support in individuals with type 1 diabetes is clear, including psychosocial support, education, diabetes monitoring and insulin-specific information and support, and multidisciplinary clinician support.(127) In particular, there is a need for interventions to actively demonstrate the link between diabetes management behaviours and the young people's daily life(128) and interventions that utilise platforms that engage young people.

Mobile health (mHealth) is the use of mobile devices, such as mobile phones, to deliver health services and information.(48) There is increasing evidence for the effectiveness of mHealth in health behaviour change and disease management, including diabetes.(61, 68) Mobile phones offer potential to reach all populations and provide access to an individual at opportune times regardless of location.(50) They also provide a tool for support outside of the hospital or clinic and in turn support increased independence. They provide a non-confrontational method for support around sensitive issues such as contraception, alcohol and drugs, and sexual health, which can have considerable impact on a young person's diabetes control.(114) In addition, mHealth interventions capitalise on existing communication behaviour in young people, who are more likely to bring their mobile phones than their glucose meters to clinic appointments.(78)

There is growing evidence that mHealth interventions can successfully engage young people with diabetes, which has traditionally been difficult to do.(73, 76, 78, 129-139) Research indicates strong patient interest in mHealth tools to support diabetes management and a preference for smartphone apps in the young adult population.(140) However, with increasing availability of diabetes-related apps there is concern regarding the accuracy and evidence base of many of these.(79) It is essential to ensure that patients have access to tools that are safe, evidence-based, and known to be effective. In addition, these tools need to attend to the issues relevant to the

young person rather than purely focusing on those considered relevant by the clinician.(130) To accommodate the preferences and priorities of the population, and thereby enhance the chances of success, it is crucial to engage the target population in the design and development of the intervention through obtaining feedback during intervention design(141, 142) and linking of diabetes management with individual goals and priorities.(128, 143)

This study aimed to investigate the current and perceived roles of mHealth in supporting young people to manage their diabetes. This will inform the development of a self-management support intervention for this population.

4.4. Methods

4.4.1 Study design

A descriptive cross-sectional survey was conducted with young adults with type 1 diabetes from March to September 2014. The survey incorporated both closed and open-ended questions to gain more in-depth information and to allow participants to elaborate further. The survey was designed in paper format and then uploaded into an electronic format using LimeSurvey (LimeSurvey Project), an Open Source survey tool. The survey was then pretested by researchers, members of the study advisory group, and young people. The survey is described according to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist.(144)

4.4.2 Ethics approval

Ethical approval for this trial was obtained from the New Zealand Health and Disability Ethics Committee (14/CEN/24). Research approval from each district health board was also obtained.

4.4.3 Inclusion criteria

Inclusion criteria were young adults aged 16-24 years (inclusive), diagnosis of type 1 diabetes, registered as a patient under one of the three Auckland regional diabetes services, able to read and understand English, and able to provide informed consent.

4.4.4 Procedures

All patients who met the inclusion criteria were sent a letter from their clinician inviting them to take part in the closed survey. Those wishing to participate could complete the survey via 1 of 3 methods: (1) by going directly to the study website and completing it online, (2) over the phone, or (3) by completing a paper copy of the survey. Participants had 3 months from the letter date to complete the survey.

Before commencing the survey, participants provided informed consent (electronic consent if completing the survey online, verbal consent if completing over the phone, or written consent if completing on paper) to participate. Participants had to enter a unique code from their letter to ensure only those eligible completed the survey. Participants only had access to the survey once their unique code was entered and verified. Upon completion of the survey, participants had the

option to enter their contact details to receive a NZ $20 voucher reimbursing them for their time. This personal information was stored separately to the main data file and password protected.

The survey was identical for all participants (no randomised items), and participants were able to go back and change their responses before submission. Adaptive questioning was used to minimise response burden and reduce complexity of questions.

4.4.5 Survey design

The survey consisted of 3 parts, with each part of the survey presented on a separate page:

1. Demographic information and technology access: including age, sex, ethnicity, occupation, age at diabetes diagnosis, and mobile phone ownership and use.
2. Using technology to manage diabetes and health: use and perceived usefulness of currently available apps, interest in text message (short message service, SMS)–based diabetes support, and preferences for mHealth content.
3. Your diabetes and how you manage it: perceptions of own diabetes management, confidence in diabetes management, diabetes self-management tasks they find most difficult, and whether they would like to learn more about diabetes and its management.

4.4.6 Statistical analysis

Survey data were analysed and summarised using descriptive quantitative analyses including means, standard deviation, and proportions. Qualitative comments were analysed using a simple, general inductive thematic approach to identify common themes and meanings from the data. Only completed surveys, with correct unique codes, were included in the analysis and no time limit was imposed. Prioritised ethnicity was used as recommended by the New Zealand Ministry of Health for the reporting of ethnicity data; only one of the ethnic categories nominated by the participant was used according to a predetermined hierarchy (Māori, Pacific Islander, Asian, European, and other ethnic groups, in order of prioritisation).(145)

4.5. Results

4.5.1 Survey response

There were 141 entries to the survey website; of these, 115 completed the survey, giving a completion rate of 82%. All participants chose to complete the survey online.

4.5.2 Part 1: Demographic information and technology access

A total of 115 young adults completed the survey, giving a response rate of 29% (see Table 6 for a breakdown of respondents) of the invited population (N=402). There was no significant difference between those invited to complete the survey and those who responded in terms of ethnicity or age. There was a significant difference (P=.02) for sex, with the participant sample having a higher proportion of females. The mean age of diagnosis as reported by participants was 11.12 years (SD 5.15, range 1-23).

Table 6. Demographics of invited population and survey respondents.

Characteristic	Total eligible (n=402), n (%)	Respondents (n=115), n (%)
Sex: male	229 (56.9)	52 (45.2)
Ethnicity		
European	301 (74.9)	89 (77.4)
Māori	27 (6.7)	10 (8.7)
Pacific Islander	41 (10.2)	7 (6.1)
Asian	22 (5.5)	6 (5.2)
Other	9 (2.2)	3 (2.6)
Not stated	2 (0.5)	0 (0.0)
Age in years, mean (SD)	19.94 (2.47)	19.51 (2.53)

All of those who completed the survey reported they owned a mobile phone, with 110/115 (96%) reporting they owned a smartphone (a mobile phone with the addition of a computer operating system). Of those who owned a smartphone, only 71/110 (65%) reported having access to data (Internet) on their phone all the time, 36/110 (33%) sometimes, and 3/110 (3%) reported never accessing the Internet on their phone. The majority of respondents reported that their mobile phone was "pay-as-you-go" (84/115, 73%) as opposed to 30/115 (26%) who were on a monthly contract, and 1 respondent did not know. Most participants (76/115, 66%) reported that they never turn their phone off.

4.5.3 Part 2: Using technology to manage diabetes and health

Apps for diabetes management

A total of 38 (33%) of the 115 respondents reported they use or have used apps to help them manage their diabetes. Rates of app usage differed by ethnicity, with Māori and Pacific Islander respondents having lower rates of app use (10% and 0%, respectively) compared with Europeans (38%), Asians (33%), or the other ethnicities (33%). A total of 43% of females who completed the survey reported they use or have used apps to help them manage their diabetes compared with 21% of males.

Of those who reported having used apps (n=38), they reported having used a mean of 1.87 different apps (SD 1.33, range 1-7). The most commonly reported apps were Carbs & Cals (n=10), Glucose Buddy (n=9), MyFitnessPal (n=6), and DAFNE Online (n=5). Of the 38 respondents who had used apps, 10 (26%) reported finding them "extremely useful" in helping them manage their diabetes, 20 (53%) reported finding them "a little useful," and 8 (21%) "not very useful". Common reasons included that they were useful for tracking diabetes data, for carbohydrate counting and insulin calculations, and that they were accessible and convenient for managing diabetes on the go. Participants reported that a key benefit of the apps was that they provided an easy and convenient way to track their diabetes and store data. They also reported that they provided an easy way to see patterns through graphs of their capillary glucose data.

> *"Helps me keep a record of what I'm eating my levels and my insulin intake along with the other medications I'm on and shows a pattern of when I go lower or higher"*
> (Female, 23, NZ European)

> *"They graph patterns of blood sugar levels, and are a great place to store data related to your diabetes"*
> (Male, 18, NZ European)

They reported that, because their phones are always with them, they provided a great way to manage their diabetes on the go. They mentioned having access to information when out as being a benefit and providing a replacement for pen and paper methods of keeping track of their diabetes.

> *"Because I always have my phone and it makes it easier to log in my blood sugars on something that I always have access to"*
> (Female, 18, NZ European)

> *"I find them useful because I'm always on the go and I always have my smartphone on me so if I ever need to check the carb content of something I can do so immediately"*
> (Male, 21, NZ European)

A number of participants also reported that apps are useful for carbohydrate counting, particularly for less common foods or meals, and for calculating insulin dosage:

> *"It [the app] gives me an idea of how many carbs are in foods I don't normally consume on a day to day basis. Takeaway foods in particular are harder to count carbs in."*
> (Female, 24, Indian)

> *"It makes the maths easier- calculating how much insulin I need when taking into account how many carbs I'm eating and what my current blood glucose is."*
> (Female, 17, NZ European)

The most common reason for why they were not useful was the data entry being tedious and therefore not being bothered to use the app.

> *"Too fiddly to mess around with and enter all the data. As well as when I test my blood, I just want to eat not mess around with my phone."*
> (Male, 22, NZ European)

> *"Just another thing to remember to do so I can't be bothered sometimes."*
> (Female, 21, NZ European)

Technical issues were also identified as a reason for apps not being perceived as useful, and the need for Wi-Fi or data connection meant they could not always use them.

> *"Sometimes I can find out how many carbs my food I'm eating has but I have trouble using it sometimes because it doesn't load and it requires internet access and if I haven't got good reception I can't see the portion sizes"*
> (Female, 18, NZ European)

Others reported that because they forget to use the app or do not enter their data regularly the app was not useful.

> *"I fail to enter in my readings from my testing machine. So therefore I have no data in the app at all."*
> (Male, 19, NZ European)

Only 1 participant identified not being able to trust the app and another identified cost as a barrier.

> *"I didn't really trust them, I was too scared to use them in case they were wrong"*
> (Female, 18, NZ European)

The majority (33/38, 87%) of the participants who had used apps reported that they would recommend diabetes-related apps to other young people with diabetes. Those who had never used apps to manage their diabetes were asked to provide the reasons. The most common reasons for not having used apps to help manage their diabetes included that they did not know of any apps or

that they existed at all, that they did not feel they would be of any help or use to them, or that they did not feel that they needed them.

Text messages for diabetes management

A total of 74 (64%) of the 115 respondents reported that they would like to receive SMS text messages designed to support them to manage their diabetes. Those who were interested were asked how often they would want to receive messages, with 21% of the 74 wanting messages more than once per day, 17% once per day, 15% only once every few days, and 12% once a week or less. They were also asked to identify topics they would want the SMS text messages to be about (see Table 7), with tips on how to manage diabetes being the most preferred topic.

Table 7. Topics for text messages (n=74).

Topics	Count[a]	Percentage of sample, %
Tips on how to manage my diabetes	57	77
Motivational messages	50	68
Reminders to test my blood glucose	45	61
Information about diabetes	38	51
Other[b]	7	10

[a] Participants could identify multiple topics.
[b] Other topics identified by participants included recreational drugs, interesting diabetes facts, and research updates.

The 41 participants who reported that they would not be interested in receiving SMS text messages to support them were asked to provide their reasons. Key responses included they did not think that they needed them and concern that they would be annoying. There were 19 participants who identified that they did not feel they needed SMS text message–based diabetes support as they felt they were already managing their diabetes well.

> *"Because I feel I'm perfectly capable of managing my diabetes myself, I know what I have to do and know what I face if I am neglectful. Someone texting me with things I already know is unnecessary."*
> (Male, 22, NZ European)

> *"I think it's unnecessary and have done fine on my own for the most part."*
> (Female, 21, NZ European)

In addition, 19 of the 41 participants reported they would not sign up as they felt that it would be annoying and would just remind them that they had diabetes when they did not want to think about it.

> *"I think I manage my diabetes quite well, I don't really need to read motivational messages and I check my blood glucose regularly on my own. I personally can find texts like that can become annoying. I may consider using the option only if there was an unsubscribe option available if I didn't want to receive them anymore."*
> (Female, 24, NZ European)

> *"Will become irritating. Sometimes it is nice to forget, [believe] that you aren't diabetic - having constant reminders will continuously remind you that you are different from everyone else"*
> (Female, 20, NZ European)

There were two participants who felt that this type of support would not be personal enough and two participants who reported they would prefer apps to SMS text messages.

4.5.4 Part 3: Diabetes and how it is managed

A majority (66/115, 57%) of the respondents reported that they felt they managed their diabetes "extremely" or "very" well. There were 44/115 (38%) who reported that they managed their diabetes "not so well" and only 5/115 (4%) "not well at all". On a scale from 0 "Not at all confident that I can manage my diabetes" to 10 "Completely sure I can manage my diabetes," participants reported a mean rating of 7.23 (SD 2.091, range 1-10). Significantly lower ratings of confidence were seen in those who reported interest in receiving SMS text messages designed to support them to manage their diabetes (mean 6.89, SD 2.10) than those who did not (mean 7.85, SD 1.94; P=.02). Although more than half the participants reported that they felt that they managed their diabetes well, 72/115 (63%) reported that they would like to learn more about diabetes and how to manage it. Participants were also asked about the 3 specific areas of diabetes management that they find most difficult; results are presented in Table 8. The most common areas identified were "Remembering to check my blood glucose" (55/115, 48%) and "Eating well" (40/115, 35%).

Table 8. Diabetes self-management tasks participants find most difficult (n=115).

Diabetes self-management tasks	Count	Percentage of sample, %
Checking my blood glucose	35	30.4
Remembering to check my blood glucose	55	47.9
Eating well	40	34.8
Managing insulin	27	23.5
Problem solving (especially around blood glucose, highs and lows, sick days)	29	25.2
Being psychically active	31	27.0
Attending my medical appointments	21	18.3
Other[a]	10	8.7

[a]Other responses included remembering to administer insulin, needles, carbohydrate counting, being in unexpected situations unprepared, correcting highs, managing alcohol, recording blood glucose levels, and the social effects.

4.6. Discussion

4.6.1 Principal findings

This study aimed to investigate the perceived role mHealth can play in supporting young people to manage their diabetes and to inform the development of a self-management support intervention for this population. Overall, results indicated interest in mHealth for supporting diabetes self-management and provides further support for mobile phones to deliver self-management support in this population group because of high access. In addition, the survey highlighted that although young adults were confident in their ability to manage their diabetes, there was strong interest in learning more about aspects of diabetes management.

As expected, mobile phone, and in particular smartphone, ownership in this population was high, although more than one-third of the respondents did not have consistent access to Internet or data on their device. Because of the demanding and continuous nature of diabetes self-management, tools to support this group need to take data access into consideration. A downside of many of the currently available apps is the need for the user to have ongoing Internet or data to access many of the apps' functionalities. Apps designed to be used offline, therefore avoiding the need for ongoing data or Internet access, can require greater storage capacity on the phone to download the app

and this can be a barrier for those with lower-level devices that typically have smaller storage capacity.

Contrary to expectations, use of currently available apps was low in this group, particularly in Māori and Pacific Islander respondents. The lack of awareness of available apps as well as a perception that these would not be of use contribute to the low utilisation of the most accessible mHealth tools for this population. The use of apps by participants for insulin calculations is of concern in light of research showing that most insulin calculation apps could be putting patients at risk of harm by providing no protection from incorrect insulin dosage recommendations.(79) A common use of apps in this study was for the collection and tracking of data, which, owing to the members of this population commonly having their phone with them and turned on at all times, is ideal. The privacy of this information was highlighted in a recent letter in the *Journal of the American Medical Association* on the lack of privacy policies in diabetes apps.(80) They reported that 81% of the diabetes apps investigated did not have privacy policies and, of those that did, many of the provisions did not actually protect the user's privacy. Health care professionals have the potential to play a key role in increasing the awareness of apps and recommending that patients choose guideline-based and secure apps to increase safety.

A strong interest in the use of SMS text messaging for diabetes self-management support was observed, particularly among those with lower confidence to manage their condition. Previous research has shown that as beliefs in the ability to maintain a healthy lifestyle increased, the need for support through SMS text messaging decreased.(146) Therefore, designing SMS text messaging interventions for those with lower confidence in their ability to manage their condition may be of greater pertinence and more positively received than for those already confident in their ability to manage their diabetes.

Of particular interest to participants was the use of SMS text messaging for providing motivation, reminders, and diabetes self-management tips. Nearly half the respondents reported that remembering to test their blood glucose was the part of their diabetes management that they found most difficult. Although the use of continuous glucose sensors, which have the option of setting high and low alerts, provides a solution, cost is currently a major barrier to widespread use of this technology.(147) Therefore, SMS text messaging is an attractive option to provide testing reminders because of the instant delivery as well as the low patient cost and high accessibility and reach of this type of mHealth tool.(57)

This study highlights key factors that need to be considered when designing SMS text messaging–based diabetes self-management support, including the potential for messages to be annoying, to be unnecessary, or to not be personal enough. Therefore, future development of tools for this group needs to be tailored and personalised, rather than a "one size fits all" approach. Although it has been previously reported that young adults with diabetes have differing priorities from their health care team, our results indicate that nearly two-thirds were interested in learning more about diabetes. mHealth could provide the ideal medium for supporting learning as it can be personalised, non-confrontational, and delivered at the time and place that it is needed and wanted.

Several limitations of the study should be noted. The response rate, although largely reflective of the wider population, was low, limiting the generalizability of the results. It is likely that those who did respond may have more interest in mHealth and therefore actual engagement with this type of tool may be even lower in the wider population. All respondents to the survey completed it online with none requesting to complete it by paper or phone. Although the alternatives were offered, it may be that those without Internet access were less likely to take part, biasing the sample to a more technological group. In addition, the self-report and cross-sectional design of the study are key limitations, as is the sex distribution of the sample differing from the target population. Although this study investigated the use of apps in this population, it did not assess how the population was using them and for how long. It is important that research into mHealth tools for this population assesses the degree of engagement, including intensity and duration, to ensure tools are designed to meet their needs and improve outcomes.

4.6.2 Conclusions

This study provides valuable insight into the engagement of young adults with type 1 diabetes with currently available mHealth tools, as well as providing insight into how future mHealth interventions can be designed to meet their need. The input of the end users regarding their use and preferences for mHealth tools provided by this survey will allow for the development of a more relevant and a potentially more efficacious intervention.

4.7. Acknowledgments

We would like to thank the study participants. The study was funded in part by an Elizabeth Ewing Memorial Scholarship and University of Auckland Postgraduate Research Student Support.

4.8. Conflicts of interest

None declared.

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List of research project topics and materials

Part 2: The development of SMS4BG

Part 1 of this thesis outlined the potential for mHealth to support self-management in those with poorly controlled diabetes. It was found that although there is support for SMS based interventions designed to support diabetes self-management, the effectiveness of these for improving glycaemic control in those with already poor control was unclear. It was also established that in young adults whose smartphone usage is highest, engagement in readily available mHealth to support diabetes self-management was low but interest in SMS was high. It identified that the types of diabetes information and support young adults want via technology aligns with the aims of the broader diabetes self-management education which shows the potential for more general interventions being appropriate. Although the background literature and systematic review highlighted that previous mHealth diabetes studies had focussed on subsets of the population, typically defined by age or diabetes type, findings from Part 1 of the thesis support the development of a generic intervention suitable for all adults with diabetes. This section of the thesis describes the development and pilot of a mHealth diabetes self-management support intervention for people with poorly controlled diabetes. Chapter 5 describes the development of the intervention (named SMS4BG), including the theoretical framework and evidence base that informed it. Finally, Chapter 6 presents a pilot study of SMS4BG to assess its acceptability and usability, before providing an outline of the final revised intervention.

CHAPTER 5. CHAPTER 5. DEVELOPMENT OF AN MHEALTH DELIVERED DIABETES SELF-MANAGEMENT INTERVENTION

5.1. Preface to the chapter

This chapter describes the process to develop a user-friendly tool which delivers motivation and information to support people to self-manage their diabetes. It contributes to the following thesis objective:

3. To develop an mHealth tool for the delivery of self-management support to people with poorly controlled diabetes.

Supporting documents associated with this chapter can be found in Appendix 3 including a copy of the content upload template.

Why was this work needed?

Poorly controlled diabetes and associated complications contributes significant burden to individuals, communities and the New Zealand healthcare system. There is strong evidence that supporting diabetes self-management improves behaviours and clinical outcomes, but it is essential that this type of intervention is appropriate for, and accessible to, the target population. Mobile phones are an ideal platform for delivering diabetes self-management interventions as outlined in Chapter 2, making the support accessible within the context of a person's daily life. Technology delivered solutions for supporting self-management have considerable potential to improve outcomes for those with poorly controlled diabetes, in particular those whose needs are not being met by current interventions.

What was undertaken?

Extensive consultation and formative research was undertaken to inform the development of a tool to support self-management in adults with poorly controlled diabetes. This included consultation with people with diabetes, healthcare professionals and vendors. Recommendations for diabetes self-management education were reviewed as well as theoretical constructs linked to successful diabetes self-management. Evidence based content was developed along with a content delivery system, before pre-testing was carried out. The outcome was a theoretically based and individually tailored SMS diabetes self-management support intervention. It was decided to call the intervention SMS4BG (Self-Management Support for Blood Glucose), which it will be referred to from this point forward for simplicity.

Contribution by the candidate:

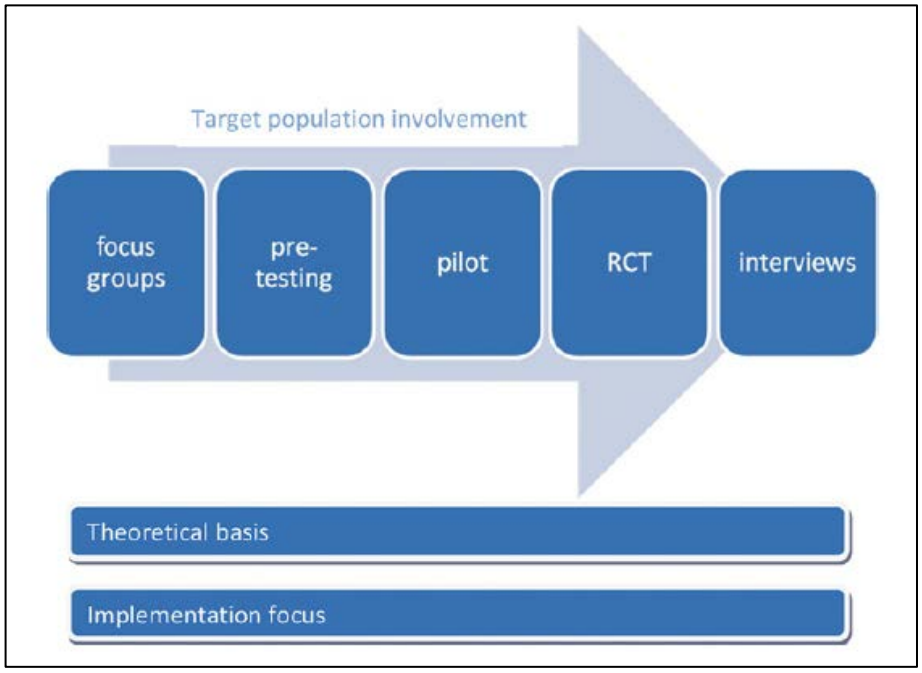
The candidate was involved with, but did not lead the conceptualisation work outlined in this chapter including the focus groups and key stakeholder consultation. The candidate led the

formative work, designed the intervention, developed the content, assisted in the development of the content management system, and led the pre-testing.

5.2. Background

In 2013 the National Institute for Health Innovation (NIHI) was contracted by Waitemata District Health Board (DHB) for a collaborative approach to develop, deploy and evaluate a programme for people with diabetes aiming to enhance and enable their self-management. The intent was to work with people with diabetes in primary and secondary care to reduce issues surrounding access barriers (e.g. location). Part of this work investigated needs and barriers to self-management of diabetes through consultation with stakeholder groups. One of the key findings from this initial work was that there was a need for innovative tools to provide motivation and information to support self-management. It was also found that there was a lack of helpful and user-friendly technology-based options for people with diabetes based on the types of technology that they have access to and feel comfortable using.(85, 148) Therefore the NIHI team proposed the development of a user-friendly mHealth intervention to support self-management.

The development process for the mHealth intervention was informed by the mHealth Development and Evaluation framework (see Figure 3).(141) The steps of the framework are; conceptualisation, formative work, pretesting, pilot, pragmatic randomised controlled trial (RCT), and qualitative follow up.



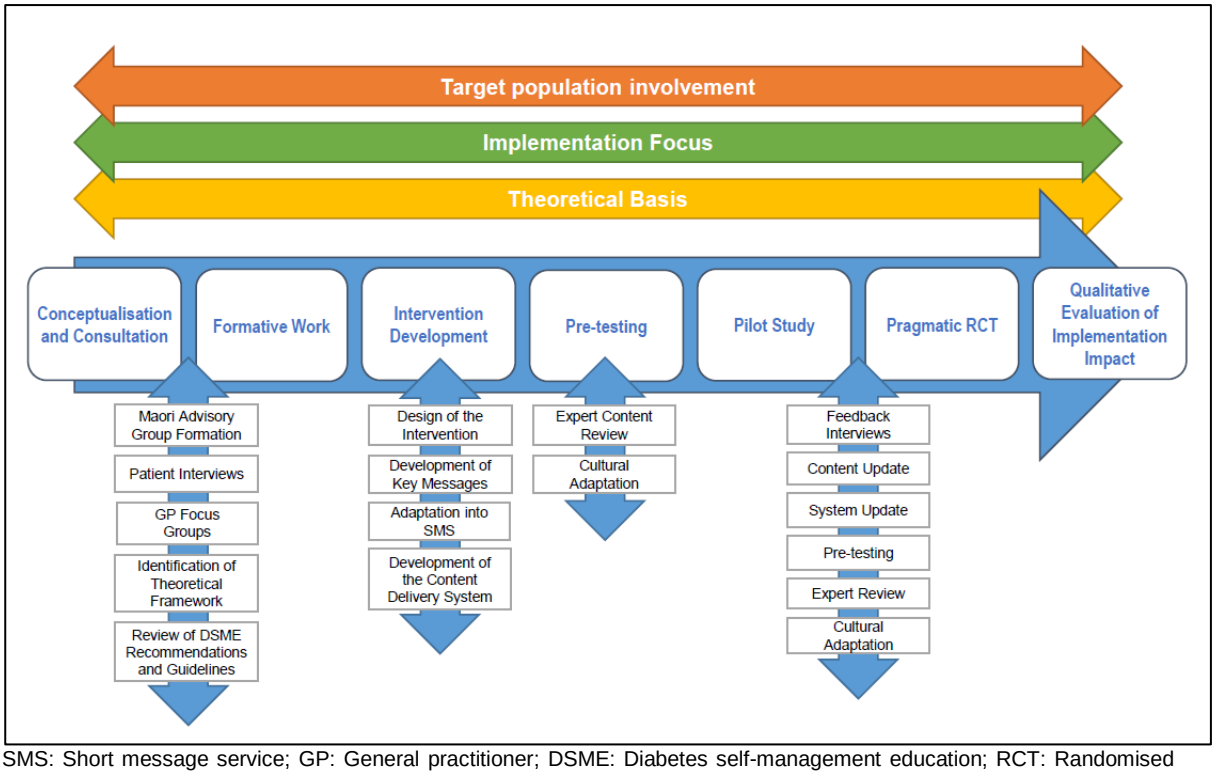
RCT: Randomised Controlled Trial

Figure 3: mHealth development and evaluation framework(141)

Key to this framework is the use of behaviour change theory, which has been described as fundamental to intervention effectiveness.(149, 150) It has been reported that Internet and mobile phone-based interventions with a theoretical basis are more effective than those that have no theoretical basis.(57, 92) An additional strength of this framework is the engagement with end users throughout the process. Understanding and incorporating the needs, priorities, and preferences of the target audience is essential to enhance an intervention's success. Therefore it is crucial to engage with the target population in the design and development process.(141, 142) The framework also recommends a focus on implementation from the beginning; it is important to

engage with key stakeholders including funders, healthcare providers, and telecommunication companies, to consider how the intervention could be delivered after the research has concluded. This means that the research should be pragmatic, conducted within the setting that it would likely be implemented.

The framework underpinned the development of the SMS4BG intervention. An adapted version of the framework as it was applied in this work can be seen in Figure 4. Conceptualisation of the SMS4BG intervention, formative work, and pre-testing are described in this chapter. The pilot of the intervention is described in Chapter 6 and the pragmatic RCT is described in Chapters 7 and 8. The qualitative follow up to inform implementation is not described within this thesis.

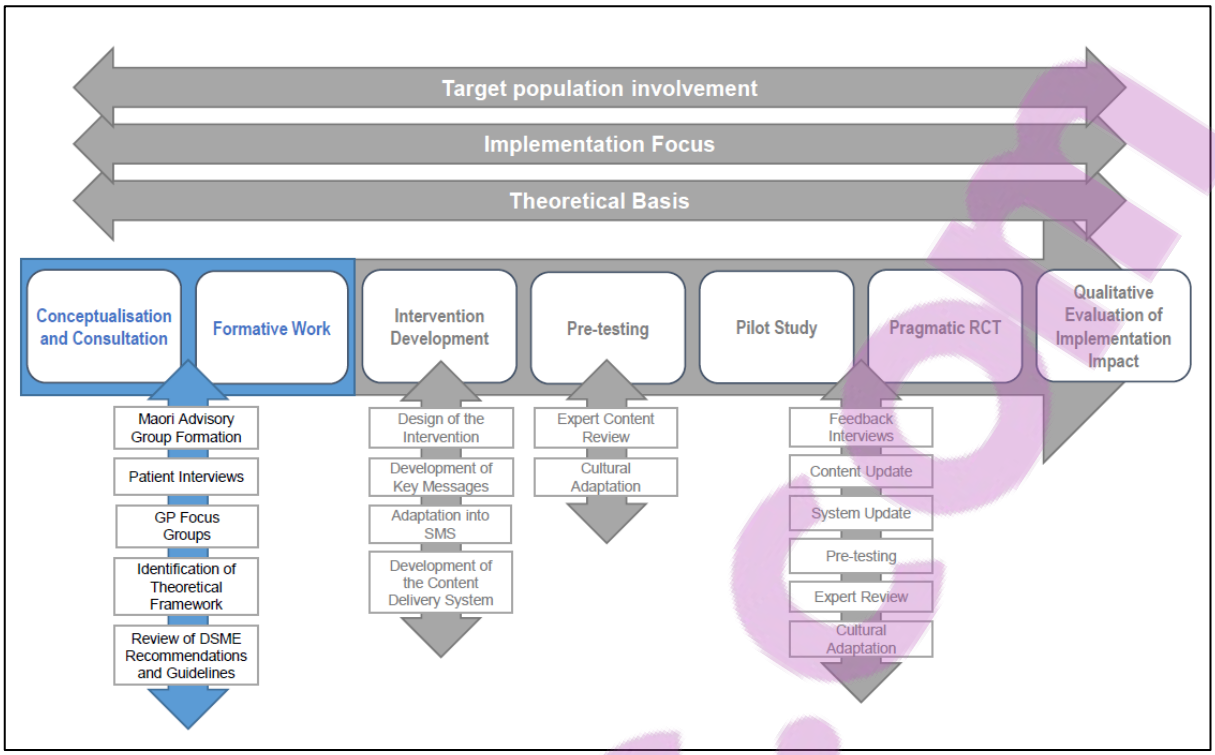


SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 4: Adapted development and evaluation framework(3)

5.3. Conceptualisation and formative work

The purpose of the conceptualisation and formative work is to have expert input into the intervention design, theoretical basis, and development process, as well as to inform the intervention content.(141) See Figure 5 for the adapted development and evaluation framework highlighting the steps covered in this section.



SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 5: Adapted development and evaluation framework highlighting the conceptualisation and formative work steps

5.3.1 Initial consultation

The conceptualisation of SMS4BG, as described in the introduction to this chapter, arose from consultation undertaken for a project investigating innovative approaches to improve self-management and reduce access barriers for people with diabetes. This initial consultation work was not carried out by the candidate, although she was involved, but was a precursor to her doctoral research.

Consultation with a number of key stakeholder groups was carried out including meetings with primary care groups across the Waitemata district (including Wai Health, Coast to Coast Healthcare, East Tamaki Health, and Kelston Medical Centre), members of the diabetes teams at Waitakere and North Shore hospitals (i.e. diabetes specialist, diabetes clinical nurse specialists), members of the West Auckland Locality Diabetes Network and Northern Regional Diabetes Network, and potential vendors (i.e. Vodafone New Zealand, HSA Global). A Māori Advisory Group was established by our Māori co-investigator Dr Matt Shepherd, consisting of Māori clinicians, a Waitemata DHB tikanga support person, a Māori researcher and psychologist, and a consumer representative. A focus group with general practitioners (GPs), and discussions with people with diabetes in waiting rooms and following an in-person self-management programme were conducted by a student for a summer student project. Concurrently a review of the existing tools for people with diabetes was carried out to ascertain what was already available and the strengths/weaknesses of these. Key findings from this stage included:

- There is a need for more tools to provide motivation and information to support self-management.

- There is a lack of accessible, helpful and user-friendly technology-based tools for people with diabetes.
- Groups in need of further intervention include those with poorer diabetes control; Māori, those of low-socioeconomic status and technology access, and those not presenting in current services.
- Clinical guidance should always be received from healthcare professionals and therefore any intervention should not be providing clinical advice but rather encourage and support people to seek advice through their healthcare professionals.
- In terms of intervention design, key themes included:
    - Content: The importance of individually tailoring content
    - Cost: The intervention must be easily accessible to those with low technology access and at no cost to the recipient
    - Adherence: Disengagement tends to occur at around 3 months and so to overcome intervention fatigue tools to maintain engagement must be included such as individual goal setting and re-engaging with the participants at key time points

Findings from the consultation led to the decisions around the proposed intervention including the use of text messaging (SMS) to maximise reach. Also, it was felt that the target population be people with poorly controlled diabetes, in particular Māori and those with low technology access. The next steps in the conceptualisation and formative stage of this project included summarising best-practice guidelines for self-management education, and determining the key theoretical frameworks including Māori models of health, to guide the development of the intervention and its content. From this point forward the candidate was responsible for the work carried out.

5.3.2 Diabetes self-management education

During the consultation diabetes specialists stated that it was important that any intervention needed to align with diabetes self-management education best practice. It is well accepted that self-management education is a critical component of diabetes care. As described in Chapter 2, self-management education in people with diabetes has been shown to result in improvements in clinical, behavioural and psychosocial outcomes.(151) As a result polices around the world state that self-management education should be available to all people from diagnosis. In New Zealand the Ministry of Health Quality Standards for Diabetes Care state that people with diabetes should receive individually and culturally tailored self-management education.(36)

The available diabetes self-management education programmes differ throughout New Zealand depending on the setting, location and population.(42) Examples of existing programmes include DAFNE (for adults with type 1 diabetes), Diabetes Stanford Programme, Diabetes EPIC Programme, Diabetes Auckland - Living Well Programme, and the DESMOND Programme. Although individual programmes delivering diabetes self-management education may differ, the purpose of all self-management education is to facilitate the knowledge, skills, confidence, motivation, and coping skills required for successful diabetes self-care.(37) Programmes should

support a person to engage in self-care behaviours, be active participants in their healthcare, and make informed decisions around their health.

It is recommended that the content of programmes be based on evidence and best practice guidelines.(41, 152) The Association of American Diabetes Educators and the American Diabetes Association have identified a number of recommended content areas for diabetes self-management education:

- Describing the disease process and treatment options.
- Developing personalised strategies to promote health and behaviour change.
- Incorporating nutritional management into lifestyle.
- Incorporating physical activity into lifestyle.
- Using medication(s) safely and for maximum therapeutic effectiveness.
- Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making.
- Preventing, detecting, and treating acute complications e.g. problem solving for blood glucose highs, lows and sick days.
- Preventing detecting, and treating chronic complications e.g. foot care.
- Developing personalised strategies to address psychosocial issues and concerns.

These recommended content areas have been linked to measurable outcomes to determine the success of diabetes self-management education programmes.(37) The key outcome of self-management education is behaviour change. There are seven self-care behaviours essential for successful diabetes self-management which can be measured to determine the effectiveness of education interventions:

- Healthy eating
- Being active
- Taking medication
- Blood glucose monitoring
- Problem solving
- Reducing the risks of diabetes complications
- Healthy coping/ psychosocial adaption

By giving the person the knowledge, skills and motivation to change their behaviour this should then translate into clinical and health status improvements following the completion of the intervention (see Figure 6: Continuum of outcome categories).

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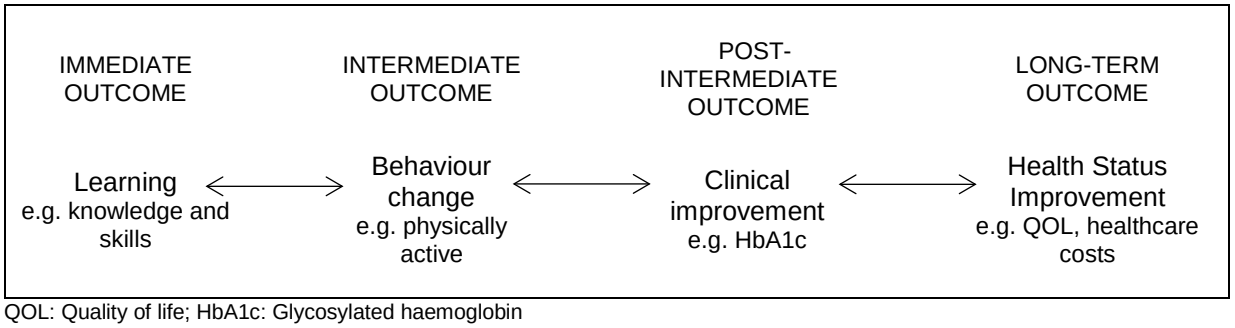


QOL: Quality of life; HbA1c: Glycosylated haemoglobin

Figure 6: Continuum of outcomes categories for diabetes self-management education(37)

5.3.3 Theoretical framework

A theoretical framework was needed to guide the development of an intervention designed to change behaviours. Ecological models of health behaviour highlight multiple levels of influence on behaviour including the intrapersonal (i.e. biological, psychological), interpersonal (i.e. social, cultural), environmental, organisational, community, and policy. For interventions designed to change behaviour to be effective they need to be multi-level.(153) People with diabetes need a range of support and resources across these levels to effectively self-manage their condition in their daily lives. The proposed intervention is designed to influence the intrapersonal and interpersonal levels of behavioural influence.

To achieve behaviour change in relation to diabetes management key influences must be considered included knowledge (knowledge is needed for the behaviour to occur but is not sufficient on its own), cognitions and perceptions (what people think affects what they will do), skills (a person needs to have adequate skills to perform the behaviour), motivations (a person needs to be motivated), and their social environment (their family/whānau, friends and environment need to be supportive and conducive of the behaviour).(153)

The Social Cognitive Theory (SCT) and the Common Sense Model (CSM) are two models which provide frameworks for understanding a person's behavioural influences and engagement with diabetes self-management. They incorporate the key influences including knowledge, cognitions/perceptions, motivations, skills and the social environment and were therefore chosen to provide a framework for the proposed intervention.

Social Cognitive Theory (SCT)

The foundation of the SCT is that behaviour is a complex interaction between individual factors, environmental factors and behavioural factors. More specifically it purports that behaviour is influenced by a person's self-efficacy, outcome expectancies, goals, and sociostructural factors (see Figure 7).

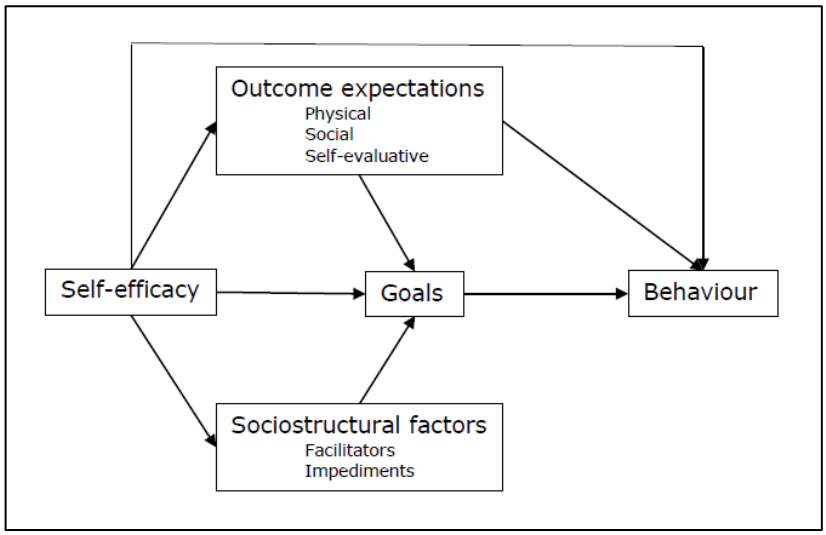


Figure 7: Social cognitive theory(154)

Bandura states that knowledge is a necessary precursor for behaviour change to occur including how behaviour is linked to health.(154) Once knowledge is acquired an individual must believe they are capable of behaviour change, a concept known as self-efficacy. Also key are the expectations the individual has about the outcomes or consequences of performing the behaviour in both the short and long term. This includes the physical outcomes (e.g. fatigue from exercise in the short term or decreased HbA1c in the long term), social outcomes (e.g. approval from family) and self-evaluative outcome expectations/expectancies (e.g. feelings of accomplishment). Sociostructural factors, that may be facilitators or barriers to the behaviour, are also key to an individual changing a behaviour. Goals, similar to intentions, determine the effort that the individual invests in the behaviour and are influenced by self-efficacy, outcome expectations and sociostructural factors.

The concept of self-efficacy has been demonstrated in previous studies to be fundamental to a person carrying out the self-care behaviours required for diabetes management.(32, 155) People demonstrating high levels of self-efficacy have been shown to be better able to engage in self-management behaviours and therefore manage their diabetes.(33) Bandura highlights four sources of self-efficacy:

1. Mastery experience/past performance accomplishments: the success the individual has had in performing the behaviour or similar behaviours, with previous success increasing self-efficacy whereas failure to perform the behaviour leads to decreased self-efficacy.
2. Vicarious experience or modelling: when the individual views someone else performing the behaviour with the more similar the model to themselves resulting in higher self-efficacy
3. Social persuasion: when the individual is persuaded verbally or non-verbally that they are capable of carrying out the behaviour they are more likely to try harder and sustain effort in changing the behaviour. The persuasion is generally more effective when the source is considered credible (e.g. healthcare professionals).
4. Physiological and affective states: when the physiological and effective/emotional responses to a behaviour are positive the level of self-efficacy increases and vice versa

When self-management interventions aim to target these constructs/sources of self-efficacy through techniques such as modelling, skills mastery and social persuasion, they increase the person's confidence in their ability to self-manage their diabetes and therefore make successful engagement in self-management behaviours more likely.

However, there are limitations to the use of SCT. Although the SCT takes into consideration a person's beliefs about the behaviour it does not consider the beliefs about the illness (in this case diabetes) to which the behaviour is linked. For example, the SCT can be used to explain the engagement in the behaviour of insulin administration but does not consider potential beliefs or perceptions about their diabetes which could prevent them engaging in the behaviour in the first place – for example, that diabetes is not able to be controlled and therefore any treatments will be ineffective. Furthermore, healthy coping and psychosocial adaption to diabetes is vital for successful engagement in self-care behaviours. People with diabetes commonly experience psychological distress with evidence indicating higher rates of distress, depression and anxiety in those with diabetes in particular in those from ethnic minorities and those with poor control.(156-160) As psychological morbidity is a barrier to good management, enhancing an individual's ability to cope with their condition and the associated emotional sequel is pertinent. Therefore further theory around coping strategies to address emotional representations and illness perceptions/beliefs of diabetes may be required to help to facilitate behaviour change alongside the SCT.

Common-Sense Model of self-regulation

The Common Sense Model (or Self-Regulation Model) can be used to describe an individual's understanding of their illness and associated coping strategies. It proposes that a person's illness perceptions and emotional representations are drivers for their coping strategies and their self-management behaviours (see Figure 8).(35) According to this model, a health threat such as diabetes is processed using cognitive and emotional representations. The individual then adopts coping procedures to deal with the threat and the individual actively appraises the success of their coping procedures. This appraisal is incorporated back into the illness and emotional representations.(161) Fundamental to this model are the principles that: 1) People are active problem solvers; 2) Illness representations guide an individual's coping efforts and appraisals of the coping outcomes; 3) Representations of the health threat are individual to the person.(162)

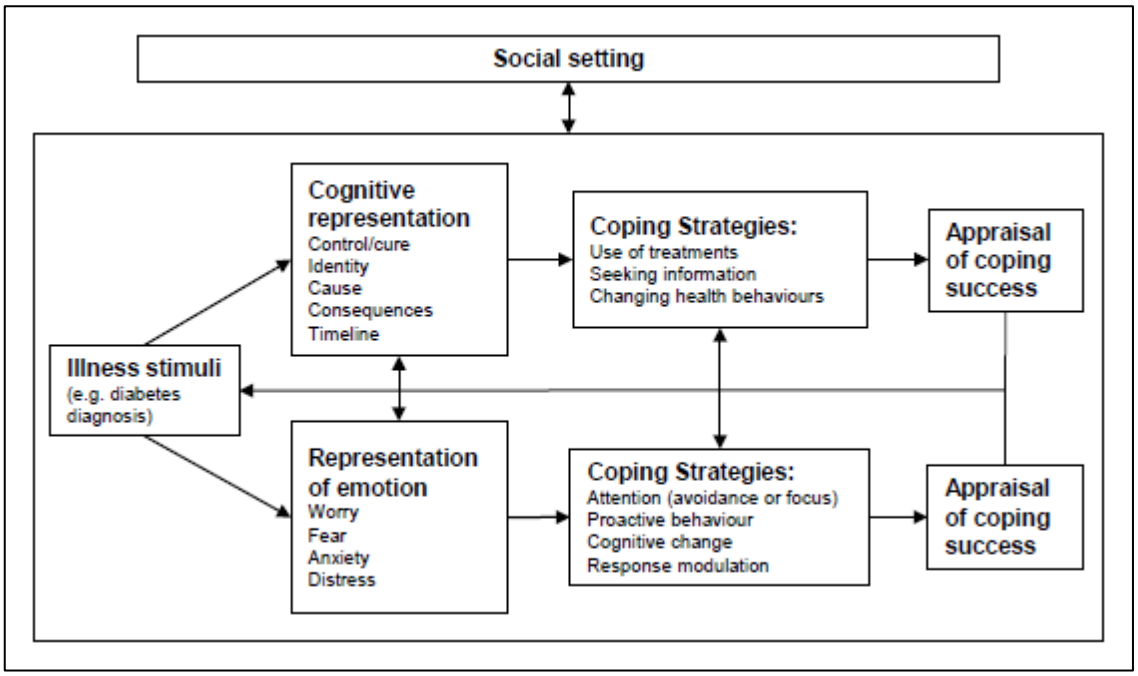


Figure 8: The common sense model of the self-regulation of illness behaviour(35, 163)

The cognitive or mental representations that a person develops in response to their illness can come from previous knowledge and experience of the illness, social or cultural experience, or information from other people including health care professionals and family. Five key dimensions of cognitive representations (also known as illness perceptions) have been identified:(35)

1. Control/Cure: Beliefs about the extent to which their diabetes can be controlled or cured
2. Identity: How the person describes/labels their diabetes and its symptoms
3. Cause: Beliefs about the cause of diabetes
4. Consequences: Beliefs about the effects of their diabetes on their life i.e. physical, social
5. Timeline: Beliefs about the duration of their diabetes i.e. acute vs chronic.

These illness representations influence the coping strategies that the person adopts to manage their illness, such as seeking information, engagement with treatment, and changing health behaviours. For example, if a person has strong beliefs that the treatment will work and that diabetes can be effectively controlled then they are more likely to adhere to their treatment than someone who believes that the treatment is unlikely to work and that their diabetes cannot be managed or cured.

Alongside these cognitive processes, the model describes the emotional processes activated in response to the illness. A person develops emotional representations in response to the illness threat such as anxiety, fear, anger and worry, which in turn influence the coping strategies and styles that a person adopts to cope with the emotions. These can include avoidance or attention (i.e. distraction or monitoring), proactive seeking of help to address the threat, finding meaning and cognitive changes, or altering the response (i.e. emotional suppression, relaxation).(163) For example if a person experiences worry about their diabetes but chooses to seek help and information from their doctor to alleviate this worry, then they will likely feel better about their

diabetes and more capable of managing it. The outcomes of these coping strategies are then appraised in relation to their success and feed back into their representations representing a dynamic self-regulatory process. The CSM also incorporates the influences of personal, social and cultural factors in an individual's response to a health threat.(164). It considers that a person's family and friends, life experiences, roles and culture may affect one's illness representations, the procedures adopted to cope with diabetes and how the outcomes are appraised (165).

Unlike the SCT, the CSM considers emotion regulation in the context of a person's response to their diabetes and corresponding engagement in self-care behaviours, and that the way a person manages their diabetes can impact their emotional response and vice versa. The CSM proposes that changing a person's illness perceptions, and addressing unhelpful emotional representations by adoption of constructive coping strategies, can lead to positive changes in their self-management behaviours. Therefore diabetes self-management interventions based on the CSM can support people to form accurate and constructive perceptions of diabetes, emotional representations of the condition, and coping strategies, which in turn can increase their likelihood of engaging in diabetes self-management behaviours.

Translating theoretical frameworks into intervention components: Behaviour Change Techniques

The SCT and CSM outline the constructs related to a person's management of their diabetes and corresponding self-care behaviours. Interventions need to incorporate specific techniques that target these constructs to improve diabetes self-management. A taxonomy of theory-based behavioural change techniques (BCTs) has been developed as a reliable method of characterising successful intervention components for behaviour change.(100) The candidate reviewed the BCT taxonomy to identify techniques that target the relevant constructs of the SCT and CSM for incorporation into the SMS4BG intervention. Relevant literature on the BCTs utilised in mHealth interventions(61) and web-based diabetes self-management programmes(166) were also reviewed. Table 9 provides a list of BCTs identified for incorporation into the SMS4BG intervention.

Table 9: Behaviour change techniques identified for incorporation into the SMS4BG intervention.

Theoretical framework	Behavioural Change Technique Grouping	Behavioural Change Technique
SCT and CSM	1. Goals and planning	1.1. Goal setting (behaviour)
		1.2. Problem solving
		1.3. Action planning
SCT and CSM	2. Feedback and monitoring	2.2. Feedback on behaviour
		2.3. Self-monitoring of behaviour
		2.4. Self-monitoring of outcome(s) of behaviour
SCT and CSM	3. Social support	3.1. Social support (unspecified)
		3.2. Social support (practical)
		3.3. Social support (emotional)
SCT	4. Shaping knowledge	4.1. Instruction on how to perform the behaviour
		4.2. Information about antecedents
SCT and CSM	5. Natural consequences	5.1. Information about health consequences
		5.2. Salience of consequences
		5.3. Information about social and environmental consequences
		5.6. Information about emotional consequences
SCT	7. Associations	7.1. Prompts/cues
SCT and CSM	8. Repetition and substitution	8.2. Behaviour substitution
		8.4. Habit reversal
		8.7 Graded tasks
CSM	11. Regulation	11.2. Reduce negative emotions
		11.3. Conserving mental resources
SCT and CSM	12. Antecedents	12.1. Restructuring the physical environment
		12.2. Restructuring the social environment
		12.4. Distraction
CSM	13. Identity	13.1. Identification of self as role model
		13.2. Framing/reframing
CSM	15. Self-belief	15.1. Verbal persuasion about capability

SCT: Social cognitive theory; CSM: Common-sense model

5.3.4 Cultural considerations

It is essential that self-management interventions are culturally appropriate and relevant to the group they are designed for.(36) Culturally appropriate programmes have been found to be effective in improving outcomes in minority populations.(167) As highlighted above the target population for this intervention is people with poorly controlled diabetes of which Māori are overrepresented. Incorporating Māori approaches are therefore essential in the design of this intervention.

Underpinning the Treaty of Waitangi (Te Tiriti o Waitangi) are the principles of partnership, participation and protection, which play a part in understanding Māori health as well as the development of health services for Māori.(168) Partnership involves working with iwi, hapū, whānau and Māori communities to create positive health strategies for Māori. It also involves Māori sharing in the decision making about their health services leading to increased control over their own health. Participation is about equal opportunity and outcomes, and emphasises that Māori be involved in the planning, development and delivery of health services. Protection is the obligation of the Government to protect Māori culture, values and practices, and ensure Māori have at least equal health as non-Māori. It is pertinent that these principles guide the development of the proposed intervention and that it incorporates Māori approaches and health models.

The individual focussed approach of most western health models and services, and focus on biomedical markers of illness, can conflict with Māori views, which place greater value on the

health of the collective. One model of Māori Health, which has been extensively used is the Whare Tapa Whā model. This holistic model addresses four key dimensions of Māori health: taha tinana (physical), taha hinekaro (mental/emotion), taha whānau (family/social) andtaha wairua (spiritual).(169) It compares health to the four walls of a house; all 4 dimensions/walls are necessary to ensure strength and balance and if one is missing or damaged then complete health cannot be achieved. Therefore it proposes that in order for services and interventions to achieve the best outcome in Māori, it is essential that each dimension is recognised and addressed.(170) In the case of diabetes all four dimensions need to be considered for optimal self-management. The medical treatment of diabetes and associated complications (taha tinana); the mental strength needed to cope with the emotional burden of living with diabetes and coping with changing behaviours (taha hinekaro); the role of whānau and their lifestyles in supporting a person's diabetes self-management (taha whānau), and the context of the persons diabetes within the larger context incorporating the past, present and future, including ancestors or future generations, while acknowledging cultural identity (taha wairua).

The dimensions of Whare Tapa Whā model, together with the principles of the Treaty, need to be carefully considered in both the development and implementation of SMS4BG to improve diabetes outcomes for Māori.

5.3.5 Bringing together the findings to inform the intervention development

Based on the findings from the conceptualisation and formative stages, the important components of a text message based diabetes self-management support intervention for adults with poorly controlled diabetes were identified. The intervention was also informed by the findings of Part 1 of this thesis. The key characteristics of the intervention based on the findings of the formative and background work are presented in Table 10.

Table 10: A summary of the key characteristics of the SMS4BG intervention with what informed it

Key intervention characteristics		Thesis section							
					Chapter 5				
					5.2 Conceptualisation and formative work				
		Chapter 2	Chapter 3	Chapter 4	5.2.1 Initial consultation	5.2.2 Diabetes self-management education	5.2.3 Theoretical framework		5.2.4 Cultural considerations
							SLT	CSM	
Intervention design	Text message based with feedback via website	X	X	X	X				
Target population	Poorly controlled diabetes	X			X				
	Māori	X			X				
	Low-socioeconomic status	X			X				
	Low technology access				X				
	Not utilising current services				X				
Intervention features	Individually tailored (i.e. content, timing of BG reminders)	X	X	X	X				
	Cultural versions: Māori and non-Māori	X			X	X			X
	Personalised	X		X	X				
	Free to receive	X		X	X				
Intervention purpose	Behaviour change	X					X	X	
	Motivational support	X		X	X		X	X	
	Diabetes education/information	X		X			X	X	
	Goal setting				X		X		
	Increase self-efficacy	X					X		
	Promote accurate illness perceptions	X						X	
	Coping strategies							X	
Intervention content	General diabetes information			X		X			
	Insulin management					X			
	Diabetes in young adults		X	X					
	Smoking cessation					X			
	Healthy eating					X			
	Exercise					X			
	Stress/mood management					X			X
	Blood glucose monitoring reminders			X		X			

BG: Blood glucose; SCT: Social cognitive theory; CSM: Common-sense model

The key characteristics can be summarised into a logic model to illustrate the specific logic of change underlying the intervention. The logic model explains how programme components (also known as inputs) relate to the outputs (immediate and intermediate outcomes) and the longer term outcomes they are targeting. The SMS4BG logic model can be seen in Figure 9, which summarises the SMS4BG components and how these fit within the theoretical constructs and self-management behaviours, to improve glycaemic control and prevent long-term diabetes complications.

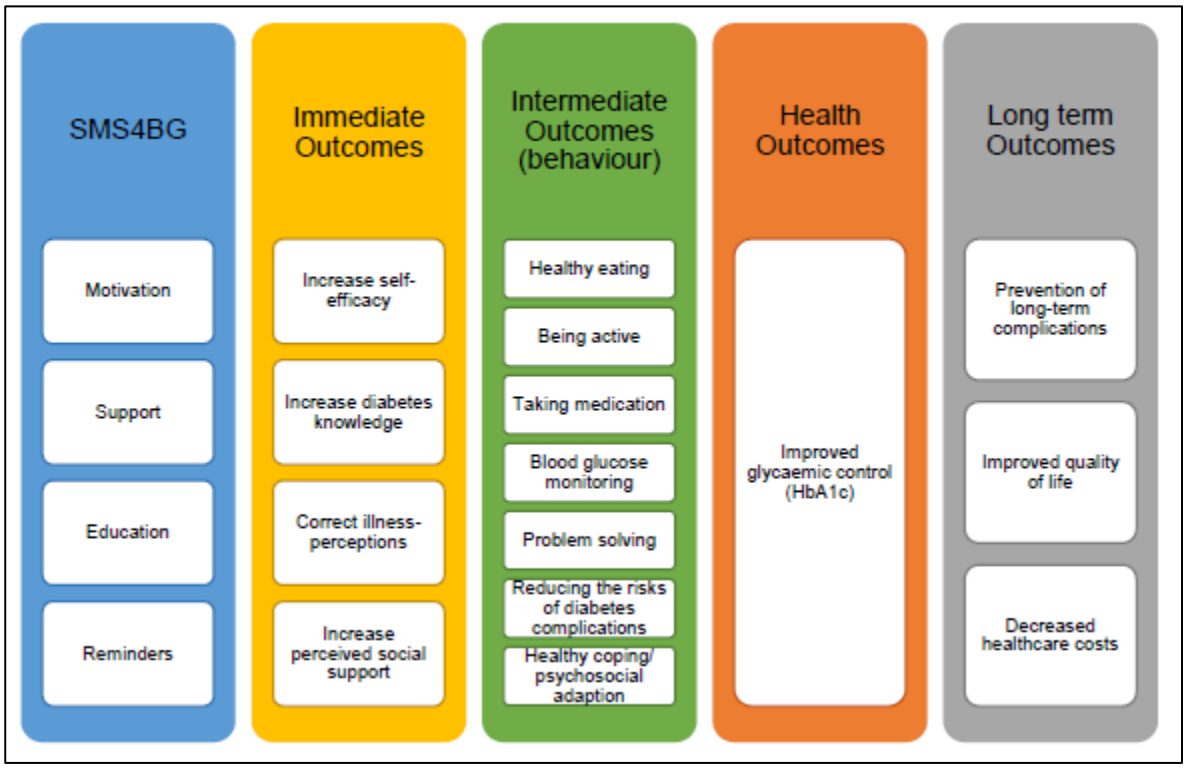
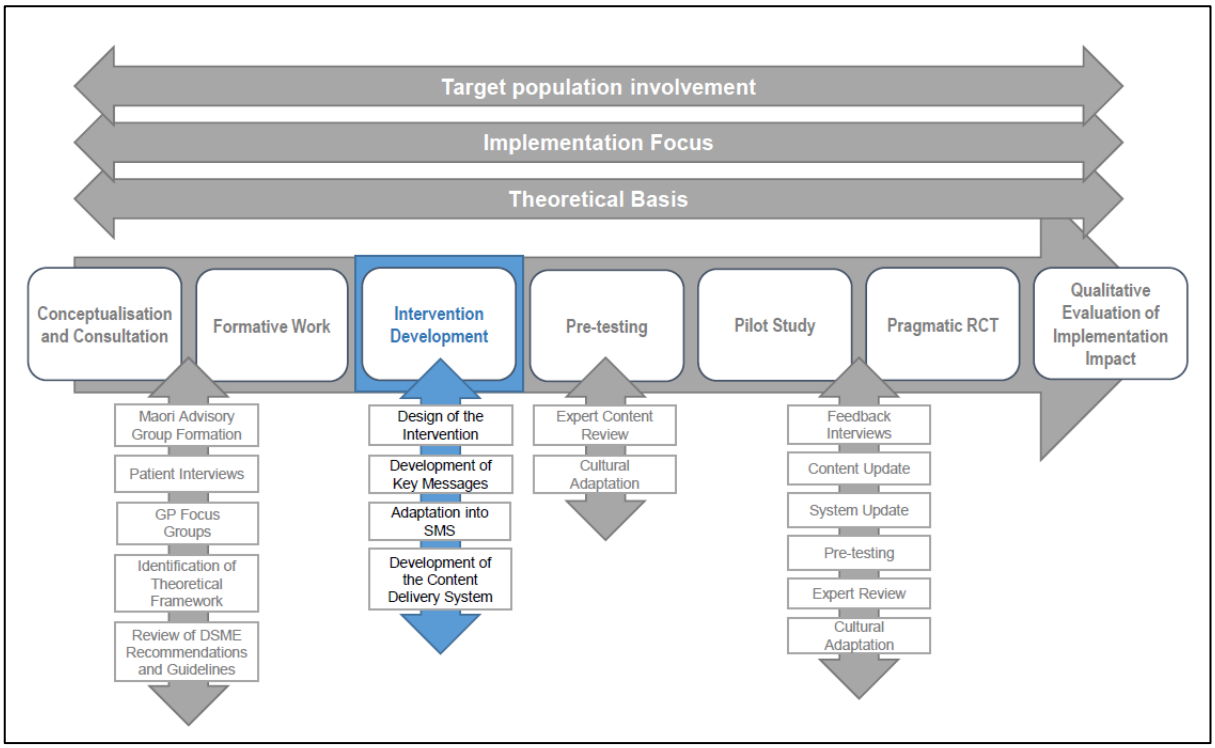


Figure 9: The logic model for SMS4BG, a text messages based diabetes self-management support programme

5.4. Intervention development

Following the formative work, the next step in the framework involves the development of the intervention – SMS4BG (Self-Management Support for Blood Glucose) (see Figure 10).



SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 10: Adapted development and evaluation framework highlighting the intervention development stage

Content development for SMS4BG started with the collation of guidelines for diabetes self-management education and current diabetes resources. The content was designed to mirror current evidence based resources and diabetes self-management education to reinforce the messages already being provided. The intervention was not designed to deliver clinical advice, but rather provide support and encouragement to engage with healthcare professionals for clinical guidance when needed.

A list of key content messages was created by the candidate across each of the topic areas identified in the formative work (see Table 10) – general diabetes information, insulin management, diabetes in young adults, smoking cessation, exercise, healthy eating, stress/mood management, and blood glucose monitoring. Each topic formed a separate module to allow for individual tailoring of the content. A summary of the different modules can be seen in Table 11. The key messages were then adapted by the candidate into SMS (160 characters) creating an SMS library. Where existing mHealth programmes existed on relevant topics (i.e. exercise(171), smoking cessation(172), and weight loss(173)) their content was also reviewed and key messages adapted for this programme if appropriate.

As well as messages designed to provide information about diabetes, its management, and self-care behaviours (BCTs 5.1, 5.2, 5.3, 5.6), specific messages targeting the other key theoretical constructs were developed by the candidate. Messages were designed to target each of the dimensions of cognitive and emotional representations identified in the CSM to promote accurate perceptions. Examples of messages for each of the dimensions can be seen in Table 12 and examples of messages developed by BCT can be seen in Table 13.

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Table 11: Description of the SMS4BG modules

Module	Description
Core module	General motivation and support for diabetes management designed to increase self-efficacy and promote accurate illness perceptions. Two versions: - Māori - Non-Māori
Insulin module	Education around insulin management for people receiving insulin
Young adult module	Managing diabetes in the context or work/school and social situations for people aged 16-24 years
Smoking cessation module	Encouragement to consider quitting smoking and information on services for support for current smokers
Lifestyle behaviour modules	Encouragement to set a lifestyle goal as well as support and tips to support the participant to achieve their goal. Three different lifestyle modules: - Exercise - Healthy eating - Stress and mood.
Blood glucose monitoring	Reminders to test blood glucose at a frequency selected by the participant (up to 4 per day). Option for the participant to reply by text message with their blood sugar readings which are uploaded onto a secure website in a graph format.

Table 12: Example of SMS4BG text message content designed to promote accurate illness perceptions

Illness perception	Example SMS4BG message
Personal control	SMS4BG: Kia ora. Control of your glucose levels involves eating the right kai, exercising & taking your medication. Your whanau, doctor & nurse can help you
Treatment control	SMS4BG: Following your doctor's advice for how to manage your diabetes, including eating well, exercise & medications will mean a healthier future
Consequences	SMS4BG: If you keep on top of your diabetes today there will be less short & long term impacts on your health. Over time good management will become a habit
Timeline	SMS4BG: Hi [firstname]. Keeping on top of your diabetes today will result in better health in the future. Diabetes management will get easier with time
Identity	SMS4BG: [hi] [firstname]. Good control of your blood glucose levels keeps you feeling good & will reduce many of the symptoms from your diabetes
Concern	SMS4BG: Kia ora [firstname]. If there is something concerning you or your whanau about diabetes it's a good idea to discuss it with your doctor or nurse
Emotions	SMS4BG: Hi [firstname]. While it can be scary to think about the impacts of having diabetes, remember that with good management these can be reduced & prevented

Note: Tokens (tailoring variables) are within square brackets e.g. [firstname]

Messages within the lifestyle models (healthy eating, exercise and stress/mood) were developed to encourage goal setting and planning (BCTs 1.1, 1.2, 1.3) and provided prompts (BCT 7.1), covered behaviour substitution (BCT 8.2), habit reversal (BCT 8.4), and graded tasks (BCT 8.7). There were messages across all of the models designed to provide social support including general support (BCT 3.1), practical support around specific diabetes self-management elements (BCT 3.2) and emotional support (BCT 3.3). Also within all modules where specific diabetes management behaviours (e.g. insulin administration) were being referred to there were messages designed to shape knowledge including instructions on how to perform the behaviour (BCT 4.1) and information about antecedents to the behaviour (BCT 4.2). Within the core and young adult modules, as well as the stress and mood lifestyle module, there were messages specifically designed to reduce negative emotions around diabetes and its management (BCT 11.2) and conserve mental resources (BCT 11.3). There were also messages developed covering the restructuring of the physical (BCT 12.1), and social (BCT 12.2), environments to be more conducive to behaviour change as well as distraction (BCT 12.4). The technique of identification of self as a role model (BCT 13.1) was also incorporated into the core model which was particularly pertinent for Māori in

regards to being a role model for whānau who might also have diabetes or be at high risk for the condition.

Table 13: Example of SMS4BG text message content by theoretical construct or behaviour change technique

Theory or BCT Grouping	Theoretical construct or BCT	Example SMS4BG message
1. Goals and planning	1.1. Goal setting (behaviour)	SMS4BG: If you want to get on top of your diabetes [firstname], start with one goal at a time. Do you have a goal? If not, set a goal today
		SMS4BG: [hi] [firstname]. It's a good idea to set an exercise goal to give you something to work towards, & then pick a reward for when you achieve it!
	1.2. Problem solving	SMS4BG: Hi. Write down any obstacles or barriers to exercising (such as lack of time or bad weather), & then write down ways to overcome them
		SMS4BG: If you are losing motivation for exercising, remind yourself about why you want to become more physically active. Do it for your [motivation1]
	1.3. Action planning	SMS4BG: Have you thought about what exercise you are going to do tomorrow? Take a moment to plan some physical activity, so you don't forget or run out of time
		SMS4BG: It's important to keep blood flowing to our feet. Move your ankles & toes for 5mins 2-3 times a day. Try doing it during the ad breaks when watching TV
2. Feedback and monitoring	2.2 Feedback on behaviour	SMS4BG: When you text us your blood glucose results we graph them. View your graph at www.diabetesstudy.co.nz. Username & password are your mobile number
		SMS4BG: Thanks for sending back your blood glucose reading
	2.3. Self-monitoring of behaviour	SMS4BG: You have selected to get reminders to check your blood glucose - that's great! We will send you reminders & ask you to text back the result
		SMS4BG: [hi] [firstname]. Just a reminder it is time to check your blood glucose. Free reply text with the result
	2.4. Self-monitoring of outcome(s) of behaviour	SMS4BG: Hi. Keeping a record of your blood glucose levels will help you & your nurse/doctor see where changes to your medication or diet may be needed
3. Social support	3.1. Social support (unspecified)	SMS4BG: [hi] [firstname]. Good management of your diabetes & your future health includes not smoking. Call Quitline on 0800 778 778 for support
		SMS4BG: Hi. Sometimes it can be tough trying to manage diabetes. Remember there are people here to support you, including [support1name] & [support2name]
	3.2. Social support (practical)	SMS4BG: Hi [firstname]. When checking your feet, if you can't see the bottom of your feet use a mirror or ask a family member to check for you
		SMS4BG: Unsure whether to tell your friends/boyfriend/girlfriend about diabetes? This can be tough but people who care about you will want to know & support you
	3.3. Social support (emotional)	SMS4BG: It's ok to feel frustrated by your diabetes, but make sure you tell someone how you feel so they can help. Talk to [supportname1] or your doctor
4. Shaping knowledge	4.1. Instruction on how to perform the behaviour	SMS4BG: Hi [firstname]. Wash & dry your feet each day & check for cuts, blisters, bruises, colour changes, swelling, in-grown toe nails & sores
		SMS4BG: If you feel sweaty, dizzy, extremely hungry, confused or irritable you could be having a hypo. Test your blood glucose & quickly eat something sugary
	4.2. Information about Antecedents	SMS4BG: A hypo can be caused by a missed or late meal, not enough starchy foods, exercise without eating extra carbs, too much insulin, or alcohol without food
5. Natural consequences	5.1. Information about health consequences	SMS4BG: Good control of your blood glucose levels prevents long term damage to your body, & will help reduce many of the symptoms of diabetes

		SMS4BG: Hi. Regularly checking your blood glucose gives you more control in managing it & helps you see how your body reacts to food, exercise & medication
	5.2. Salience of consequences	SMS4BG: With good management of your diabetes it will have less of an impact on your life & give you more time to spend with your [motivation1] & [motivation2]
	5.3. Information about social and environmental consequences	SMS4BG: Hi [firstname]. Good management of your diabetes will mean less time spent at the doctor & more time doing the things you love
	5.6. Information about emotional consequences	SMS4BG: Remember that increasing your physical activity is great for your health & your diabetes. Research shows it can also help you feel more positive
7. Associations	7.1. Prompts/cues	SMS4BG: [hi] [firstname]. If you forget to check your feet why not put a reminder in your phone or set an alarm to remind you
8. Repetition and substitution	8.2. Behaviour substitution	SMS4BG: [hi] [firstname]. Changing habits is hard. Try swapping the time that you normally spend on something like watching TV with exercise
	8.4. Habit reversal	SMS4BG: Making a few changes to your daily routine to fit in exercise time makes it easier to be physically active e.g. take the stairs not the lift
	8.7 Graded tasks	SMS4BG: Exercise Tip: Walking is a great form of exercise. Start with a small, short walk & slowly increase the distance each time
11. Regulation	11.2. Reduce negative emotions	SMS4BG: [hi] [firstname]. Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood
	11.3. Conserving mental resources	SMS4BG: Do you find counting carbs tough? If you have a smartphone, check out the carb counting apps or talk to your medical team about other tools
12. Antecedents	12.1. Restructuring the physical environment	SMS4BG: Even small changes can make us more active. Hide the TV remote so you have to get up to change the channel, or park the car further from the door
		SMS4BG: [hi]. Make sure you have plenty of healthy food options (e.g. chopped vegetables, unsalted nuts, yoghurt) ready for your next meal or snack
	12.2. Restructuring the social environment	SMS4BG: [hi] [firstname]. Exercising is easier with a friend. Find a friend or family member to walk, swim or attend exercise classes with
	12.4. Distraction	SMS4BG: Healthy eating tip: It's a good idea to plan something to keep you busy before dinner time when most people get food cravings
		SMS4BG: [hi] [firstname]. Take a few minutes to focus on your breathing, saying to yourself CALM as you breathe in & RELAXED as you breathe out
13. Identity	13.1. Identification of self as role model	SMS4BG: Kia ora [firstname]. Taking a positive approach to living with diabetes will likely have a positive impact on the health & happiness of those around you
	13.2. Framing/reframing	SMS4BG: Diabetes isn't who you are, but rather something you have to manage. Think of it as someone who is joining you for the journey
		SMS4BG: If you get asked about diabetes at job interviews, mention the positive sides – managing diabetes takes discipline & maturity, which are great qualities
15. Self-belief	15.1. Verbal persuasion about capability	SMS4BG: Hi [firstname]. Remember you can successfully manage your diabetes so that it has less of an effect on your life, now & in the future
		SMS4BG: Hi [firstname]. Your diabetes can be controlled, reducing the impact on your health & your life! Do it for your [motivation1] & [motivation2]

Note: Tokens (tailoring variables) are within square brackets e.g. [firstname]

The information included in the messages was designed to reflect best practice guidelines and current resources as specified above. Additionally, the content of the young adult module was aimed to prioritise the preferences outlined in Chapter 4 – topics for incorporation into an SMS

based intervention and areas of diabetes that they would like more information about. In particular this module was designed to support young adults in managing diabetes within the context of social situations, work, or school.

As quitting smoking is important in good diabetes management it was important to include smoking cessation as a topic module for those participants identified as smokers. There are current SMS based programmes for smoking cessation available free in New Zealand and so rather than replicate these existing services this module was designed to encourage participants to consider quitting smoking in the context of good diabetes management and provide them with the details of support services available to support them to do this.

Blood glucose monitoring is a key behaviour required for successful diabetes management; therefore messages designed to prompt and remind a person to engage in the behaviour were developed (BCTs 2.3, 2.4). As well as providing a behavioural prompt these messages were also designed to support monitoring of the behaviour and provide reinforcement when the behaviour was carried out. This was done by requesting the person to reply with their blood glucose result and when a valid response (i.e. value between 1.0 and 100.0) was received this initiated a response message reinforcing the behaviour. As feedback is an important factor in successful behaviour change (BCT 2.2) allowing for self-evaluation (as in the SCT) and appraisal of coping success (as in the CSM), blood glucose values received into the system were graphed on a secure website (see Figure 11) for participants to view.

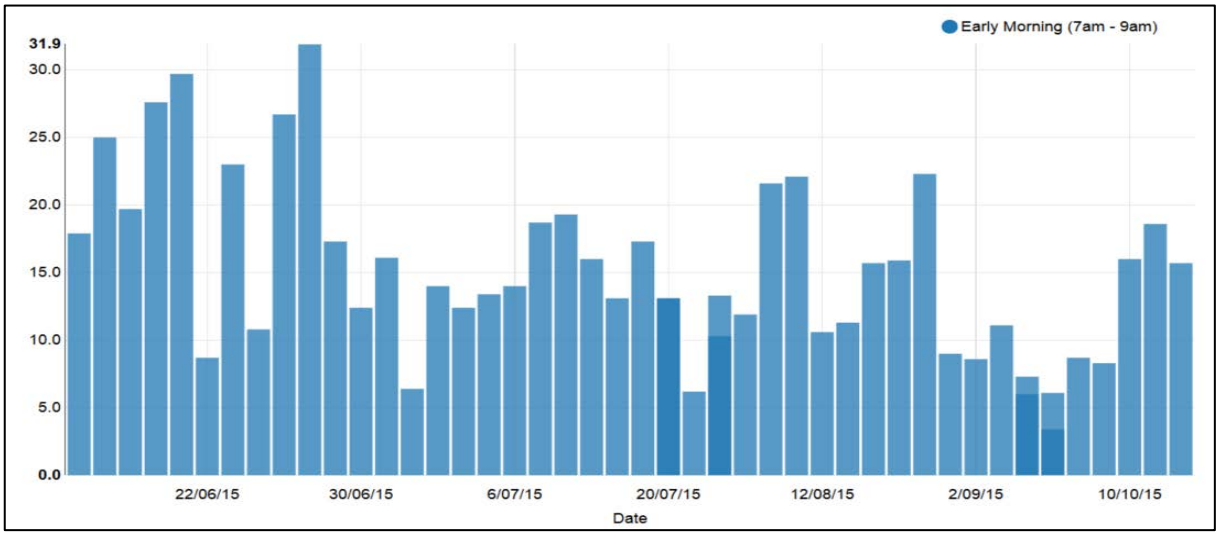
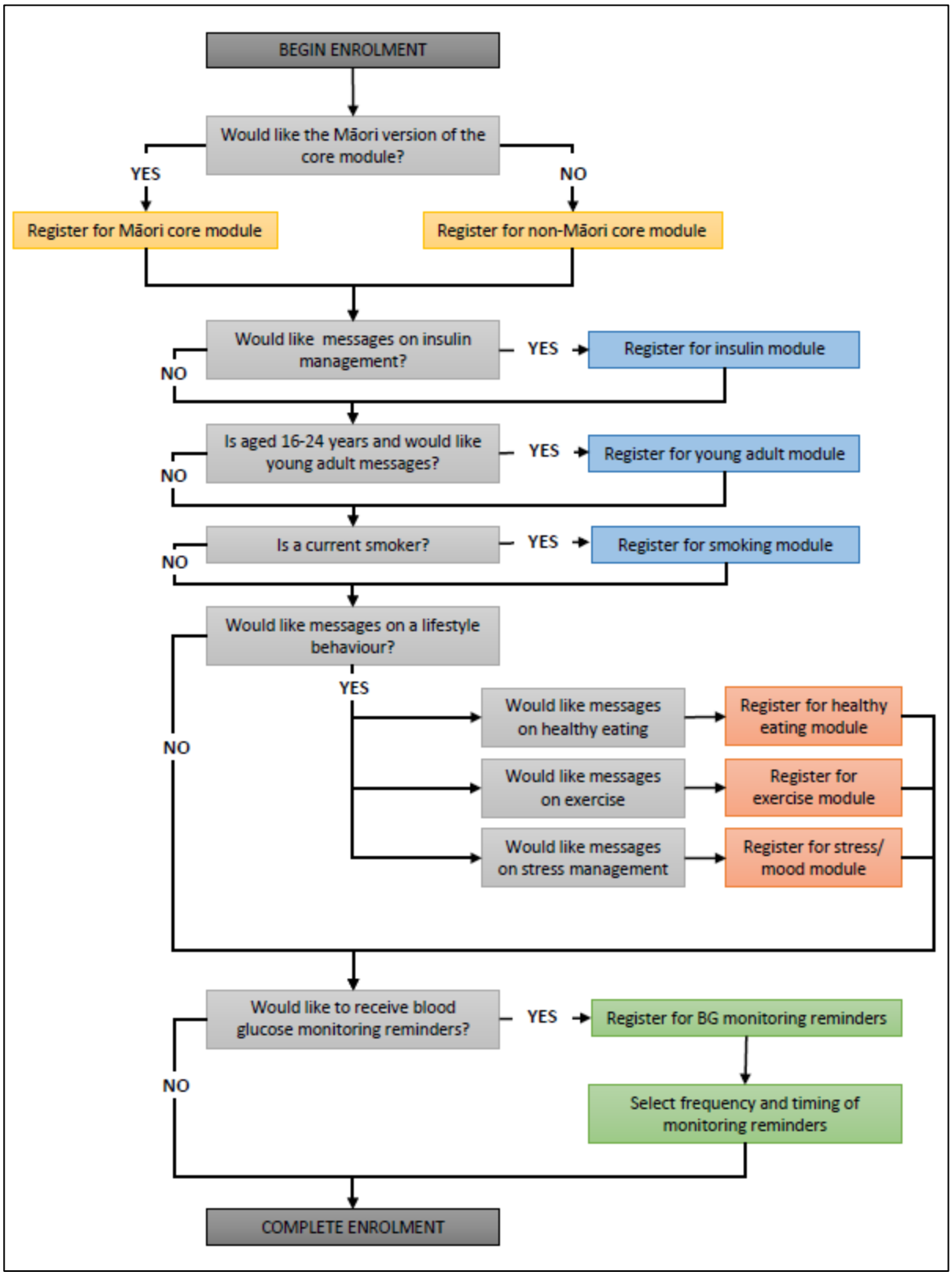


Figure 11: Example of a graph of blood glucose results available via secure website designed provide feedback on the behaviour of blood glucose self-monitoring

Tokens were created so that the system could identify variables within messages where content was to be determined by individual characteristics. The tokens were inserted into individual messages where personalisation or tailoring would occur, e.g. [firstname] where the participants name was to be inserted.

Alongside the development of the content of the intervention, our (NIHI staff) software developer created a content management system specifically for the SMS4BG intervention. The software developer was guided by business rules developed by the candidate which specified the differently functionality including how someone was enrolled, who would get which modules, and who would

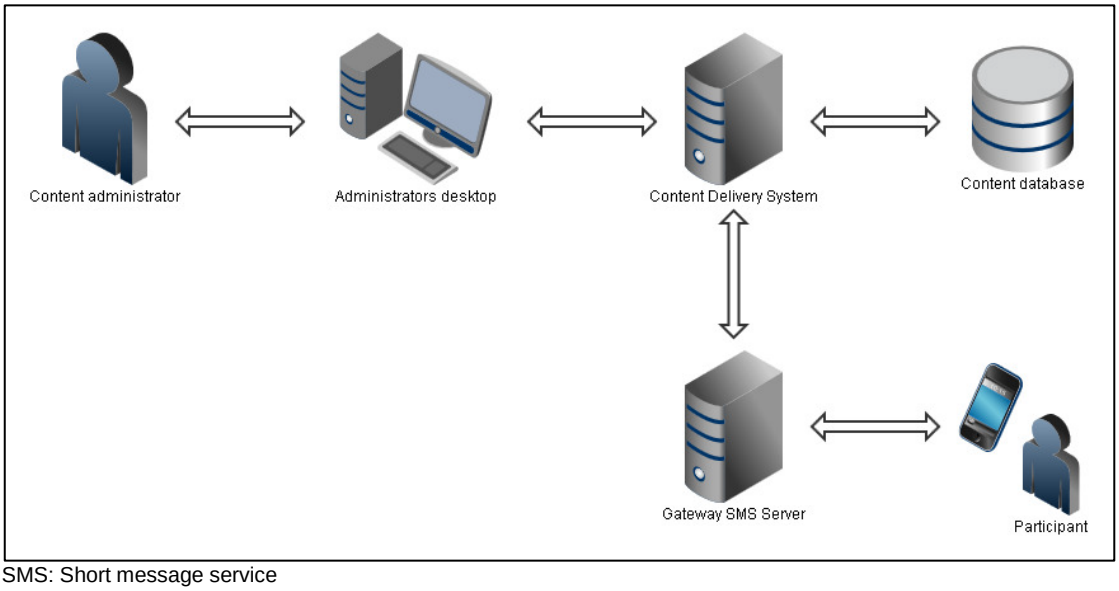
get which messages when. For example, Figure 12 shows the rules for the enrolment process for the allocation of modules.



BG: Blood glucose

Figure 12: SMS4BG enrolment process for the allocation of modules

The system was designed to send and receive messages through a message gateway company for delivery to any mobile phone registered with a New Zealand mobile network. To enrol a person their contact number, preferred name, module choices, culture, and messaging timing was entered into a form through a web interface. Once submitted message schedules were populated for each person dictating the specific messages and their delivery time for the intervention duration. Figure 13 shows the computer network diagram for SMS4BG



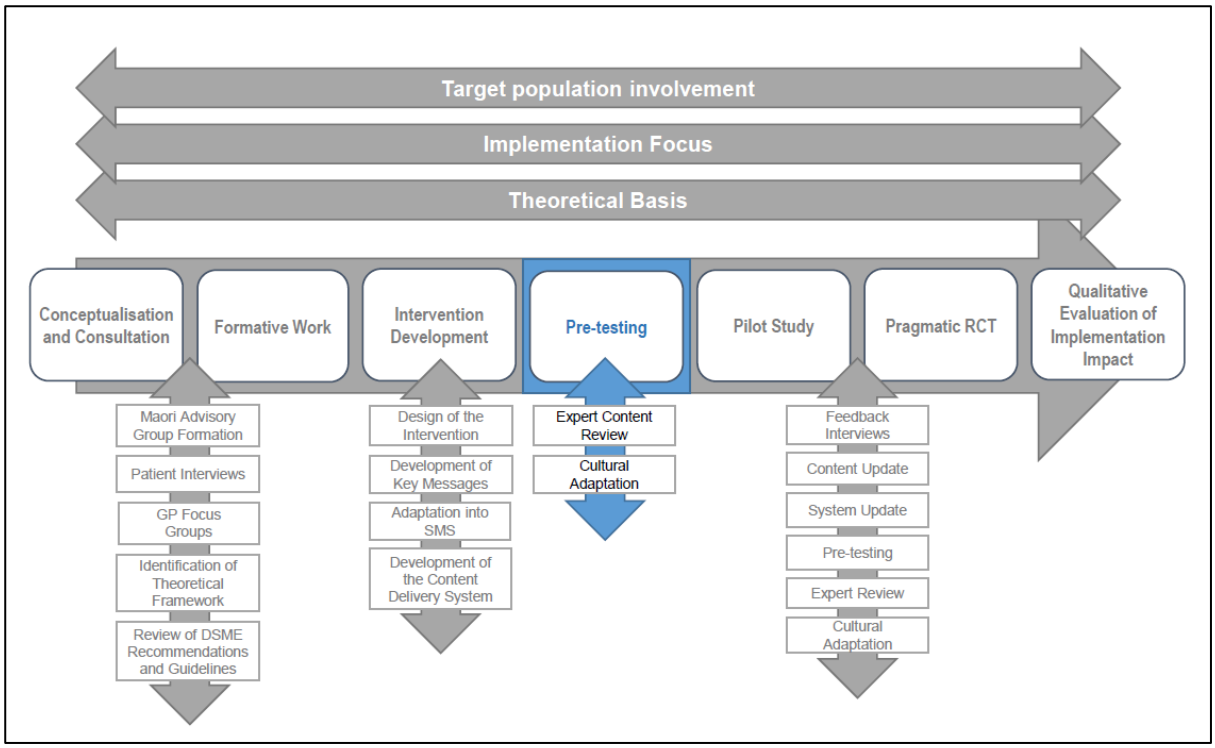
SMS: Short message service

Figure 13: The SMS4BG computer network diagram

A participant could stop their messages by replying with the word 'STOP', which automatically cancelled all remaining messages on their schedule so that they no longer received future messages. The system was designed to maintain logs of all outgoing and incoming messages, and automatically graph incoming blood glucose values. These graphs could then be viewed via a password-protected website. The website had two levels of access (administrator and participant) to give participants the ability to view their graph and administrators the ability to enrol participants and monitor all messages for issues.

5.5. Pre-testing

The purpose of pretesting the intervention is to ensure it is acceptable to the target audience.(141) See Figure 14 for the adapted development and evaluation framework highlighting the pretesting step.



SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 14: Adapted development and evaluation framework highlighting the pretesting step

The SMS library was sent to experts including diabetes clinicians and academics. The purpose of this expert review was to ensure that the messages were not only clinically and factually correct but also relevant to people with diabetes in New Zealand. Alongside this, a selection of messages were reviewed by people with diabetes in waiting rooms for comprehension and relevance. Feedback from both groups was incorporated into the messages.

Once revised the message library was then sent to the Māori Advisory Group for review. Feedback was then used to adapt the core messages to create a Māori version of the core module. This incorporated a greater focus on family (whānau) and incorporated key words in Te Reo Māori, although messages remained predominately in English. A key piece of feedback from this stage of the content development was the recommendation to remove references to targets (i.e. glucose levels, HbA1c) which could be seen unfavourably or induce feelings of failure if not achieving the targets. It was decided that this feedback was relevant across cultures and so a decision was made to remove the reference to targets across all versions of the programme.

The Māori version was then reviewed by a sample of Māori people with diabetes within the diabetes clinic at North Shore Hospital. They were asked to rate the usefulness and relevance of the individual messages to themselves and provide comments. The majority rated the messages very favourably, particularly the motivational messages. There were a few messages that were identified as being unclear or less relevant and these were therefore revised. Once finalised the messages were entered into a content database ready for testing (see Appendix 3 for the content template used to upload the final messages into the database).

Once the messages were loaded into the content database these were tested extensively. This process involved recruiting volunteers to be registered for the programme. A range of potential

participant ‘personas’ were created to cover the different types of people who might register with the programme. Each persona was designed to cover the different combination of modules and tailoring variables. Each tester was allocated a persona and given a corresponding table of all messages they were to receive and the timing of the message. The tester was then enrolled in the system as a true participant would be and asked to check that the correct messages were delivered exactly as per there individual schedule. Other features that were tested included:

- The enrolment process worked correctly including allocation of programmes, tailoring variables (e.g. timing of messages) and personalisation variables (e.g. the participants name)
- Delivery worked to different mobile numbers registered on different networks and plans
- Incoming messages were interpreted correctly by the content management system
- Incoming blood glucose results were graphed correctly
- The message content was correct on delivery (i.e. no errors, typos, character set)
- That the STOP functionality worked as planned

Any issues identified were rectified by working with the developer and then the personas affected were re-registered and testing recommenced until the system was working consistently as designed and all features had been tested.

5.6. Summary

The SMS4BG intervention was developed to address the need for innovative tools to provide motivation and information to support self-management in adults with poorly controlled diabetes. The individually tailored intervention was designed to motivate and support a person to engage successfully in the behaviours required to manage diabetes effectively for long term health improvement. It was the accumulation of extensive formative work to ensure it not only met the needs of the population it was designed to reach, but was evidence based and theoretically grounded. The innovative intervention has the potential to extend the reach of traditional self-management support across New Zealand.

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CHAPTER 6. DIABETES TEXT-MESSAGE SELF-MANAGEMENT SUPPORT PROGRAMME (SMS4BG): A PILOT STUDY

6.1. Preface to the chapter and publication

The first aim of Chapter 6 is to determine the usability and acceptability of SMS4BG among adults with poorly controlled diabetes in a non-randomised pilot study. This is presented in the form of a published manuscript in Sections 6.2 through 6.8. Minor changes to formatting have been made to the published manuscript to ensure consistency across the thesis. It contributes to the following thesis objective:

4. Assess the acceptability and effectiveness of an mHealth self-management support intervention.

The second part of this chapter (not published) aims to refine and finalise the SMS4BG intervention and is described in section 6.9 through 6.13. It contributes to the following thesis objective:

3. Develop an mHealth tool for the delivery of self-management support to people with poorly controlled diabetes.

Supporting documents associated with this chapter can be found in Appendix 4 including a copy of the ethics approval letter, follow up interview questions, enrolment form, content intervention development pre-testing checklist, and website screenshots.

Why was this work needed?

Chapter 5 described the development of the SMS4BG intervention including the conceptualisation and formative work, content development, and pre-testing. Assessing the feasibility of delivering the intervention and its acceptability and relevance to the population it aims to support is the next step in the development process. Incorporating the views of end users into intervention design is essential and therefore the findings from the pilot study informed the final version of the SMS4BG intervention.

What was undertaken?

A non-randomised pilot study among adults with poorly controlled diabetes was conducted to assess the acceptability of the SMS4BG intervention. Additional feedback from pilot study participants was used to refine the intervention before the final programme was developed. Figure 15 shows the study framework highlighting that sections covered in this chapter of the thesis. The chapter concludes with a summary of the final SMS4BG intervention incorporating the findings from the pilot study.

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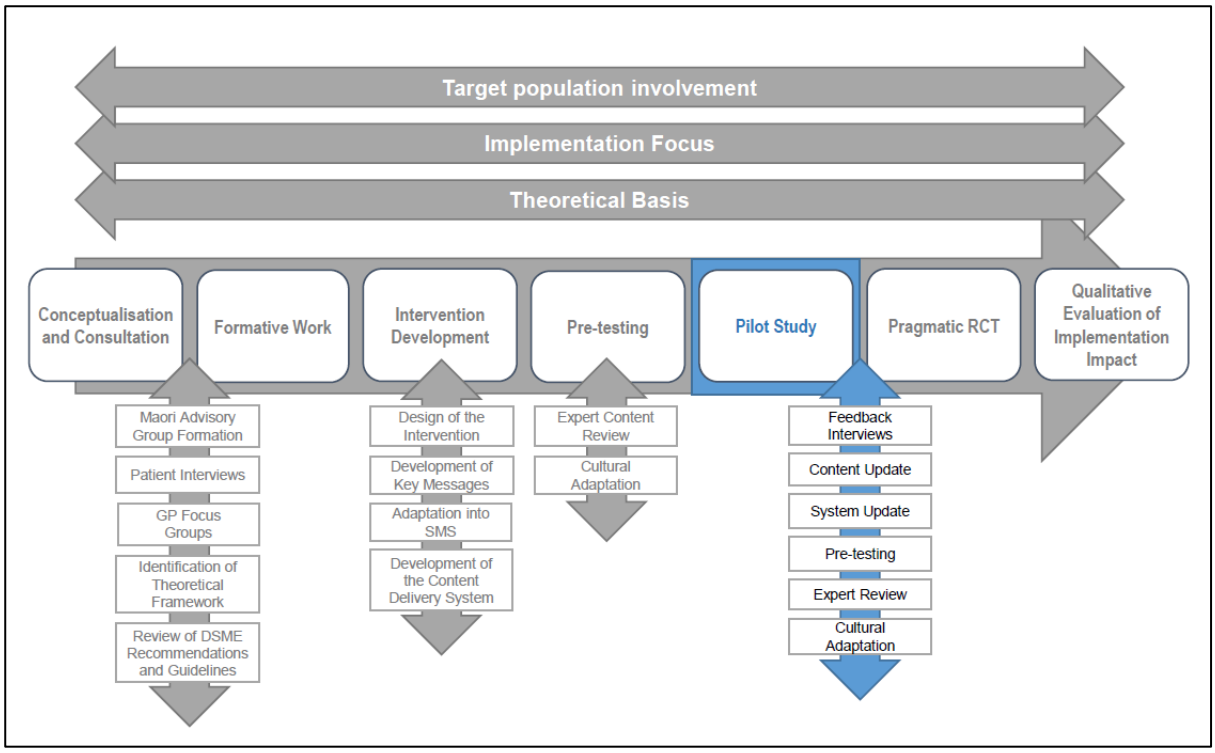

SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 15: Adapted development and evaluation framework highlighting the stages covered in Chapter 6

Publication citation:

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Contribution by the candidate:

The candidate contributed to the overall pilot study design. She was responsible for, and carried out, the study procedures with support from the co-author Karen Carter. She analysed the data and wrote the manuscript with contributions from all authors. The candidate was responsible for the revisions to the SMS4BG intervention.

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6.2. Abstract

Background: The increasing prevalence of diabetes and costly long-term complications associated with poor glycaemic control are issues facing health services worldwide. Diabetes self-management, with the support of health care providers, is critical for successful outcomes, however, frequent clinical contact is costly. Text messages via short message service (SMS) have the advantage of instant transmission at low cost and, given the ubiquity of mobile phones, may be the ideal platform for the delivery of diabetes self-management support. A tailored text message-based diabetes support intervention called Self-Management Support for Blood Glucose (SMS4BG) was developed. The intervention incorporated prompts around diabetes education, management, and lifestyle factors (healthy eating, exercise, and stress management), as well as blood glucose monitoring reminders, and was tailored to patient preferences and clinical characteristics.

Objective: To determine the usability and acceptability of SMS4BG among adults with poorly controlled diabetes.

Methods: Adults (aged 17 to 69 years) with type 1 (n=12) or type 2 diabetes (n=30), a haemoglobin A1c (HbA1c) over 70 mmol/mol (8.6%), and who owned a mobile phone (n=42) were recruited to take part in a 3-month pilot study of SMS4BG. At registration, participants selected the modules they would like to receive and, where appropriate, the frequency and timing of blood glucose monitoring reminders. Patient satisfaction and perceptions of the usability of the programme were obtained via semi-structured phone interviews conducted at completion of the pilot study. HbA1c was obtained from patient records at baseline and completion of the pilot study.

Results: Participants received on average 109 messages during the 3-month programme with 2 participants withdrawing early from the study. Follow-up interviews were completed with 93% of participants with all reporting SMS4BG to be useful and appropriate to their age and culture. Participants reported a range of perceived positive impacts of SMS4BG on their diabetes and health behaviours. HbA1c results indicated a positive impact of the programme on glycaemic control with a significant decrease in HbA1c from baseline to follow-up.

Conclusions: A tailored text message-based intervention is both acceptable and useful in supporting self-management in people with poorly controlled diabetes. A randomised controlled trial of longer duration is needed to assess the efficacy and sustainability of SMS4BG.

6.3. Introduction

Globally, diabetes is a significant health issue with increasing incidence worldwide. There is a disproportionate burden of the disease among indigenous peoples internationally,(174) and in New Zealand, where higher disease prevalence is seen in Māori compared with New Zealand Europeans.(175) With the growing incidence and prevalence, there is a subsequent growing burden of caring for those living with the disease. Substantial evidence indicates that good diabetes control provides significant benefit in relation to the reduction of risk of complications.(6, 9) Given the costly and debilitating microvascular and macrovascular complications of poorly controlled diabetes, including renal failure, visual impairment, lower limb amputation, heart disease, and stroke, intensive and sustained individual effort is required to achieve optimum control. Given the large impact that individual behaviours have on diabetes control, such as diet, energy expenditure, blood glucose monitoring, medication adherence, and self-adjustment of insulin doses, the standard of diabetes care includes self-management education and support. For those with poor control, education and support needs to extend outside the clinic setting in order to sustain the behaviours needed to manage diabetes in the context of their daily lives. One way to extend self-management support beyond the clinic is through ecological momentary interventions (EMI), which are delivered during a person's daily life providing "real-world" support in "real time".(176) Mobile phones provide an ideal method for delivering EMI, as they are carried with most people most of the time, thereby maximizing their potential to optimise support for those in need.

Mobile health (mHealth) is the use of mobile devices, including mobile phones, to deliver health services and information.(48) The field of mHealth is growing with increasing support for its use in behaviour change and disease management, including smoking cessation, weight loss, cardiac rehabilitation, and diabetes management.(61) Mobile phone ownership and use have continued to increase internationally and in New Zealand,(82, 177, 178) with high penetration across all groups including hard-to-reach populations. All digital mobile phones provide short message service (SMS), also known as text messaging, with New Zealand having the highest use of SMS by head of population in 2011 compared to other Organisation for Economic Co-operation and Development (OECD) countries.(179) Given the high level of mobile phone ownership and the prolific use of SMS, this mode of communication appears an ideal platform for the delivery of health interventions.

Recent systematic reviews show that the majority of SMS-based behaviour change interventions for disease management have positive short-term impacts on behavioural and clinical outcomes.(57, 61, 180) There is an increasing body of evidence supporting the use of mobile phones and SMS in the management of diabetes, including evidence for these interventions resulting in significant short-term improvements in glycaemic control.(68, 72) However, although studies to date have shown promising results, there are a lack of theoretically based comprehensive diabetes mHealth interventions.(61, 91) Previous research has also highlighted the need to individually tailor messages,(58, 176, 181, 182) as well as to provide people with choices to increase their sense of control over the intervention.(143) To address these previous limitations, we developed and pilot-tested

SMS4BG (Self-Management Support for Blood Glucose) a new tailored SMS self-management support programme for adults with poorly controlled diabetes in New Zealand.

6.4. Methods

6.4.1 Study design

Overview

A 3-month, nonrandomised pilot study was conducted between July and December 2013. All study documents and procedures were approved by the Health and Disability Ethics Committee (13/NTA/55).

Participants and recruitment

Eligibility criteria included adults aged 16 to 70 years, a diagnosis of type 1 or type 2 diabetes mellitus, haemoglobin A1c (HbA1c) >70 mmol/mol (8.6%) within the last 12 months, mobile phone ownership, ability to provide informed consent, and ability to read English. An HbA1c result of greater than 70 mmol/mol (8.6%) was utilised as the definition of poorly controlled diabetes in this study, a level associated with increased risk for the development of diabetes complications.

Recruitment was carried out across three primary health care practices, two secondary care hospitals, and one community-based organization in Auckland, New Zealand. Clinicians at each site identified potential participants and either enrolled them directly through the study website or referred them to a research assistant to complete registration. Registered participants then received an automated consent text message and were required to reply “Yes” to be enrolled in the programme.

The programme was free to receive but if a participant replied, they were charged NZD $0.20 per message by their network provider. Participants were given a voucher (NZD $20.00) at the conclusion of the study to reimburse them for their time and any costs associated with replying to the messages.

Measures

At the end of the programme all participants (including those that withdrew) were asked to complete questions about their satisfaction with the programme, its usefulness and usability, and perceived positive impacts, via a semi-structured telephone interview conducted by a research assistant. Engagement with the programme was assessed using system-recorded responses to the blood glucose monitoring reminder messages. In addition, participants consented to the research team obtaining their HbA1c test results from their medical records to assess change in HbA1c from baseline to follow-up.

Statistical analysis

Descriptive statistics were generated for baseline demographic and clinical characteristics, and measures of engagement with the system. Counts and percentages were reported for categorical variables, and means and standard deviations for continuous variables. To determine whether

ratings of usefulness differed between ethnic groups and diabetes type, t tests were used. Change in HbA1c was calculated using the related-samples Wilcoxon signed-rank test.

6.4.2 Intervention development

SMS4BG was developed to provide self-management support for adults with poorly controlled diabetes. The content was developed by a multidisciplinary team, led by a health psychologist (RD) and public health physician (RW). The development followed the mHealth Development and Evaluation framework,(141) which provides a process to guide the development and testing of mHealth interventions with a focus on implementation, use of behavioural change theory, and involvement of the target population.

The development of the content was informed by a review of the research literature, existing mHealth interventions (targeting diabetes management and related lifestyle behaviours), and current patient resources. The programme was informed by two behaviour change theories: Social Cognitive Theory(32) and the Common Sense Model.(183) Messages were designed to provide correct perceptions around diabetes and its management and to increase self-efficacy and perceived support for diabetes management. SMS4BG also utilised a number of different behaviour change techniques (BCTs)(184) to support behaviour change in relation to diabetes management: providing general information linking behaviour to health, providing information on consequences, prompting intention formation, prompting barrier identification, providing general encouragement, prompting self-monitoring of behaviour, providing feedback on performance, and stress management.

To accommodate personal preferences and clinical characteristics, SMS4BG was made up of modules including a core module that all participants received and additional optional modules. Clinician input determined optional module topics. The core module consisted of 2 messages per week on diabetes education, emotional encouragement, and illness perceptions (available in Māori and non-Māori versions). In addition to the core module, if registered as a smoker, the participant received an additional 1 message per month supporting smoking cessation. Participants could also opt to receive additional modules on topics relevant to diabetes management such as insulin, diet, exercise, stress management, and blood glucose monitoring reminders. A summary of the different SMS4BG modules can be seen in Table 14. There were a total of 180 different messages across all modules with the minimum number of messages a participant could receive being 30 messages over the 3-month period, unless they withdrew early. If the maximum number of modules and blood glucose monitoring reminders were selected, a participant could receive up to 461 messages over the 3-month period. All messages a participant received were unique with the exception of the blood glucose monitoring reminders for which there were 9 different reminder messages that they received.

The SMS4BG programme was designed so that text messages were send-only (unidirectional) with the exception of the blood glucose monitoring reminders, which provided the option for participants to reply with their blood glucose test results. In addition to SMS, there was an accompanying website that patients and clinicians could log onto, allowing them to review a graphical display of

the participant's blood glucose responses sent into the system. The website also provided administrators with the ability to manage the message content and monitor message delivery. To enhance participant engagement, SMS4BG was personalised with the inclusion of each participant's name in many of the messages. Individuals could also select the frequency and timing of blood glucose monitoring reminder messages—from 1 per week to up to 4 per day.

In New Zealand, there is a higher prevalence of diabetes in Māori in comparison with New Zealand Europeans.(175) To ensure the relevance of SMS4BG to this population, a Māori version of the core module was developed by the study's Māori Advisory Group. The core messages were adapted to incorporate a greater focus on family (whānau), and incorporate key words in the Te Reo Māori language, although messages remained predominately in English.

Once developed, messages were reviewed by diabetes specialists and a selection of messages were pretested by people with diabetes. Feedback from this process was incorporated into the messages before they were finalised and entered into the system for testing. Following development, a pilot study was conducted which set out to assess the usability and acceptability of the text message support programme in adults with poorly controlled diabetes.

Table 14: SMS4BG modules.

Module	Description	Participants	Example text message
Core	2 messages per week providing general motivation and support for diabetes management. Available in two versions: (1) Māori, and (2) non-Māori.	All	(1) "SMS4BG: Kia ora. Control of your glucose levels involves eating the right kai, exercise & taking your medication. Your whanau, doctor & nurse can help you" (2) "SMS4BG: There is no quick fix to diabetes but with good management it will have less impact on your life and leave you more time to do the things you enjoy"
Insulin	1 educational text message per week on insulin management for patients receiving insulin.	Available to participants prescribed insulin.	"SMS4BG: Unopened insulin should be kept in the fridge. Don't use insulin that has changed colour, lumpy, expired, cracked or leaking, has been frozen or too hot"
Young adult	1 message per week around managing diabetes in the context of work/school and social situations.	Available to participants aged 16-24.	"SMS4BG: It's important not to ignore a hypo. No one likes to be embarrassed, but ignoring a hypo can make you feel worse & can be more embarrassing"
Smoking cessation	1 message per month encouraging participants to consider quitting and providing details of services for support.	All participants who register as smokers.	"SMS4BG: Good management of your diabetes and your future health includes not smoking, call Quitline on 0800 778 778 for support"
Lifestyle behaviour	Up to 4 messages per week encouraging participants to set a lifestyle goal and supporting them to work toward this goal. Participants can receive one of these modules for 3 months. The three lifestyle modules are: (1) exercise, (2) healthy eating, and (3) stress and mood.	Available to all participants.	(1) "SMS4BG: Hi [name] if you are finding it tough to keep up your exercise think about why good management of your diabetes is important to you" (2) "SMS4BG: Healthy eating is an important part of your diabetes treatment and it will help you in controlling your blood glucose levels" (3) "SMS4BG: Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood"
Blood glucose monitoring	Reminders to test blood glucose, sent at a frequency selected by the participant (up to four per day), for which they are encouraged to reply by text message with their blood sugar readings.	Available to all participants required to monitor their blood glucose.	"SMS4BG: Hi [name]. Just a reminder it is time to check your blood glucose. Reply with the result" If valid response received, "SMS4BG: Thank you for sending your result"

6.5. Results

A total of 44 potential participants were recruited, with 42 participants consenting to participate. Table 15 presents characteristics of the registered participants. Only 2 participants requested to end the programme early, both during the third week of their messages. Of the 42 participants enrolled, 3 (7%) were lost to follow-up. Of these 3 participants, 2 could not be contacted, and the remaining participant's phone had been disconnected.

Table 15: Participant characteristics (n=42).

Characteristic		n (%) or mean (SD)
Gender		
	Male	20 (48)
Ethnicity		
	NZ European	16 (38)
	Māori	15 (36)
	Pacific	3 (7)
	Other	8 (19)
Diabetes type		
	Type 2	30 (71)
Recruitment site		
	Primary care	22 (52)
	Secondary care	18 (43)
	Other	2 (5)
Age in years, mean (SD)		45.7 (13.1)
HbA1c in mmol/mol, mean (SD)		89 (22)

SD: Standard deviation; HbA1c: haemoglobin A1c

6.5.1 Participant engagement

Due to the choice of modules, participants received varying numbers of messages during the 3-month programme. Table 16 presents a breakdown of the modules in which the participants were enrolled.

Table 16: Participants' choice of SMS4BG modules (n=42).

Module	n (%)
General	
Total	42 (100)
Non-Māori	38 (90)
Māori	4 (10)
Insulin	15 (36)
Young adult	3 (7)
Smoking cessation	10 (24)
Lifestyle	
Total	34 (81)
Exercise	12 (35)
Healthy eating	12 (35)
Stress	10 (30)
Blood glucose monitoring reminder messages	
Total	34 (81)
1/week	19 (56)
3/week	4 (12)
1/day	6 (18)
2/day	3 (9)
3/day	1 (3)
4/day	1 (3)

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Participants received on average 109 (range 8 to 437) text messages from the programme during the 3-month period, with an average of 13 messages per week. This included on average 63 (range 8 to 93) send-only text messages per participant over the 3-month programme. A total of 34 participants out of 42 (81%) opted to receive blood glucose monitoring reminders, receiving on average 58 (range 9 to 353) reminder messages each over the 3-month period. A total of 827 response messages were received from 26 (76%) of the 34 participants registered to receive reminders. Of those who responded to at least one reminder, participants on average responded to 57% of their reminder messages (range 1 to 99%). For those 8 participants that did not reply (8/34, 24%), cost was identified as the leading barrier. Only 4 (12%) of the 34 participants reported accessing their graph online to view their blood glucose results. The most frequently reported barriers were no access to computers or Internet and not responding to the messages, and as a result not having a graph to view.

6.5.2 Patient satisfaction and usability

A summary of the results of the follow-up interviews is provided in Table 17. Participants reported high levels of satisfaction with SMS4BG—all (39/39, 100%) reported the programme to be useful to some degree, and 97% (38/39) reported they would recommend the programme to others with diabetes. When asked to rate how useful the messages were on a scale from 0 (not at all useful) to 5 (extremely useful), the mean rating was 3.94 (SD 0.98). Higher mean ratings of usefulness were seen in those with type 2 diabetes (4.21, SD 0.75) compared to those with type 1 diabetes (3.17, SD 1.17) (P=.004). Although not statistically significant, higher ratings of usefulness were found for Māori (4.13, SD 0.91) compared with New Zealand European (3.68, SD 0.99) (P=.23).

All participants were able to identify at least one positive impact of the programme. The majority (32/39, 82%) of participants reported that the programme had a positive impact on their overall blood glucose control. In addition, 49% (19/39) of all participants interviewed reported a positive impact of SMS4BG on their exercise habits, 59% (23/39) on their diet and eating behaviour, and 67% (26/39) on their mood. Of the participants interviewed who received the exercise lifestyle module, 83% (10/12) reported a positive impact of SMS4BG on their exercise habits. Of those interviewed who received the healthy eating module, 82% (9/11) reported a positive impact on their diet and eating behaviour. Of those interviewed who received the stress and mood module, 67% (6/9) reported a positive impact on their mood. Of those 10 who were registered as smokers, 3 (30%) participants reported that they had quit smoking during the programme.

Suggestions for improvements in the programme included making the programme longer, allowing for two-way communication with health care professionals through the programme, making it free to reply to the messages, allowing for greater choice in the timing of the messages, and greater personalization. Few technical issues were reported – of the 39 participants interviewed, 2 (5%) reported issues accessing their graph, and 8 (21%) participants reported that not having credit/money on the phone account meant they could not reply with their blood glucose test results.

Table 17: Results of the follow-up interviews (n=39).

Question	Response ("yes"): n (%)
Was SMS4BG useful?	39 (100)
Were the messages culturally appropriate?	39 (100)
Were the messages age appropriate?	39 (100)
Do you think SMS4BG has had a positive impact on:	
Your overall BG control?	32 (82)
Your frequency of BG monitoring?	30 (77)
Your diet or eating?	23 (59)
Your exercise?	19 (49)
Your mood?	26 (67)
Your perception of your diabetes?	19 (49)
Your knowledge of diabetes?	16 (41)
Would you recommend SMS4BG to others with diabetes?	38 (97)

BG: Blood glucose

6.5.3 Metabolic control

Baseline HbA1c values were obtained for all participants, but follow-up results were only available for 26 (62%) of the 42 participants. A significant improvement in HbA1c was found from baseline (median 89.50mmol/mol) to follow-up (median 71.00 mmol/mol, Wilcoxon signed-rank test P=.001) for the 26 participants out of 42 (62%) for whom complete data was available.

6.6. Discussion

This pilot study has established that SMS4BG is an acceptable and potentially useful tool for adults with poorly controlled diabetes. Perceived positive impacts of the programme were complemented by a significant improvement in glycaemic control at follow-up. This aligns with previous text message-based interventions in people with diabetes.(68)

Further evidence of the acceptability of SMS4BG was seen in the follow-up interviews, with all participants reporting SMS4BG to be both culturally and age appropriate. Participants ranged in age from 17 to 69 years and over half of the participants were of Māori (15/42, 36%), Pacific (3/42, 7%) or Asian decent (4/42, 10%). This indicates that this type of technology is not limited by demographic characteristics and the text message content was relevant to a wide range of people with poorly controlled type 1 and type 2 diabetes.

Most participants were satisfied with the number and frequency of the messages they received, which may be due to participants being involved in the selection of the modules they received and, therefore, having some degree of control over the number of messages they received.

Although visual feedback was provided in the form of a graph of submitted blood glucose results, this feature was not utilised by the majority of participants. The leading barrier for not accessing the graph was lack of Internet access either at home or on their mobile phones. Previous studies have reported greater improvements in HbA1c with combined mobile and Internet-based interventions compared to studies utilising mobile intervention alone.(68) Our findings are in contrast to this and highlight that lack of Internet access can reduce participant access to features of the interventions. Other methods for providing feedback should be investigated, such as sending graphs via multimedia messaging service (MMS). Although it was free to take part in the pilot study, the barrier of cost of replying to text messages (NZD $0.20) was identified as preventing a number of

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participants from responding with their blood glucose results and, therefore, feedback was not available to them. To ensure that SMS4BG is able to be fully utilised by all, removing the cost of reply messaging may be needed if rolled out within a health care setting.

Strengths of the SMS4BG programme included that it was theoretically informed, system initiated (ongoing intervention not dependent on participant behaviours), personally tailored, and provided participant choice. Many previous diabetes text messaging programmes have had limited reach or were designed specifically for one diabetes type, age group, or single diabetes management behaviour. SMS4BG was designed for adults of all ages with both poorly controlled type 1 and type 2 diabetes and provided support for self-management and encouragement in people's everyday lives rather than focusing on specific diabetes-related tasks. In addition, SMS4BG utilised simple technology and, therefore, had less potential for technical issues that have been a limitation in previous mHealth studies.

Another strength of the current study was the inclusion of an indigenous version. With a higher prevalence of diabetes seen in Māori compared to New Zealand Europeans,(175) diabetes interventions need to be both relevant and culturally appropriate to this group. There were two programmes that Māori could choose from and although only 4 participants chose to register for the Māori version, no Māori participants withdrew from the programme. This acknowledgement of identity may have assisted with retention of the Māori participants. In addition, the inclusion of motivational messages linking diabetes management to family (whānau) aligns with the importance of whānau to the well-being of Māori.(185) Although not significant, the higher ratings of usefulness of SMS4BG by Māori participants compared with New Zealand Europeans warrants further investigation. In addition, future development of the programme could incorporate other cultural versions, including one for Pacific peoples.

This study had several limitations, including the absence of a control group and a small sample size. Although positive change in glycaemic control was seen without a control group or adequate sample size, this difference must be interpreted with caution. The lack of complete follow-up HbA1c results limits the generalizability of the improved glycaemic control results. The target population (poorly controlled) were likely not attending medical appointments as regularly as guidelines state and, therefore, the lack of clinical results could be expected. Future studies could include text messages around the importance of HbA1c tests and reminders to go for tests as a way of potentially overcoming this issue. The pilot study was of short duration and as diabetes is a condition requiring long-term management, longer interventions may be more appropriate. Another limitation was the lack of follow-up to assess whether any effects of SMS4BG were maintained beyond the programme itself. A larger and longer-term randomised controlled trial will need to be carried out to establish the efficacy of SMS4BG on self-management behaviours, self-efficacy and clinical outcomes, and its sustainability and cost-effectiveness.

The current study adds to the evidence for the use of mHealth in delivering personally tailored diabetes self-management support and, particularly, the use of text messaging as a medium of delivery. The positive pilot study results indicate that this type of broad reaching EMI could be successful in engaging adults with poorly controlled type 1 or type 2 diabetes and assisting with

improved diabetes self-management. Further refinement of SMS4BG is needed based on the pilot study feedback, followed by a larger randomised control trial to determine its efficacy.

6.7. Acknowledgments

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6.8. Conflicts of interest

None declared.

6.9. Additional qualitative findings from the pilot study

An additional aim of the pilot study was to obtain more detailed input from study participants that could enable the refinement or improvement of the intervention if required. For this purpose follow-up interviews included open ended questions to provide a more in-depth understanding of the acceptability of the SMS4BG intervention.

6.9.1 Methods

As outlined in the published manuscript, a total of 39 participants completed the follow up interviews contributing to the data in this section (more detail of the methods and results for the follow up interviews can be seen in Section 6.5). Inductive content analysis was used to analyse the additional qualitative data obtained from the interviews.(186) Once all data were collected the approach involved, open coding and identification of categories, grouping of categories, and abstraction. The results are summarised below by main category with example participant quotes provided.

6.9.2 General feedback

Overall participants reported the programme to be useful and liked the encouraging and supportive nature of the programme

> *"It was very helpful, it reminded me to seek help from my friends and family and that I should take the readings of the blood glucose."*
> (Male, 65+, Indian)
>
> *"It's like you have someone on your side to help you along"*
> (Female, 50-64yrs, Māori)
>
> *"I appreciated the support and it was nice to know that someone cares"*
> (Female, 25-49yrs, Māori)
>
> *"I found it very good and very useful. It helped me get back into routine"*
> (Female, 50-64yrs, New Zealand European)
>
> *"Diabetes can be a bit lonely and it felt like sometimes you had someone there to cheer you along"*
> (Female, 50-64yrs, Māori)

Participants appreciated the personalisation in the messages and regardless of their choice of cultural version found the messages culturally appropriate and easy to understand.

> *"I like that they had my name in them. I knew they came from the programme but it was good that they were named to me."*
> (Female, 16-24yrs, Other Ethnicity)
>
> *"The Māori and Te Reo references were good"*
> (Male, 50-64yrs, Māori)
>
> *"It was good that there was none of those short words that I don't understand and are annoying"*
> (Female, 16-24yrs, Other Ethnicity)

Participants also appeared to like the choice of technology, SMS, for the delivery of the programme which reinforces the selection of this modality over newer technologies.

"The thing with this is I had control, which was good. The messages came to me, I didn't have to go anywhere"
(Male, 50-64yrs, Māori)

"Considering I work long hours it was quite a good way to do it"
(Male, 25-49yrs, New Zealand European)

"Thank you for using technology to reach people like me in the community"
(Female, 25-49yrs, Other Ethnicity)

"As a Māori male over the age of 50, using the cell phone was not the best method, but on the other hand it was great, the reminders were great"
(Male, 50-64yrs, Māori)

All participants reported that they would recommend the programme to other people and identified particular relevance to those who are newly diagnosed, Māori and young people.

"It was good. Especially to people who are new to diabetes"
(Male, 25-49yrs, New Zealand European)

"I would recommend it, especially to younger people but you would have to get the parents on board because of the cost"
(Female, 16-24yrs, Other Ethnicity)

"It will help people with diabetes who have just got diagnosed, or in the early stages"
(Male, 50-64yrs, Māori)

"With my culture [Māori] we are very complacent and need a kick like this"
(Male, 25-49yrs, Māori)

6.9.3 Impacts

Participant's reported a range of impacts of the programme as reported in the published manuscript such as increased blood glucose monitoring, healthy eating, physical activity, weight loss and quitting smoking. Furthermore a key impact of the programme appeared to be that it increased awareness and provided prompts to self-mange.

"Stopped the burying your head in the sand"
(Male, 50-64yrs, New Zealand European)

"It was like you were my Mrs or my mum on my back about it, it was a good thing"
(Male, 25-49yrs, New Zealand European)

"More aware from more testing. Because the messages made you more aware of your blood glucose which got you thinking about your eating"
(Male, 50-64yrs, New Zealand European)

"Kept me aware of my diabetes, only got diabetes a couple of years ago so can forget about it, it's still a new challenge"
(Female, 25-49yrs, Other Ethnicity)

More specifically, the messages gave people confidence in their ability to manage their diabetes and impacted on how they perceived their condition which in turn positively impacted their general wellbeing

"Nice getting gentle reminders, reassuring that I can cope with diabetes"
(Female, 25-49yrs, Other Ethnicity)

"[I feel] more positive, you can think that diabetes is a bit of a fait alcompli but it makes you realise that this is only the case if you don't do anything about it"
(Male, 50-64yrs, New Zealand European)

"It gave me control, for a diabetic, sometimes, it sometimes feels like you don't have control. It reminded me – I can control this"
(Male, 50-64yrs, Māori)

"It's not all doom and gloom, [it was] really encouraging. Made my diabetes relevant everyday rather than something I battle with"
(Female, 25-49yrs, Other Ethnicity)

"I realised how much more you can do if you have more control"
(Male, 25-49yrs, Māori)

"Yeah [I am] focusing more on the future, long term. I have grandchildren and want to see them grow up"
(Female, 50-64yrs, Māori)

"When in denial it can go on for days on end so daily messages didn't allow you to do this. They were a constant reminder that you are in charge of your own destiny"
(Male, 50-64yrs, New Zealand European)

"It gave me a sense of hope, prior education focussed on the negatives, I was told I would lose my feet and go blind, your messages gave me hope that it doesn't have to end that way"
(Male, 50-64yrs, Māori)

6.9.4 Suggestions for improvement

It was identified that there was a need for individual tailoring around duration of the intervention as the majority of participants wanted the programme to be of longer duration. When asked the preferred duration, responses varied from 3 months to 1 year, with some people saying it should ideally be ongoing and individually tailored.

"Yeah I would have liked it to go for longer. How long? It depends on how long you need it for"
(Male, 16-24yrs, New Zealand European)

"Another 6 months at least - possibly as long as possible
(Male, 25-49yrs, Māori)

Participants thought it would be good to be able to add/change topics/modules as the intervention went on.

"3 months as is then three months of another topic and the option of changing programmes"
(Female, 25-49yrs, Other Ethnicity)

"[The duration should be] based on your needs at the time"
(Male, 50-64yrs, New Zealand European)

Participants reported a need for more choice in the timing of their messages, particularly for shift workers.

"Timing of the messages it would be good to be able to choose"
(Male, 50-64yrs, Māori)

"The timing of the messages wasn't always ideal. Prefer to be able to choose the timing."
(Female, 24-49yrs, New Zealand European)

"I got about 1 a day. They were at the wrong times though, about 2 hours late"
(Male, 50-64yrs, Māori)

Although it was free to receive SMS4BG, if the participant replied to the system they were charged the standard SMS cost (NZD 0.20). Participants reported that all aspects of the programme need to be free and that the cost of replying to the blood glucose monitoring reminders was a barrier to engaging with this component of the programme.

"Make it free. If free texting everyone would text in to it."
(Female, 50-64yrs, Māori)

> *"I couldn't reply at one stage because I had no credit on my phone"*
> (Female, 24-49yrs, New Zealand European)

Participants responded very positively to the cultural adaptation of SMS4BG with all participants reporting it to be culturally appropriate although it was suggested there could be further links to family/whānau particularly as a motivation for engaging in self-management behaviours.

> *"Include link to whānau and my mokopuna, if it talked about my moko, I would do anything for them. Also more Te Reo and Māori links"*
> (Male, 50-64yrs, Māori)

Some participants requested more detail particularly in relation to the nutrition messages, links to recipes or menu ideas were suggested:

> *"You know what I would have really liked would have been menu suggestions for food, like dinner ideas sent at lunch time so I could call my wife up and say how about we have this for dinner"*
> (Male, 50-64yrs, New Zealand European)

> *"It would be nice to get recipes and stuff. And reminders about specific foods [nutritional information]"*
> (Female, 50-64yrs, Māori)

> *"Give more detail around foods, ideas for meals"*
> (Female, 16-24yrs, Other Ethnicity)

The majority of participants did not view their graph, many due to access issues. Although those that did view their graph of blood glucose responses found it useful, they identified a need for additional ways to view the graph of blood glucose responses for those without internet access.

> *[I didn't view my graph] "because I don't have internet"*
> (Female, 25-49yrs, New Zealand European)

> *[I didn't view my graph] "because I haven't got a computer"*
> (Male, 25-49yrs, New Zealand European; Female, 25-49yrs, Māori))

Lastly a couple of participants expressed concern that when they left New Zealand they couldn't receive the messages and that there should be the option to put their messages on hold.

> *"I didn't get the messages when I went overseas so they all came in when I got back"*
> (Male, 50-64yrs, Māori)

6.10. Feedback from key stakeholder groups

All of the pilot study findings were presented and discussed with key stakeholder groups including the Māori Advisory Group, the diabetes teams involved in the initial consultation, and the DHB funder. Further improvements were recommended as a result of these discussions. For example, the pilot study highlighted that many people were not undergoing routine HbA1c tests as often as guidelines recommend. Therefore additional messages were needed to promote the importance of routine testing and reminding participants to go for a test. The blood glucose result graphs were also shown to clinicians. Considerable variation in the results was noted, including low values indicating potential hypoglycaemic episodes (hypos). This resulted in the recommendation for additional informational messages around managing hypos to be sent to all participants opting for blood glucose monitoring reminders.

As the cultural tailoring of the SMS4BG intervention for Māori was very well received, it was decided that the programme should also be adapted specifically for Pacific peoples. This group

also experiences poorer diabetes outcomes, as described in Chapter 2, and could potentially benefit from a culturally adapted version. Finally, as highlighted in Chapter 2, people with poorly controlled diabetes are at risk of cardiovascular disease and foot complications. Providers/funders felt that messages promoting routine preventive care activities, such as foot care and cardiovascular checks, would be pertinent and useful additions to the content.

6.11. Integrating the findings into the SMS4BG intervention

The SMS4BG content as well as the content management system were updated to incorporate the feedback from the pilot study and stakeholder groups highlighted in the above sections. Table 18 shows the list of the key characteristics previously described in Table 10 of the SMS4BG intervention plus the refinements/improvements made as a result of the pilot study in blue.

Table 18: Revised SMS4BG key characteristics

Key intervention characteristics	
Intervention design	Text message based with feedback via website - 3 months, ***with the ability to select additional 3 months up to a maximum 9 months*** - ***Choice to receive graph of blood glucose results in paper form if no internet access***
Target population	Poorly controlled diabetes
	Māori
	Low-socioeconomic status
	Low technology access
	Not utilising current services
Intervention features	Individually tailored - Content ***with the ability to change/add modules every 3 months*** - ***Timing of all messages*** - ***Local support services***
	Cultural versions (Māori, ***Pacific***, or non-Māori/***Pacific***)
	Personalised - Name - ***Personal motivations for good diabetes control (i.e. mokopuna)*** - ***Reference to key support people***
	Free to receive ***and reply to messages***
	Ability to pause messages
Intervention purpose	Behaviour change
	Motivational support
	Diabetes education/information
	Goal setting
	Increase self-efficacy
	Promote accurate illness perceptions
	Coping strategies
Intervention content	General diabetes information - ***Including information about HbA1c tests***
	Insulin management
	Diabetes in young adults
	Smoking cessation
	Healthy eating - ***Links to recipe ideas***
	Exercise
	Stress/mood management
	Blood glucose monitoring reminders ***and information***
	Foot care
	Cardiovascular check reminder

To address the need for the intervention duration to be individually tailored additional content was needed. To provide up to 9-months of intervention an extra 6 months of messages were developed

for the core, insulin, young adult and smoking modules. The process to do this followed the same steps outlined in Section 5.4 (development of key messages from guidelines, evidence, and resources, adaption into SMS, and cultural adaption). The development of the messages for the new foot care module, the information messages for the blood glucose monitoring module, and the cardiovascular check reminder, also followed the steps outlined in Section 5.4.

To allow for tailoring of the duration of the intervention the content of each module was separated into 3 parts (or sub-modules), each 3 months in duration. At the end of the first part (i.e. at 3 months) there was a message inserted asking if they would like to continue for another 3 months. If the reply was yes they were then sent a message asking if they would like to make any changes to the programme they were receiving before they were enrolled in the corresponding part 2 modules. If they responded 'no', they would get a message confirming that their messages would now stop. This process also occurred at the end of part 2 (i.e. at 6 months).

The core module was adapted to create a Pacific version. Both the non-Māori and Māori versions of the core module were reviewed by a Pacific Island GP and Pacific Island nurse. Feedback provided was then used by the candidate to adapt the core messages to create the Pacific version. This version incorporated a greater focus on family, similar to the Māori version, focused on others as key motivators for good diabetes management (a collective rather than individual view), incorporated Pacific greetings based on the participant's ethnicity, and included specific messages to promote accurate perception of insulin and its use in the core module.

To incorporate the new tailoring variables and personalisation additional tokens were added to messages where the messages referred to support and motivations. A greeting token was also added to allow for tailoring of the message greeting for the Pacific and Māori participants. The final list of tokens used in the messages can be seen in Table 19. To provide the system with the individual data needed for the tokens the enrolment form was also updated to ensure all required information was gathered (see Appendix 4).

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Table 19: Tokens used for tailoring and personalisation of messages

Token	Applicable modules	Details	
[firstname]	All	Enter preferred name as in enrolment Q5	
[hi]	All	Enter greeting based on participant culture	IF: Pacific-Tongan → insert 'Malo e lelei' Pacific-Samoan → insert 'Talofa' Pacific-Other → insert 'Hi' Māori → insert 'Kia ora' Non Māori/Pacific → insert 'Hi'
[support1name]	All	Insert support person's name as specified in enrolment Q7	
[support2name]	All	Insert support person's name as specified in enrolment Q9	
[motivation1]	All	Insert motivation from enrolment Q10	IF: family → insert "family" whanau → insert "whanau" partner→ insert "partner" husband→ insert "husband" wife→ insert "wife" mum→ insert "mum" dad→ insert "dad" child→ insert "child" children→ insert "children" grandchild→ insert "grandchild" grandchildren→ insert "grandchildren" friends→ insert "friends" career → then insert "career" future health → then insert: "health in the future" sport→ then insert: "sport" fitness→ then insert: "fitness"
[motivation2]	All	Insert motivation from enrolment Q11	
[motivationother]	Young adult	Insert motivation from enrolment Q12	IF: career → then insert "career" future health → then insert: "health in the future" sport→ then insert: "sport" fitness→ then insert: "fitness" friends→ then insert: "friends"
[monitoring]	Blood glucose	Enter blood glucose preference:	IF: 1/week → insert "once a week" 3/week → insert "3 times a week" 1/day → insert "once a day" 2/day → insert "twice a day" 3/day → insert "3 times a day" 4/day → insert "4 times a day"
[servicescontactinfo]	Core Pacific Core Māori Core other Young adult	Enter service contact information based on participant location	IF: Auckland → insert "Go to www.diabetesauckland.org.nz or call 09 623 2508" Non-Auckland → insert "Go to www.diabetes.org.nz to search for support in your area"

As previously described (Section 5.5), the revised content library was sent out for expert review (see Appendix 4 for the content intervention development pre-testing checklist list which includes the names of the reviewers). This resulted in some minor wording changes before the content library was finalised. The SMS4BG intervention was then extensively tested using the procedures outlined in Section 5.5. The following section describes the final intervention.

6.12. The final SMS4BG intervention

SMS4BG is a theoretically based and individually tailored SMS based self-management support programme for adults with poorly controlled diabetes. It is tailored according to a patients individual needs and goals, their treatment, and culture. As well as core education, motivation and support messages (available in Māori, Pacific and non-Māori/Pacific versions), a person can opt to receive additional messages (modules) on topics such as healthy eating, physical activity, stress management, reminders to check blood glucose levels, insulin and its use, foot care, managing diabetes as a young adult, and smoking cessation. A summary of the structure of SMS4BG can be seen in the Table 20.

Table 20: Description of SMS4BG modules

Module	Description	Sub-modules[1]	Number of messages
Core module	Two messages per week providing general motivation and support for diabetes management. Available in 3 version: - Māori - Pacific - Non-Māori/Non-Pacific	Core Māori module part 1	74 messages 3 response messages
		Core Māori module part 2	
		Core Māori module part 3	
		Core Pacific module part 1	74 messages 3 response messages
		Core Pacific module part 2	
		Core Pacific module part 3	
		Core other module part 1	74 messages 3 response messages
		Core other module part 2	
		Core other module part 3	
Insulin module	One educational text message per week around insulin management and hypos for people receiving insulin	Insulin module part 1	12
		Insulin module part 2	11
		Insulin module part 3	11
Young adult module	One message per week around managing diabetes in the context or work/school and social situations	Young adult module part 1	12
		Young adult module part 2	12
		Young adult module part 3	12
Smoking cessation module	One message per month encouraging participants to consider quitting smoking and providing details of services for support	Smoking module part 1	3
		Smoking module part 2	3
		Smoking module part 3	3
Lifestyle behaviour modules	Up to 4 messages per week encouraging participants to set a lifestyle goal and supporting them to work towards this goal Participants can receive one of these modules at a time. The three lifestyle modules are: Healthy eating, Exercise, and Stress and mood.	Healthy eating module	30
		Exercise module	30
		Stress and mood module	30
Blood glucose monitoring	Reminders to test blood glucose, sent at a frequency selected by the individual, for which they are encouraged to respond by reply text message with their blood sugar readings. Also informational messages around managing hypos.	BG reminders module	12 reminder messages 12 responses
		BG info module part 1	10
		BG info module part 2	7
		BG info module part 3	6
Foot care module	Reminders and motivational messages supporting engagement in foot care	Foot care module part 1	12
		Foot care module part 2	11
		Foot care module part 3	10
Cardiovascular check reminder	Reminder to engage in a yearly cardiovascular assessment	Cardiovascular check reminder module	1

[1]All sub-modules are 3 months in duration allowing for tailoring of the duration of the intervention i.e. they only receive part 1 if they choose to end the programme at 3 months, part 1 and 2 if they end the programme at 6 months, and parts 1, 2 and 3 if they continue the full 9 months.

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Participants who opt to receive blood glucose monitoring reminders can reply via SMS (at no cost) with their blood glucose levels. They are then able to view their blood glucose levels graphically over time on a secure website. If they do not have access to the internet they can receive their graphs in paper format posted monthly. Participants can select the timing of their messages and blood glucose monitoring reminders. They are asked to identify their support people (e.g. partner) and their motivations for diabetes management (e.g. grandchildren), and these are then incorporated into their messages to personalise them. Messages are also personalised by including the person's name. The length/duration of the programme is tailored to individual preferences, with the opportunity to continue at 3- and 6-month time points, up to a maximum intervention duration of 9 months. If they opt to continue, they are given the opportunity to re-select their modules. Participants can stop their messages at any time by replying with the word 'STOP' or can put their messages on hold by sending the text 'HOLIDAY' with the number of days they would like to pause their messages for.

The final SMS4BG message library consisted of a total of 481 unique messages across all modules. It was designed so that all messages that a person received were unique across the intervention – that is, every message they received was different – with the exception of blood glucose monitoring reminders for which there were 12 different reminders and 12 different responses that the system randomly selects each time. The minimum number of messages a participant could receive was 28, approximately 2 per week (unless they stopped their messages before completing the programme). A participant could receive over 2000 messages if they choose additional modules, opted to receive the maximum number of blood glucose reminders (4 per day), replied with blood glucose results so received the feedback messages, and continued the programme for the full 9 months. Sending and receiving of all messages was free to the participants.

6.13. Summary

The SMS4BG intervention was found to be acceptable to people with poorly controlled diabetes in New Zealand. Furthermore, there is support for a positive impact on diabetes outcomes. Feedback from the pilot study allowed for improvements to the programme to be made and the next step is to assess its effectiveness in terms for clinical outcomes.

Part 3: The evaluation of SMS4BG

The work carried out in Parts 1 and 2 of this thesis culminated in SMS4BG, a well received and acceptable, SMS based self-management support programme for adults with poorly controlled diabetes. The effectiveness of this theoretically grounded and individually tailored programme was still unknown. Therefore, Part 3 of this thesis evaluates the effectiveness of the intervention in a pragmatic 2-arm randomised controlled trial. Chapter 7 presents the published study protocol and Chapter 8 presents the trial results.

CHAPTER 7. TEXT MESSAGE-BASED DIABETES SELF-MANAGEMENT SUPPORT (SMS4BG): STUDY PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

7.1. Preface to the chapter and publication

The first aim of Chapter 7 is to describe the study protocol for a randomised controlled trial to assess the effectiveness of SMS4BG among adults with poorly controlled diabetes. This is presented in the form of a published manuscript in Sections 7.2 through 7.8 of the chapter. Minor changes to formatting have been made to the published manuscript to ensure consistency across the thesis.

The second aim of this chapter (not published) is to describe the running of the trial and the challenge faced with recruitment (Section 7.9). The entire chapter contributes to the following thesis objective:

4. Assess the acceptability and effectiveness of an mHealth self-management support intervention.

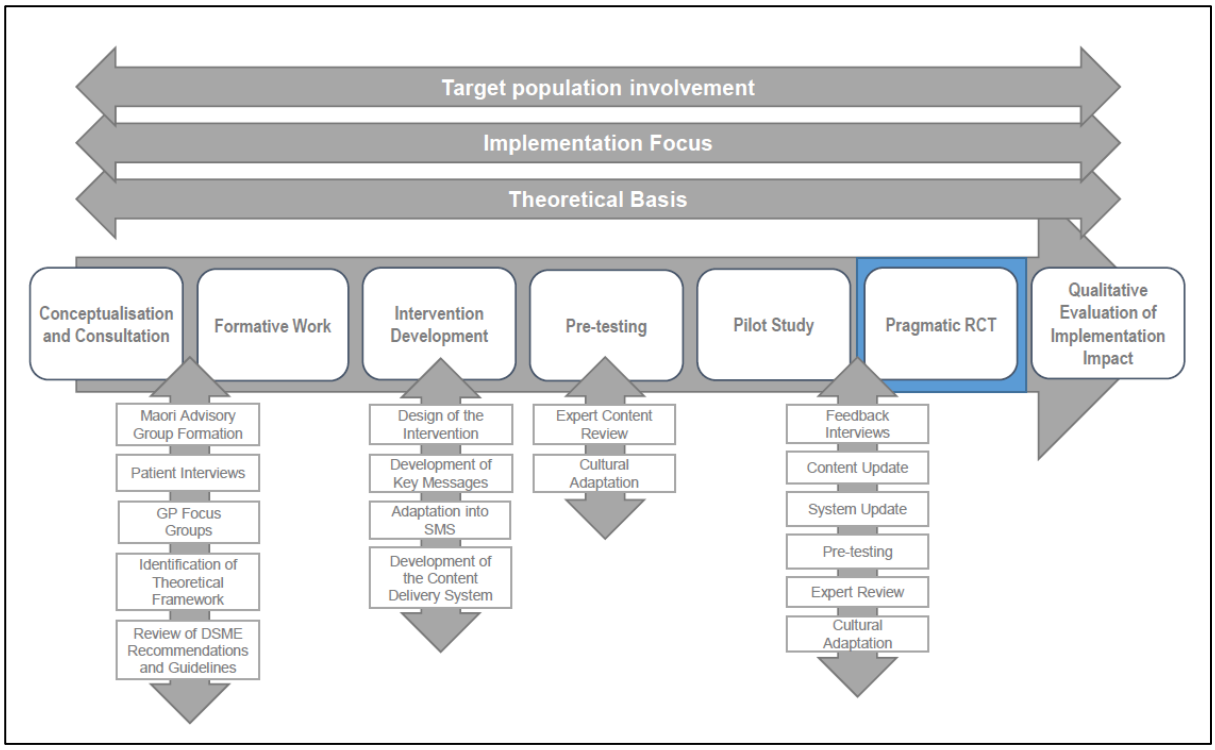
Supporting documents associated with this chapter can be found in Appendix 5 including a copy of the SPIRIT checklist, ethics approval letter, participant information sheet, consent form, baseline forms, follow up forms, and referral forms.

Why was this work needed?

To assess the effectiveness of the SMS4BG intervention in comparison to a control group, a pragmatic community-based randomised controlled trial was needed. The protocol of a trial is key for study planning, conduct, analysis, and reporting. It details the study from start (e.g. ethical approval) through to close (e.g. dissemination of findings). The document facilitates assessment of ethical and safety issues before the trial begins; the rigor of trial conduct; and appraisal of the results.(101) The importance of protocols is well documented.(187, 188)

What was undertaken?

A study protocol was prepared outlining the study processes for the SMS4BG trial. Ethical approval was obtained and the study was registered with the Australian New Zealand Clinical Trials Registry. The trial was conducted according to the published protocol from June 2015 through August 2017. Figure 16 shows the study framework highlighting that sections covered in this chapter of the thesis.



SMS: Short message service; GP: General practitioner; DSME: Diabetes self-management education; RCT: Randomised controlled trial

Figure 16: Adapted development and evaluation framework highlighting the stage covered in Chapters 7 and 8

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Contribution by the candidate:

The candidate along with co-authors contributed to the study concept, design, and procedures. She gained ethical approval for the study. She created the statistical analysis plan with co-author Yannan Jiang. The candidate, with input from the co-authors, wrote the manuscript.

Text message-based diabetes self-management support (SMS4BG): Study protocol for a randomised controlled trial

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7.2. Abstract

Background: Addressing the increasing prevalence, and associated disease burden, of diabetes is a priority of health services internationally. Interventions to support patients to effectively self-manage their condition have the potential to reduce the risk of costly and debilitating complications. The utilisation of mobile phones to deliver self-management support allows for patient-centred care at the frequency and intensity that patients desire from outside the clinic environment. Self-Management Support for Blood Glucose (SMS4BG) is a novel text message-based intervention for supporting people with diabetes to improve self-management behaviours and achieve better glycaemic control and is tailored to individual patient preferences, demographics, clinical characteristics, and culture. This study aims to assess whether SMS4BG can improve glycaemic control in adults with poorly controlled diabetes. This paper outlines the rationale and methods of the trial.

Methods/design: A two-arm, parallel, randomised controlled trial will be conducted across New Zealand health districts. One thousand participants will be randomised at a 1:1 ratio to receive SMS4BG, a theoretically based and individually tailored automated text message-based diabetes self-management support programme (intervention) in addition to usual care, or usual care alone (control). The primary outcome is change in glycaemic control (HbA1c) at 9 months. Secondary outcomes include glycaemic control at 3 and 6 months, self-efficacy, self-care behaviours, diabetes distress, health-related quality of life, perceived social support, and illness perceptions. Cost information and healthcare utilisation will also be collected as well as intervention satisfaction and interaction.

Discussion: This study will provide information on the effectiveness of a text message-based self-management support tool for people with diabetes. If found to be effective it has the potential to provide individualised support to people with diabetes across New Zealand (and internationally), thus extending care outside the clinic environment.

Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12614001232628

7.3. Background

Addressing increasing diabetes prevalence, its associated morbidity and health inequalities, is a current priority in New Zealand and internationally.(21, 174, 189, 190) The burden of diabetes is greater in indigenous peoples (174) with higher disease prevalence and poorer outcomes seen in Māori.(175, 191) Good diabetes self-management, including glucose monitoring, engaging in health behaviours, insulin administration, and healthcare provider contact, is associated with improved glycaemic control, and even small improvements in glycaemic control are associated with reduction in costly and debilitating long-term complications.(6, 9, 121, 192-194)

Mobile phones are ubiquitous, with increasing ownership and use across hard-to-reach populations.(82, 177) Text message (short message service, SMS) volumes have remained high over recent years with nearly 14 billion SMS messages sent in New Zealand in the year ending June 2012.(179) Mobile health (mHealth) is the use of mobile devices, including mobile phones, to deliver health services and information.(48) Mobile phones have been used effectively to support healthy behaviour change and disease management,(51, 57, 61, 180, 195) and offer an ideal way of providing patient-centred care at the frequency and intensity that patients desire. In addition there is potential for mobile phones to provide an effective way of providing support to patients in rural and remote areas where healthcare provider contact may be less accessible.(176, 196)

There is a growing body of evidence supporting the use of mobile phones in the management of diabetes,(68, 72, 197) with previous studies showing positive impacts on glycaemic control,(72, 73) patient satisfaction with healthcare,(72) healthcare costs,(72) self-efficacy,(76) and self-management behaviours, e.g. adherence and blood glucose monitoring.(76-78) Although promising, many previous studies have lacked sufficient sample sizes, were of insufficient duration, or interventions lacked theoretical grounding. Learnings has identify that for this type of intervention to be successful it needs to be theoretically based,(61, 91) individually tailored,(52, 58, 176, 181, 182) and to provide individual choice to increase patients' sense of control.(143)

In light of the increasing prevalence of diabetes in New Zealand, as well as increasing mobile phone penetration, we hypothesise that mobile-based tools are important options for self-management support in this population. A mobile phone-based text messaging programme designed to enhance self-management support for people with diabetes (SMS4BG: Self-Management Support for Blood Glucose) has been developed and piloted.(198) Development of the SMS4BG followed the mHealth Development and Evaluation framework,(141) with a focus on implementation, use of behavioural change theory, and engagement of key stakeholders including clinicians and patients. Conceptualisation, formative research and pretesting, including a pilot study, have been previously reported.(198, 199)

SMS4BG was developed by a multidisciplinary team including public health and mHealth experts, psychologists, diabetes nurse specialists, a Māori advisory group, with review and input from diabetes specialists and primary care teams. The intervention is grounded in behaviour change theory to enhance people's self-efficacy,(32) and to promote accurate illness perceptions.(35) It uses Behaviour Change Techniques (BCTs)(100) (see Chapter 5 for a list of BCTs utilised in SMS4BG) to address the behaviours required for successful self-management and is made up of

modules allowing for tailoring to the individual patient. The intervention content is designed to address the seven key self-management behaviours identified by the Association of American Diabetes Educations: (1) healthy eating, (2) being active, (3) monitoring, (4) taking medication, (5) problem solving, (6) reducing risks, and (7) healthy coping.(41) In addition the intervention includes versions for Māori and Pacific peoples incorporating concepts and elements specific to these cultures. Involvement of primary and secondary care teams throughout the development attempts to ensure integration into clinical pathways. The pilot study found the programme acceptable, useful, and culturally and age-appropriate.(198) Feedback from the SMS4BG pilot study allowed for further development and refinement of SMS4BG including increasing the duration of the programme based on patient preference, the addition of new modules including a foot care module and a cardiovascular check reminder module, and increased tailoring to incorporate individual motivations and names of support people. While the pilot study yielded positive results, a larger-scale randomised controlled trial (RCT) of the effectiveness of SMS4BG is now required including the effectiveness of SMS4BG in urban, and rural and remote areas. The findings from this RCT will inform the decision on whether to scale up and implement the programme across New Zealand.

7.3.1 Aim

This study aims to determine the effectiveness of the mHealth diabetes self-management support programme (SMS4BG) in adults with poorly controlled type 1 or type 2 diabetes, in addition to their usual diabetes care. Specific objectives include:

1. Enabling improved diabetes self-management as measured by improvements in glycosylated haemoglobin (HbA1c)
2. Assessing the effectiveness of SMS4BG

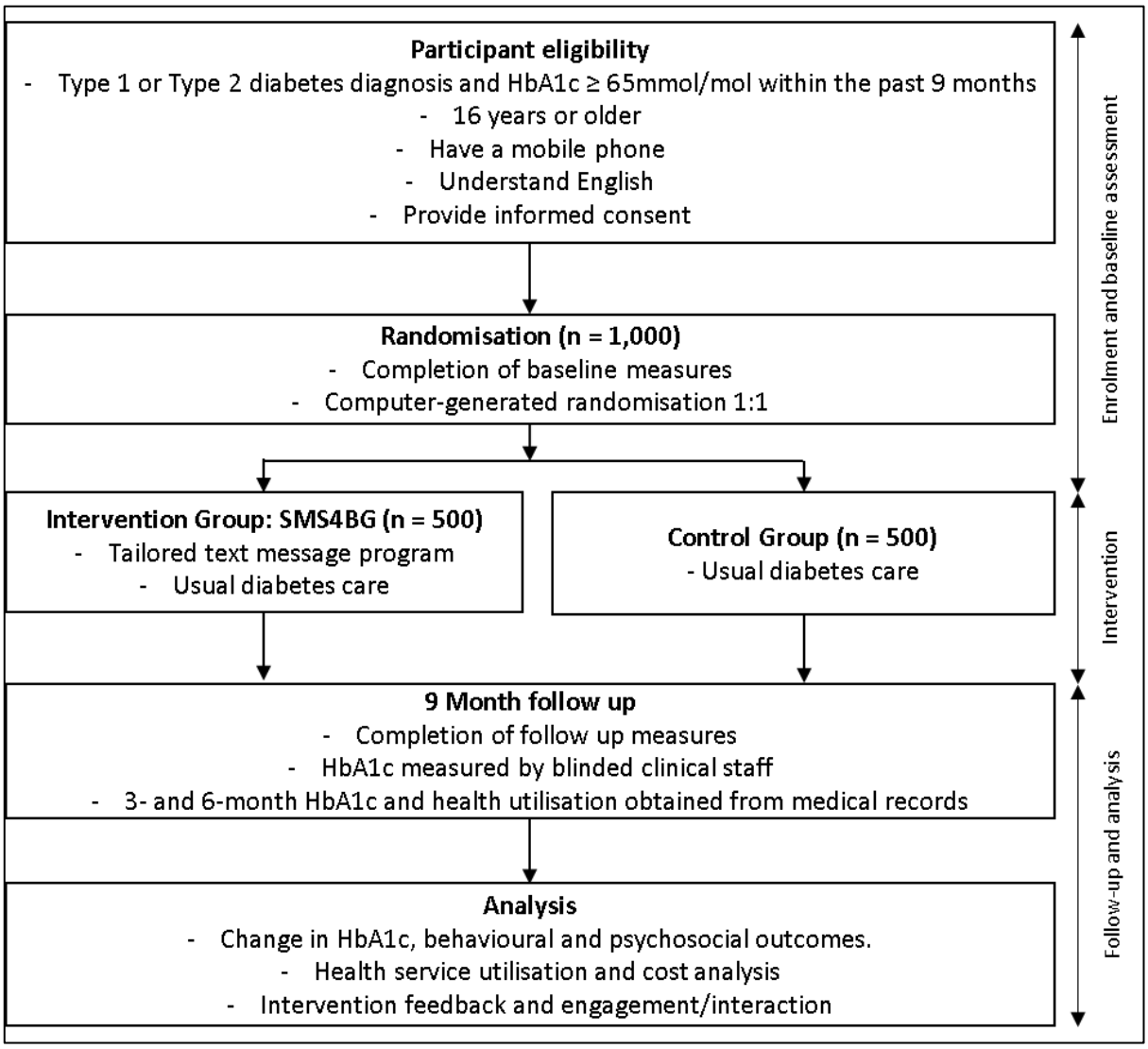
7.4. Methods/design

This protocol describes a 9-month, two-arm, parallel, RCT to evaluate the effectiveness of a text message-based diabetes self-management support programme (SMS4BG), on glycaemic control as measured by HbA1c. This protocol is in accord with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement,(200) and the intervention is described according to the Consolidated Standards of Reporting Trials (CONSORT)-EHEALTH checklist.(201) See Appendix 5 for the completed SPIRIT checklist.

7.4.1 Study population and recruitment

Eligible participants are adults (aged 16 years and over) with poorly controlled diabetes (defined as an HbA1c over 65 mmol/mol in the preceding 9 months) who own a text message-capable mobile phone, are able to read English, provide informed consent, and are available for the study duration. Exclusion criteria are not being available for the duration of the study, or being unable to use a mobile phone due to physical disabilities affecting eyesight or dexterity and not having a carer who wishes to use the mobile tools on their behalf. Recruitment for the trial commenced June 2015.

Potential participants will be identified by clinicians within primary and secondary care services across New Zealand health districts. Districts will be categorised as either high urban population or high rural/remote population based on population destiny data. Recruitment processes will build on those used successfully in the pilot study with clinicians forwarding the contact details of interested and eligible participants to the research team who will contact the patient by phone to discuss the study and gain informed consent. Informed consent will be obtained from all participants before they are enrolled in the study.



HbA1c: Glycosylated haemoglobin

Figure 17: Study flow diagram

7.4.2 Outcome assessments

Assessments will be conducted at baseline and 9 months post randomisation (see Figure 17). Baseline assessments will involve collection of demographic information and self-reported outcome measures via phone interview, and collection of clinical measures via patient records. Following completion of baseline data collection the patient will be randomised and, if allocated to the intervention arm, will be asked a small number of intervention-tailoring questions and will then be enrolled in the intervention. Intervention-tailoring questions include:

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- Preferred first name
- Preferred mobile number
- Preferred message delivery time (early morning: 7–9 am, mid-morning: 9 am–12 pm, early afternoon: 12–3 pm, late afternoon: 3–5 pm, evening: 5–8 pm, or day: 9 am–5 pm)
- Region (Auckland or non-Auckland)
- Names and relationship of two support people (partner, parent/caregiver, child, friend, other)
- Motivations for diabetes management (your family, your whānau, your partner, your husband, your wife, your mum, your dad, your child, your children, your grandchild, your grandchildren, your friends, your career, your health in the future, sport, your fitness)
- Module choices (See Table 21).

Follow-up assessments will involve completion of self-reported outcome measures via phone interview, and collection of clinical measures via patient records.

Table 21: Description of SMS4BG modules with example messages

Module	Description	Participants	Duration	Example message
Core module	Two messages per week providing general motivation and support for diabetes management. Available in 3 version: - Māori - Pacific - Non-Māori/Non-Pacific	All	3 to 9 months	SMS4BG: Kia ora. Control of your glucose levels involves eating the right kai, exercise & taking your medication. Your whānau, doctor & nurse can help you
				SMS4BG: Talofa [name]. by managing your diabetes well (including eating well and exercising) you can show your family that diabetes can be controlled
				SMS4BG: There is no quick fix to diabetes but with good management it will have less impact on your life and leave you more time to do the things you enjoy
Insulin module	One educational text message per week around insulin management and hypos for patients receiving insulin	Available to participants who are prescribed insulin	3 to 9 months	SMS4BG: Keep unopened insulin in the fridge. Don't use insulin that has changed colour, is lumpy, expired, cracked or leaking, or has been frozen or too hot
Young adult module	One message per week around managing diabetes in the context or work/school and social situations	Available to participants aged 16 - 24	3 to 9 months	SMS4BG: Unsure whether to tell your friends/boyfriend/girlfriend about diabetes? This can be tough but people who care about you will want to know & support you
Smoking cessation module	One message per month encouraging participants to consider quitting smoking and providing details of services for support	All participants who register as smokers	3 to 9 months	SMS4BG: [hi] [name]. Good management of your diabetes & your future health includes not smoking, call Quitline on 0800 778 778 for support
Lifestyle behaviour modules	Up to 4 messages per week encouraging participants to set a lifestyle goal and supporting them to work	Available to all participants.	Each module 3 months	SMS4BG: Healthy eating is an important part of your diabetes treatment and it will help you in controlling your blood glucose levels

	towards this goal Participants can receive one of these modules for three months. The three lifestyle modules are: - Healthy eating - Exercise - Stress and mood.			SMS4BG: If you are too tired to exercise at the end of the day, try waking up early & doing your exercise in the morning. It will energise you for the day
				SMS4BG: [hi] [name]. Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood
Blood glucose monitoring	Reminders to test blood glucose, sent at a frequency selected by the patient, for which they are encouraged to respond by reply text message with their blood sugar readings. In addition informational messages around managing hypos.	Available to all participants required to monitor their blood glucose	3 to 9 months	SMS4BG: [hi] [name]. Just a reminder it is time to check your blood glucose. Reply with the result
				If valid response received to reminder, "SMS4BG: Thank you for sending your result"
				SMS4BG: Hypoglycaemia (hypos) are when your blood glucose drops too low (i.e. less than 4mmol/L). If this happens take something with sugar immediately
Foot care module	Reminders and motivational messages supporting engagement in foot care	Available to those that are high risk or have active foot disease	3 to 9 months	SMS4BG: Looking after your feet will help to prevent issues in the future. Check your feet daily & contact your doctor, nurse or podiatrist if there are changes
Cardiovascular check reminder	Reminder to engage in a yearly cardiovascular assessment	Available to those that qualify	3 months	SMS4BG: [hi] [name]. Next time you see your doctor ask about getting a cardiovascular check done. You should have one each year.

7.4.3 Ethics approval

Ethical approval for this trial was obtained from the Health and Disability Ethics Committee (14/STH/162).

7.4.4 Sample size

One thousand participants (500 per arm) will be recruited for the trial, stratified by the health districts with either high urban or high rural/remote populations. Recruiting 500 participants (250 per arm) in each of the health district populations will provide 90 % power at the 5 % significance level to detect an overall clinically meaningful difference of 0.5 % (6 mmol/mol) change in HbA1c from baseline to 9 months between the two arms in each of the populations, assuming a standard deviation of 1.7 %. Targeted recruitment strategies will be used to preferentially recruit Māori and Pacific participants where possible.

7.4.5 Randomisation and blinding

Eligible participants will be randomised to either intervention or control group in a 1:1 ratio. Randomisation will be stratified by health district category (high urban or high rural/remote), diabetes type (1 or 2), and ethnicity (Māori and Pacific, or non-Māori and non-Pacific). The

randomisation sequence will be generated by computer programme using variable block sizes of 2 or 4, and overseen by the study statistician (YJ). The treatment allocation will be concealed until the point of randomisation. Due to the nature of the intervention participants will be aware of their treatment allocation. Although it will not be possible for research staff conducting the phone interviews to be blinded to the treatment allocation, the primary outcome HbA1c is an objective measure and assessors of this outcome will be blinded to treatment allocation.

7.4.6 Intervention

Both intervention and control groups will continue with their usual diabetes care including all medical visits, tests, and diabetes support programmes. In addition the intervention group will receive the automated text message-based self-management support programme (SMS4BG) for up to 9 months. SMS4BG is tailored according to the needs and goals of the patient, their care plan, and demographic factors including ethnicity. As well as core motivational and support messages (available in Māori, Pacific and non-Māori/non-Pacific versions), participants can opt to receive additional modules such as a lifestyle module around healthy eating, physical activity or stress management. Where appropriate to their care, they can also receive reminders to check blood glucose levels, messages around insulin, foot care, managing diabetes as a young adult, and smoking cessation, and also messages encouraging preventive behaviours (e.g. cardiovascular risk assessment). Participants who opt to reply to glucose monitoring reminders, by sending in their blood glucose levels by text message, will be able to view their blood glucose levels graphically over time on a secure website. If at baseline they are identified as not having access to the Internet they will be mailed their graphs on a monthly basis. At registration the intervention group will be able to select the timing of their messages and blood glucose monitoring reminders, and to identify their support people and motivations for diabetes management for incorporation into the messages. The length of the programme will also be tailored to patient preferences from 3 to 9 months, and at 3 and 6 months participants will receive a text message asking if they would like to continue the programme for an additional 3 months and will be given the opportunity to re-select their modules. Participants can stop their messages at any time by texting the word ‘STOP’, or put their messages on hold for 1 week by sending the text word ‘HOLIDAY’. A summary of the structure of SMS4BG can be seen in Table 21. More detail on the intervention and its development is available in the pilot study paper.(198)

The message delivery will be managed by a specifically developed SMS4BG Content Management System with the messages sent and received through a gateway company to allow for participants to be registered with any New Zealand mobile network. Sending and receiving messages will be free to all participants with costs covered by the study. The system will maintain logs of all outgoing and incoming messages, and incoming blood glucose values will be automatically graphed by the system which individuals can view via a password-protected website.

7.4.7 Outcome measures

The primary outcome measure is change in glycaemic control from baseline to 9 months, measured as HbA1c (in mmol/mol or %) by registered laboratories. Secondary outcome measures include:

- *Glycaemic control* measured by registered laboratory measurements of HbA1c (in mmol/mol or %) at 3 months and at 6 months. Both 3-month and 6-month HbA1c results will be obtained from patient records at the 9-month follow-up
- *Self-efficacy for diabetes management* measured by the Stanford self-efficacy for Diabetes Management scale (SEDM) (202) at baseline and at 9 months. The SEDM is an 8-item measure which respondents use to indicate, on a Likert scale from 1 (not at all confident) to 10 (totally confident), how confident they feel that they can carry out the listed tasks regularly at the present time. The score is calculated using the mean of the eight items with higher scores indicating higher self-efficacy. The SEDM has been found to have good internal consistency and test-retest validity.(202)
- *Diabetes self-care behaviours* measured by the Summary of Diabetes Self-Care Activities (SDSCA) (203) at baseline and at 9-month follow-up. The SDSCA is a brief self-reported questionnaire which asks respondents 11 items relating to five different domains of diabetes self-management: diet, exercise, blood-glucose monitoring, foot care, and smoking. The SDSCA has been shown to have good validity and reliability in research and practice,(203) with higher scores on the scale indicating greater engagement in self-care behaviours
- The presence of *diabetes-related distress* measured by the 2-item Diabetes Distress Scale (DDS2) (204) at baseline and at 9 months. This 2-item brief diabetes distress screening instrument detects diabetes-specific distress. Respondents indicate, on a 6-point Likert scale, to what degree each item has caused them distress over the past month with higher score indicating higher distress. The DDS2 has been shown to discriminate highly distressed patients from patients with low diabetes distress,(204) with an average item score of 3 or more used as the cut off for high distress
- *Cognitive and emotional representations of diabetes* measured by the Brief Illness perception Questionnaire (BIPQ) (205) at baseline and at 9 months. The BIPQ is a 9-item self-reported measure which assesses consequences, timeline, personal control, treatment control, identity, concern, emotions, illness comprehensibility, and causes of diabetes. Each item (except causality) is rated using an 11-point Likert scale with higher scores indicating greater agreement with the item. The causal representation is assessed via an open-ended item. The BIPQ has been shown to have good reliability and validity,(205) and has previously been used in a New Zealand diabetes population to assess differences in illness perceptions between Europeans, South Asians and Pacific Islanders.(24)
- *Health-related quality of life* measured by the EuroQol 5 dimensions (EQ-5D) questionnaire (206) at baseline and at 9-month follow-up. The EQ-5D provides a descriptive profile of health status and a single index value for health status. Five dimensions of health are assessed in the descriptive system: mobility, self-care, usual activities, pain/discomfort and

anxiety/depression. The respondent indicates under each dimension their health state by choosing the severity level most appropriate to themselves. A lower number indicates a better health status and quality of life. The EQ-5D visual analogue scale allows the respondent to mark, on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state), their health state. There is evidence to support the validity and reliability of the EQ-5D in people with diabetes.(207)

- *Perceived social support* for diabetes management measured using a 4-item measure developed for this study at baseline and at 9-month follow-up. The measure is split into two sections. The first assesses general support and asks how supported they feel in regards to their diabetes management on a 6-point Likert scale, from 1 (not at all supported) to 6 (extremely supported). The second section assesses appraisal, emotional and advice/information aspects of support (one item each). Users indicate, on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree), to what degree they agree with the statements
- *Healthcare utilisation* measured by number of hospitalisations, and primary and secondary care visits during the study period compared to the 9 months prior to randomisation. Healthcare utilisation will be obtained from patient records at 9-month follow-up
- *Patient satisfaction and engagement* with SMS4BG (for those in the intervention group). At 9 months participants will be asked, via semi-structured interview, about their satisfaction with the programme, including ease of use, issues arising, satisfaction with the text messages, salience and usefulness of the messages, and suggestions for improvement. In addition the overall number of text messages sent and received, response rates, and intervention duration will be measured by the SMS4BG content management system
- *Cost-effectiveness* of the intervention using cost information obtained at 9 month follow-up, including the costs of the SMS4BG programme, the direct medical costs (including cost of treatment, primary care, secondary care) and Quality-adjusted Life Years (QALYs)

7.4.8 Statistical analysis

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc. Cary, NC, USA). All statistical tests will be two-sided at the 5 % significance level. All treatment evaluations will be performed on the principle of intention-to-treat (ITT), using the observed data collected from all randomised participants. Appropriate imputation methods will be applied to the missing data on the primary outcome. No imputation will be considered on other secondary outcomes. A per-protocol analysis may be conducted on the subset of participants who are more compliant with the protocol with pre-defined criteria.

Demographics and baseline characteristics will be summarised using descriptive statistics. Continuous variables will be summarised as numbers of observed values, mean, standard deviation, median, minimum and maximum. Categorical variables will be described as frequency and percentage. Information collected on all primary and secondary outcomes will be first summarised using descriptive statistics at baseline and at 9 months as appropriate. Results will be presented for each of the two treatment groups separately. Linear regression model will be used to

test the effect of intervention on the primary outcome between two groups, adjusting for baseline outcome value, health district category, type of diabetes, and ethnicity (i.e. the stratification factors). Model-adjusted means and their difference will be presented with 95 % confidence intervals. As pre-planned, the analysis will also be conducted for each health district category separately as stratified, and the consistency of intervention effects will be tested in the main model using an interaction term between treatment group and health district category. A similar approach will be applied to other continuous secondary outcomes. Generalised linear regression models will be applied to categorical outcomes using an appropriate link function (e.g. a logit link for binary distribution).

Sensitivity analysis may be conducted on the primary outcome if the proportion of missing data is greater than 10 %. Both single and multiple imputations' methods may be considered based on different assumptions on the missing data, in order to assess the robustness of treatment evaluation.

If enough participants are recruited, subgroup analyses by diabetes type and ethnic group will be conducted on the primary outcome and key secondary outcomes, to test possible interactions with the intervention.

7.5. Discussion

This paper describes the protocol for the SMS4BG trial to evaluate a text message-based diabetes self-management support programme compared with usual care. This type of intervention can provide tailored support between clinic visits for people with poorly controlled diabetes. This protocol builds on previous evidence for the role of mHealth in people with diabetes. The SMS4BG study has been designed to address limitations of previous diabetes text message studies. The intervention, developed by a multidisciplinary team, is comprehensive in design, individually tailored, and theoretically grounded, and the study design will allow for accurate assessment of the impact of this type of intervention.

Findings from the pilot study of SMS4BG show that this type of intervention is acceptable and perceived as useful by people with diabetes in New Zealand although the effectiveness must be proven in a rigorously conducted trial. If found to be effective, SMS4BG has the potential to be implemented into health services across New Zealand and the potential to be adapted for other populations.

7.6. Trial status

Recruiting: participants are currently being recruited and enrolled.

7.7. Competing interests

The authors declare that they have no competing interests.

7.8. Acknowledgements and funding

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7.9. Recruitment issues with the conduct of the SMS4BG trial

The SMS4BG trial commenced as planned with the candidate engaging with secondary care and primary care clinics across New Zealand to refer their eligible patients to the study. Despite extensive efforts recruitment for the study was very slow raising concern that there would not be adequate referrals to study within the proposed 12 month recruitment period to achieve the target sample (see Figure 18 for a graph showing the progress over the recruitment period). If the recruitment target was not going to be achieved ensuring the study would still be able to provide an answer to the research question was pertinent.

The study methods had been designed to ensure minimal effort/burden for clinicians but ensuring maximum sensitivity and confidentiality of patient information. Therefore the only necessary step involving clinician time and involvement was for the identification of suitable patients and obtaining patients permission for someone from the study team to contact them to discuss the study (see Section 7.4.1). This ensured that the patient was aware and gave permission for their details to be sent to the research team at the university and they expected the call from the research team. Clinicians had the option of emailing, faxing, or mailing the patient details to the research team (see Appendix 5 for an example of referral forms) or these could be collected from the clinics. Although the amount of time needed for this process was small, clinicians regularly reported that it wasn't feasible due to lack of time and the inability to prioritise research over their other work.

As a barrier to recruitment was clinician time in identifying and referring suitable patients, an ethics amendment was submitted (approved 05/11/2015) to allow advertising of the study and for people to self-refer to take part. Posters, flyers, community newspapers and Facebook were then used to market the study with information on how people could self-refer. Although this method did result in some additional participants (see Figure 18) it was not enough to get recruitment back on track.

Another way of overcoming the barrier of clinician time was for the candidate or another member of the research team to help clinics to refer patients. The candidate offered clinics the option of a member of the research team visiting the clinic to ring eligible patients that they had identified to ascertain their interest in the study. If interested, patient details would then be taken back to the NIHI where the patient was contacted again as per the usual processes (See Section 7.4.1). The candidate and other members of the research team travelled to primary care practices in Gisborne and Kaikohe, as well as six primary care practices and a secondary care clinic in Auckland for this purpose. It was found that this method was extremely successful but again it wasn't enough to get recruitment to the level needed, even when timelines were adjusted to allow for an additional 6 months of recruitment.

Throughout this period the funders were kept updated on the study. The MOH disseminated information about the study through its networks (i.e. National diabetes network) in newsletters and emails to try and encourage more clinics to be involved in the study.

Overwhelmingly clinicians and clinic staff were positive about the study, the SMS4BG programme, and their patients being involved. Equally when contacted patients were very positive about the study and keen to take part. Only one clinic in a very rural area felt it was not appropriate to refer

their patients due to the lack of cellular reception throughout their area. One other iwi based primary care clinic was not able to refer patients to the study due to their systems not at the time being able to identify patients who qualified and not having the capability to do this by hand.

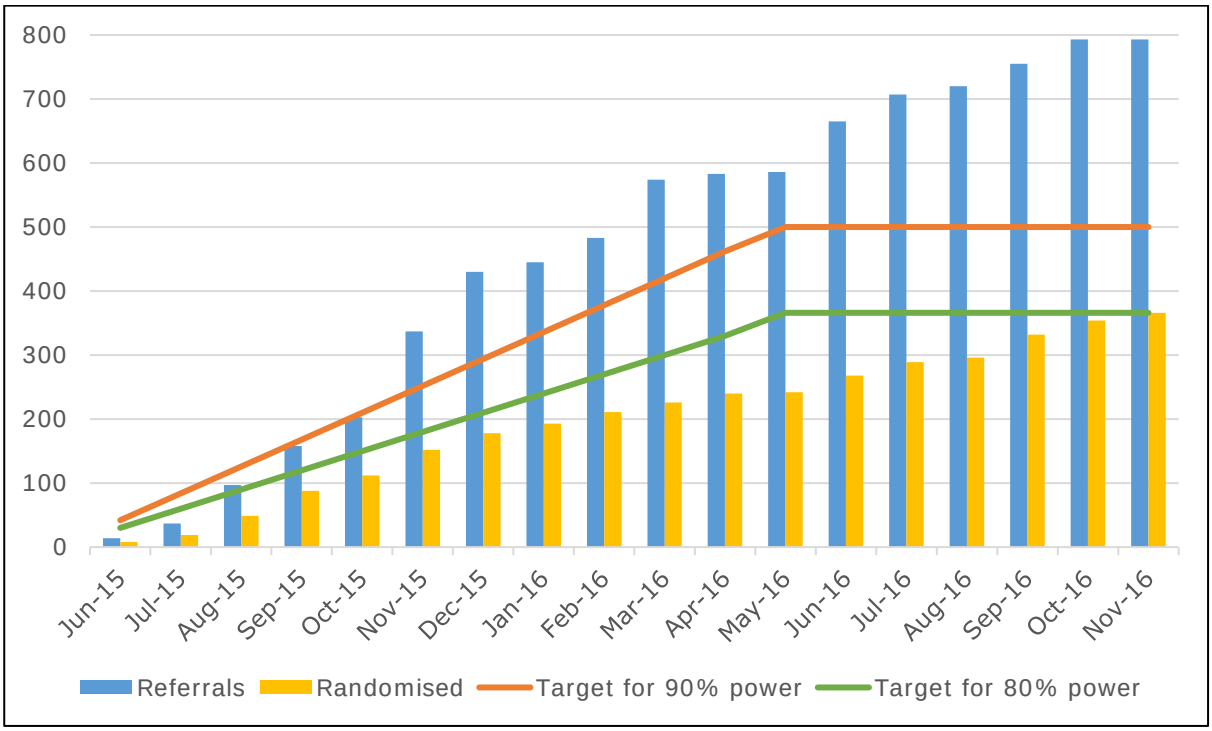

Figure 18: Graph showing the progress with recruitment (including numbers referred and numbers randomised) compared to the recruitment target based on 80% and 90% power

The initial power calculation was based on achieving 90% power to detect a meaningful difference between groups in both an urban population and a rural/remote population, resulting in an ambitious target of 500 participants (250 per arm) in each of the populations (rural/remote and urban) (total 1000).

When it became apparent that the recruitment target was not achievable within the study timeline the candidate met with the biostatistician and co-investigator Yannan Jiang. Power analyses indicated that a total sample size of 366 would have 80% power under the same conditions as the original calculation; group sample sizes of 183 and 183 achieve 80% power to reject the null hypothesis of equal means when the population mean difference is 0.5 with a standard deviation for both groups of 1.7 and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test.

The target sample size was therefore revised to 366 which was achieved in November 2016. Study follow up was completed in July 2017. No other major deviations from the published protocol were made.

CHAPTER 8. A RANDOMISED CONTROLLED TRIAL OF A TEXT MESSAGE-BASED DIABETES SELF-MANAGEMENT SUPPORT PROGRAMME (SMS4BG)

8.1. Preface to the chapter and publication

The aim of Chapter 8 is to determine the effectiveness of SMS4BG among adults with poorly controlled diabetes in a RCT. This is presented in two parts, the first in Sections 8.2 through 8.8, in the form of a manuscript, which has been submitted for publication. This was initially submitted to Lancet Diabetes & Endocrinology but is now under review with the BMJ. Minor changes to formatting have been made to the submitted manuscript to ensure consistency across the thesis. The second part presents additional results not included in the manuscript in section 8.9 through 8.10.

The chapter contributes to the following thesis objective:

4. Assess the acceptability and effectiveness of an mHealth self-management support intervention.

Supporting documents associated with this chapter can be found in Appendix 6 including a copy of the CONSORT checklist.

Why was this work needed?

Findings from the pilot study showed that SMS4BG was acceptable and perceived as useful by people with diabetes although the effectiveness still needs to be proven in a rigorously conducted trial. Evidence of the effectiveness of the SMS4BG intervention can provide decision makers, providers, and funders with the information needed to inform potential implementation of the programme. A pragmatic community-based RCT would not only provide the required evidence of the effectiveness of the SMS4BG intervention in comparison to usual care but, if found to effective, provides valuable information about scaling up and implementation of the programme.

What was undertaken?

A two-arm, parallel, randomised controlled trial was conducted across New Zealand. Three hundred and sixty six participants were randomised at a 1:1 ratio to receive the SMS4BG programme (intervention) in addition to usual care, or usual care alone (control). Participants completed baseline interviews and follow up interviews 9 months later. HbA1c results were obtained from medical records at 3, 6 and 9 months.

Publication citation:

Dobson R, Whittaker, R. Jiang, Y. Shepherd, M. Maddison, R. McNamara, C. Cutfield, R. Khanolkar, M. Murphy, R. A randomised controlled trial of a text message-based diabetes self-management support programme (SMS4BG). *Submitted to BMJ*.

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Contribution by the candidate:

The candidate along with co-authors contributed to the study concept, design, and procedures. She gained ethical approval for the study. The candidate recruited participants, completed baseline assessments, randomised participants, and completed follow up assessments with the help of study Research Assistants Hannah Bartley, Rachel Sullivan, Anne Duncan and Gillian Lockhart. The candidate administered and monitored the SMS4BG intervention with support from the Michelle Jenkins and NIHI's IT team. The candidate cleaned the data and analysed the engagement and feedback on the intervention. The analysis of primary and secondary outcomes was performed by co-author Yannan Jiang. The candidate, with input from the co-authors, wrote the manuscript.

A randomised controlled trial of a text message-based diabetes self-management support programme (SMS4BG)

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8.2. Abstract

Background: With the growing global burden of poorly controlled diabetes there is a need for low cost and scalable methods to support diabetes self-management in order to prevent costly and debilitating long term complications. A theoretically based and individually tailored text message intervention (SMS4BG) was designed to motivate and support a person to engage successfully in the behaviours required to manage their diabetes effectively.

Methods: A 9-month, two-arm, parallel, randomised controlled trial was conducted in New Zealand to assess the effectiveness of SMS4BG among adults with poorly controlled diabetes (HbA1c≥65mmol/mol). Participants recruited through primary and secondary care were randomised to receive SMS4BG (intervention) in addition to usual care, or usual care alone (control). The primary outcome was HbA1c. Secondary outcomes included self-efficacy, self-care behaviours, diabetes distress, health-related quality of life, perceived support, and intervention acceptability at 9 months.

Findings: 366 participants were randomised to intervention (n=183) or control (n=183). At 9 months HbA1c was significantly lower in the intervention group compared with the control group (-4.23mmol/mol, 95%CI [-7.30, -1.15], p=0.01). High levels of satisfaction with SMS4BG were found with intervention participants reporting it to be useful (95%), culturally appropriate (97%), and would recommend the programme to other people with diabetes (97%).

Interpretation:

This study found that a tailored text-message based self-management support programme was effective at improving HbA1c in adults with poorly controlled diabetes providing support for the implementation of SMS4BG to supplement current practice.

Funding:

Health Research Council of New Zealand; New Zealand Ministry of Health; Waitemata & Auckland District Health Boards.

Trial registration:

Australian New Zealand Clinical Trials Registry: ACTRN12614001232628

8.3. Background

The growing prevalence of diabetes is considered to be one of the biggest global health issues.(15) People of ethnic minority, including Pacific and Māori (New Zealand indigenous population), are particularly vulnerable to the development of diabetes, experience poorer control, and increased rates of complications.(19-23) In New Zealand it has been found that 29% of patients with diabetes (including 43% of Māori and 50% of Pacific people with diabetes) have HbA1c levels indicative of poor control (≥65mmol/mol) putting them at risk for the development of debilitating and costly complications.(18) Addressing the increasing burden of diabetes as well as the associated health disparities is a priority in the care of people with diabetes.

Diabetes complications can be prevented or delayed with good blood glucose control, which is not only advantageous for a person's quality of life but will substantially decrease healthcare costs associated with treating or managing the complications.(5, 10-13) Therefore, stabilising blood glucose levels or achieving good glycaemic control is one of the primary goals of diabetes management. To achieve good control, significant engagement from patients and their healthcare providers is needed with diabetes being one of the most demanding chronic conditions both behaviourally and psychologically. Successful diabetes management involves managing medical responsibilities including blood glucose monitoring, medication adherence, and insulin administration alongside engaging in health behaviours around diet and physical activity. The flexibility of mobile phones and their adoption into everyday life mean they are an ideal tool in supporting people with diabetes whose condition requires constant management.

Although there is growing support for the use of mobile health (mHealth) in diabetes and evidence for high technology access across cultural and societal groups,(81, 82) there is increasing evidence of a digital divide with lower use of technologies in those that have low health literacy, low income, and members of ethnic minorities.(83-88) Contributing factors include low technology literacy, mismatch between individual needs and the available tools, lack of local information, cost, literacy and language barriers, and lack of cultural appropriateness.(89) For mHealth tools to be used to address the issue of poor diabetes control they need to be designed to the needs and preferences of those that need greatest support by considering these factors.

The SMS4BG intervention was developed to address the need for innovative solutions to support self-management in adults with poorly controlled diabetes.(198) The individually tailored intervention provides information and support designed to motivate a person to engage in the behaviours required to manage their diabetes effectively for long term health improvement. The development of SMS4BG followed the mHealth Development and Evaluation Framework(141) including extensive formative work and end-user engagement to ensure it met the needs of the population it was designed to reach, is evidence based, and theoretically grounded. A pilot study found SMS4BG to be acceptable and perceived as useful,(198) but its effectiveness is not known.

This study aimed to determine the effectiveness of the mHealth diabetes self-management support programme - SMS4BG in adults with poorly controlled type 1 or type 2 diabetes, in addition to their usual diabetes care.

8.4. Methods

8.4.1 Study Design

A 9-month, two-arm, parallel, RCT was conducted in adults with poorly controlled diabetes between June 2015 and August 2017. The study received ethical approval from the Health and Disability Ethics Committee (14/STH/162), and the protocol was published,(208) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614001232628). Trial development and reporting was guided by the CONSORT (110) and CONSORT EHEALTH (201) statements (see Appendix 1 for the CONSORT checklist).

8.4.2 Participants

Participants were referred to the study by healthcare professionals at their primary and secondary care centres across New Zealand. Additionally, potential participants could self-refer to the study by contacting the research team directly. Primary care practices with high Māori and Pacific populations were particularly targeted. Eligible participants were English speaking adults aged 16 years and over with poorly controlled type 1 or 2 diabetes (defined for this study as an HbA1c ≥65mmol/mol in the preceding 9 months). Participants required access to a mobile phone and needed to be available for the 9 month study duration.

8.4.3 Randomisation and masking

Eligible participants were randomised to either intervention or control group in a 1:1 ratio. Randomisation was stratified by health district category (high urban or high rural/remote), diabetes type (1 or 2), and ethnicity (Māori & Pacific, or non-Māori & non-Pacific). The randomisation sequence was generated by computer programme using variable block sizes of 2 or 4, and overseen by the study statistician (YJ). Following participant consent and completion of the baseline interview, the Research Assistant then randomised the participant to intervention or control, using the REDCap™ randomisation module. The treatment allocation was concealed until the point of randomisation. Due to the nature of the intervention, participants were aware of their treatment allocation. Research staff conducting the phone interviews covering secondary outcomes were also aware of the treatment allocation. However, the objective primary outcome was measured by blinded assessors throughout the study period.

8.4.4 Procedures

Eligible participants completed informed consent followed by baseline assessment over the phone with a trained researcher prior to randomisation. All participants continued with their usual diabetes care including all medical visits, tests, and diabetes support programmes. In addition, the

intervention group received the automated text message-based self-management support programme (SMS4BG) for up to 9 months. All participants completed a follow up phone interview at 9 months (± 3 weeks) post-randomisation and underwent regular HbA1c blood tests through standard care.

8.4.5 Intervention

SMS4BG is a self-management support programme delivered by SMS to motivate and support a person to engage in the behaviours needed for successful management of the condition. The programme was tailored according to the needs and goals of the individual, and demographic factors including ethnicity. As well as core motivational and support messages (available in Māori, Pacific and non-Māori/Pacific cultural versions), participants could opt to receive additional modules (a summary of the modules can be seen in Table 22). All messages were delivered in English although the Māori version included key worked in Te Reo Māori and the Pacific version key words in either Samoan or Tongan dependent on participant ethnicity.

Participants could choose to receive blood glucose monitoring reminders which they could reply to by sending in their result by text message. They could then view their blood glucose levels graphically over time on a password protected website. If at baseline they were identified as not having access to the internet they were mailed their graphs on a monthly basis. Participants were able to select the timing of their messages and blood glucose monitoring reminders, and identify the names of their support people and motivations for diabetes management for incorporation into the messages. The duration of the programme was also tailored to individual preferences; at 3 and 6 months, participants received a text message asking if they would like to continue the programme for an additional 3 months and were given the opportunity to re-select their modules receiving up to a maximum 9 months of messages. Participants could stop their messages at any time by texting the word ‘STOP’ or put their messages on hold for one week by sending the text ‘HOLIDAY’.

The message delivery was managed by a specifically developed SMS4BG Content Management System with the messages sent and received through a gateway company to allow for participants to be registered with any New Zealand mobile network. Sending and receiving messages was free to all participants with costs covered by the study. The system maintained logs of all outgoing and incoming messages. Further details of the intervention and its development can be seen in the published pilot study,(198) and protocol(208) papers.

Table 22: Description of the SMS4BG modules and example text messages

Module	Description	Example messages
Core module	Two messages per week providing general motivation and support for diabetes management. Available in 3 versions: - Māori - Pacific - Non-Māori/Non-Pacific	SMS4BG: Kia ora. Control of your glucose levels involves eating the right kai, exercise & taking your medication. Your whānau, doctor & nurse can help you
		SMS4BG: Talofa [name]. by managing your diabetes well (including eating well and exercising) you can show your family that diabetes can be controlled
		SMS4BG: There is no quick fix to diabetes but with good management it will have less impact on your life and leave you more time to do the things you enjoy
Insulin module	One educational text message per week around insulin management and hypos for people receiving insulin	SMS4BG: Keep unopened insulin in the fridge. Don't use insulin that has changed colour, is lumpy, expired, cracked or leaking, or has been frozen or too hot
Young adult module	One message per week around managing diabetes in the context or work/school and social situations. Designed for people aged 16-24 years	SMS4BG: Unsure whether to tell your friends/boyfriend/girlfriend about diabetes? This can be tough but people who care about you will want to know & support you
Smoking cessation module	One message per month encouraging participants to consider quitting smoking and providing details of services for support. Designed for people who are current smokers.	SMS4BG: [hi] [name]. Good management of your diabetes & your future health includes not smoking, call Quitline on 0800 778 778 for support
Lifestyle behaviour modules	Up to 4 messages per week encouraging participants to set a lifestyle goal and supporting them to work towards this goal. Participants can receive one of these modules at a time. The three lifestyle modules are: Healthy eating, Exercise, and Stress and mood.	SMS4BG: Healthy eating is an important part of your diabetes treatment and it will help you in controlling your blood glucose levels
		SMS4BG: If you are too tired to exercise at the end of the day, try waking up early & doing your exercise in the morning. It will energise you for the day
		SMS4BG: [hi] [name]. Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood
Blood glucose monitoring	Reminders to test blood glucose, sent at a frequency selected by the individual, for which they are encouraged to respond by reply text message with their blood sugar readings. Also informational messages around managing hypos.	SMS4BG: [hi] [name]. Just a reminder it is time to check your blood glucose. Reply with the result
		If valid response received to reminder, "SMS4BG: Thank you for sending your result"
		SMS4BG: Hypoglycaemia (hypos) are when your blood glucose drops too low (i.e. less than 4mmol/L). If this happens take something with sugar immediately
Foot care module	Reminders and motivational messages supporting engagement in foot care. Designed for those that are high risk or have active foot disease.	SMS4BG: Looking after your feet will help to prevent issues in the future. Check your feet daily & contact your doctor, nurse or podiatrist if there are changes
Cardiovascular check reminder	Reminder to engage in a yearly cardiovascular assessment	SMS4BG: [hi] [name]. Next time you see your doctor ask about getting a cardiovascular check done. You should have one each year.

8.4.6 Outcome measures

Primary outcome

The primary outcome measure was glycaemic control at 9 months, measured as HbA1c (in mmol/mol, or equivalently in %).

Secondary outcomes

Secondary outcome measures included glycaemic control as measured by HbA1c at 3 months and 6 months, and the following outcomes at 9 months post intervention: self-efficacy for diabetes

management as measured by the Stanford Self-efficacy for Diabetes scale (SEDM),(202) diabetes self-care behaviours (diet, exercise, blood glucose monitoring and foot care) as measured by the Summary of Diabetes Self-Care Activities (SDSCA) measure,(203) the presence of diabetes-related distress as measured by the 2-item Diabetes Distress Scale (DDS2),(204) cognitive and emotional representations of diabetes as measured by the Brief Illness Perception Questionnaire (BIPQ),(205) health related quality of life as measure by the EQ-5D (index score and visual analogue scale (VAS))(206) perceived social support for diabetes management measured using a measure developed for this study. In addition, cost-effectiveness was assessed as well as healthcare utilisation during the study period compared to the 9-months prior to randomisation (this will be reported in a separate paper). Patient satisfaction and engagement with SMS4BG (for those in the intervention group) was measured using semi-structured interviews and data from the SMS4BG content management system.

8.4.7 Statistical analysis

As published in the protocol, the initial recruitment target was 500 participants in each regional population (high urban and rural/remote). A total sample size of 500 participants (250 per arm) was estimated to provide 90% power at 5% significance level to detect a clinically meaningful group difference of 0.5% (5.5mmol/mol) in HbA1c at 9 months, assuming a standard deviation of 1.7% (18.6mmol/mol). Despite extensive efforts recruitment for the study was slower than expected raising concern that there would not be adequate referrals to the study within the proposed recruitment period to achieve the target sample. As a result, a post-hoc power calculation was conducted in September 2016. A revised sample size of 366 participants (183 per arm) was targeted, which would provide 80% power to detect the same effect size under the same assumptions. Although not ideal, we were confident that this sample size would still result in sufficient study power as considered in most other trials

Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc. Cary NC). All statistical tests were two-sided at a 5% significance level. Treatment evaluations were performed on the principle of intention to treat (ITT), including all randomised participants who provided at least one valid measure on the primary outcome post randomisation. Demographics and baseline characteristics of all participants were first summarised by treatment group using descriptive statistics. Continuous variables were summarised as mean and standard deviation (SD). Categorical variables were described as frequency and percentage. No formal statistical tests were conducted at baseline, as any baseline imbalance observed between two groups could have occurred by chance with randomisation. The primary and secondary outcomes were summarised using descriptive statistics at each scheduled visit. Random effects mixed model was used to evaluate the effect of intervention on HbA1c at 3, 6, and 9 months, adjusting for baseline HbA1c and stratification factors and accounting for repeated measures over time. Model-adjusted mean differences in HbA1c between two groups were estimated at each visit, by including an interaction term between treatment and month. Missing data on the primary outcome were taken into account in modelling based on the missing at random assumption. Both 95% confidence interval and p-value were reported. The size of treatment effects were also compared between important

subgroups considered in stratification, including type of diabetes (type 1 and 2), ethnicity (Māori/Pacific and non-Māori non-Pacific), and region (urban and rural). For other secondary outcomes measured at 9 months post intervention, generalised linear regression models were used with same covariate adjustment using a link function appropriate to the distribution of outcomes. Model-adjusted estimates on the treatment difference between two groups at 9 months were reported, together with 95% confidence intervals and p-values. No imputation was considered on secondary outcomes.

8.4.8 Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

8.5. Results

A total of 793 individuals were referred to the study and assessed for eligibility between June 2015 and November 2016. Of these, 366 were randomised to the intervention (n=183) and control (n=183) groups (see Figure 19). Nine-month follow up assessments were completed in August 2017 with the loss to follow-up (no follow up data on any outcome) rate low in both groups (overall 7/366=2%). A total of 12 participants (6 in intervention group and 6 in control group) were excluded from the primary outcome analysis due to no follow up HbA1c results post randomisation.

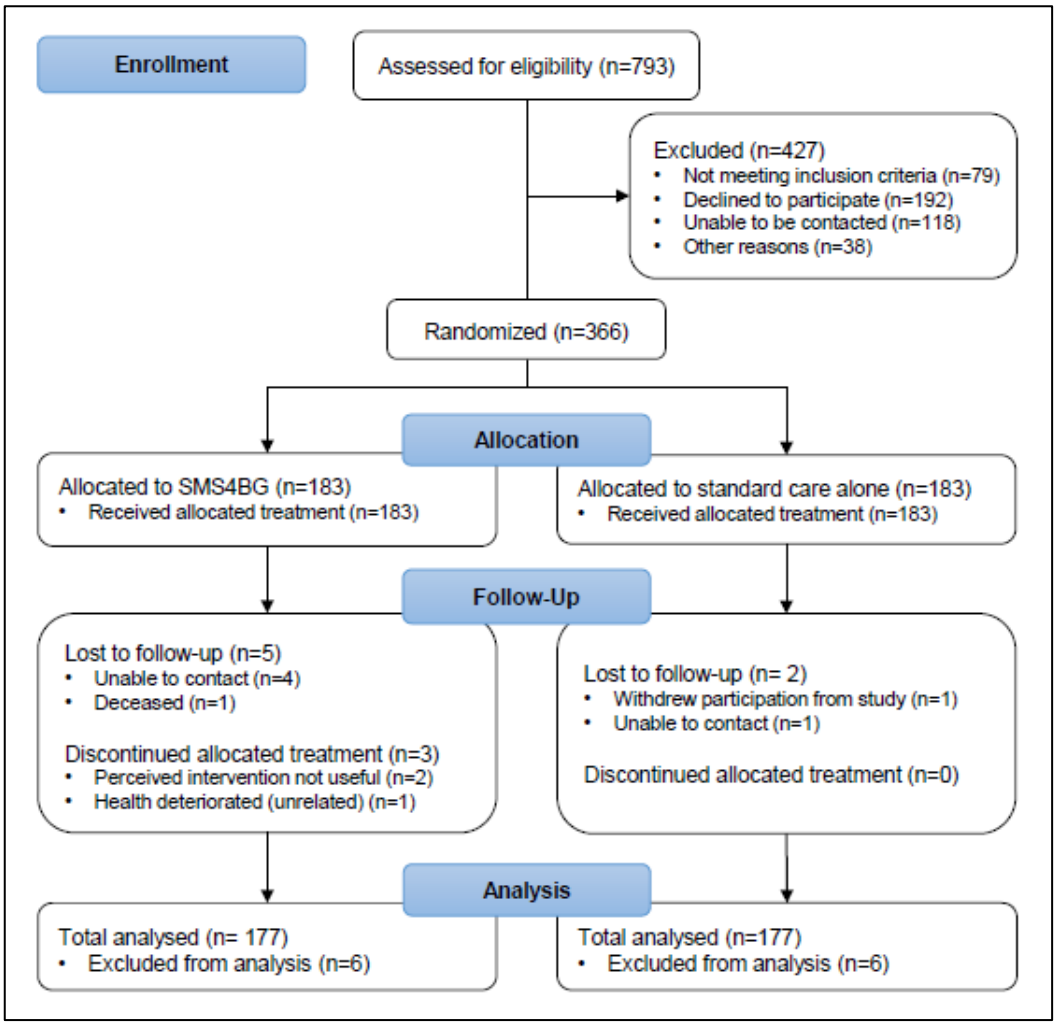

Figure 19: Trial registration flow chart

Participants predominantly had type 2 diabetes (n=237, 65%), lived in urban areas (n=242, 66.12%), with a mean age of 47 years (range 16-80 years) (Table 23). Approximately half (n=181, 49.45%) were of New Zealand European descent and 132 (36.07%) were Māori or Pacific. The majority, 287 (78.42%), were on insulin for their diabetes (intervention group = 142 (77.60%), control group = 145 (79.23%)), and the majority, 302 (82.51%), were non-smokers (intervention group=154 (84.15%), control group=148 (80.87%)). At baseline 42% (76/183) of intervention participants, and 35% (64/183) of control participants had HbA1c levels at baseline greater than or equal to 86mmol/mol. There were no adverse events from the study or protocol deviations.

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Table 23: Baseline characteristics of participants

Characteristic	Intervention group (N=183)		Control group (N=183)	
	n	%	n	%
Gender: Male	92	50.3	97	53.0
Ethnicity				
Māori	37	20.2	46	25.1
Pacific	29	15.9	20	10.9
Asian	8	4.4	12	6.6
New Zealand European	93	50.8	88	48.1
Other	16	8.7	17	9.3
Ethnicity category				
Māori/Pacific	66	36.1	66	36.1
non-Māori/non-Pacific	117	63.9	117	63.9
Diabetes type				
Type 1	65	35.5	64	35.0
Type 2	118	64.5	119	65.0
Location				
High urban	125	68.3	117	63.9
High rural/remote	58	31.7	66	36.1
Smoking status				
Smoker	29	15.9	35	19.1
Non-smoker	154	84.2	148	80.9
Treatment: Insulin	142	77.6	145	79.2
Referral source				
Primary care	72	39.3	77	42.1
Secondary care	106	57.9	105	57.4
Self-referred	5	2.7	1	0.6
Age grouping				
16-24 years	25	13.7	21	11.5
25-49 years	66	36.1	65	35.5
50-64 years	73	39.9	77	42.1
≥65 years	19	10.4	20	10.9
Age (years), mean (SD)	47 (15)		47 (15)	
Time since diagnosis (years), mean (SD)	13 (11)		12 (9)	

SD: Standard deviation

8.5.1 Primary outcome

The main treatment effect on the primary outcome is presented Table 24. At 9 months HbA1c was significantly lower in the intervention group compared with the control group (adjusted mean difference,-4.23 [95%CI,-7.30, -1.15], p=0.01).

Table 24: Treatment effect on HbA1c (mmol/mol) at follow up visits

	Intervention		Control		Adjusted Mean difference (95% CI)[1]	P value for difference
	Mean	SD	Mean	SD		
Baseline	86.4	17.8	83.3	14.8		
3 months	77.7	18.5	79.6	17.6	-4.76 (-8.1, -1.43)	0.0053
6 months	76.4	20.5	79.8	17.2	-2.36 (-5.75, 1.04)	0.1729
9 months	76.8	18.3	78.7	17.3	-4.23 (-7.30, -1.15)	0.0072

[1]Random effects mixed model has adjusted for baseline outcome, diabetes type, ethnicity and region. Both treatment group and visit were included in the model with their interaction term. A random subject effect was added to account for repeated measures on same participant.
SD – standard deviation. CI – confidence interval.

A decrease in HbA1c from baseline to 9 month follow up was observed in 75% of intervention participants compared to 61% of control participants (Chi-square test, p=0.01). At 9 months 28% of participants in the intervention group and 18% in the control group achieved the HbA1c target of below 65mmol/mol (p=0.04). Among them 6% of intervention participants and 5% of control

participants whose HbA1c levels dropped below 53mmol/mol indicative of good diabetes control (p=0.75).

Subgroup analyses showed significant treatment effects on HbA1c at 9 months, for type 1 diabetes patients (-5.75 [95%CI,-10.08, -1.43], p=0.01), non-Māori/non-Pacific people (-4.97 [95%CI,-8.51, -1.43], p=0.01), and those living in high urban areas (-4.54 [95%CI,-8.40, -0.68], p=0.02). No significant treatment effects were detected for type 2 diabetes patients, Māori/Pacific, and those living in high rural/remote areas (Table 25).

As seen in Table 24 and Table 25, a significant treatment effect was also seen at 3 months across all participants, those with type 1 diabetes, non-Māori/non-Pacific people, and those living in high urban areas. No significant treatment effects were seen at 6 months.

Table 25: Treatment effect on HbA1c (mmol/mol) at follow up visits, by key subgroups

		Intervention		Control		Adjusted Mean difference (95% CI)[1]	P value for difference
		Mean	SD	Mean	SD		
Diabetes type							
Type 1	Baseline	87.6	19.0	82.6	12.3		
	3 months	80.6	19.8	82.5	17.8	-7.67 (-12.45, -2.88)	0.0019
	6 months	80.4	22.7	80.3	15.1	-1.05 (-5.92, 3.82)	0.6703
	9 months	78.4	17.5	81.4	16.4	-5.75 (-10.08, -1.43)	0.0094
Type 2	Baseline	85.7	17.2	83.6	16.0		
	3 months	76.2	17.7	78.0	17.4	-3.42 (-7.82, 0.98)	0.1275
	6 months	74.0	18.9	79.5	18.2	-3.32 (-7.80, 1.16)	0.1459
	9 months	75.9	18.8	77.2	17.7	-3.64 (-7.72, 0.44)	0.0803
Ethnicity							
Māori/ Pacific	Baseline	91.1	20.0	85.2	13.6		
	3 months	81.2	19.9	82.0	18.3	-5.36 (-1180, 1.07)	0.1018
	6 months	82.3	25.2	82.3	18.4	-0.77 (-7.31, 5.78)	0.8175
	9 months	83.4	21.8	81.0	19.5	-3.21 (-9.11, 2.70)	0.2848
non-Māori/ non-Pacific	Baseline	83.7	16.0	82.2	15.4		
	3 months	75.8	17.5	78.5	17.3	-4.50 (-8.33, -0.67)	0.0213
	6 months	73.6	17.5	78.3	16.4	-3.29 (-7.19, 0.61)	0.0982
	9 months	73.0	14.9	77.5	16.0	-4.97 (-8.51, -1.43)	0.0061
Location							
High rural/ remote	Baseline	85.2	18.9	83.1	17.1		
	3 months	80.0	17.7	80.3	14.5	-1.34 (-6.89, 4.21)	0.6336
	6 months	75.4	23.6	78.0	16.3	0.14 (-5.53, 5.80)	0.9622
	9 months	75.1	18.2	76.8	13.4	-3.94 (-9.00, 1.12)	0.1263
High urban	Baseline	86.9	17.4	83.4	13.3		
	3 months	76.7	18.9	79.2	19.1	-6.53 (-10.69, -2.37)	0.0022
	6 months	76.8	19.2	80.7	17.7	-3.62 (-7.84, 0.60)	0.0925
	9 months	77.6	18.4	79.8	19.1	-4.54 (-8.40, -0.68)	0.0214

SD: Standard deviation; CI: Confidence Interval.
[1] Random effects mixed model has adjusted for baseline outcome, diabetes type, ethnicity and region. Both treatment group and visit were included in the model with their interaction term. A random subject effect was added to account for repeated measures on same participant.

8.5.2 Secondary outcomes

The main effect of the intervention on other secondary outcomes measured at 9 months are presented in Table 26. A statistically significant improvement in foot care behaviour was seen in the intervention group compared with the control group (adjusted mean difference, 0.85 [95% CI 0.40, 1.29], p=0.0002). There was also a significant improvement in how supported the participants felt in relation to their diabetes management between the intervention and control groups (adjusted mean difference, 0.26 [95% CI 0.03, 0.50], p=0.0303).

There was no significant group difference in quality of life index score as measured by the EQ-5D, however, a significant improvement in health status on the EQ-5D VAS (visual analogue scale) was observed in favour of the intervention (adjusted mean difference, 4.38 [95% CI 0.44, 8.33], p=0.0294). No significant differences were observed for all other outcomes.

Table 26: Treatment effect on other secondary outcomes. Values are mean (SD) unless stated otherwise.

	Intervention		Control		Adjusted Mean difference (95% CI)[1]	P value for difference
	Baseline	9 months	Baseline	9 months		
SEDM: Self-efficacy	6.9 (1.5)	7.6 (1.3)	6.9 (1.7)	7.4 (1.5)	0.11 (-0.13, 0.36)	0.3598
SDSCA: General diet	4.3 (2.0)	4.9 (1.8)	4.4 (2.1)	5.0 (1.8)	-0.10 (-0.45, 0.25)	0.5840
SDSCA: Specific diet	3.8 (1.4)	4.3 (1.4)	3.9 (1.6)	4.2 (1.4)	0.09 (-0.18, 0.36)	0.5040
SDSCA: Exercise	3.1 (2.1)	3.5 (2.0)	3.3 (2.3)	3.5 (2.2)	0.06 (-0.35, 0.48)	0.7625
SDSCA: BG test	4.4 (2.6)	4.8 (2.6)	4.2 (2.7)	4.9 (2.5)	-0.13 (-0.58, 0.33)	0.5937
SDSCA: Foot care	1.9 (2.2)	2.7 (2.5)	2.0 (2.2)	1.9 (2.1)	0.85 (0.40, 1.29)	0.0002
DDS2: Distress	3.4 (1.5)	3.0 (1.5)	3.4 (1.5)	3.3 (1.6)	-0.18 (-0.45, 0.10)	0.2056
Support	4.8 (1.4)	5.1 (1.1)	4.9 (1.3)	4.9 (1.2)	0.26 (0.03, 0.50)	0.0303
EQ-5D: QOL Index	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)	0.00 (-0.03, 0.04)	0.8081
EQ-5D: QOL Health status VAS	66.2 (19.0)	73.2 (19.9)	70.0 (19.9)	70.0 (19.5)	4.38 (0.44, 8.33)	0.0294

SEDM: Self efficacy for diabetes management; SDSCA: Summary of Diabetes Self-Care Activities; DDS2: Diabetes Distress Scale 2-item; QOL; Quality of life; VAS: Visual analogue scale; SD: Standard deviation; CI: Confidence interval.
[1] Linear regression model has adjusted for baseline outcome, diabetes type, ethnicity and region

8.5.3 Participant satisfaction and acceptability

Among the 183 intervention participants, 169 (92%) completed questions in the follow up interview about satisfaction and the acceptability of the intervention (see Table 27). Participants reported high levels of satisfaction with SMS4BG; the overwhelming majority reported SMS4BG to be useful (161; 95%), culturally appropriate (164; 97%), age appropriate (166; 98%), and would recommend the programme to other people with diabetes (164; 97%). When asked to rate how useful the messages were on a scale from 0 (not at all useful) to 5 (extremely useful) the mean rating was 4.01 (SD 1.17). All but two participants (167; 99%) thought that text messaging was a good way to deliver this type of support.

The majority of participants reported that receiving the SMS4BG programme helped them learn about their diabetes (120; 71%) and impacted on how they manged their diabetes or helped them change their behaviours (140; 83%). Specifically as a result of the programme, 128 (76%) reported they thought their overall blood glucose control had improved, 111 (66%) reported they had increased how often they monitored their blood glucose, 99 (59%) reported their diet or eating had improved, 70 (41%) reported their level of exercise had improved, and 85 (50%) reported that their mood had improved. Of the 26 participants who received the smoking module, 5 (19%) reported that they had quit smoking as a result of the programme.

Table 27: Intervention satisfaction and acceptability results (n=169)

Question	Response yes n (%)
Was SMS4BG useful?	161 (95%)
Were the messages culturally appropriate?	164 (97%)
Were the messages age appropriate?	166 (98%)
Would you recommend SMS4BG to others with diabetes?	164 (97%)
Did you share the messages with any other people?	85 (50%)
Did taking part in this programme help you learn about your diabetes?	120 (71%)
Did taking part in this programme impact on how you manage your diabetes or help you change your behaviours?	140 (83%)

Participants were asked what they thought of the number of messages they received, 129 (76%) reported that they thought it was the right number, 34 (20%) reported they received too many messages and the remaining would have preferred more messages. There were ten participants who reported technical issues while receiving the SMS4BG intervention, the most common issues were issues replying to the messages (n=4), issues accessing graphs (n=2), and mobile reception issues (n=2).

8.5.4 Participant engagement

Due to individual tailoring, intervention participants received varying numbers of messages during the programme. Half of the participants received messages for 3 months, an additional 18% chose to continue the messages for a total of 6 months and the remaining 22% chose to continue the messages to the maximum duration of 9 months. Only three participants chose to stop their messages early. Table 28 presents a breakdown of the modules that the participants received.

Table 28: Participants choice of SMS4BG modules (n=183)

Module	N (%)
General module:	183 (100%)
Māori	21 (11%)
Pacific	15 (8%)
Non-Māori/non-Pacific	147 (80%)
Insulin module	76 (42%)
Young adult module	15 (8%)
Smoking module	26 (14%)
Foot care module	29 (16%)
Cardiovascular check reminder	183 (100%)
Lifestyle modules	
Exercise	89 (49%)
Healthy Eating	128 (70%)
Stress	90 (49%)
No lifestyle module	10 (5%)
Blood glucose monitoring modules	121 (66%)

A total number of 76,523 messages were sent by the system to intervention participants (median per participant: 242; IQR: 122-511; range: 14-2050), and a total of 16,251 blood glucose results were sent into the system by participants receiving the reminders (median per participant: 68; IQR: 1-169; range: 0-917).

8.6. Discussion

This study found that a tailored theoretically based SMS diabetes self-management support programme led to significant improvements in glycaemic control. Significant improvements in foot care behaviour and ratings of diabetes support were also seen in intervention participants compared with control group participants. There was a high level of acceptability of the intervention with the overwhelming majority finding the intervention useful, culturally appropriate, and would recommend it to others.

It is well documented that any decrease in HbA1c is likely to be associated with a decrease in the risk of diabetic complications.(9) In a less ethnically diverse population of people with type 2 diabetes a decrease in HbA1c of 1% (11mmol/mol) has been found to result in declines in microvascular complications of 37%, myocardial infarction of 14%, and risk of death by 21%.(9) With over 75% of intervention participants experiencing a decrease in HbA1c at 9 months with a mean reduction in HbA1c of approximately 10mmol/mol from baseline, and a statistically significant group difference of 4mmol/mol in favour of the intervention, the results seen in this study have potential to be clinically relevant.

In particular, those who live rurally, are Māori or Pacific, or have type 2 diabetes, are those who we would particularly wish to support to manage their diabetes. Although non-significant, a positive difference between groups was seen in each of these subgroups, as well as positive feedback about the programme, indicating that the programme was worthwhile. Small sample sizes in the sub-groups resulting in inadequate power for sub-group analyses could be a factor in the lack of significance.

This study adds to the growing evidence supporting the use of SMS to support diabetes management.(64, 68, 72) The improvements in HbA1c seen in this study are similar to those reported in meta-analyses of SMS interventions in diabetes not limited to those with poor control.(67, 68, 99) This provides evidence to support the use of this modality to provide diabetes education and support to those with poor control. Guidelines for diabetes management typically recommend diabetes education interventions are provided soon after diagnosis.(152) With the sample in the current study having a mean diabetes duration of 12 years (range 0 to 62 years) our results suggest diabetes education delivered through SMS can engage people at any stage of their diabetes trajectory and positively impact on outcomes.

Previous research investigating diabetes management interventions in people with type 2 diabetes has reported that trials with larger sample sizes (>100) compared to smaller sample sizes, find smaller effect sizes.(64, 209) Unlike previous studies that typically study a particular population defined by diabetes type, age, or treatment, the current study provided an intervention for all adults with either type 1 or type 2 diabetes under any treatment regimen making the potential reach greater and enhancing generalisability. The only limit on the population was the requirement that participants had poor diabetes control. This is particularly important given associated costs and debilitating complications of poorly controlled diabetes. Few trials to date have examined the effectiveness of mHealth interventions in this group.

Improvements were seen in all secondary outcomes in the intervention group and although the majority of these did not achieve statistical significance compared to the control group the results are encouraging. The development of SMS4BG was informed by the Social Cognitive Theory and therefore it would have been expected that improvements in self-efficacy would have been seen in the intervention group. The intervention group did experience increased self-efficacy from baseline to follow up but this was not statistically significant when compared with the control group.

The control group also experienced a decrease in HbA1c from baseline to 9 month follow up and experienced improvements in secondary outcomes, which could indicate trial effects. Previous research has shown that recruitment to a clinical trial alone can result in improvements in HbA1c,(210) but it is not expected that these would be sustainable past the initial few months without intervention. There is potential that the type of support provided by the contact and assessment involved in the baseline and follow up interviews was of particular significance to this population resulting in these effects but it is clear that SMS4BG provided significant benefit over and above these effects.

8.6.1 Strengths

Strengths of the current study included its adequate sample size, diverse population, low loss to follow up, pragmatic design, absence of protocol violations, and objectively measured primary outcome. Although the initial sample size target was not reached the final sample of 366 is larger than previous randomised controlled trials in this area. This study contributes valuable evidence to the literature on the use of text messages in diabetes particularly for those with poor control. Considering poorer outcomes are experienced by ethnic minority groups particularly Māori and Pacific peoples, a strength of this study was its high proportion of participants representing these groups. A key strength of the current study is its pragmatic design and implementation focus, this means that it will likely be easy to implement into current practice now the trial is complete.

Strengths of the SMS4BG intervention are that it was theoretically based, the information reinforced messages from standard care, it was system initiated, personally tailored, and utilised simple technology. These strengths result in high relevance to diverse individuals increasing its reach and acceptability. Previous diabetes SMS programmes have largely focused on specific groups e.g. type 1 or older adults, limiting their generalisability. Furthermore, the SMS4BG intervention was tailored and personalised to the individual. Although this results in a more complex intervention in relation to its delivery, it appears that this is a worthwhile endeavour with high satisfaction with the intervention and the majority of participants happy with their message dosage. Similarly, nearly all participants reported the intervention to be culturally appropriate providing support for the additional work in creating the cultural versions of the programme.

8.6.2 Limitations

The biggest limitation of this study was the difficulty with recruitment, which resulted in a sample size smaller than initially planned. Although the final sample size still gave us adequate power to determine the effectiveness of SMS4BG on the primary outcome, it did not allow us adequate

power for the planned sub group analyses in particular the effectiveness of SMS4BG in Māori and Pacific peoples, as well as people living rurally. A key factor in the low recruitment to the study was the required time on the part of the clinician, something that wasn't always available. Furthermore, there were a number of referred patients who did not meet the HbA1c inclusion criteria; this occurred because clinicians referred patients as they felt they would benefit from the programme. This highlights the difference between research and implementation where strict criteria can be relaxed. In addition to systems being put in place within clinical settings to facilitate the uptake of this type of intervention, alternative methods of recruitment could be explored such as through laboratory test facilities or pharmacies to ensure patients can access the intervention regardless of clinician availability.

Due to time restrictions, longer term follow up of participants was not feasible within the current study. Ascertaining whether the improvements in HbA1c are sustainable over the long term is essential and it is hoped that a 2-year follow up of the participants in this study will be possible in the future. Although the sustainability of the impacts of SMS4BG are unknown, the significant group difference seen at 3 months, dropping slightly at 6 months before reaching significance again at 9 months could be an indication of sustained change.

Another limitation of the study design was that secondary outcome assessors were not blinded to treatment allocation, which could have introduced bias in follow up data collection of secondary variables.

8.6.3 Implications

This study shows the potential of SMS4BG to provide a low-cost, scalable solution for increasing the reach of diabetes education and self-management support for those in need. The nature of diabetes requiring daily management means ongoing support between clinic visits is often needed. As was seen in this study, a text messaging programme can increase a patient's feelings of diabetes support without the need for personal contact from a health care professional. The benefits of diabetes self-management education are well established,(151, 152) but these are typically delivered using resource intense methods (such as face-to-face contact). With current diabetes management education services differing across New Zealand, SMS4BG allows for consistent support to be easily provided across the country.

The reach to the wider family of this type of intervention must also be mentioned. In this trial 50% of participants reported sharing the messages with others. Traditional diabetes self-management education and support is delivered to individual patients but there is benefit of key support people being involved in this.(211) This is particularly pertinent to ethnic groups such as Māori whose family/whanau play an important role in supporting a person's diabetes self-management.(169) Not only can SMS4BG be shared with family and other support people there is the potential for the programme to be adapted for delivery to this group.

With technology advancing rapidly and the proliferation of smartphones there is potential for mHealth to move towards more complex interventions. This study has shown that text messaging, although simple, is effective for improving glycaemic control. Recruitment for this study was not

confounded by device specifications allowing anyone with a mobile phone to take part. Equally there were very few technical issues experienced in the current study, likely contributing to the high satisfaction with the intervention.

Although SMS4BG was designed for adults with poorly controlled diabetes much of the content, such as the lifestyle modules, is relevant to other populations including those at high risk for the development of diabetes or diagnosed with pre-diabetes. Therefore there is potential for SMS4BG to be adapted for other groups in the future.

The individual tailoring of the intervention and participants being able to choose varying intervention components and dosages means that we are unable to determine the ideal duration for implementation as well as the components most important for effectiveness. Further research is needed to understand the components of this intervention that are most effective and the ideal intervention dosage to further refine this intervention and the development of future interventions. With participants highly satisfied with the intervention they received and largely happy with their intervention dosage, but great variability in the modules, durations and dosages, it may be that SMS4BG must remain individually tailored resulting in a more complex intervention for delivery until further investigation on this can be made.

8.6.4 Conclusions

A tailored SMS based self-management support programme was effective at improving glycaemic control in adults with poorly controlled diabetes. Although the duration of these effects are yet to be determined, implementation of SMS4BG to supplement current practice is warranted.

8.7. Declaration of interests

The authors declare no conflicts of interest.

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8.9. Additional findings from the RCT

During the follow up interviews in the RCT, intervention participants were asked about their engagement with, and perceptions of, the SMS4BG intervention. The purpose of this was to provide further evidence of the acceptability of the SMS4BG intervention, how participants engaged with it, and suggestions for further improvement. Sections 8.5.3 and 8.5.4 presented the key results on the acceptability and engagement of participants with SMS4BG. The following section provides additional information not presented in the manuscript. Results presented in this section will be used to inform improvements to the programme, potential implementation, and the development of future mHealth interventions.

8.9.1 Methods

As outlined in the manuscript, a total of 169 (92%) of the intervention participants completed the questions on intervention feedback during the follow up interview (see Appendix 6 for questions) and therefore contributed to the data in this section (more detail of the methods and results can be seen in Sections 8.4 and 8.5). Counts and percentages were reported for categorical variables, and means and standard deviations for continuous variables. To determine whether ratings of usefulness differed between groups, independent sample t-tests and one way-ANOVAs were used. Inductive content analysis was used to analyse the additional qualitative data.(186) This involved open coding and identification of categories, grouping of categories, and abstraction. Frequency counts were computed to determine the number of responses in each category. Participant quotes are presented to provide examples and further context.

8.9.2 Results

Overall participants reported the programme to be useful, engaged highly with the programme, liked the messages, and enjoyed the positive and supportive nature of the programme. Participants were also very appreciative of the opportunity to take part in the study and keen to see the programme available to others, in many cases their family and friends.

> *"It was the most helpful thing I've ever done with trying to control my diabetes. Not remembering to test was my number one problem before. Just not being aware - forgetting that you have diabetes and making decisions without thinking. The messages not only remind you to test, but also helps you monitor how you are in that moment."*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

> *"They were really really good. Some of them I knew I had been told by my doctor but when you're in with them you know it and when you come out it's hard to remember so it was really good to get the reminder of things that I'd forgotten. Prior to the programme I was testing sporadically, throughout the programme just became more of a habit to always test"*
> (Female, 25-49yrs, Māori/Pacific, urban, T2D)

> *"I felt more in control of my diabetes and that flowed into other areas of my life where I felt more confident. It kept it at the forefront of my mind so it impacted everything. I didn't learn anything new, for me it was about behaviour modification and it worked. I would love it to continue."*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

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"Loved it, 10/10 It really made you know where your levels are at I became very lazy after having diabetes for 10 years and I wouldn't test, I just didn't pay attention to myself, the messages made me more aware/conscious of what you should be doing and whether you're doing it or not"
(Female, 50-64yrs, non-Māori/Pacific, rural, T2D)

"A great way of getting to people with diabetes, text is personal and comes to you, it gives you a better a chance to do well having someone there for you, you weren't on your own with it."
(Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

"I thought they were really good and really helpful, because it's like having your health professional there in your ear just reminding you, but you didn't have to ring them or see them, they were good and kept you focussed"
(Female, 50-64yrs, non-Māori/Pacific, urban, T1D)

"Absolutely fantastic. Constant reminders kept me honest. I'm a lot more educated because of the programme. My life got really busy with a new stressful job and so much else going on, the texts kept me on track with having to eat properly, test myself, and keep up with my meds."
(Male, 25-49yrs, Māori/Pacific, urban, T2D)

"It was a good programme. It would be great for anyone starting out or suffering from depression - it's like a life-line'. It helped me feel less alone/isolated, and gave me confidence. My family was also very involved, and it helped develop their understanding of my diabetes. My kids used to love getting the messages. They would read them out, and we did it together. The [use of] text messages meant that I could go back and re-read the messages, especially the ones that were most helpful for me."
(Female, 50-64yrs, non-Māori/Pacific, urban, T1D)

"'Stoked I could be a part of the programme, especially for someone my age, a lot of the diabetes support is aimed at older type 2's rather than young people"
(Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

"I highly recommend it, very worthwhile. I like that it's a proactive approach rather than an ambulance at the bottom of the cliff, it makes you take ownership of your diabetes now rather than waiting for the issues in the future."
(Male, 50-64yrs, non-Māori/Pacific, urban, T2D)

"'I think you guys are doing an awesome job. Hopefully the programme can get out there to other people like my brothers and sisters."
(Female, 50-64yrs, Māori/Pacific, rural, T2D)

Usefulness of the SMS4BG intervention

As presented in Section 8.53, when participants were asked to rate how useful the messages were on a scale from 0 (not at all useful) to 5 (extremely useful) the mean rating was 4.01 (SD 1.17). As can be seen in Table 29, mean ratings of usefulness were significantly higher in participants who had type 2 diabetes (4.25, SD=1.04) compared to type 1 diabetes (3.58, SD=1.28; $p<0.01$), and who were Māori or Pacific (4.36, SD=0.87) compared to non-Māori/non-Pacific (3.83, SD=1.26; $p=0.01$). Participants who lived rurally rated the programme just as useful as those who lived in urban areas.

Table 29: t-Test results for ratings of SMS4BG usefulness by ethnicity, location and diabetes type groupings

Variable	n	Mean	SD	t	p
Diabetes type					
Type 1	60	3.58	1.28		
Type 2	109	4.25	1.04	-3.67	<0.01
Ethnicity					
Māori	58	4.36	0.87		
Non-Māori/non-Pacific	111	3.83	1.26	2.87	0.01
Location					
Rural	53	4.06	0.95		
Urban	116	3.99	1.26	0.34	0.74

SD = Standard deviation
Scale: 0 (not at all useful) to 5 (extremely useful)

A one-way analysis of variance was conducted to evaluate the relationship between ratings of SMS4BG usefulness and intervention duration (3 months, 6 months, or 9 months). Statistically significant differences, ($F(2, 166) = 1.04$, P = 0.02) in ratings of perceived usefulness of SMS4BG were observed between people who had received the intervention for different lengths of time. Post-hoc analyses found that there was a significant difference between ratings of usefulness for those that received the intervention for 3 months (3.75, SD=1.37) and those that received it for 6 months (4.32 SD=0.75; p<0.05) with people receiving the programme for 6 months rating its usefulness higher than those who received it for 3 months. There were no significant differences between those that received the programme for 9 months (4.21, SD=0.97) and those that received it for 3 and 6 months.

Engagement with the SMS4BG intervention

To ascertain engagement with the programme, intervention participants were asked how many messages they read. Of the 168 participants who responded to this question, 93% (n=157) of self-reported they had read more than half of the messages, with 65% (n=110) reporting that they read all or nearly all of the messages. The remaining participants (11; 7%) reported reading some (less than half) of the messages.

A total of 33.6% of the 48,417 blood glucose reminder messages sent by the system were replied to resulting in a total of 16,251 blood glucose test results received by the system.

Intervention dosage

Participants were asked what they thought of the dosage of messages they received with the majority (129; 76%) reporting they were happy with the number of messages they received. A total of 34 (20%) reported that they received too many messages and only five (3%) too few.

Perceived impacts of the SMS4BG intervention

Participants were asked about the perceived impact of the programme. As reported in the preceding manuscript (Section 8.5.3), 71% reported that the programme helped them learn about their diabetes, and 83% reported that it impacted on how they managed their diabetes and change their behaviours. In addition, participants were asked about a number of specific impacts which can be seen in Table 30.

Table 30: Self-reported impacts of SMS4BG for those completing follow up interviews (n=169)

Impact	Response yes n (%)
Your overall blood glucose control improved (glycaemic control)	128 (76%)
You increased how often you monitor your blood glucose	111 (66%)
Your understanding of diabetes increased	111 (66%)
You improved your diet or eating	99 (59%)
You improved your level of exercise or how often you exercise	70 (41%)
How you have been feeling improved (your mood)	85 (50%)
You were less stressed	56 (33%)
You quit smoking	5 (3%)

The rates of perceived impacts of SMS4BG increased when limited to those receiving corresponding modules on the topics. For those that had received reminders to test their blood glucose, 79% reported they had increased the frequency they monitored their blood glucose. 61% of those that received the healthy eating module reported improving their diet or eating and 44% of those receiving the exercise module reporting improvements to their exercise. Of those that had received the stress and mood module, 59% reported their mood had improved and 47% reported feeling less stressed. 19% of those that received the smoking module reporting quitting smoking as a result of the messages.

What was liked most?

A total of 91% (n=154) of participants who completed the follow up interview responded to the question asking them what they liked most about SMS4BG. Five participants (3%) reported that they couldn't think of anything they liked most about the programme or said there was nothing they liked about it. The most common themes were: the reminding nature of the messages, the blood glucose reminder messages, the informative aspect, the easiness of it, the tailoring, the encouraging and motivating approach, the support provided, and the lifestyle modules.

Participants liked the fact that the messages were a reminder for them to engage in their diabetes management and engage in self-care (n=29). They reported that the messages brought diabetes to the forefront and kept them thinking about diabetes.

> *"Reminders, triggers to bring diabetes to the front of your mind. Sometimes you don't want to remember about it [diabetes], and the text messages are a good way of reminding you"*
> (Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

> *"Messages kept me thinking/remembering about diabetes so that even when a message came that wasn't a reminder message it still made me think about when I'd last tested, if I needed to take any insulin, just kept diabetes in the forefront of my mind."*
> (Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

> *"Made you really focus - jogged your memory and acted as good general reminders. The exercise messages really gave me that reminder I needed to actually do it - sometimes I felt like 'I can't be bothered', but the message came through, and I was like 'wait on, what does it say?'"*
> (Male, 65+yrs, non-Māori/Pacific, urban, T1D)

> *"The reminder of information, the reminding aspect of it, the reminder of the access to help that is there, and the reminders about exercise and eating habits, I thought it was all really good"*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

"I am busy with work, my family, and my grandkids. I am always putting other people before me and so it made me put myself first."
(Female, 25-49yrs, Māori/Pacific, urban, T2D)

"That reminder that you need to take a couple of minutes for yourself"
(Male, 25-49yrs, non-Māori/Pacific, urban, T1D)

The blood glucose monitoring reminders were also a frequently liked aspect of SMS4BG (n=38).

"Reminder messages, easy for a day to just go by and not think about testing as you don't feel like it's been long enough, so very good prompts"
(Female, 25-49yrs, non-Māori/Pacific, rural, T1D)

"Kept reminding me to test, made me stop what I was doing and test, even when I was really busy. Having to reply meant I had to test then"
(Female, 25-49yrs, non-Māori/Pacific, rural, T1D)

"They force people who don't test properly to test blood glucose on a regular basis"
(Male, 50-64yrs, non-Māori/Pacific, urban, T1D)

SMS4BG was designed to be motivational and encouraging and the messages were positively framed, which was noted and liked by participants (n=23). Specifically, participants also reported that the programme was a source of motivation and empowerment resulting in positive changes.

"The motivational messages, I found them more helpful particularly when they were telling me to do things for my family, that's the lever for me"
(Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

"Empowerment I have felt by the constant text messages. They felt cumbersome and overwhelming at times but to have come out the other end and see the results is fantastic - my HbA1c is the lowest it's been in 12 years, I'm more active, can spend more time with my kids, and I will live a longer life because of it"
(Male, 25-49yrs, Māori/Pacific, urban, T2D)

"Sometimes I don't have a lot of motivation - receiving the messages gave me a boost and made me feel more confident, like someone else understood."
(Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

"Inspiring, motivating messages. Nice to know you're not alone and other people are having similar problems/issues with diabetes"
(Male, 16-24yrs, Māori/Pacific, urban, T1D)

"Really appreciated the positivity of the messages, it was reminding and information but in a positive way, not like someone nagging you to do it"
(Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

"All of the messages were focused around taking your medication or doing things to keep on top of your diabetes rather than negative things."
(Male, 50-64yrs, Māori/Pacific, urban, T2D)

"That it was generally quite positive, it [diabetes] can be daunting, but it was positive and short and sweet"
(Female, 25-49yrs, Māori/Pacific, urban, T2D)

Participants liked that the messages were supportive (n=22). They reported that they provided needed support and made them feel less alone in relation to their diabetes.

"Made you realise that there was someone out there. It reduced feelings of isolation, and made you realise you weren't alone."
(Male, 65+yrs, non-Māori/Pacific, urban, T1D)

"My family has been going through a tough time and the support was great. Messages helped me keep my diabetes under control, reminded me of why I should keep trying. The messages supported me when my family wasn't able to."
(Female, 16-24yrs, Māori/Pacific, urban, T1D)

"Nice to know that someone is there to care for you, like an angel of hope. Reminder all the time, always there."
(Female, 50-64yrs, non-Māori/Pacific, urban, T2D)

The informative aspect of the programme was also identified as aspect of the programme that people liked (n=20). Even if the information was previously known to some participants many reported that it was nice to have the reminder.

"[I liked the] information about what I could do to make life easier and reduce diabetes eventually. Helped me better manage it"
(Male, 50-64yrs, non-Māori/Pacific, urban, T2D)

"They [the messages] were informative and they seemed to apply to me"
(Male, 50-64yrs, non-Māori/Pacific, rural, T1D)

"I liked the informative, encouraging messages, reminding you what to do, and had knowledge I didn't know."
(Female, 50-64yrs, Māori/Pacific, urban, T2D)

"[It was a] eye-opener more information than I'd had before"
(Male, 25-49yrs, non-Māori/Pacific, rural, T1D)

"Gave me ideas that I had probably heard before but didn't take in. A reminder of things that I could do"
(Female, 50-64yrs, Māori/Pacific, rural, T2D)

Some participants particularly liked the lifestyle modules (n=11).

"Relaxation messages about deep breathing and the motivational messages. It was like having a psychologist there with me"
(Female, 50-64yrs, Māori/Pacific, urban, T2D)

"Really helped with my knowledge of options for healthy eating and exercising. Didn't know gardening or vacuuming could be exercise too"
(Male, 50-64yrs, non-Māori/Pacific, rural, T1D)

"Exercise and food messages were the best - some better than others. They were most appropriate for what I wanted to change. And I could get my whole family involved and we would do it together. My kids loved these messages."
(Female, 50-64yrs, Māori/Pacific, urban, T2D)

Participants liked that the programme was individually tailored and personalised (n=7).

"That it was tailored to me, they asked me what types I wanted, they sent me texts on things that I thought applied to myself'
(Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

"Tailored to things that I'd picked - included my dad and friends name and what I enjoy"
(Female, 16-24yrs, non-Māori/Pacific, rural, T1D)

"I liked that at the start I told them how many messages I wanted and when and they stuck to that which was great."
(Female, 25-49yrs, Māori/Pacific, urban, T1D)

"Liked that you could choose the options based on whatever you felt you wanted at the time."
(Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

The utilisation of text messaging, a basic and wide-reaching technology, was identified as a positive of the programme that people liked (n=5). The fact that the programme was easy, not time consuming, stress free, and people could receive the messages anywhere.

> "*Ease of it. Simple, easy, no stress, no pressure. It was awesome."*
> (Male, 50-64yrs, non-Māori/Pacific, rural, T2D)

> *"Texts meant I could get them wherever I was"*
> (Female, 25-49yrs, Māori/Pacific, urban, T2D)

> *"Easy to get text, not too time consuming, kept me on track"*
> (Female, 25-49yrs, non-Māori/Pacific, urban, T1D)

There participants reported that they particularly liked the blood glucose result graphs.

> *"The graph really helped so I could actually see the result of when I'd fallen off track. With the graph I was able to take it to my doctor and have a discussion about patterns, I could actually contribute and be a part of the conversation rather than just being told what to do"*
> (Female, 25-49yrs, Māori/Pacific, urban, T2D)

Four respondent's reported that they liked everything about the programme.

What was liked least?

Of the participants interviewed, 148 participants (88%) responded to the question about what they liked least about the programme. The majority (90; 61%) reported that there was nothing they could think of that they didn't like.

The most common theme for what people liked least about SMS4BG was the timing of the messages, in particular the reminder messages (n=13). Participants reported that they would have preferred the messages to be delivered at different times, more specific times or to have had more choice in the time slots (i.e. overnight for shift workers).

> *"Random nature of texts, would've preferred same time each day"*
> (Male, 50-64yrs, non-Māori/Pacific, urban, T1D)

> *"Timing of the messages, would have preferred reminder messages at specific set times as opposed to the time frame of a few hours"*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T1D)

> *"Reminders came at inconvenient times - would have been better to have them at specific times. Morning reminder came too late, evening reminder too late"*
> (Female, 50-64yrs, Māori/Pacific, urban, T2D)

There were also people who felt there was too many messages (n=12).

> *"Just that there was too many messages' 'If I could have had less messages I would have continued longer."*
> (Male, 50-64yrs, non-Māori/Pacific, urban, T2D)

> *"Messages came too often, at annoying times. I didn't read some of the messages because there were so many."*
> (Male, 50-64yrs, non-Māori/Pacific, urban, T2D)

> *"Too overwhelming, too many messages. When at work can't check my phone all day, can't be checking my bloods all day."*
> (Female, 50-64yrs, Māori/Pacific, urban, T2D)

Although many people liked the informative nature of the programme there were some participants that disliked this aspect because it was information they already knew or not detailed enough (n=9).

> *"Reiterated information I already knew, but nothing that offended or that I thought shouldn't be there."*
> (Male, 65+yrs, non-Māori/Pacific, urban, T1D)

> *"I appreciate anything that's trying to help me but the messages were covering a lot of what I already knew."*
> (Male, 50-64yrs, Māori/Pacific, urban, T2D)

> *"Knew most of the information already, nothing was really new. Wasn't bad, just was information already told by my nurses."*
> (Male, 50-64yrs, Māori/Pacific, rural, T2D)

> *"The messages were not detailed enough in terms of medical information."*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T1D)

Other dislikes included that the messages were too repetitive (n=3), they became annoying or frustrating (n=7), that there was no feedback or interpretation of results (n=2), that the messages made them do things they didn't want to do (e.g. test their BG or think about their diabetes) (n=3), and that the messages weren't relevant to them personally (e.g. felt that they were for people with more complications or older people) (n=2).

How SMS4BG could be further improved

Of those interviewed approximately half (92; 54%) had no suggestions for how the programme could be improved or thought the programme was good as is. The remaining 46% provided suggestions for improvement of the programme including changes to message dosage and timing of messages, changes to the programme duration, content, tailoring and graphs, and the addition of feedback.

Conflicting suggestions around message dosage were received. Two participants felt that the dosage should be increased whereas eight felt that it should be decreased.

Although participants could chose the timing of their messages this was done using time slots not specific times to keep an element of randomness to the timings. Feedback identified that for the blood glucose monitoring reminder messages being able to choose the specific timing would be more beneficial to suit their testing schedule (n=11).

> *"Reminder message timing e.g. 7am, 12pm, 4pm, 8pm exactly."*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T1D)

> *"Testing at a single time slot everyday e.g. 2pm so would be a few hours after I had eaten rather than random"*
> (Male, 65+yrs, non-Māori/Pacific, urban, T1D)

> *"Customising messages so they suit a particular person, the exact time of day to send the reminder messages. A lot of my reminder messages came when I was at work and couldn't stop and check - it was frustrating to get the message but not be able to do anything about it, would then forget about it later on"*
> (Female, 16-24yrs, non-Māori/Pacific, urban, T1D)

Five participants reported that they would have liked the programme to go for longer. Of these 3 had forgotten to continue after 3 or 6 months and regretted this, and the other two, although

received the full 9 months of messages, would have liked them to continue for longer. One participant reported the ideal duration would be 6 months rather than 9 months.

There were 18 participants who suggested improvements to the content of the messages. These included:

- Specific medical information
- Adding medication reminders
- Information about developments in the diabetes field
- More messages around stress and mood, and healthy eating i.e. lifestyle modules should be available for the full 9 months not just 3 months
- More links to other resources e.g. books, websites, meal plans
- More specific detail (e.g. the physiology of exercise)
- Take into consideration socioeconomic status as this may impact engagement particular around healthy eating
- More positive reinforcement in the messages
- Include pictures or emoji/emoticons in the messages
- Include clinical targets

Three participants reported that the programme could be improved by including more accountability particularly in relation to texting back blood glucose results.

> *"If I didn't send a result in there was no consequence. Often I would take my medication without even testing myself when what I really needed to do was test. If I got the text then forgot that was it, would've been more helpful for me to have another text an hour later saying 'we haven't got a result from you', or something along those lines"*
> (Male, 25-49yrs, Māori/Pacific, urban, T1D)

> *"If someone doesn't respond with a number [blood glucose result] should follow-up with a text like 'still waiting' or 'you must be busy...reply with your result when you can'"*
> (Male, 25-49yrs, non-Māori/Pacific, urban, T2D)

Another common theme for improvements to the programme was additional contact providing support and feedback. Some people wanted a 2-way messaging functionality as a way of asking questions and getting feedback (n=4),and others reported adding a check in functionality either monthly or weekly to follow up on how people were going e.g. "how are you feeling today" (n=4). Furthermore there were four participants that felt additional support could come in the form of a contact phone number that people could call if they had questions. Only three participants reported wanting contact through additional modalities such as phone calls (n=2) or in-person contact (n=1).

Participants also suggested that the content could be further tailored (n=12) including further tailoring using support people and motivations, tailoring based on diabetes type, age, blood sugar levels, diabetes duration, or diabetes knowledge.

> *"May be worth having programmes tailored to Type 1 - Type 2, Younger-Older, and whether someone has had diabetes for a long time or is newly diagnosed as the information might differ"*
> (Male, 16-24yrs, non-Māori/Pacific, urban, T1D)

> *"More personalised to help with sugar levels, whether someone needed help getting them down, or if they kept going low for no known reason"*
> (Male, 50-64yrs, non-Māori/Pacific, urban, T2D)

It was also suggested by five participants that being able to change tailoring variables during the programme could be an improvement, for example being able to change the timings and frequencies of messages.

> *"Keep checking with when people want the messages. I picked early morning messages cause that's when I had to test but then my testing time changed so messages would've been better in the afternoon"*
> (Male, 25-49yrs, Māori/Pacific, rural, T2D)

> *"Having more flexibility around the timing of the reminders, be able to change timing and frequency during the programme"*
> (Female, 25-49yrs, Māori/Pacific, urban, T1D)

Two participants provided suggestions relating to the blood glucose results and graphs. One felt that there needed to be other options for providing results such as multiple messages in one go. The other felt that the graphs needed to be more specific and detailed

> *"I stopped using the graph and stopped texting my results in because the graph wasn't accurate enough. It gave you the picture but not the exact number so if I wanted to text my results in instead of using my log book the nurse couldn't see accurately enough my results and so needed me to write results down - too much work to write them in a book for the nurse and text them in for a graph that they can't use."*
> (Male, 25-49yrs, Māori/Pacific, urban, T1D)

> *"Could improve the reporting of blood glucose. If someone did miss a day, there should be an option where you can report several days (am & pm) retrospectively, and have them graphed on the day of measurement, rather than the day the reply was received."*
> (Male, 25-49yrs, Māori/Pacific, urban, T2D)

Other less frequent suggestions included targeting the programme specifically at people who are newly diagnosed (n=2) or isolated (n=1), make the programme into an app (n=2), add additional functionality to the website (e.g. community, information) (n=1), integrating the programme into clinical practice (n=1), and making the programme more accessible (n=1).

> *"Implementing it alongside treatment, more integrated approach. I ended up showing the graphs and texts to my doctors/nurses so then had to go through and explain it all before they could understand it"*
> (Female, 25-49yrs, Māori/Pacific, urban, T2D)

> *"Make the programme more readily available to anyone with diabetes. As I said it helped me feel less alone and isolated."*
> (Female, 50-64yrs, non-Māori/Pacific, urban, T1D)

8.9.3 Summary

Participants reported high acceptability and usefulness of the SMS4BG intervention. Although sub-group analyses did not find significant treatment effects on glycaemic control for type 2 diabetes patients and Māori/Pacific participants (see Section 8.5.1), these groups rated the programme significantly more useful than those who were Type 1 and non-Māori/non-Pacific respectively (for which treatment effects were observed). Similarly, significant treatment effects were only seen for urban participants, not rural participants, but these two groups rated the usefulness of the programme equally. This shows that the programme has potential for these groups (type 2,

Māori/Pacific, and rural) and lack of power could have been a contributor to the lack of treatment effects seen.

The findings from the interviews with intervention participants provide support for the design, format and content of SMS4BG including that it is tailored, includes reminders, information and lifestyle information, is positively framed, and utilises SMS technology. Feedback suggests that the programme could be further enhanced with additional tailoring including to the timing of reminder messages, additional contact and feedback, more detailed graphs, and refinements to the content.

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Part 4: Discussion

CHAPTER 9. DISCUSSION

Addressing the individual and system burden of poorly controlled diabetes is a public health priority. Supporting a person to self-manage their diabetes can improve their behaviours and clinical outcomes, but ensuring that such self-management education and support is appropriate and accessible is essential for ensuring people engage and adhere. Given their ubiquitous ownership and use, mobile phones provide an ideal platform for the delivery of diabetes self-management interventions. There is increasing research evidence for the effectiveness of mHealth interventions for improving outcomes in people with diabetes, but ensuring these tools meet the needs of the population they are designed to target is important. The overall aim of this thesis was therefore to develop and evaluate an mHealth diabetes self-management support programme specifically for people with poorly controlled diabetes in New Zealand.

To achieve this aim a comprehensive body of work was undertaken to inform, develop and evaluate an intervention – SMS4BG. First, a systematic review was conducted to evaluate what is currently known about the use of SMS to support self-management in people with poorly controlled diabetes (Chapter 3). A survey of young adults with type 1 diabetes was then undertaken to investigate current engagement in already available mHealth and explore perceived roles of mHealth in supporting diabetes management (Chapter 4). An mHealth tool, SMS4BG, for the delivery of self-management support to people with poorly controlled diabetes, was developed with input from clinicians and other experts, people with diabetes, and a Māori Advisory Group (Chapter 5). Next, feasibility and acceptability of SMS4BG were demonstrated in a non-randomised pilot study (Chapter 6). Finally, effectiveness of the mHealth tool was demonstrated through a pragmatic randomised controlled trial (Chapters 7 and 8).

This discussion presents a summary of the research findings, the implications for research and practice, and the strengths and limitations of the thesis. This discussion addresses the following thesis objective:

5. Discuss the thesis findings in relation to the current literature and identify implications for clinical practice and areas for future research.

9.1. Overview of the thesis findings

The background literature review in Chapter 2 provided evidence for the significant burden poorly-controlled diabetes has on individuals as well as on the healthcare system more broadly. It highlighted the disparities in diabetes outcomes experienced by ethnic minority groups, including Māori and Pacific, and the importance of addressing these. Successful engagement in diabetes self-management behaviours (e.g. blood glucose monitoring, insulin administration, healthy eating, physical activity) within a person's daily life is needed for good control of the condition but this can be challenging with diabetes being one of the most demanding conditions both behaviourally and psychologically. The increasing evidence for mHealth tools in the delivery of diabetes self-management support was outlined particularly for the use of SMS, and the potential for this to provide in-the-moment support with fewer access barriers than traditional in-person interventions.

The systematic review (Chapter 3) sought to understand the impact of SMS interventions on glycaemic control in people with poorly controlled diabetes; arguably the group most in need of intervention to reduce the costly and debilitating complications of the condition. The findings from seven studies included in this review found that the evidence for effectiveness was mixed. Due to the small number and heterogeneity of the included studies, as well as their variable methodological quality, a meta-analysis of the data was not conducted. Therefore, it was difficult to draw conclusions on the effectiveness of SMS interventions on glycaemic control in poorly controlled diabetes. This is in contrast to previous reviews reporting positive impacts on glycaemic control for SMS interventions in people with diabetes without limitation on level of diabetes control. Considering that diabetes management is one of the most investigated areas for the use of mHealth, this highlighted the lack of focus on those with poorly controlled diabetes, a group where intervention could be of greatest benefit.

A cross-sectional survey of young adults with type 1 diabetes (Chapter 4) showed that although there are a plethora of apps already available to support diabetes management, engagement with these in young adults, a population group where smartphone ownership was prolific, was low. Furthermore, the study showed that there was interest in the use of mHealth for supporting diabetes self-management in this group. The survey highlighted that although young adults were confident in their ability to manage their diabetes, there was strong interest in learning more about aspects of diabetes management and for support with management tasks such as checking blood glucose and eating well. With their preferences for support aligning with general diabetes self-management topics, it showed the potential for more general interventions (not specific to this age group) being potentially appropriate and useful for this group.

The SMS4BG intervention was developed to address the need for tools to provide motivation and information to support self-management in adults with poorly controlled diabetes (Chapter 5). A development framework was used that ensured end-user engagement throughout, adherence to a theoretical basis, and an implementation focus. The individually tailored intervention was designed to motivate and support a person to engage successfully in the behaviours required to manage diabetes for long term health improvement. It was the accumulation of extensive formative work to ensure it not only met the needs of the population it was designed to reach, but was evidence based and theoretically grounded. The resulting intervention was made up of modules allowing for tailoring to the individual patient, including a core diabetes module (available in Māori, Pacific and non-Māori/Pacific versions), an insulin module, a young adult module, a smoking cessation module, lifestyle behaviour modules, blood glucose monitoring reminders, and a foot care module. Participants could reply to monitoring reminders, by sending in their blood glucose levels by text message, and then view their blood glucose levels graphically over time on the study website. The length of the programme was tailored to patient preferences from three to nine months, and at registration there was the option to select the timing of messages.

A 3-month pilot study of 42 adults with poorly controlled diabetes (Chapter 6) found the SMS4BG intervention to be acceptable in engaging adults with poorly controlled type 1 or type 2 diabetes. Participants reported the intervention to be useful, culturally appropriate, and that the programme had a range of perceived positive impacts on their diabetes management behaviours. Additionally,

a significant improvement in HbA1c was seen for those with complete data, indicating a potential for improved clinical outcomes. The pilot study provided preliminary support for the use of mHealth in delivering personally and culturally tailored diabetes self-management support and, particularly, the use of text messaging as a medium of delivery. The findings from the pilot study informed further refinement of the final SMS4BG intervention.

To evaluate the effectiveness of SMS4BG an RCT was conducted (Chapters 7 and 8) where a total of 366 participants were randomised to receive either the SMS4BG programme (intervention) in addition to usual care (n=183) or usual care alone (control; n=183). At nine months, glycaemic control (as measured by HbA1c levels) was significantly improved in the intervention group compared with the control group (adjusted mean difference in HbA1c of -4.23 [95%CI,-7.30, -1.15], p=0.01). Statistically significant improvements in foot care behaviour and diabetes related support were seen in the intervention group compared with the control group. Improvements were seen in all other secondary outcomes in the intervention group, and although the majority of these were not statistically significant compared to the control group, the results were encouraging. High levels of satisfaction with SMS4BG were found with 95% of intervention participants reporting SMS4BG to be useful, 97% stated it was culturally appropriate, and 97% said they would recommend the programme to other people with diabetes. Participants supported the use of text messaging for this type of intervention with 99% reporting that text messaging was a good way to deliver diabetes self-management support. In summary SMS4BG was found to not only be acceptable and engaging, but was effective in improving glycaemic control at nine months compared with a control group.

SMS is the most extensively researched form of mHealth and although more advanced technologies have been developed and are widely available, SMS remains a relevant, useful, and well received modality for the delivery of health interventions. Participants in the pilot study and RCT represented broad demographic groups including a range of ethnicities, ages (16 to 80 years), and locations (rural and urban), showing its applicability across the population. With increasing smartphone ownership and data access, the potential of apps (rather than SMS) becomes more pertinent; however the survey showed that in young adults, whose smartphone ownership is most prolific, SMS was still of interest, indicating that SMS may remain useful for some time yet.

The findings of this thesis add to the literature around the use of SMS to provide support to people with diabetes, and in particular the use of SMS in poorly controlled diabetes. The results support the use of tailoring and cultural adaptation of interventions for high acceptability in diverse populations. To date, there have been few studies investigating the use of SMS in those with poorly controlled diabetes, but findings from the RCT provide high-quality evidence for the effectiveness of SMS for this group. The RCT had a larger sample size and lower attrition than the studies included in the systematic review. When limited to only those utilising a higher HbA1c cut off used to indicate poor control the RCT in this thesis is the first study to show a positive effect of SMS on glycaemic control.

This thesis set out to develop a mHealth tool for those with poorly controlled diabetes. Given the heterogeneity of this population including differences associated with diabetes types and

implications of age and cultures, developing one tool that could be acceptable and also useful for all seemed unlikely. Previous trials of the effectiveness of SMS interventions on glycaemic control have focused on one type of diabetes,(74, 75, 77, 103, 104, 106) particular age sub-groups (e.g. older adults),(75) or only one aspect of diabetes management (e.g. exercise, monitoring).(103) The Candidate initially envisaged that this would be the same for this thesis, hence the survey targeting only young adults; however findings from the survey and formative work indicated the value of an SMS solution incorporating tailoring to reach a broader population. Therefore, the findings not only add to the literature supporting the use of technology to deliver low risk psychosocial intervention, but with the use of tailoring these can be generalizable across ages, diabetes types, and cultures.

9.2. Strengths of the research

The strengths of the thesis are outlined in the following section and include the use of a framework and behaviour change theory in the development of the intervention, the robust research methods utilised throughout the thesis, the cultural adaptation and tailoring of the intervention, and the inclusion of minority groups in the respective studies.

9.2.1 The use of a framework

The development of SMS4BG followed an established and tested framework(141) incorporating behaviour change theory and end-user engagement throughout the development process. Although the resulting development process was labour intensive and time consuming, this culminated in high acceptability, satisfaction, and appropriateness of the intervention seen in both the pilot study and RCT.

The initial steps in the framework ensured extensive formative work was undertaken for the development of SMS4BG. This included reviews of relevant theoretical constructs and diabetes self-management education, and consultation with key stakeholders including people with diabetes, healthcare professionals and vendors, and vital input from the Māori advisory group. This formative work led to a feasible and acceptable intervention delivering relevant and culturally appropriate evidence-based content.

The stepped process of the development allowed for feedback to be incorporated at each step; improving the final intervention. Suggestions for improvement from the pilot study that were incorporated into the final intervention were possible factors in its success:

- The addition of the foot-care module likely contributed to the statistically significant improvement in foot care behaviour seen in the intervention group compared with the control group
- The addition of the Pacific version saw high acceptability ratings for SMS4BG in Pacific participants
- The inclusion of messages about the importance of HbA1c tests may have contributed to the increased results available at follow up in the RCT compared to the pilot study
- The addition of personalisation using support people and motivations could have contributed to the increased perceived support and high engagement with the intervention

- The addition of tailoring of the duration of the programme, and increased choice in the tailoring of message timings, could have also impacted on the high acceptability and engagement with the intervention

In addition, the incorporation of the content suggestions identified by young adults in the survey into the young adult module likely helped increase the usefulness in this population.

9.2.2 Theoretical basis

Theoretical frameworks provide a basis for guiding intervention development. To date, there have been few theoretically based mHealth interventions and even less that target disease management.(90, 91) A strength of this thesis was the use of behaviour change theories in the development of the intervention. Research has shown that the use of theory and BCTs in technology based interventions is linked to better outcomes(92). Unfortunately, the systematic review was unable to identify key BCTs and theories that were associated with positive outcomes. The use of theory and BCTs in the development of SMS4BG is likely a factor in the positive results found although further work is needed to identify which BCTs are potentially the most potent for positive outcomes. As well as being an ideal medium to deliver theoretically based interventions the process of delivering interventions via SMS aligns with theoretical constructs.(57) Specifically, the SMS4BG message content was designed to increase support and provide reminders to engage in behaviours. Moreover, the nature of the delivery of text messages is such that they act as a reminder and cue-to-action, and utilises a tool congruent with support. The reinforcing and supportive nature of the technology along with the theoretically based content likely strengthened these theoretical elements in SMS4BG.

9.2.3 The use of robust research methods

Throughout this thesis, robust and evidence based research methods have been used to answer the research questions. A combination of quantitative and qualitative methods were utilised to answer the research questions where appropriate. Systematic reviews (as was utilised in Chapter 3) are the ideal method for accurate and reliable summarising of the evidence for the effectiveness of healthcare interventions.(102) High quality RCTs (as used in Chapter 8) are considered one of the best and most reliable methods for determining the effectiveness of interventions due to their random allocation of treatments.(110) Additionally, qualitative methods (as used in Chapters 4, 6 and 8) help inform the development of interventions and deepen understanding regarding acceptability and facilitators to their success.(141, 212-214)

Recommended research guidelines were followed for the reporting of the studies; including the PRISMA statement (101) for the systematic review, the CHERRIES checklist (144) for the survey, the SPIRIT statement (200) for the RCT protocol, and the CONSORT and eHealth-CONSORT checklists (110, 201) for the RCT. The RCT was registered before commencing recruitment and the protocol peer reviewed and published. The pilot study and RCT followed good clinical practice (GCP) recommendations and the RCT procedures and processes underwent external audit before commencement of recruitment to ensure GCP processes were followed. In the RCT, risk of bias

was low given that a random sequence generation was used, allocation was concealed until the point of randomisation, primary outcome assessors were blinded to treatment allocation, there was no protocol violations, low attrition, and ITT analyses performed.

The community based and pragmatic design of the RCT has meant that the results provide not only the required evidence of the effectiveness of the SMS4BG intervention in comparison to usual care but also provide valuable information about the potential scaling up and implementation of the programme. It is envisaged that if implemented and rolled out then SMS4BG would be delivered in a similar way to during the trial with few changes required. Given this, feedback and suggestions for improvement from RCT participants are of particular value when considering implementation and further refinement of SMS4BG.

9.2.4 Cultural adaption

Health inequalities are arguably more obvious in diabetes than other conditions.(215) Not only is diabetes more common in Māori but this population are diagnosed with the condition younger, experience poorer outcomes, and have higher mortality from the condition.(19-21) It is vital that research not only aims to minimise these disparities but that interventions for this group are culturally appropriate. Therefore, it was essential that the SMS4BG programme was adapted specifically to the needs and preferences of Māori. Not only did Māori models of health inform the development of the Māori version of SMS4BG but the study Māori Advisory Group also provided guidance and input throughout the development process. Feedback from early pretesting with Māori provided valuable insight into how messages were perceived and resulted in significant changes to wording of the messages (e.g. removal of blood glucose targets). In the pilot study, Māori participants reported high cultural appropriateness of SMS4BG regardless of the cultural version they chose.

Feedback from the pilot study identified the potential of a Pacific version of SMS4BG. Input from a Pacific advisor then saw the core module adapted for this group incorporating a greater focus on family, similar to the Māori version, and on others as key motivators for good diabetes management. This version also incorporated Pacific greetings based on participant ethnicity, and included specific messages to promote accurate perception of insulin and its use.

Over 36% of the final sample in the trial were Māori or Pacific, which is greater than the approximate proportion of people with diabetes in New Zealand who are of these ethnic groups.(18) This is in contrast to research that has shown an underrepresentation of minority ethnic groups in mHealth and eHealth studies.(216) It is likely that the involvement of the Māori Advisory Group, and later a Pacific Advisor, was a key factor ensuring relevance to this groups resulting in the high recruitment. Similar to the pilot study, overwhelmingly, participants in the RCT who received the SMS4BG intervention, regardless of cultural version, reported it to be culturally appropriate, and 20% of intervention participants chose to receive either the Māori or Pacific version of SMS4BG.

9.2.5 Tailoring

Tailoring of SMS4BG was an integral feature in its design. Findings from the literature review, along with the findings from the survey and formative work for the development of SMS4BG, highlighted that tailoring would be fundamental to the intervention's success. Not only did people with diabetes report wanting the intervention to be tailored but clinicians also reported that tailoring was needed. Although the findings from the systematic review were not able to draw conclusions on the benefit of tailoring for the target population, other mHealth reviews have shown the importance of this for the success of SMS interventions.(52, 58) Features of the initial SMS4BG intervention that were individually tailored included the content (by choice of modules), timing of blood glucose reminder messages, cultural versions, and the use of the participants preferred name. Based on the feedback from the pilot study, the final SMS4BG was further tailored with the addition of tailoring by location, intervention duration, personal motivations, and support people. Furthermore, the original tailoring was enhanced with the addition of a Pacific cultural version, additional content modules, and choice in the timing of all messages.

This degree of tailoring meant that there was considerable variation in what each individual received. Individuals were presented with a complex package of tailored messages rather than a prescribed dose and structure. There was considerable variation in what was chosen (for example the range in dosage of messages that individual participants received in the RCT was 14 to 2050 messages). Thus, people had more control over their intervention and only received information relevant to them. Feedback from participants validated this approach; people reported that their personalised version of SMS4BG was useful to them which supports the additional work and complexity involved in tailoring interventions. As suggested by other work (52) and in agreement with participant feedback, we feel that SMS4BG could be further enhanced by the addition of tailoring based on age, diabetes type, and baseline self-efficacy, and this could translate into even greater effectiveness.

9.3. Limitations of the research

Although this thesis has many strengths, there are also limitations that require consideration. The most important of these relates to the recruitment of participants in the RCT. Additional limitations include the inability to ascertain the sustainability of the results, the lengthy development duration, potential detection bias, the intervention being delivered in English language, and issues associated with the measure of engagement. These limitations are discussed more fully below.

9.3.1 Recruitment

Recruitment for the RCT was the biggest limitation of this thesis resulting in the study sample size being smaller than initially planned and resulting in reduced power (80% from a planned 90%) to detect a significant difference between groups. Although the final sample size still gave adequate power to determine the effectiveness of SMS4BG, it did not allow adequate power for the planned sub-group analyses. Although overwhelmingly, clinicians and clinic staff were positive about the trial, the SMS4BG programme, and about their patients being involved, a key factor in the low

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recruitment to the trial was the identification of patients by clinicians. Asking clinicians to identify suitable participants for the study ensured that they were aware that they details had been passed to the study team and only appropriate people were contacted about the study, but this required time on the part of the clinician, and it seems likely that this created a barrier to engagement. Potential participants contacted by the study team were, overall, positive about the study indicating that removing the step involving clinicians in the referral process would potentially have resulted in higher recruitment. However, allowing people to self-refer to the study did not yield numbers sufficient to meet our targets. A factor contributing to this was the requirement that people must have had an HbA1c test in the preceding nine months. Many of the people who had undertaken a test had adequate control of their diabetes and so did not meet the inclusion criteria. People with poor control are less likely to undergo regular testing(217) and this was evident in our work as people did not have the required recent test to take part and commonly were reluctant to have one done. As those people with poor control may be more likely to be disengaged from healthcare services alternative methods of recruitment still need to be explored.

Low recruitment was also experienced in the survey (Chapter 4) with a response rate of only 29%. The low response rate, although largely reflective of the wider target population, limited the generalisability of the survey results. In contrast to the recruitment issues in the RCT there were no issues with recruitment during the pilot study and, additionally, the survey found that young adults wanted to learn more about diabetes and how to manage it, and were interested in receiving SMS to do this. This dissonance could potentially be due to the randomisation component in the trial; the chance of being allocated to the control group and burden of the research process may have outweighed the wish to receive the SMS programme.

This thesis has highlighted the difficulties in recruiting people with poorly controlled diabetes (particularly in rural areas), the associated burden of research processes, as well as the lack of clinician time available to support research procedures.

9.3.2 Longer term follow up

Due to time restrictions associated with study funding, and the duration of this Ph.D., longer term follow-up of participants was not feasible within the pilot study or RCT. Ascertaining whether the improvements in HbA1c and other outcomes are sustainable over the long term is essential. It is thought that the trend revealed in our RCT results - the significant improvements seen at three months, dropping slightly at six months before reaching significance again at nine months - could be an indication of sustained change.

9.3.3 Development duration and technology advances

The development if SMS4BG was lengthy; the initial consultation and conceptualisation work for SMS4BG began in 2013 and it was over four years before an answer on its effectiveness was available. Although a strength of SMS4BG was the extensive formative work and development work, this was time consuming. With advances in technology made daily, this lengthy and labour intensive process could mean that the technology used is no longer relevant by the time

implementation occurs.(141) Although the findings from this thesis have shown that text messaging is still an appropriate and liked modality for this type of intervention, in the future SMS4BG may need to be adapted for other platforms e.g. messaging apps.

It is essential that future work that considers alternative delivery platforms maintains the benefits associated with SMS. Such benefits include its low cost, extensive reach, its ubiquity as a mode of communication, its ability to be tailored and personalised, and the fact that it is a passive intervention, allowing for direct delivery of information to the targeted person. Although more advanced technology would allow for better functionality (including the incorporation of the feedback graphs within the messaging), at this stage no other technology is better suited to provide all of these benefits across all demographic groups. As data access across New Zealand increases, and the digital divide reduces, there is potential for messaging apps such as WeChat to provide improved platforms for the delivery of SMS4BG.

9.3.4 Detection bias

It is possible that there may have been detection bias in the results of the secondary outcomes in the RCT. This is due to the outcomes assessors (the Candidate and study Research Assistants) not being blinded to treatment allocation when undertaking the follow-up interviews. The primary outcome assessors in the RCT were blinded, which is a strength of the study but, ideally, all outcome assessors should be blinded to minimise bias. Additionally, intervention acceptability in both the pilot study and RCT were assessed during phone interviews (the majority by the Candidate herself). This could have resulted in bias with participants being more positive in their responses about the intervention to 'please' the interviewer compared to if they had been assessed through more disconnected methods i.e. paper/electronic questionnaire.

9.3.5 Language

SMS4BG was delivered in the English language (with the exception of some Māori, Samoan, and Tongan words). With high rates of diabetes in ethnic minority groups, delivery of this type of intervention in languages native to these groups may result in greater benefit. The survey and pilot study did not explore whether delivery of the programme in other languages would have been preferred. It is likely that some people were not referred to the pilot study or RCT, or were unable to take part, due to the criteria that they must be able to read English. Translation of SMS health programmes into other languages such as Te Reo and Samoan has been done successfully,(218, 219) and so further research needs to look at whether this would be of benefit in SMS4BG.

9.3.6 Engagement

Assessing engagement with SMS interventions is challenging. In the pilot study and RCT, although the content system was able to tell us that messages had been delivered to participants, it could not tell us if the participant had read the message or not. Participants could easily have ignored or deleted messages without reading them but there is no way of obtaining his information through the system. Therefore estimations of engagement in these studies are limited and should be

interpreted with caution. In the RCT 93% of intervention participants self-reported that they read more than half of the messages with 65% reporting that they read all or nearly all of the messages. This indicated high engagement but could be impacted by reporting bias. To understand the impact of SMS interventions, as well as the impacts of content versus the technology functionality, future research needs to look at ways to successfully and accurately measure engagement.

9.4. Implications

When considering the findings of this thesis it is important to consider their implications for both research and clinical practice. The implications of the findings for future mHealth research as well as further research for SMS4BG are outlined below followed by the implications of SMS generally, and the SMS4BG programme, for future clinical practice.

9.4.1 Implications for future research

This thesis has identified a number of areas for future research. As mention above (Section 9.3.2), further research is needed to ascertain the sustainability of the impacts of SMS4BG and other mHealth based diabetes support programmes. One way of doing this would be to follow-up participants in the RCT at two years post randomisation. As was outlined in the study protocol, lab test results could be obtained from medical records at two years, in a similar way as they were during the trial. Although further ethical approval would be needed, the Candidate hopes that it will be both feasible and possible to do this.

Future research also needs to look specifically at the acceptability of SMS4BG in other cultural groups. New Zealand is ethnically diverse and with high rates of diabetes seen in South Asian (e.g. Indian) people in New Zealand(16, 189) there is potential for SMS4BG to be adapted for this cultural group. Research could be done with South Asian people with diabetes to ascertain their preferences for support, diabetes beliefs, and practices, and other cultural factors that could be incorporated into a South Asian version. The candidate believes that this would be both beneficial and well received as previous research has shown high acceptability of a culturally adapted SMS health intervention, TextMATCH, in New Zealand South Asian communities.(218)

With much of the content of the SMS4BG intervention relevant to both those with adequately controlled diabetes and prediabetes (e.g. lifestyle modules), there is potential for the programme to be adapted to these groups to either prevent the progression to poor control, or the onset of diabetes in the first place. Further research would be needed to explore the issues and needs of these groups before adaptation of the original programme.

The individual tailoring of SMS4BG allowing participants to choose varying intervention components, durations, and dosages, means that it is not possible to determine the ideal duration as well as the components most important for effectiveness. Further research is needed to understand the components of this intervention that are most effective and to determine the ideal intervention dosage to further refine this intervention and the development of future interventions. Participants were highly satisfied with the intervention they received in both the pilot study and the

RCT, and largely happy with their intervention dosage and duration, such that it may be important that SMS4BG remains individually tailored resulting in a more complex intervention for delivery.

The systematic review found that the majority of the previous studies that had successful outcomes in the target population incorporated monitoring devices. Cost and accessibility are currently barriers to the widespread use of such technologies (e.g. continuous glucose monitors) therefore preventing their incorporation into SMS4BG. However, these technologies would not only have clinical benefit but would also prevent the need for participants to manually text back values. Thus, they could provide a mechanism for alerting participants to high or low blood glucose results. The survey and feedback from the pilot and RCT showed high interest and support for the monitoring aspect of SMS4BG and therefore the potential for monitoring devices to be included in SMS4BG once accessibility and cost are not barriers could be further investigated.

9.4.2 Implications for practice

Findings from this thesis support the implementation of SMS4BG into clinical practice. The research shows the potential of SMS4BG to provide a low-cost, scalable solution for increasing the reach of diabetes education and self-management support for those most in need. The nature of diabetes requiring daily management means ongoing support between clinic visits is often needed. This thesis has shown that a text messaging programme can increase a person's feelings of support without the need for personal contact from a healthcare professional. The benefits of diabetes self-management education are well established,(151, 152) but these are typically delivered using resource intense methods (such as face-to-face). Across New Zealand, diabetes services vary between regions.(220) With one in four New Zealanders living in rural areas or small towns,(221) and a greater percentage of Māori living in these areas, ensuring consistent access to quality diabetes education and support is imperative in order to reduce health disparities. SMS4BG allows for consistent support to be easily provided across the country regardless of proximity to in-patient services.

Furthermore, traditional diabetes self-management education and support is typically delivered to patients alone but there is benefit of key support people being involved.(211) This is particularly pertinent to ethnic groups such as Māori whose family/whānau play an important role in supporting a person's diabetes self-management.(169) Reach of SMS4BG to the wider family was an unexpected benefit; in the RCT 50% of participants reported sharing the messages with others. Not only can SMS4BG be shared with family and other support people, there is also potential for the programme to be specifically adapted for delivery to this group.

Findings from this thesis support the continued use of messaging technology such as SMS in mHealth interventions. The survey of young people, a group considered most comfortable and highly engaged with technology in general, found that although more complex technologies exist SMS was still an ideal, appropriate, and relevant technology for the delivery of diabetes support interventions. Again, our findings from the RCT were that 99% of participants in the intervention group reported that SMS was a good way to deliver this type of intervention. Few technical issues

were experienced in either the pilot study or RCT, and the majority of these were related to the website used to view the blood glucose graphs rather than the SMS.

If SMS4BG was to be implemented as an ongoing service, the issues experienced in the RCT with recruitment would need to be explored to ensure that appropriate people get access to the programme with minimal barriers. Ideally, the programme would be implemented within clinical systems (primary and secondary care) giving nurses, doctors or other healthcare providers the ability to register a patient during usual clinical care. Importantly, however, if those with poor control are less likely to attend their appointments, then the very people who this programme is designed to give benefit may be those who miss out. Other potential ways of reaching potential people for the programme could be through pharmacists (when patients collect prescriptions), national telehealth services (such as Healthline) or community groups (as has been successfully done with TextMATCH(218)). While these other avenues could hold potential for increasing the reach of the programme, ideally, the programme belongs within healthcare services to ensure patients have the correct clinical support.

The findings from this thesis also have implications broader than the field of diabetes. The value of support and self-care for positive health outcomes and improved quality of live is well established. But with clinician time limited across the majority of health services the potential of SMS to deliver this is important. In population groups such as the elderly who can be particularly isolated, or other chronic disease groups requiring a focus on self-care, a generic health intervention could be a low cost and scalable solution to improve quality of life and increase engagement with self-care behaviours.(30) An individually tailored SMS-based generic self-care programme could be developed in a similar way to SMS4BG, incorporating important topics such as stress-management, sleep hygiene, healthy eating, physical activity, and support. A generic programme such as this could potentially be relevant and useful across the population.

9.5. Conclusions

In summary, this thesis found that text message based self-management support is effective in improving outcomes for people with poorly controlled diabetes. This evidence presents a strong case for the implementation of SMS4BG. Although the potential for delivery of such interventions is exciting, questions remain including the sustainability of positive effects. This comprehensive SMS based intervention, designed to provide self-management support to all adults with poorly controlled diabetes, has the potential to make self-management support accessible to nearly all people with diabetes regardless of location. The findings from this thesis provide valuable support for the use of SMS in population health interventions, the value of cultural adaption to minority groups, and the benefits of providing an individually tailored intervention.

APPENDIX 1: SUPPORTING DOCUMENTS FOR CHAPTER 3

A1.1 PRISMA Checklist

A1.2 Risk of bias table

A1.1 PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #	Section of thesis
TITLE				
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1	3.1
ABSTRACT				
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2	3.2
INTRODUCTION				
Rationale	3	Describe the rationale for the review in the context of what is already known.	3	3.3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3	3.3
METHODS				
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4	3.4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4	3.4.1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4	3.4.2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5	3.4.2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5	3.4.3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5	3.4.4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5	3.4.4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6	3.4.5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5	3.4.4
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA	NA
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA	NA

Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA	NA
RESULTS				
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6	3.5
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8	3.5.2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	7	3.5.1
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11	3.5.5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA	NA
DISCUSSION				
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13	3.6
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14	3.6.2
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15	3.7
FUNDING				
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16	3.8

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097.
Note: Page numbers refer to manuscript

A1.2 Risk of bias table

	Selection bias				Detection bias		Attrition bias		Reporting bias	
Study	**Sequence generation**		**Allocation concealment**		**Blinding of outcome assessment**		**Incomplete outcome data**		**Selective outcome reporting**	
	Judgement	**Evidence**	**Judgement**	**Evidence**	**Judgement**	**Evidence**	**Judgement**	**Evidence**	**Judgement**	**Evidence**
Agboola (2016)	Low risk	Computer generated	Low risk	Numbered opaque envelopes	High risk	Research assistants not blinded	Low risk	High rates of attrition. 25% lost to follow up: power calculation allowed for 20% drop out, loss to follow up similar across groups and no difference in those who dropped out compared with those who completed	Low risk	All outcomes specified in trial registration reported.
Arora (2014)	Low risk	Computer generated	Unclear	Method not reported	Unclear	Method not reported	Low risk	High rates of attrition. 28% lost to follow up: study design accounted for this, statistical power was maintained & loss to follow up did not differ across treatment groups.	High risk	Not all secondary outcomes specified in trial registration are reported
Capozza (2015)	Low risk	Computer generated	Low risk	Central allocation (web). Allocation concealed until randomisation.	Unclear	Method not reported	Low risk	High rates of attrition. 40% lost to follow up: post-hoc analyses showed unlikely to affect outcome measures. No different in loss to follow up across study arms.	High risk	Not all outcomes specified in trial registration are reported
Goodarzi (2012)	Low risk	Computer generated	Unclear	Method not reported	Unclear	Method not reported	High risk	Moderate rates of attrition. 19% lost to follow up: uneven between groups and reasons for drop out differed between groups.	Low risk	Nothing to suggest: All outcomes specified in trial registration reported but

										retrospective registration
Kim (2010)	Low risk	Computer generated	Unclear	Method not reported	Unclear	Method not reported	Low risk	Low rates of attrition. 8% lost to follow up: power calculation allowed for 10% drop out and reasons for drop out similar between groups.	Low risk	All outcomes specified in trial registration reported.
Lim (2016)	Unclear	Block randomisation, process not further described	Unclear	Method not reported	Unclear	Method not reported	Low risk	Low rates of attrition. 15% lost to follow up: balanced between groups and reasons for drop out similar between groups.	High risk	Not all outcomes specified in trial registration are reported
Shetty (2011)	Low risk	Computer generated	Unclear	Method not reported	Unclear	Method not reported	High risk	High rates of attrition. 36% lost to follow up: uneven between groups.	Unclear	No published protocol or trial registration

APPENDIX 2: SUPPORTING DOCUMENTS FOR CHAPTER 4

A2.1 CHERRIES checklist

A2.2 Ethics approval letter

A2.3 Participant Information Sheet

A2.4 Consent Form

A2.5 Survey questions

A2.1 CHERRIES checklist

Checklist for Reporting Results of Internet E-Surveys (CHERRIES)				
Item Category	***Checklist Item***	***Reported?***	***Page***	***Thesis section***
Design	Describe survey design	Yes	2	4.4.3
IRB (Institutional Review Board) approval and informed consent process	IRB approval	Yes	2	4.4.2
	Informed consent	Yes	3	4.4.4
	Data protection	Yes	3	4.4.4
Development and pre-testing	Development and testing	Yes	2	4.4.1
Recruitment process and description of the sample having access to the questionnaire	Open survey versus closed survey	Yes	2	4.4.4
	Contact mode	Yes	2	4.4.4
	Advertising the survey	Yes	2	4.4.4
Survey administration	Web/E-mail	Yes	3	4.4.4
	Context	N/A	N/A	N/A
	Mandatory/voluntary	Yes	3	4.4.4
	Incentives	Yes	3	4.4.4
	Time/Date	Yes	3	4.4.4
	Randomisation of items or questionnaires	Yes	3	4.4.4
	Adaptive questioning	Yes	3	4.4.4
	Number of Items	Yes	3	4.4.5
	Number of screens (pages)	Yes	3	4.4.5
	Completeness check	N/A	N/A	N/A
	Review step	Yes	3	4.4.4
Response rates	Unique site visitor	N/A	N/A	N/A
	View rate (Ratio of unique survey visitors/unique site visitors)	N/A	N/A	N/A
	Participation rate (Ratio of unique visitors who agreed to participate/unique first survey page visitors)	Yes	2	4.5.1
	Completion rate (Ratio of users who finished the survey/users who agreed to participate)	Yes	2	4.5.2
Preventing multiple entries from the same individual	Cookies used	N/A	N/A	N/A
	IP check	N/A	N/A	N/A
	Log file analysis	N/A	N/A	N/A
	Registration	Yes	2	4.4.4
Analysis	Handling of incomplete questionnaires	Yes	2	4.4.6
	Questionnaires submitted with an atypical timestamp	N/A	N/A	N/A
	Statistical correction	N/A	N/A	N/A

N/A: Not applicable
Note: Page numbers refer to manuscript

A2.2 Ethics approval letter

Health and Disability Ethics Committees

Health and Disability Ethics Committees
1 The Terrace
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

18 March 2014

Ms Rosie Dobson
National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142

Dear Ms Dobson

Re:	**Ethics ref:**	**14/CEN/24**
	Study title:	Cross-sectional survey of the use of mobile health interventions in young people with type 1 diabetes

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

The main issues considered by the HDEC in giving approval were as follows.

Please ensure participants are aged 16+ otherwise consent and assent forms will be required for minors. Please confirm via email to HDEC.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

A2.3 Participant information sheet

PARTICIPANT INFORMATION SHEET

Type 1 diabetes youth mHealth survey

THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

National Institute for Health Innovation
The University of Auckland
Level 4, School of Population Health
Tamaki Campus
Morrin Road, Glen Innes, Auckland
Private Bag 92019
NEW ZEALAND
Telephone: 64 9 373 7599
Email: r.dobson@nihi.auckland.ac.nz

You are invited to take part in a survey investigating how young people with type 1 diabetes manage their diabetes and how technology might be able to help them do this.

To help you decide if you want to take part in the study, please read this information sheet.

Who is co-ordinating this study?
The study is co-ordinated by the National Institute for Health Innovation (The University of Auckland).

What is the aim of this study?
The aim of the survey is to investigate how young people with type 1 diabetes in Auckland manage their diabetes and how technology might be able to help them do this. The results from the survey will be used to help develop a mobile phone based tool to help young people effectively manage diabetes.

Who can be in the study?
To take part in the study you have to:

- Be aged between 16 and 24 years
- Have type 1 diabetes
- Be able to read English
- Have received a letter of invitation to participate
- Able to provide informed consent

Where will the study take place?
There are three ways you can complete the survey:
1. Online: You can access the survey by going to www.diabetesinyouth.org.nz on your computer.
2. Over the phone: If you would prefer to complete the survey over the phone you can call or text your name to 021 0853 3322 and the researcher will call you back to arrange completing the survey over the phone
3. On paper: If you would prefer to complete a paper copy of the survey you can call or text your name to 021 0853 3322 and the researcher will call you back to arrange to send a printed copy of the survey to you.

How long will the study take?
It will take approximately 20-30 minutes to complete the survey.

How many people will be recruited into the study?
All young people aged 16 to 24 years with Type 1 diabetes who receive medical care through the adolescent clinics at Auckland District Health Board, Counties Manukau District Health Board and Waitemata District Health Board will be invited to participate.

What is involved if I take part?
If after reading this information sheet, you decide that you would like to take part in the study, you can access the survey online at a time that suits you. If you do not have access to a computer or the internet, or do not want to complete it online you can contact the lead researcher by texting 021 0853 3322 and you will be called back to arrange for you to either complete the survey over the phone or on paper.

What are the risks and benefits of this study?
We do not anticipate any risks with this study. However, taking part in this study will take some time.

Your participation in the study will help us to better understand how young people with diabetes manage their diabetes and will inform the development of a new tool to help young people with diabetes in the future. To acknowledge your time to take part in this study, **you will receive a $20 voucher** if you take part.

Will the information about me be kept confidential?
The study files and all information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. The information will be kept securely at the National Institute for Health Innovation, The University of Auckland for 15 years. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994.

During the study, ethics committee representatives, study personnel and members of the research team may check your records during the study. This will only be done to check the accuracy of information collected for the study and the information will remain confidential.

When will the results be available?
This study will take 3 months in total to conduct, so results will be available in 2014. You will be asked if you would like to be sent a copy of the overall results.

Has the study received ethical approval?
This study has received ethics approval from the Health and Disability Ethics Committee (HDEC) (ref: 14/CEN/24).

What are my legal rights?
Your participation in this study is entirely voluntary (your choice). You do not have to take part. If you choose not to take part in this study you will not be affected in any way. You may withdraw from the study at any time, without having to give a reason. Your withdrawal from the study will not affect your future health care or your relationship with the University of Auckland. You are encouraged to ask questions at any time. If you have any questions please contact the lead researcher:

Rosie Dobson
National Institute for Health Innovation
University of Auckland, Private Bag 92019
(09) 3737599 ext 84728
021 0853 3322
r.dobson@nihi.auckland.ac.nz

If you have any questions or concerns regarding your rights as a participant in this study you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Thank you for taking time to read about this study.
Please keep this sheet for your information.

A.2.4 Online consent form

www.diabetesinyouth.org.nz

Survey of young people with type 1 diabetes

You are invited to take part in a survey investigating how young people with type 1 diabetes manage their diabetes and how technology might be able to help them do this. The aim of the survey is to investigate how young people with type 1 diabetes in Auckland manage their diabetes and how technology might be able to help them do this. The results from the survey will be used to help develop a mobile phone based tool to help young people effectively manage diabetes. The study is co-ordinated by the National Institute for Health Innovation (The University of Auckland).

The study files and all information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study.

Your participation in this study is entirely voluntary (your choice). You do not have to take part. If you choose not to take part in this study you will not be affected in any way. You may withdraw from the study at any time, without having to give a reason. Your withdrawal from the study will not affect your future health care or your relationship with the University of Auckland.

What does the study involve? This study involves completing a one off survey about your diabetes and how you manage it. It will take approximately 20-30 minutes to complete the survey. To acknowledge your time to take part in this study, you will receive a $20 voucher if you take part.

Who can take part? To take part in the study you have to:

- Be aged between 16 and 24 years
- Have type 1 diabetes
- Be able to read English
- Have received a letter of invitation to participate

If you have any questions please contact the lead researcher:

Rosie Dobson
National Institute for Health Innovation
University of Auckland, Private Bag 92019
(09) 3737599 ext 84728 / 021 0853 3322
r.dobson@auckland.ac.nz

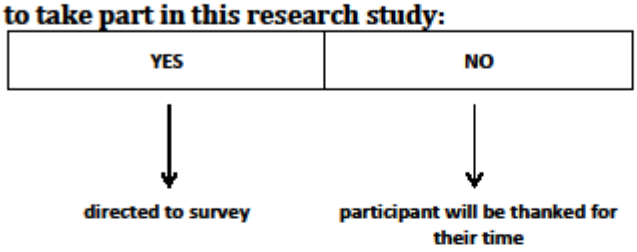
This study has received ethics approval from the Health and Disability Ethics Committee (HDEC) (ref: 14/CEN/24).

CONSENT:

- I have read and I understand the information sheet (Version 1) dated 02/02/2014 for volunteers taking part in this study. The study is designed to help us to investigate how young people manage their diabetes and how technology might be able to help them do this.
- I have had the opportunity to discuss this study with study researchers and I am satisfied with the answers I have been given.
- I have had the opportunity to use whānau/family support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care or my continuing health care.
- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- I understand the compensation provisions for this study.
- I have had time to consider whether to take part.
- I know whom to contact if I have any questions about the study.
- I understand that any data collected as part of this study will be stored securely for 15 years at the National Institute for Health Innovation, The University of Auckland, in accordance with the Privacy Act, 1994. After this time the information will be safely destroyed.

- I understand that any information collected, as part of this study will not be used for any other purpose, without my permission and ethical approval, nor given to any other third party outside of the research team.
- I understand that there may be a significant delay between data collection and publication of the results.
- I understand that the results of the study will be published in medical journals but none of these publications will contain information about me personally.

I agree to take part in this research study:



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A.2.5 Survey questions

Survey of young people with type 1 diabetes

VERIFICATION:

Before you start the survey please enter your 7 digit code below. You can find the code on the letter sent to you by your doctor. The code starts with one letter (not case sensitive) and then has six numbers e.g. A123456. (This is so we can check that only people invited to complete the survey do so and make sure that no one completes it twice)

The survey is split into two parts. The first part is going to ask questions about your diabetes and how you manage it and then the second part includes questions about you and what you do.

Please remember that your answers are not going to be shown to your doctors or nurses and will be kept confidential. Please answer the questions honestly.

If you have any questions please contact the researcher on 021 0853 3322.

PART 1: The first part of this survey is going you questions related to your diabetes and how you manage it.

SECTION 1: Diabetes management

First of all, how old were you when you were diagnosed with diabetes? _____

1. We want to know how much the management of your diabetes is controlled by you or your parents/caregivers/family. Please choose a point on the line that indicates the degree of input you and your parents/caregivers/family have.

   For example: If you select a point on the line towards the left this shows that your parents/family have most of the control over your diabetes management. If you select a point on the line towards the right hand side then this indicates that you have most of the control over your diabetes management

   My parents have all of the control over managing my diabetes ⟷ I have all of the control over managing my diabetes

2. Overall how well do you feel that you manage your diabetes?
   - Extremely well
   - Very well
   - Not so well
   - Not well at all
3. Overall how confident are you in your ability to manage your diabetes? (please select the number)

   0 1 2 3 4 5 6 7 8 9 10

   Not at all confident I can manage my diabetes — Moderately confident I can manage my diabetes — Completely confident I can manage my diabetes

4. How sure are you that you can do each of the following, **almost all the time**? (please select the number)

	Not sure at all									Completely sure
Adjust your insulin correctly when you eat more or less than usual.	1	2	3	4	5	6	7	8	9	10
Choose healthful foods when you go out to eat.	1	2	3	4	5	6	7	8	9	10
Exercise even when you don't really feel like it.	1	2	3	4	5	6	7	8	9	10
Adjust your insulin or food accurately based on how much exercise you get.	1	2	3	4	5	6	7	8	9	10
Talk to your doctor or nurse about any problems you're having with taking care of your diabetes.	1	2	3	4	5	6	7	8	9	10
Do your blood sugar checks even when you are really busy.	1	2	3	4	5	6	7	8	9	10
Manage your diabetes the way your health care team wants you to.	1	2	3	4	5	6	7	8	9	10
Manage your diabetes even when you feel overwhelmed	1	2	3	4	5	6	7	8	9	10
Find ways to deal with feeling frustrated about your diabetes.	1	2	3	4	5	6	7	8	9	10
Identify things that could get in the way of managing your diabetes.	1	2	3	4	5	6	7	8	9	10

5. What parts of your diabetes management do you find most difficult? (select up to 3)
    - Monitoring my blood glucose
    - Remembering to check my blood glucose
    - Eating well
    - Managing insulin
    - Problem solving (especially around blood glucose, highs and lows, sick days)
    - Being psychically active
    - Attending my medical appointments
    - Other (please specify):
6. Would you like to learn more about diabetes and how you can manage it?
    - No, I already know everything I need to know about diabetes and how to manage it
    - No, I don't want to know about diabetes and how to manage it
    - Yes, I would like to learn **a bit more** about diabetes and how to manage it
    - Yes, I would like to learn **a lot more** about diabetes and how to manage it
    - [if replied Yes] what areas would you like to learn more about:
        - About diabetes generally i.e. general facts
        - How to monitoring my blood glucose
        - Nutrition and eating well
        - Managing insulin
        - How to problem solve, especially around blood glucose, highs and lows, sick days etc
        - Physical activity/ Exercise
        - How to manage stress
        - Other (please specify)

7. Who do you get advice from about your diabetes?

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List of research project topics and materials

8. Where do you go when you have questions about your diabetes or how to manage it?

9. How often do you attend your clinic appointments?
    - Always
    - Sometimes
    - Once in a while but not very often
    - Never
    - [If sometimes/rarely/never] What prevents you from attending your appointments?
        - Transport issues
        - Timing of appointments doesn't suit me
        - I forget
        - Don't want to go
        - Don't need to go
        - Other (please specify)
10. Would you be interested in having your clinic appointments online via video calling such as Skype?
    - Yes
    - No
    - Please comment
11. How do you communicate with your diabetes doctors and nurses? (select all that apply)
    - When I am at my clinic appointment
    - Over the phone
    - Via text message
    - Other (please specify)

The following questions are going to ask you about your beliefs and attitudes towards managing your diabetes. When a question refers to diabetes management what we are referring to are all the things you do to manage your diabetes such as blood glucose monitoring and insulin use.

12. What do you think makes it **difficult** to manage your diabetes well?

13. What do you think makes it **easier** to manage your diabetes well?

14. How do you feel about managing your diabetes?

15. What do you **like or enjoy** about managing your diabetes?

16. What would you **dislike or hate** about managing your diabetes?

17. What do you think are the **advantages/benefits** of you managing your diabetes well?

18. What do you think are the **disadvantages/consequences** of you managing your diabetes well?

19. Are there any people (or groups of people) that **help you and are supportive of you** managing your diabetes well?

20. Are there any people (or groups of people) that are **stop you from** managing your diabetes well?

21. Living with diabetes can sometimes be difficult. In day-to-day life, there may be many problems and hassles with your diabetes. The problems may range from minor hassles to major life difficulties. Listed below are a variety of possible problem areas which people with diabetes may have. Think about how much each of the items below may have **upset or bothered you DURING THE PAST MONTH** and circle the appropriate number.

    Please note that we are asking you how much each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that an item is not a bother or a problem for you, you would circle "1". If it very bothersome to you, you would circle "6".

	Not a problem			Moderate problem		Serious problem
1. Feeling sad when I think about having and living with diabetes.	1	2	3	4	5	6
2. Not knowing if the mood or feelings I am having are related to my blood sugar levels.	1	2	3	4	5	6
3. Feeling overwhelmed by my diabetes regimen.	1	2	3	4	5	6
4. Feeling angry when I think about having and living with diabetes.	1	2	3	4	5	6
5. Feeling constantly concerned about food and eating.	1	2	3	4	5	6
6. Worrying about the future and the possibility of serious complications.	1	2	3	4	5	6
7. Feeling upset when my diabetes management is "off track."	1	2	3	4	5	6
8. Feeling "burned-out" by the constant effort to manage diabetes.	1	2	3	4	5	6
9. Feeling that I am not checking my blood sugars often enough.	1	2	3	4	5	6
10. Feeling unclear about exactly what or how much I should be doing to take care of my diabetes properly.	1	2	3	4	5	6
11. Not feeling motivated to keep up with my daily diabetes tasks.	1	2	3	4	5	6
12. Feeling discouraged or defeated when I see high blood sugar results on my meter.	1	2	3	4	5	6
13. Feeling that my friends or family act like "diabetes police" (e.g. nag about eating properly, checking blood sugars, not trying hard enough).	1	2	3	4	5	6
14. Feeling like my parents don't trust me to care for my diabetes.	1	2	3	4	5	6
15. Feeling I must be perfect in my diabetes management.	1	2	3	4	5	6
16. Missing or skipping blood sugar checks.	1	2	3	4	5	6
17. Feeling that my blood sugars are often swinging wildly, no matter how hard I try.	1	2	3	4	5	6
18. Feeling that I am often failing with my diabetes regimen.	1	2	3	4	5	6
19. Feeling like my parents blame me for blood sugar numbers they don't like.	1	2	3	4	5	6
20. Feeling that my friends or family don't understand how difficult living with diabetes can be.	1	2	3	4	5	6
21. Feeling that I can't control my eating.	1	2	3	4	5	6
22. Worrying about my weight.	1	2	3	4	5	6
23. Worrying that diabetes gets in the way of having fun and being with my friends.	1	2	3	4	5	6
24. Fitting my diabetes regimen into my day when I'm away from home (e.g. school, work, etc.).	1	2	3	4	5	6
25. Worrying about getting low during a sports activity.	1	2	3	4	5	6
26. Feeling like my parents worry about complications too much.	1	2	3	4	5	6

22. The following questions are about how you feel about taking care of your diabetes.

If I do everything I'm supposed to do to take care of my diabetes, it would...	Not at All									A lot
1. Be too much to think about.	1	2	3	4	5	6	7	8	9	10
2. Save me money in the future.	1	2	3	4	5	6	7	8	9	10
3. Keep me from living my life the way I want to.	1	2	3	4	5	6	7	8	9	10
4. Take too much time.	1	2	3	4	5	6	7	8	9	10
5. Make me have fewer high blood sugars.	1	2	3	4	5	6	7	8	9	10
6. Cost too much.	1	2	3	4	5	6	7	8	9	10
7. Make me be admired by my friends.	1	2	3	4	5	6	7	8	9	10
8. Save me money now.	1	2	3	4	5	6	7	8	9	10
9. Keep me from having fun at parties or on holidays.	1	2	3	4	5	6	7	8	9	10
10. Be too much work.	1	2	3	4	5	6	7	8	9	10
11. Keep me from missing too much school.	1	2	3	4	5	6	7	8	9	10
12. Give me too many marks on my skin from checking my blood.	1	2	3	4	5	6	7	8	9	10
13. Help me avoid fighting with my parents/guardians.	1	2	3	4	5	6	7	8	9	10
14. Be too strict of a schedule.	1	2	3	4	5	6	7	8	9	10
15. Keep my diabetes in better control.	1	2	3	4	5	6	7	8	9	10
16. Make me feel good about myself.	1	2	3	4	5	6	7	8	9	10
17. Help me do better in my schoolwork.	1	2	3	4	5	6	7	8	9	10
18. Keep me healthy.	1	2	3	4	5	6	7	8	9	10
19. Keep me from eating what I want.	1	2	3	4	5	6	7	8	9	10
20. Make me better in sports.	1	2	3	4	5	6	7	8	9	10
21. Make me gain weight.	1	2	3	4	5	6	7	8	9	10
22. Be too much responsibility.	1	2	3	4	5	6	7	8	9	10
23. Give me more energy.	1	2	3	4	5	6	7	8	9	10
24. Keep me from doing things with my friends.	1	2	3	4	5	6	7	8	9	10

SECTION 2: Using technology to manage diabetes

1. Do you use any of the following to help you manage your diabetes, track your diabetes or learn about diabetes:
    - Apps
        - [if yes] Please specify the name of the app(s):
        - [if yes] How useful do you find this app(s)
            - Extremely useful
            - A little useful
            - Not very useful
            - Not at all useful
            - [if extremely useful/a little useful] Why is it useful?
            - [if not very useful/not at all useful] Why isn't it useful?
    - Websites
        - [if yes] Please specify the name of the website(s):
        - [if yes] How useful do you find this website(s)
            - Extremely useful
            - A little useful
            - Not very useful
            - Not at all useful
            - [if extremely useful/a little useful] Why is it useful?

        - [if not very useful/not at all useful] Why isn't it useful?
    - Is there anything else that you use or have used in the past to manage your diabetes? [please specify]
2. If a text message based programme was available to help you manage your diabetes would you be interested in this?
    - Yes
    - No
    - [If yes] How frequently would you want to receive messages?
        - Multiple times per day
        - Once a day
        - Once every few days
        - Once a week
        - Less than once a week
    - [If yes] Are there any specific things you would want the messages to be about?
    - [if no] Why not
3. If available would you be interested in receiving text messages about the following topics:
    - Eating healthier
    - Being more physically active
    - Stress management
    - Depression or anxiety prevention
    - Other topics: Please specify

PART 2: The second part of this survey is about you and the things you like to do. It is split into three sections

SECTION 1: General information

1. How old are you?
    - _____ years
2. Are you:
    - Male
    - Female
3. Which ethnic group or groups do you identify with?
    - New Zealand European
    - Māori
    - Samoan
    - Cook Island Maori
    - Tongan
    - Niuean
    - Chinese
    - Indian
    - Other such as *DUTCH, JAPANESE, TOKELAUAN*. Please state: _____
4. What best describes your occupation (select all that apply)
    - High school student
    - University or polytechnic student
    - Work full time
    - Work part time
    - Unemployed or not working
    - Other, please specify: _____
5. Where do you go for general health and medical advice
    - Internet
    - Parents/caregivers
    - Other family/whanau
    - Friends
    - Qualified medical professionals (e.g. GP, nurse)
    - Other (please specify)

6. Do you own a mobile phone:
    - Yes
    - No [if no redirected to question 11]
7. Is your phone a Smartphone (i.e. iPhone, Android)
    - Yes
    - No
    - Don't know
    - [if yes] How often do you have access to data (internet) on your smartphone?
        - All the time
        - Sometimes
        - When I have access to Wi-Fi (at home/work/school)
        - Never
        - Other (Please specify)
8. Is your phone on a plan/contract or is it prepay (pay as you go)?
    - Prepay
    - Plan
    - Don't know
9. How old were you when you got your first mobile phone?
    - _____ years
10. When do you have your phone turned off:

	Always turn it off	Sometimes turn it off	Never turn it off	Not applicable
At school/university/work				
When going to sleep				
Other (please specify)				

11. Do you have access to internet at home?
    - Yes
    - No

SECTION 2: Wellbeing

1. Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

    Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	Over the last two weeks	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1	I have felt cheerful and in good spirits	5	4	3	2	1	0
2	I have felt calm and relaxed	5	4	3	2	1	0
3	I have felt active and vigorous	5	4	3	2	1	0
4	I woke up feeling fresh and rested	5	4	3	2	1	0
5	My daily life has been filled with things that interest me	5	4	3	2	1	0

SECTION 3: Self-care behaviours

1. In the last 7 days, how many times have you done any exercise or activity for a total of at least 60 minutes that makes you sweat or breathe hard, or gets your heart rate up (such as soccer or rugby, running, swimming laps, fast bicycling, etc.)?
    - I don't exercise
    - Not in the last 7 days
    - 1 time
    - 2 times
    - 3 times
    - 4 times
    - 5 times
    - 6 times
    - 7 or more times

2. This next section asks about cigarettes, alcohol and other drugs. Remember, you don't have to answer the questions if you don't want to and that if you do your answers will be kept confidential.
   Do you currently smoke cigarettes?
   - Yes
   - No
   - [If yes] How often do you smoke cigarettes?
     - Daily
     - Occasionally
     - Once or twice a month
     - Once or twice a week
     - Most days
3. We would now like to now ask some questions about alcohol. By this we mean beer, wine, spirits, pre-mixed drinks. During the past 4 weeks, about how often did you drink alcohol?
   - Not at all - I don't drink alcohol
   - Not in the last 4 weeks
   - Once in the last 4 weeks
   - Two or three times in the last 4 weeks
   - About once a week
   - Several times a week
   - Most days
4. How many alcoholic drinks do you usually have in one session - within about 4 hours? (Count one drink as one small glass of wine, one can or stubbie, one ready-made alcoholic drink, e.g. rum and Coke)
   - 1 drink
   - 2 drinks
   - 3 to 4 drinks
   - 5 to 9 drinks
   - 10 to 20 drinks
   - More than 20 drinks
5. Have you ever used recreational drugs, by this we mean marijuana (pot, grass, weed, cannabis), party pills, acid, solvents, speed, ecstasy, etc.
   - Yes
   - No
   - [if yes] During the past 4 weeks, about how often did you use recreational drugs?
     - Not in the last 4 weeks
     - Once in the last 4 weeks
     - Two or three times in the last 4 weeks
     - About once a week
     - Several times a week
     - Most days
6. That's the end of the survey, do you have any comments about anything that has been mentioned in this survey?

Thank you for taking the time to complete this survey. Your responses will help us to develop tools to support young people with diabetes.

If you have any concerns about anything mentioned in this survey please contact the lead researcher on 021 0853 3322.

If you have any concerns about your diabetes or your health please contact you diabetes nurse or doctor or your GP.

Additionally you can contact youthline 0800 37 66 33 or lifeline 0800 543 354 for free 24 hour confidential support

REINBURSEMENT AND FUTURE RESEARCH:

At this point all survey responses have been anonymous. If you would like to receive a $20 Westfield voucher as reimbursement for time taken to complete this survey, or would like a copy of the study results, we need some additional information in order to contact you (this is optional):

1. If you would like a voucher please enter your full name and postal address:
2. Would you like to know the results of this study when they are made available?
    - Yes – please enter your name and postal address or email address

      _____
    - No
3. Would you like to be contacted about upcoming research studies on young people with type 1 diabetes?
    - Yes – please enter your name and email address

      _____
    - No

Thank you again for taking the time to complete this survey!

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APPENDIX 3: SUPPORTING DOCUMENTS FOR CHAPTER 5

A3.1 Content upload template

A.3.1. Content upload template with example content

Module	Day	Question	Message	ID	Response1
Core_Maori1	0	FALSE	SMS4BG: Kia ora [firstname]. Welcome to the SMS4BG program. We will be sending you text messages over the next few months to support you to manage your diabetes	M0	
Core_Maori1	1	FALSE	SMS4BG: Kia ora. You & your whanau can become experts in managing your diabetes. Your doctor/nurse & SMS4BG are here to support you as well as [support1name]	M1	
Core_Maori1	4	FALSE	SMS4BG: Kia ora. Sometimes it can be hard to keep on top of your diabetes. Remember there are lots of great benefits to good diabetes management	M2	
Core_Maori1	85	TRUE	SMS4BG: We have been sending you messages for 3 months. Would you like us to continue for another 3 months? Free reply text YES to continue or NO to stop	M25	[if reply YES] SMS4BG: Ka pai. That's great to hear. Would you like any changes to the type or number of messages you are getting? Let us know by free reply message.

APPENDIX 4: SUPPORTING DOCUMENTS FOR CHAPTER 6

A4.1 Ethics approval letter

A4.2 Follow up interview questions

A4.3 Enrolment form

A4.4 Content intervention development pre-testing checklist

A4.5 Website screenshots

A4.1 Ethics approval letter

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
1 the Terrace
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

07 May 2013

Dr Robyn Whittaker
National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland Mail Centre
Auckland 1142

Dear Dr Whittaker

Re:	**Ethics ref:**	**13/NTA/55**
	Study title:	Self Management Support For Blood Glucose

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).
3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

A4.2 Follow up interview questions

SMS4BG Pilot Study Follow up Questionnaire

Study ID:			
Preferred name:			
Mobile number:			
Programmes received:	**Main programme**	General	
		Māori	
	Smoker	Smoking	
	Insulin	Insulin	
	Adolescent	Adolescent	
	Lifestyle add on	Exercise	
		Healthy eating	
		Stress and mood	
	Monitoring	1 per week	
		3 per week	
		1 per day	
		2 per day	
		3 per day	
		4 per day	
Messages	**# valid responses received**		
	# unrecognised responses		
	# invalid responses		
Interview completed by:			
Date completed (dd/mm/yyyy):			

Attempts to contact	**Details**
Attempt 1:	
Attempt 2:	
Attempt 3:	
Attempt 4:	
Attempt 5:	
Attempt 6:	
Attempt 7:	
Attempt 8:	

Hi, my name is ___ and I am ringing from the University of Auckland. We would just like to ask you a few questions about your experience with the diabetes text messaging study.

Is now a good time? [If not confirm a suitable time and call back]

1. What did you think about the SMS4BG programme?

2. Did you find the messages useful? Yes/No
   if yes-> a little 1 2 3 4 5 Extremely

   a. Were there any particular messages or type of messages that you found most useful or not so useful?

3. Did you find the messages culturally appropriate? Yes/No

4. Did you find the messages age appropriate? Yes/No

5. Did you have any technical issues with the system? Yes/No

6. What did you think about the frequency of the messages?

7. We would like to know if the SMS4BG programme has had any impacts on you and your diabetes. Do you think the programme has had any impacts?

	Did the programme impact…	Yes?	No?	Comments?
a	how often you monitor your blood glucose?			
b	your BG control			
c	your diet or eating			
d	your exercise			
e	how you have been feeling (mood)?			
f	how you perceive/view your diabetes?			
g	your knowledge and understanding of your diabetes?			
h	anything else?			

8. Did you choose to receive reminders to check your blood glucose as part of the programme? [if no go to question 11]
    a. Did you find the reminders to check your BG useful? Yes/No
    b. Do you think having the reminders increased how often you tested your blood glucose? Yes/No
    c. Was the frequency of reminders too much/just right/too little?
        i. If too much or too little: What do you think the most helpful frequency of messages would be?

    d. Did you view your graph online? Yes/No
        i. If yes, was this useful?

        ii. If no, was there any particular reason why you choose not to view your graph?

9. If it was available would you have wanted to programme to go on for longer? Yes/No [if no go to next question]
    a. How long do you think the programme should go for?

b. If the programme went for longer would you like it to change or just continue as is?

10. We would like to know if you have any suggestions for how we could improve the programme.

11. Would you find it useful to be able to text in questions? (2-way communication): Yes/No

12. Would you recommend the programme to other people with diabetes? Yes/No
    a. Why/why not?

13. Do you have any final comments or feedback?

For participating in the study we would like to send you a voucher to say thank you and reimburse you for any costs you incurred as a result of replying to the text messages, what address should we send your voucher too?

Thank you for your time. We will send you a link via text message when the study findings have been made available.

A4.3 Enrolment form

No.	Question	Answer options
0	ID	SMS_ _ _ _
1	Programme start date:	__ __ __ 2 0 __ *day month year*
2	Preferred mobile number	**02** |_| |_||_||_||_||_||_||_||_|
3	Confirm mobile number	**02** |_| |_||_||_||_||_||_||_||_|
4	Preferred message delivery time	◯ Early morning (7-9am) ◯ Mid-morning (9.30am-12pm) ◯ Early Afternoon (12.30-3pm) ◯ Late Afternoon (3.30-5.30pm) ◯ Evening (6-8pm) ◯ Day (9am-5pm)
	Region	◯ Auckland (ADHB or WDHB) ◯ Non-Auckland
Tailoring questions		
5	Preferred name	Name: _____
6	Key support person 1 - role	◯ Partner ◯ Parent/Caregiver ◯ Child ◯ Friend ◯ Other (please specify)_____
7	Key support person 1 - name	Name: _____
8	Key support person 2 - role	◯ Partner ◯ Parent/Caregiver ◯ Child ◯ Friend ◯ Other (please specify)_____
9	Key support person 2 - name	Name: _____
10	Motivations for good diabetes management (people) (1)	◯ your family ◯ your whanau ◯ your partner ◯ your husband ◯ your wife ◯ your mum ◯ your dad ◯ your child ◯ your children ◯ your grandchild ◯ your grandchildren ◯ your friends
11	Motivations for good diabetes management (people) (2)	◯ your family ◯ your whanau ◯ your partner ◯ your husband ◯ your wife ◯ your mum ◯ your dad ◯ your child ◯ your children ◯ your grandchild ◯ your grandchildren ◯ your friends ◯ career ◯ health in the future ◯ sport ◯ fitness
12	Motivations for good diabetes management (young adult only) (limit 1)	◯ career ◯ health in the future ◯ sport ◯ fitness ◯ friends

Module selection		
9	Core module	○ Maori ○ Pacific: Samoan ○ Pacific: Tongan ○ Pacific: Other pacific islander ○ Non-Maori/Pacific
10	Lifestyle module	○ None ○ Healthy eating ○ Exercise ○ Stress management
11	Blood glucose monitoring reminders	○ None ○ 1/week (timeslot option selected in Q4) ○ 3/week (timeslot option selected in Q4) ○ 1/day – early morning timeslot ○ 1/day – mid morning timeslot ○ 1/day – early morning timeslot ○ 1/day – late afternoon timeslot ○ 1/day – evening timeslot ○ 2/day – early morning & late afternoon ○ 2/day – mid morning & late afternoon ○ 2/day – early morning & evening ○ 2/day – mid morning & evening ○ 3/day – early morning, early afternoon & evening ○ 4/day – early morning, mid-morning, late afternoon & evening
12	[If no internet access at home] Would you like your results graph emailed to you or posted?	○ Not applicable – internet access ○ Emailed ○ Posted
13	Insulin module → if on insulin	○ Yes ○ No
14	Young adult module → if aged 16 to 24 years	○ Yes ○ No
15	Smoking module → if smoker	○ Yes ○ No
16	Foot care module → if category = high risk or active disease	○ Yes ○ No

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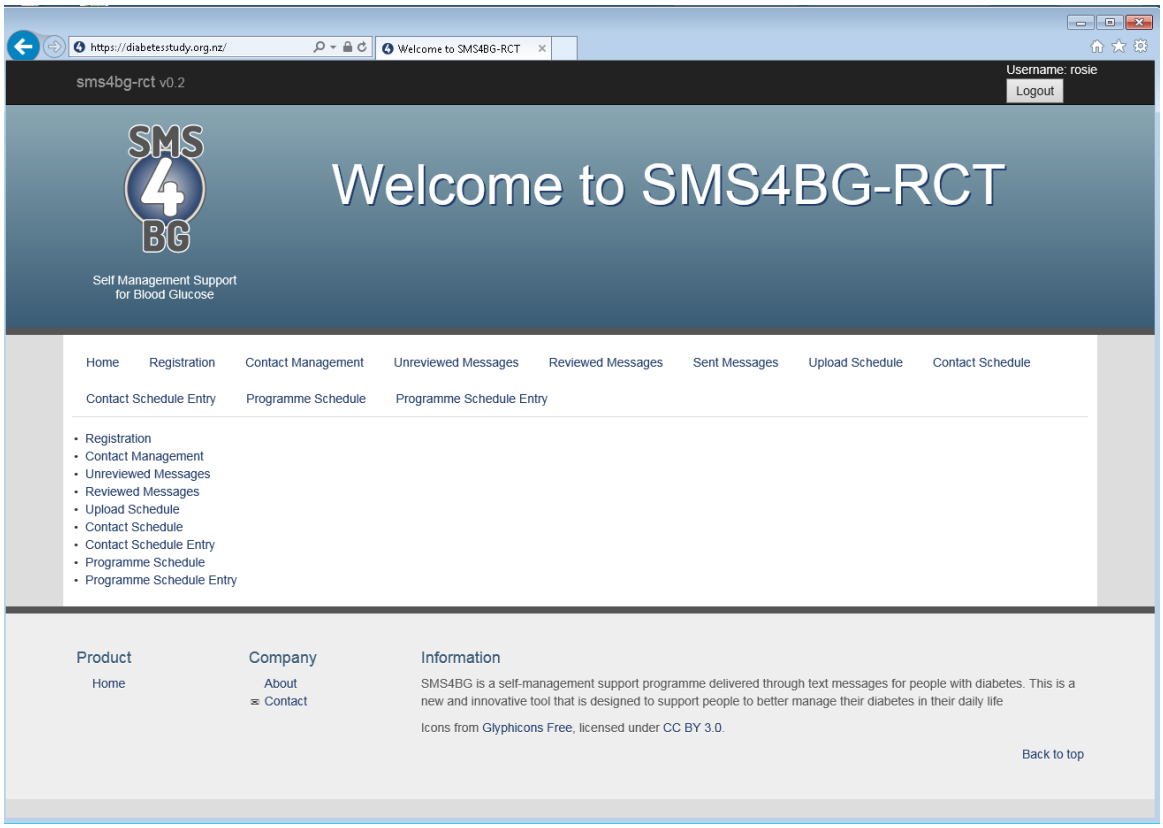
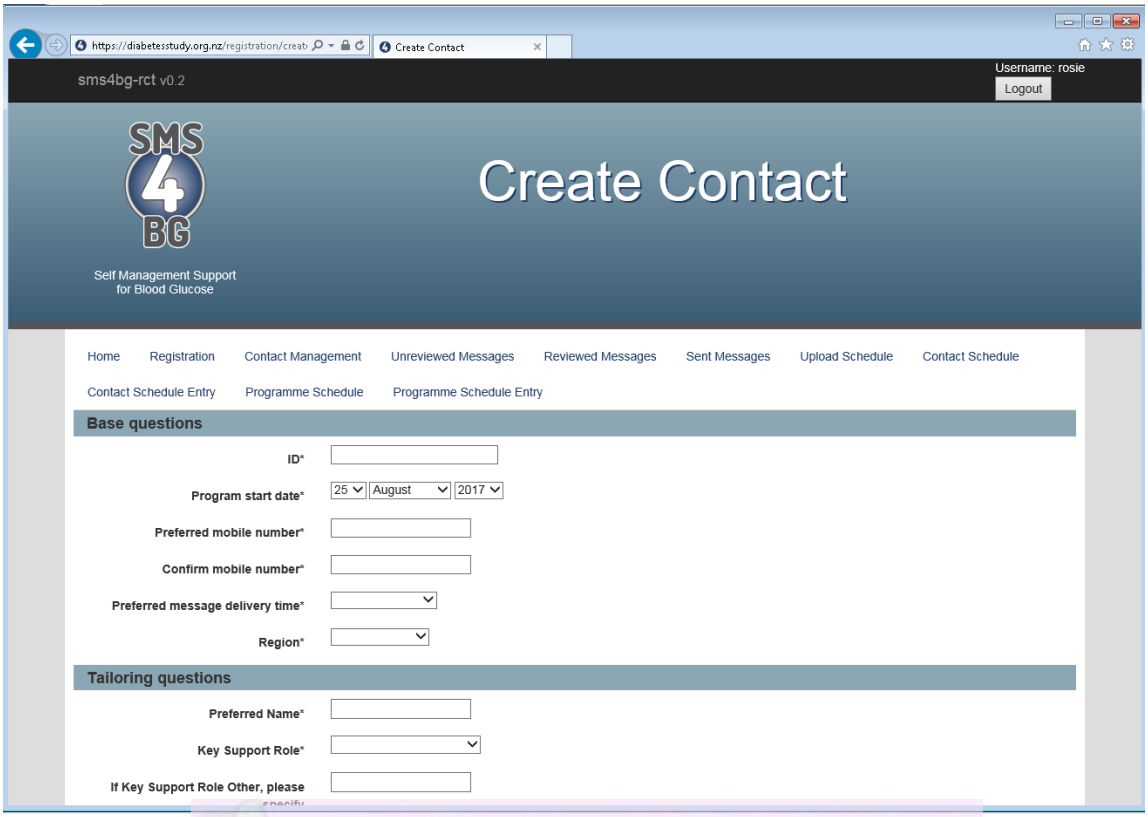
A4.4 Content intervention development pre-testing checklist

MODULE	Content finalised	External review	Finalised	System tested
Core 1	Yes	Dr Rinki Murphy (Diabetes Specialist) Jo Naylor (Diabetes Nurse Specialist)	Yes	Yes
Core 2				Yes
Core 3				Yes
Maori 1	Yes	Māori Advisory Group	Yes	Yes
Maori 2				Yes
Maori 3				Yes
Pacific 1	Yes	Dr Aumea Herman (Pacific GP)	Yes	Yes
Pacific 2				Yes
Pacific 3				Yes
Smoking 1	Yes	Dr Robyn Whittaker (Public Health Physician)	Yes	Yes
Smoking 2				Yes
Smoking 3				Yes
Young adult 1	Yes	Dr Rinki Murphy (Diabetes Specialist) Jo Naylor (Diabetes Nurse Specialist)	Yes	Yes
Young adult 2				Yes
Young adult 3				Yes
Insulin 1	Yes	Dr Rinki Murphy (Diabetes Specialist) Jo Naylor (Diabetes Nurse Specialist)	Yes	Yes
Insulin 2				Yes
Insulin 3				Yes
Monitoring	Yes	Dr Rinki Murphy (Diabetes Specialist)	Yes	Yes
Monitoring Info 1	Yes	Dr Rinki Murphy (Diabetes Specialist) Jo Naylor (Diabetes Nurse Specialist)	Yes	Yes
Monitoring Info 2				Yes
Monitoring Info 3				Yes
Foot care 1	Yes	Michelle Garrett (Diabetes Podiatrist)	Yes	Yes
Foot care 2				Yes
Foot care 3				Yes
Healthy eating	Yes	Rebecca McLean (Dietitian)	Yes	Yes
Exercise	Yes	Leila Dale (Research Fellow)	Yes	Yes
Stress/Mood	Yes	Dr Lisa Reynolds (Health Psychologist)	Yes	Yes
Cardio	Yes	Dr Rinki Murphy (Diabetes Specialist)	Yes	Yes

A4.5 Website screenshots

Afministrator view:





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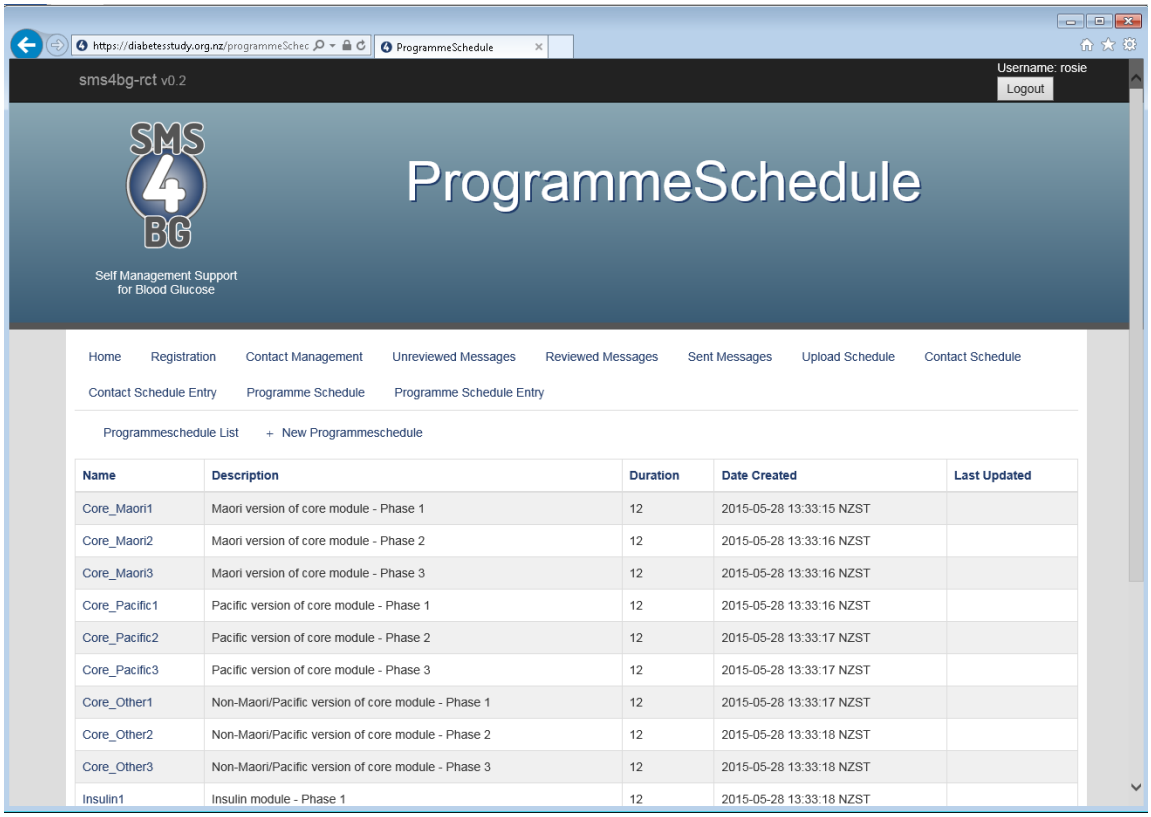
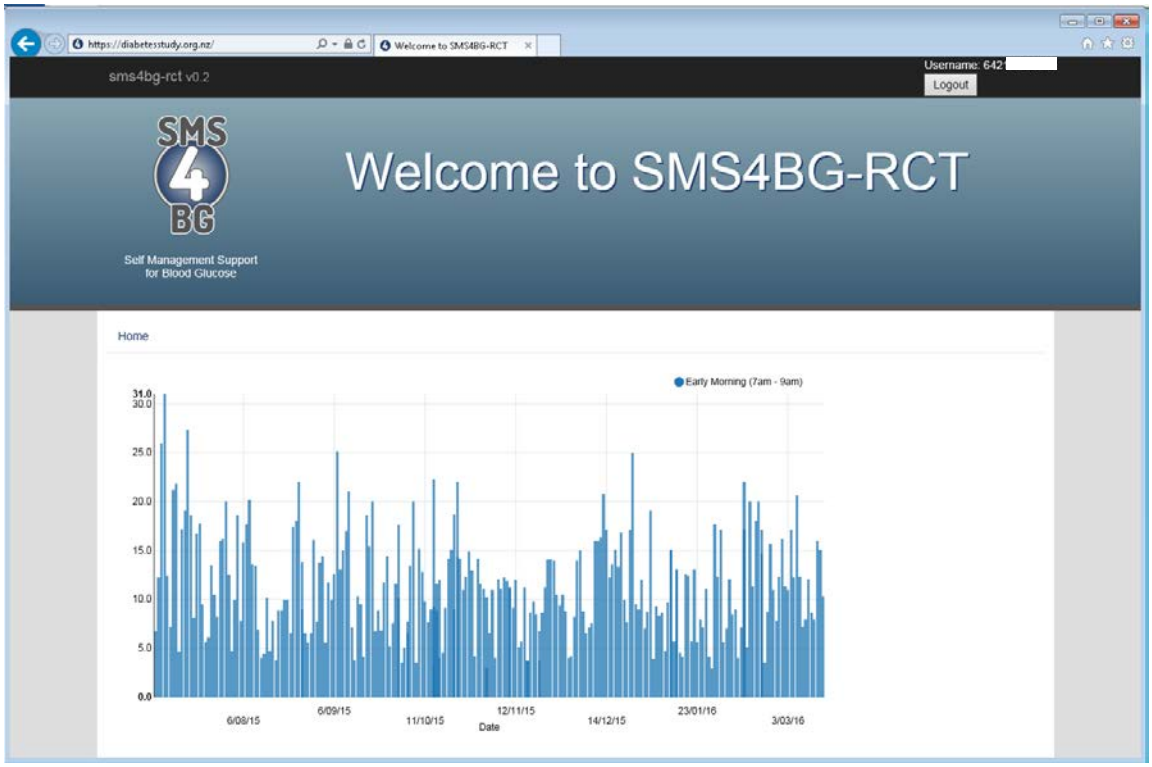
List of research project topics and materials



Participant view:



APPENDIX 5: SUPPORTING DOCUMENTS FOR CHAPTER 7

A5.1 SPIRIT checklist

A5.2 Ethics approval letter

A5.3 Participant information sheet

A5.4 Consent form

A5.5 Baseline forms

A5.6 Follow up forms

A6.6 Example referral forms

A5.1 SPIRIT checklist

Section/item	Item No	Included in manuscript (Y/N) or described below
Administrative information		
Title	1	Y
Trial registration	2a	Y
	2b	Y
Protocol version	3	Version 4: 16/09/2015
Funding	4	Y
Roles and responsibilities	5a	Y
	5b	Y
	5c	Y
	5d	The trial steering committee is comprised of the protocol authors. The National Institute for Health Innovation IT team is responsible for the SMS content management system and data management is overseen by the National Institute for Health Innovation data management team.
Introduction		
Background and rationale	6a	Y
	6b	Y
Objectives	7	Y
Trial design	8	Y
Methods: Participants, interventions, and outcomes		
Study setting	9	Y
Eligibility criteria	10	Y
Interventions	11a	Y
	11b	Y
	11c	Y
	11d	Y
Outcomes	12	Y
Participant timeline	13	Y
Sample size	14	Y
Recruitment	15	Y
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Y
Allocation concealment mechanism	16b	Y
Implementation	16c	Y
Blinding (masking)	17a	Y
	17b	Y
Data collection methods	18a	Y – All data collection forms are located in the Trial Master File
	18b	Y
Data management	19	Y – All data collection methods are described in the Manual of Procedures located in the trial master file. All data will be entered into REDCap. At least 10% of data in the electronic system will be checked and validated against the source document (where a hard copy exists).
Statistical methods	20a	Y – The statistical methods are described in full in the Statistical Analysis Plan located in the Trial Master File
	20b	Y
	20c	Y
Methods: Monitoring		
Data monitoring	21a	The study does not meet two or more of the criteria outlined by Ellenburg et al. (2002) and therefore a DMC will not be established for the trial. An independent project monitor will be appointed. The monitor will be trained in GCP. The project is considered to be low risk. The monitor will check primary outcome measures, and TMF and consent forms for completeness and accuracy.

	21b	NA – The trial is low risk and no interim analyses are planned
Harms	22	Y – The trial is low risk
Auditing	23	Y - The trial will be subject to independent auditing.
Ethics and dissemination		
Research ethics approval	24	Y
Protocol amendments	25	Amendments will be communicated to the Trial Steering Committee, ethics boards and trial registry where needed.
Consent or assent	26a	Y
	26b	NA
Confidentiality	27	Y – Confidentiality will be protected by the use of study registration numbers, and only aggregated and anonymous data will be reported. Personal information will be kept confidential and stored securely. Computerised information will be password protected. All reports from the study will be written in a way that no individuals can be identified. Information about study subjects will be kept confidential in keeping with the obligations set out in the Privacy Act 1993, the Health Information Code 1994 and Section 22B to 221 of the Health Act 1956. Data will be entered, stored and backed-up in a secure manner on a server at the National Institute for Health Innovation.
Declaration of interests	28	Y
Access to data	29	Y
Ancillary and post-trial care	30	Described in the Participant Information Sheet and Consent Form located in the Trial Master File
Dissemination policy	31a	Y – A copy of the trial Publication Plan included in the Trial Master File
	31b	Outlined in the trial Publication Plan included in the Trial Master File. No professional writers will be used.
	31c	Y – There is no plan to make the data set public
Appendices		
Informed consent materials	32	Version 3, (27/02/2015) located in the Trial Master File
Biological specimens	33	NA

A5.2 Ethics approval letter

Health and Disability Ethics Committees

Health and Disability Ethics Committees
C/- MEDSAFE, Level 6, Deloitte House
10 Brandon Street
PO Box 5013
Wellington

0800 4 ETHICS
hdecs@moh.govt.nz

05 November 2014

Ms Rosie Dobson
National Institute for Health Innovation
University of Auckland
Private Bag 92019
Auckland 1142

Dear Ms Dobson

Re:	**Ethics ref:**	**14/STH/162**
	Study title:	SMS4BG: A randomised controlled trial of a text message based diabetes self-management support intervention

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).
3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 5 November 2015.

A5.3 Participant information sheet

Participant Information

SMS4BG:
Diabetes Text Message Support Study

THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

National Institute for Health Innovation
The University of Auckland
Level 4, School of Population Health
Tamaki Campus, Morrin Road, Glen Innes
Private Bag 92019
Auckland
NEW ZEALAND
Telephone: 64 9 373 7599
Facsimile: 64 9 373 1710
Email: r.dobson@auckland.ac.nz
www.nihi.auckland.ac.nz

You are invited to take part in the SMS4BG study that will help us evaluate whether a text message programme delivered by mobile phone is effective in supporting people with diabetes. To help you decide if you want to take part in the study, please read this information sheet. Please take your time to think about the information provided below and feel free to discuss it with your whanau, family or significant other support people before deciding whether to take part. Taking part is completely voluntary (your choice). If you have any questions you can contact the researchers at any time.

Who is co-ordinating this study?
The study is co-ordinated by the National Institute for Health Innovation (The University of Auckland) and is funded by the Health Research Council, in partnership with Waitemata and Auckland District Health Boards, and by the Ministry of Health.

What is the aim of this study?
The aim of the study is to evaluate whether a text message programme delivered by mobile phone is effective in supporting people with diabetes.

About this study:
We plan to recruit 1000 people to take part in the 9 month study. At the start of the study and again 9 months later you will be required to complete questions over the phone with a researcher at a time that suits you. If you agree to take part in the study, you will be randomly allocated (like the toss of a coin) to one of two groups:

- **Intervention group:** Everyone in this group will receive a personalised text message programme to support them to manage their diabetes for 3 to 9 months. Everyone in this group will be encouraged to continue with their usual diabetes care and medical appointments.
- **Control group:** Everyone in this group will be encouraged to continue with their usual diabetes care and medical appointments.

What will my participation in the study involve?
A researcher will contact you by phone to check your eligibility, answer any questions and obtain verbal consent. We encourage you to talk to your family, whanau and friends about taking part before you make a decision however you can withdraw at any time. We will post you a copy of the consent form for you to keep. To help confirm your eligibility we will obtain a copy of your most recent HbA1c test result from your medical records (through your hospital or PHO). You will also be asked questions about yourself, your diabetes and how you manage your diabetes. This should take about 20-30 minutes.

At the end of the study you will be contacted again by phone for another interview. We will ask questions about your diabetes and how you manage it. This should also take around 20-30 minutes.

	Phone interview	
	Study start	**Study end**
How long will it take?	20-30 minutes	20-30 minutes
Study explained, verbal consent obtained	✓	
Inclusion and exclusion criteria checked	✓	
Questions about your lifestyle and diabetes related behaviors	✓	✓
Intervention group only: Feedback on the intervention		✓

We are interested in whether taking part in this study affects your blood glucose control and how much you use healthcare services. Therefore at the end of the study you will be sent a lab test form for you to have an HbA1c test (glucose blood test). We will also obtain, from your medical records, your HbA1c test results and healthcare utilisation (e.g. number of GP or hospital visits) from 9 months before the study begins through to the end of the study.

Please note that HbA1c tests are a part of regular diabetes care and so you may be requested by your doctor to have these tests done while taking part in the study and it is important that you continue to do this as your doctor recommends.

Phone calls can be at a time that suits you.

At the end of the study you will receive a $20 voucher as reimbursement for your time taking part in the study.

Who can take part in this study?
To take part in the study you must:

- Be aged 16 years or older
- Have type 1 or type 2 diabetes
- Have an HbA1c >65mmol/ml in the last nine months
- Have a mobile phone that can be used for this programme
- Be able to provide informed consent
- Be able to read English
- Be available for the 9 month study duration

How long will the study take?
This study is 9 months in duration.

What are the risks and benefits of this study?
We do not anticipate any risks with this study. However, taking part in this study will take some time. Your participation will help us to test this new way to deliver diabetes information and support, and may benefit people with diabetes in the future. It may also help you to self-manage your diabetes and prevent the long term complications associated with the disease.

Will the information about me be kept confidential?
The study files and all information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. The information will be kept securely by the National Institute for Health Innovation, The University of Auckland for 15 years. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994.

During the study, ethics committee representatives, study personnel, members of the research team and possibly representatives of the study sponsor may check your records during the study. This will only be done to check the accuracy of information collected for the study and the information will remain confidential.

When will the results be available?
This study will take 18 months in total to conduct, so results will be available early 2017. You will be asked if you would like to be sent a copy of the overall results.

Has the study received ethical approval?
This study has received ethics approval from the Health and Disability Ethics Commission (ref: 14/STH/162).

What are my legal rights?
Your participation in this study is entirely voluntary (your choice). You do not have to take part. If you choose not to take part in this study you will not be affected in any way. You may withdraw from the study at any time, without having to give a reason. Your withdrawal from the study will not affect your future health care or your relationship with the University of Auckland. You are encouraged to ask questions at any time during the study. If you have any questions please contact the Study co-ordinator:

Rosie Dobson
National Institute for Health Innovation
University of Auckland, Private Bag 92019
Ph: 64 9 373 7599 ext. 84766
r.dobson@auckland.ac.nz

Research Team:
Dr Robyn Whittaker (Principal Investigator)
Mr Tim Wood (Co-investigator)
A/P Ralph Maddison (Co-investigator)
Ms Rosie Dobson (Co-investigator and Study coordinator)
Dr Matt Shepherd (Co-investigator)
Dr Rick Cutfield (Co-investigator)
Dr Catherine McNamara (Co-investigator)
Dr Rinki Murphy (Co-investigator)
Dr Manish Khanolkar (Co-investigator)
Dr Yannan Jiang (Co-investigator)

If you have any questions or concerns regarding your rights as a participant in this study you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Thank you for taking time to read about this study.
Please keep this sheet for your information.

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A5.4 Consent form

SMS4BG:
Diabetes Text Message Support Study

THE UNIVERSITY OF AUCKLAND
NEW ZEALAND
National Institute for Health Innovation
The University of Auckland
Level 4, School of Population Health
Tamaki Campus, Morrin Road, Glen Innes
Private Bag 92019
Auckland
NEW ZEALAND
Telephone: 64 9 373 7599
Facsimile: 64 9 373 1710
Email: r.dobson@auckland.ac.nz
www.nihi.auckland.ac.nz

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to discuss this study with study researchers and I am satisfied with the answers I have been given.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study.
I understand that a copy of this consent form will be mailed to me and that I have the right to withdraw consent after discussion with friends, family, whanau by contacting the researchers.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I agree for the researchers to have access to my hospital and/or primary care medical records to obtain my laboratory test results and health information related to this study.
I understand that any data collected as part of this study will be stored securely for 15 years at the National Institute for Health Innovation, The University of Auckland, in accordance with the Privacy Act, 1994. After this time the information will be safely destroyed.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, National Institute for Health Innovation or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I understand that the results of the study will be published in medical journals but none of these publications will contain information about me personally.

I understand that there may be a significant delay between data collection and publication of the results.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant and agree to be contacted for an interview at the end of the 9 month study period.

Verbal declaration by participant:

I agree with all the statements above and hereby consent to take part in this study.

Participant's full name: Date:

I wish to receive a summary of the results from the study. Yes / No

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Researcher's contact number:

Signature: Date:

Once copy of the completed consent form is to be mailed to the participant and the second completed consent form is to be placed in the trial record file.

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List of research project topics and materials

A5.5 Baseline forms

Confidential

Registration

SMS Registration number _____

Date of assessment _____
(DD-MM-YYYY)

Referral received from : Referrer name _____

Referral: DHB/PHO name _____

Are you aged 16 years or over
○ Yes
○ No

Do you have Type 1 or 2 diabetes
○ Yes
○ No

Latest HbA1c over 65mmol/mol
○ Yes
○ No

Own & able to use mobile phone
○ Yes
○ No

Can you understand and read English?
○ Yes
○ No

Consent to study participation obtained?
○ Yes
○ No

Available for the next 9 months
○ Yes
○ No

Baseline

SMS Registration number	_____
Gender	◯ Male ◯ Female
Date of birth	_____ (DD-MM-YYYY)
Age (years)	_____

Ethnicity: Which ethnic group or groups do you belong to? (please select all that apply)

	Yes
New Zeland European	◯
Maori	◯
Samoan	◯
Cook Island Maori	◯
Tongan	◯
Niuean	◯
Tokelauan	◯
Fijian	◯
Other Pacific peoples	◯
Chinese	◯
Indian	◯
Other	◯

If other, specify	_____
Ethnicity: Please select the appropriate category for the participants ethnicity	◯ Maori/Pacific ◯ non-Maori/non-Pacific (If any of the following are selected in previous question then select "1, Maori/Pacific": Maori, Samoan, Cook Island Maori, Tongan, Niuean, Tokelauan, Fijian, Other Pacific Peoples)
Postcode	_____ (https://www.nzpost.co.nz/tools/address-postcode-finder)
Urban/Rural classification	◯ Urban ◯ Rural
DHB region	◯ Auckland (WDHB or ADHB) ◯ non-Auckland

Employment status: At present are you (selection one only)

- ○ Self-employed
- ○ Full-time salray or wage earner
- ○ Part-time salary or wage earner (less then 30 hours/week)
- ○ Retired
- ○ Full-time home-maker
- ○ Student
- ○ Unemployed
- ○ Other beneficiary
- ○ Refuse to answer

Self-Efficacy for Diabetes

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

Summary of Diabetes Self-care Activities

The next questions ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days please think back to the last seven days when you were not sick.

On how many of the last 7 days have you followed a healthful eating plan?

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

On average, over the past month, how many days per week have you followed your eating plan?

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

On how many of the last 7 days did you eat five or more servings of fruits and vegetables?

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

On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?

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

On how many of the last 7 days did you participate in at least 30 minutes of physical activity?

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

On how many of the last 7 days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work?

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

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

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

On how many of the last 7 days did you test your blood sugar the number of times recommended by your health care provider?

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

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

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

On how many of the last 7 days did you inspect the inside of your shoes?

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

Have you smoked a cigarette, even one puff, during the past 7 days?

- ○ Yes
- ○ No

If yes, how many cigarettes did you smoke on an average day?

_____

Diabetes Disttress

Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. I am going to list 2 potential problems that people with diabetes may experience. Please consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH from 1 = 'not a problem' to 6 = 'serious problem'. Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would choose "1." If it is very bothersome to you, you might choose "6."

Feeling overwhelmed by the demands of living with diabetes

- ○ 1 (Not a problem)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Serious Problem)

Feeling that I am often failing with my diabetes regimen.

- ○ 1 (Not a problem)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Serious Problem)

Quality of life

For the next series of questions you will be asked to indicate which statements best describe your own health state today.

Mobility

- ○ I have no problems in walking about
- ○ I have some problems in walking about
- ○ I am confined to bed

Self-care	◯ I have no problems with self-care ◯ I have some problems washing or dressing myself ◯ I am unable to wash or dress myself
Usual Activities (e.g work, study, housework, family or leisure activities)	◯ I have no problems with performing my usual activities ◯ I have some problems with performing my usual activities ◯ I am unable to perfom my usual activities
Pain/discomfort	◯ I have no pain or discomfort ◯ I have moderate pain or discomfort ◯ I have extreme pain or discomfort
Anxiety/Depression	◯ I am not anxious or depressed ◯ I am moderately anxious or depressed ◯ I am extremely anxious or depressed
How good or bad your own health today - 0 worst imaginable or 100 Best imaginable	_____

Illness Perceptions

For the following questions, please choose the number that best corresponds to your views:

How much does your diabetes affect your life?	◯ 0 (No affect at all) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Severely affects my life)
How long do you think your diabetes will continue?	◯ 0 (A very short time) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Forever)
How much control do you feel you have over your diabetes?	◯ 0 (Absolutely no control) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Extreme amount of control)

How much do you think your treatment can help your diabetes?

- ○ 0 (Not at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely helpful)

How much do you experience symptoms from your diabetes?

- ○ 0 (No symptoms at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Many severe symptoms)

How concerned are you about your diabetes?

- ○ 0 (Not concerned at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely concerned)

How well do you feel you understand your diabetes?

- ○ 0 (Don't understand at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Understand very clearly)

How much does your diabetes affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

- ○ 0 (Not at all affected emotionally)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely affected emotionally)

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Please list in rank-order the 3 most important factors that you believe caused your illness. The most important causes for me:

1 _____

2 _____

3 _____

Social support

Consider the people and/or services that are available to you when you want support around your diabetes management e.g. family members, your partner, friends, doctors, nurses and other health professionals and other people with diabetes. These can be people/services that you visit, meet with in person, talk to on the phone, online, via email or text message.

In general how supported do you feel with your diabetes management

- ○ 1 (Not supported at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Extremely supported)

Now consider your support over the past month and select the number which best corresponds to how much you agree with the following statements.

If you needed to talk to someone about your diabetes management you knew who you could talk to

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

You felt that there was someone you could go to for support if you had any concerns or worries about your diabetes care

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

If you needed advice or information about diabetes you knew who you could go to or how to access it

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

Clinical

SMS Registration number _____

NHI _____

Diabetes type
- ○ Type 1
- ○ Type 2

Latest HbA1c test result mmol/mol _____

Date of HbA1c test _____ (DD-MM-YYYY)

Foot screening category
- ○ Low/moderate
- ○ High
- ○ Active foot disease
- ○ Unknown

Smoking status
- ○ Current smoker
- ○ Non-smoker
- ○ Unknown

On insulin
- ○ No
- ○ Yes

Date of diabetes diagnosis (if only year provided please mark day and month with X) _____ (DD-MM-YYYY)

Healthcare utilisation (prior 9 months) If nil please write 0

Number of hospitalisations _____

Number of primary care visits _____

Number of ED visits _____

Number of secondary care encounters _____

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Randomization Form

SMS Registration number _____

Date of randomisation _____
(DD-MM-YYYY)

General Comments

Randomization Group

- ◯ Intervention
- ◯ Control

A5.6 Follow up forms

Confidential

Followup

SMS Registration number _____

Date of assessment _____
(DD-MM-YYYY)

Self-efficacy

How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

- ○ 1 (Not at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (totally confident)

Summary of Diabetes Self-care Activities

The questions below ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days please think back to the last seven days when you were not sick.

On how many of the last 7 days have you followed a healthful eating plan?

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

On average, over the past month, how many days per week have you followed your eating plan?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you eat five or more servings of fruits and vegetables?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you participate in at least 30 minutes of physical activity?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you test your blood sugar	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7
On how many of the last 7 days did you test your blood sugar the number of times recommended by your health care provider?	○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

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

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

On how many of the last 7 days did you inspect the inside of your shoes?

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

Have you smoked a cigarette even one puff during the past 7 days?

- ○ Yes
- ○ No

If yes, how many cigarettes did you smoke on an average day? _____

Diabetes Disttress

Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. I am going to list 2 potential problems that people with diabetes may experience. Please consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH from 1 = 'not a problem' to 6 = 'serious problem'. Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would choose "1." If it is very bothersome to you, you might choose "6."

Feeling overwhelmed by the demands of living with diabetes

- ○ 1 (Not a problem)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Serious Problem)

Feeling that I am often failing with my diabetes regimen.

- ○ 1 (Not a problem)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Serious Problem)

Quality of life

For the next questions please indicate which statements best describe your own health state today.

Mobility

- ○ I have no problems in walking about
- ○ I have some problems in walking about
- ○ I am confined to bed

Self-care

- ○ I have no problems with self-care
- ○ I have some problems washing or dressing myself
- ○ I am unable to wash or dress myself

Usual Activities (e.g work,s tudy, housework, family or leisure activites)	◯ I have no problems with performing my usual activities ◯ I have some problems with performing my usual activities ◯ I am unable to perfom my usual activities
Pain/discomfort	◯ I have no pain or discomfort ◯ I have moderate pain or discomfort ◯ I have extreme pain or discomfort
Anxiety/Depression	◯ I am not anxious or depressed ◯ I am moderately anxious or depressed ◯ I am extremely anxious or depressed
How good or bad your own health today - 0 worst imaginable or 100 Best imaginable	_____
Illness perceptions	
How much does your diabetes affect your life?	◯ 0 (No affect at all) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Severely affects my life)
How long do you think your diabetes will continue?	◯ 0 (A very short time) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Forever)
How much control do you feel you have over your diabetes?	◯ 0 (Absolutely no control) ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 (Extreme amount of control)

How much do you think your treatment can help your diabetes?

- ○ 0 (Not at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely helpful)

How much do you experience symptoms from your diabetes?

- ○ 0 (No symptoms at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Many severe symptoms)

How concerned are you about your diabetes?

- ○ 0 (Not concerned at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely concerned)

How well do you feel you understand your diabetes?

- ○ 0 (Don't understand at all)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Understand very clearly)

How much does your diabetes affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

- ○ 0 (Not at all affected emotionally)
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 (Extremely affected emotionally)

Please list in rank-order the 3 most important factors that you believe caused your illness. The most important causes for me:

1 _____

2 _____

3 _____

Social support

Consider the people and/or services that are available to you when you want support around your diabetes management e.g. family members, your partner, friends, doctors, nurses and other health professionals and other people with diabetes. These can be people/services that you visit, meet with in person, talk to on the phone, online, via email or text message.

In general how supported do you feel with your diabetes management

- ○ 1 (Not supported at all)
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6 (Extremely supported)

Now consider your support over the past month and select the number which best corresponds to how much you agree with the following statements.

If you needed to talk to someone about your diabetes management you knew who you could talk to

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

You felt that there was someone you could go to for support if you had any concerns or worries about your diabetes care

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

If you needed advice or information about diabetes you knew who you could go to or how to access it

- ○ 1 Strongly disagree
- ○ 2 Disagree
- ○ 3 Slightly disagree
- ○ 4 Slightly agree
- ○ 5 Agree
- ○ 6 Strong agree

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Clinical Followup

SMS Registration number _____

HbA1c

9 month HbA1c test result mmol/mol _____

Date of HbA1c test _____ (DD-MM-YYYY)

6 month HbA1c test result mmol/mol (if available) _____

Date of HbA1c test _____ (DD-MM-YYYY)

3 month HbA1c test result mmol/mol (if available) _____

Date of HbA1c test _____ (DD-MM-YYYY)

Other clinical

Foot screening category
- ○ Low/moderate
- ○ High
- ○ Active foot disease
- ○ Unknown

Smoking status
- ○ Current smoker
- ○ Non-smoker
- ○ Unknown

On insulin
- ○ No
- ○ Yes

Healthcare utilisation (prior 9 months) If nil please write 0

Number of hospitalisations _____

Number of primary care visits _____

Number of ED visits _____

Number of secondary care encounters _____

Exit Interview

SMS Registration number _____

General feedback

What did you think about the SMS4BG programme?

_____

Overall did you find the messages useful?
- ○ Yes
- ○ No

How useful?
- ○ 0 (not at all useful)
- ○ 1 (a little useful)
- ○ 2
- ○ 3
- ○ 4
- ○ 5 (extremely useful)

Did you find the messages culturally appropriate?
- ○ Yes
- ○ No

Did you find the messages age appropriate?
- ○ Yes
- ○ No

How many of the text messages did you read
- ○ None: I didn't receive any
- ○ None: I didn't read any
- ○ Some (less than half)
- ○ Most (more than half)
- ○ All or nearly all messages

Did you share any of the messages with others? (Friends, partner, family members, etc)
- ○ Yes
- ○ No

What did you think about the number of messages we sent? (Select 1 only)
- ○ Too many messages
- ○ The right amount
- ○ Too few messages: I would have liked more

[Interviewer to complete] Did participant stop the messages early?
- ○ Yes
- ○ No

You stopped the messages early, what was your reason for doing this?

_____

Do you think using text messages is a good way to deliver this programme?
- ○ Yes
- ○ No

Did you have any technical issues with the system?
- ○ Yes
- ○ No

If Yes, please explain

_____

What did you like most about the programme?

_____

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What did you like least about the programme?

Do you have any suggestions on how we could improve the programme?

Would you recommend the programme to other people with diabetes?
- ○ Yes
- ○ No

Impacts of the programme

Did taking part in this programme help you learn about your diabetes?
- ○ Yes
- ○ No

Did taking part in this programme impact on how you manage your diabetes or help you change your behaviours?
- ○ Yes
- ○ No

As a result of taking part in this programme did you experience the following?

Your overall blood glucose control improved (glycaemic control)
- ○ Yes
- ○ No

You increased how often you monitor your blood glucose
- ○ Yes
- ○ No
- ○ Not applicable

Your understanding of your diabetes increased
- ○ Yes
- ○ No

You improved your diet or eating
- ○ Yes
- ○ No

You improved your level of exercise or how often you exercise
- ○ Yes
- ○ No

How you have been feeling improved (your mood)
- ○ Yes
- ○ No

You lost weight
- ○ Yes
- ○ No

You quit smoking
- ○ Yes
- ○ No
- ○ Not applicable (i.e. non-smoker)

You were less stressed
- ○ Yes
- ○ No

Other

Do you have any final comments about the SMS4BG programme?

- ○ Yes
- ○ No

If yes, please comment

Additional comments

This is the end of the follow up interview. Please remind them that they will need to have their HbA1c test done within the next three weeks if they haven't already this month. Also let them know that their voucher will be mailed to them and check their address from baseline is correct.

Intervention Engagement

SMS Registration number _____

Modules received

Duration of programme
- ◯ 3 months
- ◯ 6 months
- ◯ 9 months

Opted out?
- ◯ Yes
- ◯ No

Date STOP message received
_____ (DD-MM-YYYY)

Core module
- ◯ Maori
- ◯ Pacific
- ◯ Non-Maori/Pacific

Insulin module
- ◯ Yes
- ◯ No

Insulin module stage
- ◯ stage 1
- ◯ stage 1 - 2
- ◯ stage 1 - 3

Young adult module
- ◯ Yes
- ◯ No

Young adult module stage
- ◯ stage 1
- ◯ stage 1 - 2
- ◯ stage 1, 2, 3

Smoking module
- ◯ Yes
- ◯ No

Smoking module stage
- ◯ stage 1
- ◯ stage 1 - 2
- ◯ stage 1, 2, 3

Foot care module
- ◯ Yes
- ◯ No

Foot care module stage
- ◯ stage 1
- ◯ stage 1 - 2
- ◯ stage 1, 2, 3

Cardiovascular check module
- ◯ Yes
- ◯ No

Lifestyle modules

First 3 months:
- ○ None
- ○ Healthy eating
- ○ Exercise
- ○ Stress management

Second 3 months:
- ○ Not applicable (did not continue)
- ○ None
- ○ Healthy eating
- ○ Exercise
- ○ Stress management

Final 3 months:
- ○ Not applicable (did not continue)
- ○ None
- ○ Healthy eating
- ○ Exercise
- ○ Stress management

Blood glucose monitoring reminders

First 3 months:
- ○ Not applicable
- ○ None
- ○ 1/week
- ○ 3/week
- ○ 1/day
- ○ 2/day
- ○ 3/day
- ○ 4/day

Second 3 months:
- ○ Not applicable (did not continue)
- ○ None
- ○ 1/week
- ○ 3/week
- ○ 1/day
- ○ 2/day
- ○ 3/day
- ○ 4/day

Final 3 months:
- ○ Not applicable (did not continue)
- ○ None
- ○ 1/week
- ○ 3/week
- ○ 1/day
- ○ 2/day
- ○ 3/day
- ○ 4/day

Total number of messages sent _____

Total incoming messages received _____

Total blood glucose results received _____

A6.6 Example referral forms

SMS4BG Referral Form

Please complete the following information for the patient you are referring to the SMS4BG study and send completed form to the SMS4BG Study Coordinator. The patient will be contacted within 1-week of the research team receiving the referral form. PLEASE PRINT CLEARLY.

Patient details		
1	Patients preferred first name	
2	Patients preferred contact phone number	
3	NHI number	
Eligibility criteria		
4	Is the patient aged 16 years and over?	○ Yes → DOB ___ / ___ / ___ ○ No
5	Does the patient have Type 1 or Type 2 diabetes?	○ Yes → Type 1 Diabetes ○ Yes → Type 2 Diabetes ○ No
6	Is there latest* HbA1c over 65mmol/mol? * within the last 9 months	○ Yes → Value: _____ mmol/mol Date of test: ___ / ___ / ___ ○ No
7	Do they own a mobile phone?	○ Yes ○ No
8	Can they understand and read English?	○ Yes ○ No
9	Have they given permission for their details to be given to the research team?	○ Yes ○ No
Additional information		
10	Foot screening category	○ Low/ moderate risk ○ High risk ○ Active foot disease ○ Unknown
11	Smoking status	○ Current smoker ○ Non-smoker ○ Unknown
12	On insulin	○ Yes ○ No ○ Unknown
13	Date of diabetes diagnosis – If day and month are unknown please just provide year of diagnosis	___ / ___ / ___ *day* *month* *year*

Name of person referring: _____ **Clinic name:** _____

Contact phone number or email: _____

For more information please contact the SMS4BG Study-coordinator on:
Email: SMS4BG@auckland.ac.nz / Phone: 09 3737599 ext 84766 / Fax: 09 3731710

SMS4BG Referral Form

Name of person making referrals:______________________________ **Clinic name:** ____

Contact phone number/email: ______________________________________

Patients name and number	NHI	DOB (DD/MM/YY)	Diabetes type	Latest HbA1c test result and date of test	Able to speak English?	Permission for referral to study?	Smoking status	On Insulin	Foot screening category:	Year of diabetes diagnosis
Preferred first name: ____________ Patients phone number: ____________			◯ Type 1 ◯ Type 2	Test result: _______mmol/mol Test date: __________	◯ Yes ◯ No	◯ Yes ◯ No	◯ Smoker ◯ Non-smoker ◯ Unknown	◯ Yes ◯ No	◯Active foot disease ◯ High risk ◯ Med/low risk ◯ Unknown	
Preferred first name: ____________ Patients phone number: ____________			◯ Type 1 ◯ Type 2	Test result: _______mmol/mol Test date: __________	◯ Yes ◯ No	◯ Yes ◯ No	◯ Smoker ◯Non-smoker ◯ Unknown	◯ Yes ◯ No	◯Active foot disease ◯ High risk ◯ Med/low risk ◯ Unknown	
Preferred first name: ____________ Patients phone number: ____________			◯ Type 1 ◯ Type 2	Test result: _______mmol/mol Test date: __________	◯ Yes ◯ No	◯ Yes ◯ No	◯ Smoker ◯Non-smoker ◯ Unknown	◯ Yes ◯ No	◯Active foot disease ◯ High risk ◯ Med/low risk ◯ Unknown	
Preferred first name: ____________ Patients phone number: ____________			◯ Type 1 ◯ Type 2	Test result: _______mmol/mol Test date: __________	◯ Yes ◯ No	◯ Yes ◯ No	◯ Smoker ◯Non-smoker ◯ Unknown	◯ Yes ◯ No	◯Active foot disease ◯ High risk ◯ Med/low risk ◯ Unknown	

Email: SMS4BG@auckland.ac.nz / Phone: 09 3737599 ext 88908 / Fax: 09 3731710

APPENDIX 6: SUPPORTING DOCUMENTS FOR CHAPTER 8

A6.1 CONSORT checklist

A6.1 CONSORT checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6-7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6-7

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10-11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10-11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11-12
	13b	For each group, losses and exclusions after randomisation, together with reasons	11-12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12-13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13-15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-22
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21-22

NOTE: Page numbers refer to submitted manuscript

REFERENCES

1. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2014;37(Supplement 1):S81-S90.
2. Adeghate E, Schattner P, Dunn E. An Update on the Etiology and Epidemiology of Diabetes Mellitus. Annals of the New York Academy of Sciences. 2006;1084(1):1-29.
3. American Diabetes Association. Standards of Medical Care in Diabetes - 2017: 2. Classification and Diagnosis of Diabetes. Diabetes Care. 2017;40(Supplement 1):S11-S24.
4. American Diabetes Association. Standards of Medical Care in Diabetes - 2017: 9. Cardiovascular Disease and Risk Management. Diabetes Care. 2017;40(Supplement 1):S75-S87.
5. Williams R, Van Gaal L, Lucioni C. Assessing the impact of complications on the costs of Type II diabetes. Diabetologia. 2002;45(1):S13-S7.
6. Diabetes Control Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl j Med. 1993;1993(329):977-86.
7. Diabetes Control Complications Trial Research Group (DCCT), Epidemiology of Diabetes Interventions Complications Research Group (EDIC). Effect of intensive diabetes therapy on the progression of diabetic retinopathy in patients with type 1 diabetes: 18 years of follow-up in the DCCT/EDIC. Diabetes. 2014:DB_140930.
8. Nathan D, Cleary P, Backlund J, Genuth S, Lachin J, Orchard T, et al. Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes. New England Journal of Medicine. 2005;353(25):2643-53.
9. Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ. 2000;321(7258):405-12.
10. Eastman RC, Javitt JC, Herman WH, Dasbach EJ, Copley-Merriman C, Maier W, et al. Model of complications of NIDDM: II. Analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of normoglycemia. Diabetes Care. 1997;20(5):735-44.
11. Eastman RC, Javitt JC, Herman WH, Dasbach EJ, Zbrozek AS, Dong F, et al. Model of complications of NIDDM: I. Model construction and assumptions. Diabetes Care. 1997;20(5):725-34.
12. Diabetes Control and Complications Trial Research Group. Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. JAMA. 1996;276:1409-15.
13. Wagner EH, Sandhu N, Newton KM, McCulloch DK, Ramsey SD, Grothaus LC. Effect of improved glycemic control on health care costs and utilization. JAMA. 2001;285(2):182-9.
14. American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2012. Diabetes Care. 2013;36(4):1033-46.
15. International Diabetes Federation. IDF Diabetes Atlas, 7th edn. Brussels, Belgium http://www.idf.org/diabetesatlas: International Diabetes Federation; 2015.
16. Ministry of Health. Annual Update of Key Results 2015/16: New Zealand Health Survey. Wellington: Ministry of Health; 2016.
17. Sundborn G, Metcalf P, Scragg R, Schaaf D, Dyall L, Gentles D, et al. Ethnic differences in the prevalence of new and known diabetes mellitus, impaired glucose tolerance and impaired fasting glucose. Diabetes heart and health survey (DHAH) 2002-2003, Auckland New Zealand. The New Zealand Medical Journal (Online). 2007;120(1257).
18. Elley CR, Kenealy T, Robinson E, Bramley D, Selak V, Drury PL, et al. Cardiovascular risk management of different ethnic groups with type 2 diabetes in primary care in New Zealand. Diabetes Research and Clinical Practice. 2008;79(3):468-73.
19. Joshy G, Dunn P, Fisher M, Lawrenson R. Ethnic differences in the natural progression of nephropathy among diabetes patients in New Zealand: hospital admission rate for renal complications, and incidence of end-stage renal disease and renal death. Diabetologia. 2009;52(8):1474-8.
20. Isaacs R, Scott D. Diabetic patient discharges from Middlemore Hospital in 1983. The New Zealand Medical Journal. 1987;100(833):629-31.
21. Joshy G, Simmons D. Epidemiology of diabetes in New Zealand: revisit to a changing landscape. New Zealand Medical Journal. 2006;119(1239).
22. Negandhi PH, Ghouri N, Colhoun HM, Fischbacher CM, Lindsay RS, McKnight JA, et al. Ethnic Differences in Glycaemic Control in People with Type 2 Diabetes Mellitus Living in Scotland. PLOS ONE. 2013;8(12):e83292.

23. Abouzeid M, Philpot B, Janus ED, Coates MJ, Dunbar JA. Type 2 diabetes prevalence varies by socio-economic status within and between migrant groups: analysis and implications for Australia. BMC Public Health. 2013;13(1):252.
24. Bean D, Cundy T, Petrie KJ. Ethnic differences in illness perceptions, self-efficacy and diabetes self-care. Psychology & Health. 2007;22(7):787-811.
25. Majeed-Ariss R, Jackson C, Knapp P, Cheater FM. A systematic review of research into black and ethnic minority patients' views on self-management of type 2 diabetes. Health Expectations. 2015;18(5):625-42.
26. Wilson C, Alam R, Latif S, Knighting K, Williamson S, Beaver K. Patient access to healthcare services and optimisation of self-management for ethnic minority populations living with diabetes: a systematic review. Health & social care in the community. 2012;20(1):1-19.
27. Nelson AR, Stith AY, Smedley BD. Unequal treatment: confronting racial and ethnic disparities in health care. National Academies Press; 2002.
28. American Diabetes Association. Standards of Medical Care in Diabetes - 2017: 6. Glycemic Targets. Diabetes Care. 2017;40(Supplement 1):S48-S56.
29. Funnell MM, Anderson RM. The problem with compliance in diabetes. JAMA. 2000;284(13):1709-.
30. de Silva D. Helping people help themselves: A review of the evidence considering whether it is worthwhile to support self-management. The Health Foundation; 2011.
31. Mazzuca SA. Does patient education in chronic disease have therapeutic value? Journal of chronic diseases. 1982;35(7):521-9.
32. Bandura A. Human agency in social cognitive theory. American Psychologist. 1989;44:1175-84.
33. Hurley AC, Shea CA. Self-efficacy: strategy for enhancing diabetes self-care. The Diabetes Educator. 1992;18(2):146-50.
34. Sarkar U, Fisher L, Schillinger D. Is Self-Efficacy Associated With Diabetes Self-Management Across Race/Ethnicity and Health Literacy? Diabetes Care. 2006;29(4):823-9.
35. Leventhal H, Brissette I, Leventhal EA. The common-sense model of self-regulation of health and illness. In: The self-regulation of health and illness behaviour. Vol. 1,2003. p. 42-65.
36. Ministry of Health. Quality Standards for Diabetes Care Toolkit. Wellington; 2014.
37. Mulcahy K, Maryniuk M, Peeples M, Peyrot M, Tomky D, Weaver T, et al. Diabetes Self-Management Education Core Outcomes Measures. The Diabetes Educator. 2003;29(5):768-803.
38. Brown SA. Interventions to Promote Diabetes Self-Management: State of the Science. The Diabetes Educator. 1999;25(6):52-61.
39. Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient Education and Counseling. 2016;99(6):926-43.
40. Norris SL, Engelgau MM, Venkat Narayan KM. Effectiveness of Self-Management Training in Type 2 Diabetes. A systematic review of randomized controlled trials. 2001;24(3):561-87.
41. Funnell MM, Brown TL, Childs BP, Haas LB, Hosey GM, Jensen B, et al. National standards for diabetes self-management education. Diabetes Care. 2009;32(Supplement 1):S87-S94.
42. Health Navigator New Zealand. Diabetes Self-Management 2017 [cited 2017 16 May]. Available from: https://www.healthnavigator.org.nz/healthy-living/self-care/programmes-courses/diabetes-self-management/
43. Chatterjee S, Davies MJ, Heller S, Speight J, Snoek FJ, Khunti K. Diabetes structured self-management education programmes: a narrative review and current innovations. The Lancet Diabetes & Endocrinology. 2017.
44. Healthcare Commission. The views of people with diabetes. Key findings from the 2006 survey. Healthcare Commission http://wwwyearofcarecouk/sites/default/files/pdfs/Diabetes_survey_2006_summarypdf. 2007.
45. International Telecommunication Union. ICT Facts and Figures 20162016. Available from: http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2016.pdf
46. Commerce Commision New Zealand. Annual Telecommunications Monitoring Report 2015. 2016.
47. Research New Zealand. A Report on a Survey of New Zealanders' Use of Smartphones and Other Mobile Communication Devices 2015. Wellington; 2016.

48. World Health Organization. mHealth: New horizons for health through mobile technologies: second global survey on eHealth 2011. Available from: http://www.who.int/goe/publications/goe_mhealth_web.pdf. Archived at http://www.webcitation.org/6VaF4ZrjI
49. Gibbons MC. A Historical Overview of Health Disparities and the Potential of eHealth Solutions. J Med Internet Res. 2005;7(5):e50.
50. Militello LK, Kelly SA, Melnyk BM. Systematic Review of Text-Messaging Interventions to Promote Healthy Behaviors in Pediatric and Adolescent Populations: Implications for Clinical Practice and Research. Worldviews on Evidence-Based Nursing. 2012;9(2):66-77.
51. Hall AK, Cole-Lewis H, Bernhardt JM. Mobile text messaging for health: a systematic review of reviews. Annual review of public health. 2015;36:393.
52. Head KJ, Noar SM, Iannarino NT, Grant Harrington N. Efficacy of text messaging-based interventions for health promotion: A meta-analysis. Social Science & Medicine. 2013;97(0):41-8.
53. Stephens J, Allen J. Mobile phone interventions to increase physical activity and reduce weight: a systematic review. The Journal of cardiovascular nursing. 2013;28(4):320.
54. Shaw R, Bosworth H. Short message service (SMS) text messaging as an intervention medium for weight loss: A literature review. Health informatics journal. 2012;18(4):235-50.
55. Weinschenk S. Are you addicted to texting? Psychology Today Blog, [Internet]. 2014. Epub August 27, 2014. Available from: https://www.psychologytoday.com/blog/brain-wise/201408/are-you-addicted-texting
56. Tatango. SMS Open Rates Exceed 99%. Mobile Messaging Blog [Internet]. 2013 (April 10, 2013). Available from: https://www.tatango.com/blog/sms-open-rates-exceed-99/
57. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. Epidemiologic Reviews. 2010;32(1).
58. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. American journal of preventive medicine. 2009;36(2):165-73.
59. Wei J, Hollin I, Kachnowski S. A review of the use of mobile phone text messaging in clinical and healthy behaviour interventions. Journal of Telemedicine and Telecare. 2011;17(1):41-8.
60. Fry JP, Neff RA. Periodic Prompts and Reminders in Health Promotion and Health Behavior Interventions: Systematic Review. J Med Internet Res. 2009;11(2):e16.
61. Free C, Phillips G, Galli L, Watson L, Felix L, Edwards P, et al. The Effectiveness of Mobile-Health Technology-Based Health Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review. PLoS Med. 2013;10(1):e1001362.
62. Thakkar J, Kurup R, Laba T, et al. Mobile telephone text messaging for medication adherence in chronic disease: A meta-analysis. JAMA Internal Medicine. 2016;176(3):340-9.
63. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2016(4).
64. Saffari M, Ghanizadeh G, Koenig HG. Health education via mobile text messaging for glycemic control in adults with type 2 diabetes: A systematic review and meta-analysis. Primary care diabetes. 2014;8(4):275-85.
65. Job J, Fjeldsoe B, Eakin E, Reeves M. Effectiveness of extended contact interventions for weight management delivered via text messaging: a systematic review and meta-analysis. Obesity Reviews. 2017.
66. Spark LC, Fjeldsoe BS, Eakin EG, Reeves MM. Efficacy of a text message-delivered extended contact intervention on maintenance of weight loss, physical activity, and dietary behavior change. JMIR mHealth and uHealth. 2015;3(3).
67. Faruque LI, Wiebe N, Ehteshami-Afshar A, Liu Y, Dianati-Maleki N, Hemmelgarn BR, et al. Effect of telemedicine on glycated hemoglobin in diabetes: A systematic review and meta-analysis of randomized trials. Canadian Medical Association Journal. 2016:cmaj-150885.
68. Liang X, Wang Q, Yang X, Cao J, Chen J, Mo X, et al. Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. Diabet Med. 2011;28(4):455-63.
69. Su D, Zhou J, Kelley MS, Michaud TL, Siahpush M, Kim J, et al. Does telemedicine improve treatment outcomes for diabetes? A meta-analysis of results from 55 randomized controlled trials. Diabetes Research and Clinical Practice. 2016;116:136-48.
70. Wu Y, Yao X, Vespasiani G, Nicolucci A, Dong Y, Kwong J, et al. Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review of Randomized Controlled Trials to Identify Functions Associated with Glycemic Efficacy. JMIR Mhealth Uhealth. 2017;5(3):e35.

71. Bonoto BC, de Araújo VE, Godói IP, de Lemos LLP, Godman B, Bennie M, et al. Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth. 2017;5(3):e4.
72. Nundy S, Dick JJ, Chou CH, Nocon RS, Chin MH, Peek ME. Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. Health Affairs. 2014;33(2):265-72.
73. Rami B, Popow C, Horn W, Waldhoer T, Schober E. Telemedical support to improve glycemic control in adolescents with type 1 diabetes mellitus. European Journal of Pediatrics. 2006;165(10):701-5.
74. Kim CS, Park SY, Kang JG, Lee SJ, Ihm SH, Choi MG, et al. Insulin dose titration system in diabetes patients using a short messaging service automatically produced by a knowledge matrix. Diabetes Technol Ther. 2010;12(8):663-9.
75. Lim S, Kang SM, Kim KM, Moon JH, Choi SH, Hwang H, et al. Multifactorial intervention in diabetes care using real-time monitoring and tailored feedback in type 2 diabetes. Acta Diabetol. 2016;53(2):189-98.
76. Franklin VL, Waller A, Pagliari C, Greene SA. A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. Diabet Med. 2006;23(12):1332-8.
77. Arora S, Peters AL, Burner E, Lam CN, Menchine M. Trial to examine text message-based mhealth in emergency department patients with diabetes (TExT-MED): A randomized controlled trial. Annals of Emergency Medicine. 2014;63(6):745-54.e6.
78. Hanauer DA, Wentzell K, Laffel N, Laffel LM. Computerized Automated Reminder Diabetes System (CARDS): e-mail and SMS cell phone text messaging reminders to support diabetes management. Diabetes Technol Ther. 2009;11(2):99-106.
79. Huckvale K, Adomaviciute S, Prieto JT, Leow MK-S, Car J. Smartphone apps for calculating insulin dose: A systematic assessment. BMC Medicine. 2015;13(1):106.
80. Blenner SR, Köllmer M, Rouse AJ, Daneshvar N, Williams C, Andrews LB. Privacy policies of android diabetes apps and sharing of health information. JAMA. 2016;315(10):1051-2.
81. Pew Research Centre. Digital Differences 2012. Available from: http://pewinternet.org/Reports/2012/Digital-differences.aspx
82. Statistics New Zealand. Household use of information and communication technology: 2009 [Internet].2010. Available from: www.statistics.govt.nz
83. McCloud RF, Okechukwu CA, Sorensen G, Viswanath K. Beyond access: barriers to internet health information seeking among the urban poor. Journal of the American Medical Informatics Association. 2016;23(6):1053-9.
84. Mossberger K, Tolbert CJ, Bowen D, Jimenez B. Unraveling Different Barriers to Internet Use. Urban Affairs Review. 2012;48(6):771-810.
85. Knapp C, Madden V, Wang H, Sloyer P, Shenkman E. Internet Use and eHealth Literacy of Low-Income Parents Whose Children Have Special Health Care Needs. J Med Internet Res. 2011;13(3):e75.
86. Lorence D, Park H. Group disparities and health information: a study of online access for the underserved. Health Informatics Journal. 2008;14(1):29-38.
87. Sarkar U, Karter AJ, Liu JY, Adler NE, Nguyen R, López A, et al. Social disparities in internet patient portal use in diabetes: evidence that the digital divide extends beyond access. Journal of the American Medical Informatics Association. 2011;18(3):318-21.
88. Sarkar U, Karter AJ, Liu JY, Adler NE, Nguyen R, Lopez A, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system—results from the diabetes study of northern California (DISTANCE). Journal of health communication. 2010;15(S2):183-96.
89. Chang BL, Bakken S, Brown SS, Houston TK, Kreps GL, Kukafka R, et al. Bridging the digital divide: reaching vulnerable populations. Journal of the American Medical Informatics Association. 2004;11(6):448-57.
90. Painter JE, Borba CP, Hynes M, Mays D, Glanz K. The use of theory in health behavior research from 2000 to 2005: A systematic review. Annals of Behavioral Medicine. 2008;35(3):358-62.
91. Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, Mermelstein R. Health behavior models in the age of mobile interventions: are our theories up to the task? Translational behavioral medicine. 2011;1(1):53-71.
92. Webb T, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. J Med Internet Res. 2010;12(1):e4.

93. Nathan D, DCCT/EDIC Research Group. The diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: Overview. Diabetes Care. 2014;37(1):9-16.
94. Ohkubo Y, Kishikawa H, Araki E, Miyata T, Isami S, Motoyoshi S, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. Diabetes research and clinical practice. 1995;28(2):103-17.
95. UK Prospective Diabetes Study Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). The Lancet. 1998;352(9131):854-65.
96. UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). The Lancet. 1998;352(9131):837-53.
97. Braatvedt G, Cundy T, Crooke M, Florkowski C, Mann JI, Lunt H, et al. Understanding the new HbA1c units for the diagnosis of Type 2 diabetes. 2012.
98. Lawrenson R, Gibbons V, Joshy G, Choi P. Are there disparities in care in people with diabetes? A review of care provided in general practice. Journal of Primary Health Care. 2009;1(3):177-83.
99. Arambepola C, Ricci-Cabello I, Manikavasagam P, Roberts N, French DP, Farmer A. The impact of automated brief messages promoting lifestyle changes delivered via mobile devices to people with type 2 diabetes: a systematic literature review and meta-analysis of controlled trials. J Med Internet Res. 2016;18(4).
100. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Annals of behavioral medicine. 2013;46(1):81-95.
101. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. PLoS med. 2009;6(7):e1000097.
102. Higgins J, Green S. Cochrane handbook for systematic reviews of interventions. Version 5.1.0 [updated March 2011] ed: The Cochrane Collaboration; 2011.
103. Agboola S, Jethwani K, Lopez L, Searl M, O'Keefe S, Kvedar J. Text to Move: A Randomized Controlled Trial of a Text-Messaging Program to Improve Physical Activity Behaviors in Patients With Type 2 Diabetes Mellitus. J Med Internet Res. 2016;18(11):e307.
104. Capozza K, Woolsey S, Georgsson M, Black J, Bello N, Lence C, et al. Going mobile with diabetes support: a randomized study of a text message-based personalized behavioral intervention for type 2 diabetes self-care. Diabetes Spectrum. 2015;28(2):83-91.
105. Shetty AS, Chamukuttan S, Nanditha A, Raj RK, Ramachandran A. Reinforcement of adherence to prescription recommendations in Asian Indian diabetes patients using short message service (SMS)--a pilot study. J Assoc Physicians India. 2011;59:711-4.
106. Goodarzi M, Ebrahimzadeh I, Rabi A, Saedipoor B, Jafarabadi MA. Impact of distance education via mobile phone text messaging on knowledge, attitude, practice and self efficacy of patients with type 2 diabetes mellitus in Iran. J. 2012;11(1):10.
107. El-Gayar O, Timsina P, Nawar N, Eid W. A systematic review of IT for diabetes self-management: Are we there yet? International Journal of Medical Informatics. 2013;82(8):637-52.
108. Liu C-T, Yeh Y-T, Lee T-I, Li Y-C. Observations on online services for diabetes management. Diabetes Care. 2005;28(11):2807a-8.
109. Becker S, Miron-Shatz T, Schumacher N, Krocza J, Diamantidis C, Albrecht U-V. mHealth 2.0: Experiences, Possibilities, and Perspectives. JMIR mHealth uHealth. 2014;2(2):e24.
110. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. Annals of internal medicine. 2010;152(11):726-32.
111. Pfaeffli Dale L, Dobson R, Whittaker R, Maddison R. The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: A systematic review. European journal of preventive cardiology. 2016;23(8):801-17.
112. De Leon E, Fuentes LW, Cohen JE. Characterizing periodic messaging interventions across health behaviors and media: systematic review. J Med Internet Res. 2014;16(3):e93.
113. Rothman AJ, Salovey P, Antone C, Keough K, Martin CD. The influence of message framing on intentions to perform health behaviors. Journal of experimental social psychology. 1993;29(5):408-33.

114. Court JM, Cameron FJ, Berg-Kelly K, Swift PGF. Diabetes in adolescence. Pediatric Diabetes. 2009;10:185-94.
115. Wysocki T, Hough BS, Ward KM, Green LB. Diabetes Mellitus in the Transition to Adulthood: Adjustment, Self-Care, and Health Status. Journal of Developmental & Behavioral Pediatrics. 1992;13(3):194-201.
116. Devendra D, Liu E, Eisenbarth GS. Type 1 diabetes: recent developments. BMJ: British Medical Journal. 2004;328(7442):750.
117. Derraik JGB, Reed PW, Jefferies C, Cutfield SW, Hofman PL, Cutfield WS. Increasing Incidence and Age at Diagnosis among Children with Type 1 Diabetes Mellitus over a 20-Year Period in Auckland (New Zealand). PLoS ONE. 2012;7(2):e32640.
118. Diabetes Control and Complications Trial Research Group. Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus: Diabetes Control and Complications Trial. The Journal of Pediatrics. 1994;125(2):177-88.
119. White N, Cleary P, Dahms W, Goldstein D, Malone J, Tamborlane W. Beneficial effects of intensive therapy of diabetes during adolescence: outcomes after the conclusion of the Diabetes Control and Complications Trial (DCCT). The Journal of pediatrics. 2001;139(6):804.
120. American Diabetes Association. Standards of Medical Care in Diabetes—2013. Diabetes Care. 2013;36(Supplement 1):S11-S66.
121. Karter AJ, Ackerson LM, Darbinian JA, D'Agostino Jr RB, Ferrara A, Liu J, et al. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes registry. American Journal of Medicine. 2001;111(1):1-9.
122. Du Pasquier-Fediaevsky L, Chwalow AJ, the PCG, Tubiana-Rufi N. Is the relationship between adherence behaviours and glycaemic control bi-directional at adolescence? A longitudinal cohort study. Diabet Med. 2005;22(4):427-33.
123. Kyngäs HA. Predictors of good adherence of adolescents with diabetes (insulin-dependent diabetes mellitus). Chronic illness. 2007;3(1):20-8.
124. Law GU, Kelly TP, Huey D, Summerbell C. Self-management and well-being in adolescents with diabetes mellitus:: Do illness representations play a regulatory role? Journal of Adolescent Health. 2002;31(4):381-5.
125. Levine B-S, Anderson BJ, Butler DA, Antisdel JE, Brackett J, Laffel LMB. Predictors of glycemic control and short-term adverse outcomes in youth with type 1 diabetes. The Journal of Pediatrics. 2001;139(2):197-203.
126. Guo J, Whittemore R, He G-P. The relationship between diabetes self-management and metabolic control in youth with type 1 diabetes: An integrative review. Journal of Advanced Nursing. 2011;67(11):2294-310.
127. Cradock S, Cranston IC. Type 1 diabetes education and care: time for a rethink? Diabet Med. 2012;29(2):159-60.
128. Christie D. Current recommendations and considerations for psychosocial and psychoeducational support of adolescents with Type 1 diabetes. Diabetes Management. 2013;3(2):161-9.
129. Franklin VL, Greene A, Waller A, Greene SA, Pagliari C. Patients' engagement with "Sweet Talk" - a text messaging support system for young people with diabetes. J Med Internet Res. 2008;10(2):e20.
130. Harris MA, Hood KK, Mulvaney SA. Pumpers, skypers, surfers and texters: technology to improve the management of diabetes in teenagers. Diabetes, Obesity and Metabolism. 2012;14(11):967-72.
131. Krishna S, Boren SA. Diabetes self-management care via cell phone: A systematic review. J Diabetes Sci Technol. 2008;2(3):509-17.
132. Herbert L, Owen V, Pascarella L, Streisand R. Text Message Interventions for Children and Adolescents with Type 1 Diabetes: A Systematic Review. Diabetes Technol Ther. 2013;15(5):362-70.
133. Sutcliffe P, Martin S, Sturt J, Powell J, Griffiths F, Adams A, et al. Systematic review of communication technologies to promote access and engagement of young people with diabetes into healthcare. BMC endocrine disorders. 2011;11(1):1.
134. Mulvaney SA, Rothman RL, Dietrich MS, Wallston KA, Grove E, Elasy TA, et al. Using mobile phones to measure adolescent diabetes adherence. Health Psychology. 2012;31(1):43-50.
135. Farmer A, Gibson OJ, Tarassenko L, Neil A. A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes. Diabet Med. 2005;22(10):1372-8.

136. Han Y, Faulkner MS, Fritz H, Fadoju D, Muir A, Abowd GD, et al. A Pilot Randomized Trial of Text-Messaging for Symptom Awareness and Diabetes Knowledge in Adolescents With Type 1 Diabetes. Journal of Pediatric Nursing. 2015;30(6):850-61.
137. Bin-Abbas B, Jabbari M, Al-Fares A, El-Dali A, Al-Orifi F. Effect of mobile phone short text messages on glycaemic control in children with type 1 diabetes. Journal of Telemedicine & Telecare. 2014;20(3):153-6.
138. Kirwan M, Vandelanotte C, Fenning A, Duncan MJ. Diabetes self-management smartphone application for adults with type 1 diabetes: Randomized controlled trial. J Med Internet Res. 2013;15(11):e235.
139. Peterson A. Improving type 1 diabetes management with mobile tools: A systematic review. J Diabetes Sci Technol. 2014;8(4):859-64.
140. Humble JR, Tolley EA, Krukowski RA, Womack CR, Motley TS, Bailey JE. Use of and interest in mobile health for diabetes self-care in vulnerable populations. Journal of Telemedicine and Telecare. 2016;22(1):32-8.
141. Whittaker R, Merry S, Dorey E, Maddison R. A development and evaluation process for mHealth interventions: Examples from New Zealand. Journal of health communication. 2012;17(sup1):11-21.
142. Abroms LC, Whittaker R, Free C, Mendel Van Alstyne J, Schindler-Ruwisch JM. Developing and Pretesting a Text Messaging Program for Health Behavior Change: Recommended Steps. JMIR mHealth uHealth. 2015;3(4):e107.
143. Mulvaney SA, Ritterband LM, Bosslet L. Mobile intervention design in diabetes: review and recommendations. Current Diabetes Reports. 2011;11(6):486-93.
144. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res. 2004;6(3):e34.
145. Ministry of Health. Ethnicity Data Protocols for the Health and Disability Sector. Wellington; 2004.
146. Militello LK, Melnyk BM, Hekler E, Small L, Jacobson D. Correlates of Healthy Lifestyle Beliefs and Behaviors in Parents of Overweight or Obese Preschool Children Before and After a Cognitive Behavioral Therapy Intervention With Text Messaging. Journal of Pediatric Health Care. 2016;30(3):252-60.
147. Rodbard D. Continuous glucose monitoring: a review of successes, challenges, and opportunities. Diabetes Technol Ther. 2016;18(S2):S2-3-S2-13.
148. Whittaker R. mDiabetes Project Report and Recommendations for Implementation. Report prepared for Waitemata District Health Board. National Institute for Health Innovation; 2013.
149. Noar SM, Zimmerman RS. Health Behavior Theory and cumulative knowledge regarding health behaviors: are we moving in the right direction? Health Education Research. 2005;20(3):275-90.
150. Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. Annual review of public health. 2010;31:399-418.
151. Steinsbekk A, Rygg LØ, Lisulo M, By Rise M, Fretheim A. Group based diabetes self-management education compared to routine treatment, waiting list control or no intervention for people with type 2 diabetes mellitus. Cochrane Database of Systematic Reviews. 2015(6).
152. American Diabetes Association. Standards of Medical Care in Diabetes - 2017: 4. Lifestyle Management. Diabetes Care. 2017;40(Supplement 1):S33-S43.
153. Glanz K, Rimer BK. Theory at a glance: A guide for health promotion practice. US Dept. of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute; 1997.
154. Bandura A. Health promotion by social cognitive means. Health education & behavior. 2004;31(2):143-64.
155. Luszczynska A, Schwarzer R. Social cognitive theory. In: Conner M, Norman P, editors. Predicting Health Behaviour. 2nd ed. Buckingham, England: Open University Press; 2005.
156. Pouwer F, Geelhoed-Duijvestijn P, Tack C, Bazelmans E, Beekman AJ, Heine R, et al. Prevalence of comorbid depression is high in out-patients with Type 1 or Type 2 diabetes mellitus. Results from three out-patient clinics in the Netherlands. Diabet Med. 2010;27(2):217-24.
157. Hislop A, Fegan P, Schlaeppi M, Duck M, Yeap B. Prevalence and associations of psychological distress in young adults with Type 1 diabetes. Diabet Med. 2008;25(1):91-6.
158. Northam E, Matthews L, Anderson P, Cameron F, Werther G. Psychiatric morbidity and health outcome in Type 1 diabetes–perspectives from a prospective longitudinal study. Diabet Med. 2005;22(2):152-7.

159. Fisher L, Skaff M, Mullan J, Arean P, Glasgow R, Masharani U. A longitudinal study of affective and anxiety disorders, depressive affect and diabetes distress in adults with Type 2 diabetes. Diabet Med. 2008;25(9):1096-101.
160. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes. Diabetes Care. 2001;24(6):1069-78.
161. Leventhal H, Brissette I, Leventhal EA. The common-sense model of self-regulation of health and illness. In: Cameron LD, Leventhal H, editors. The self-regulation of health and illness behaviour. London: Routledge; 2003. p. 42-65.
162. Diefenbach MA, Leventhal H. The common-sense model of illness representation: Theoretical and practical considerations. Journal of Social Distress & the Homeless. 1996;5:11-38.
163. Cameron LD, Jago L. Emotion regulation interventions: A common-sense model approach. British Journal of Health Psychology. 2008;13(2):215-21.
164. Leventhal H, Leventhal EA, Contrada RJ. Self-regulation, health, and behavior: A perceptual-cognitive approach. Psychology & Health. 1998;13(4):717-33.
165. Leventhal H, Leventhal EA, Cameron LD. Representations, proceedures, and affect in illness self-regulation: A perceptual-cognitive model. In: Baum A, Revenson TA, Singer JE, editors. Handbook of health psychology. Mahwah: Lawrence Erlbaum Associates; 2001. p. 19-48.
166. van Vugt M, de Wit M, Cleijne WH, Snoek FJ. Use of behavioral change techniques in web-based self-management programs for type 2 diabetes patients: systematic review. J Med Internet Res. 2013;15(12).
167. Hawthorne K, Robles Y, Cannings-John R, Edwards AGK. Culturally appropriate health education for type 2 diabetes mellitus in ethnic minority groups. Cochrane Database of Systematic Reviews. 2008(3).
168. Ministry of Health. He Korowai Oranga: Māori Health Strategy. 2002.
169. Durie M. Whaiora: Māori health development. 2nd ed. Auckland, NZ: Oxford University Press; 1994.
170. Rochford T. Whare Tapa Wha: A Mäori model of a unified theory of health. The Journal of Primary Prevention. 2004;25(1):41-57.
171. Maddison R, Pfaeffli L, Whittaker R, Stewart R, Kerr A, Jiang Y, et al. A mobile phone intervention increases physical activity in people with cardiovascular disease: Results from the HEART randomized controlled trial. European journal of preventive cardiology. 2015;22(6):701-9.
172. Whittaker R, Maddison R, McRobbie H, Bullen C, Denny S, Dorey E, et al. A multimedia mobile phone–based youth smoking cessation intervention: Findings from content development and piloting studies. J Med Internet Res. 2008;10(5).
173. Mhurchu CN, Whittaker R, McRobbie H, Ball K, Crawford D, Michie J, et al. Feasibility, acceptability and potential effectiveness of a mobile health (mHealth) weight management programme for New Zealand adults. BMC obesity. 2014;1(1):10.
174. International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium http://www.idf.org/diabetesatlas: International Diabetes Federation; 2013.
175. Ministry of Health. New Zealand Health Survey: Annual update of key findings 2012/13. Wellington: Ministry of Health,; 2013.
176. Heron KE, Smyth JM. Ecological momentary interventions: Incorporating mobile technology into psychosocial and health behaviour treatments. British journal of health psychology. 2010;15(1):1-39.
177. Research New Zealand. The rise and rise of smartphones and other mobile devices. Media Release; 5 March 2013; 2013 5 March 2013.
178. International Telecommunication Union. The World in 2014: ICT Facts and Figures. 2014. Available from: http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2014-e.pdf
179. Commerce Commision New Zealand. Annual Telecommunications Monitoring Report 2012. 2013 April 2013.
180. Whittaker R, McRobbie H, Bullen C, Borland R, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. The Cochrane Library. 2012.
181. Noar SM, Benac CN, Harris MS. Does tailoring matter? Meta-analytic review of tailored print health behavior change interventions. Psychological bulletin. 2007;133(4):673.
182. Ryan P, Lauver DR. The Efficacy of Tailored Interventions. Journal of Nursing Scholarship. 2002;34(4):331-7.
183. Leventhal H, Diefenbach M, Leventhal EA. Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. Cognitive therapy and research. 1992;16(2):143-63.

184. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychology. 2008;27(3):379-87.
185. Durie M. Mauri Ora: The Dynamics of Maori Health. Auckland: Oxford University Press; 2001.
186. Elo S, Kyngäs H. The qualitative content analysis process. Journal of advanced nursing. 2008;62(1):107-15.
187. Jones G, Abbasi K. Trial protocols at the BMJ. BMJ. 2004;329(7479):1360.
188. Krleža-Jerić K, Chan A-W, Dickersin K, Sim I, Grimshaw J, Gluud C. Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1). BMJ. 2005;330(7497):956-8.
189. Ministry of Health. Virtual Diabetes Register (VDR): Estimated diagnosed cases of diabetes by DHB as at December 2013. 2013. Available from: http://www.health.govt.nz/our-work/diseases-and-conditions/diabetes/about-diabetes/virtual-diabetes-register-vdr
190. Coppell KJ, Mann JI, Williams SM, Jo E, Drury PL, Miller JC, et al. Prevalence of diagnosed and undiagnosed diabetes and prediabetes in New Zealand: Findings from the 2008/09 Adult Nutrition Survey. NZ Med J. 2013;126(1370):23-42.
191. Jeffreys M, Wright C, Huang K, Pearce N. Ethnic differences in cause specific mortality among hospitalised patients with diabetes: A linkage study in New Zealand. Journal of epidemiology and community health. 2005;59(11):961-6.
192. Morrison F, Shubina M, Turchin A. Encounter frequency and serum glucose level, blood pressure, and cholesteral level control in patients with diabetes mellitus. Archives of Internal Medicine. 2011;171(17):1542-50.
193. Bailey TS, Zisser HC, Garg SK. Reduction in hemoglobin A1C with real-time continuous glucose monitoring: results from a 12-week observational study. Diabetes Technol Ther. 2007;9(3):203-10.
194. Cho J-H, Chang S-A, Kwon H-S, Choi Y-H, Ko S-H, Moon S-D, et al. Long-Term Effect of the Internet-Based Glucose Monitoring System on HbA1c Reduction and Glucose Stability A 30-month follow-up study for diabetes management with a ubiquitous medical care system. Diabetes Care. 2006;29(12):2625-31.
195. Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemedicine and e-Health. 2009;15(3):231-40.
196. Boland P. The emerging role of cell phone technology in ambulatory care. The Journal of ambulatory care management. 2007;30(2):126-33.
197. Russell-Minda E, Jutai J, Speechley M, Bradley K, Chudyk A, Petrella R. Health technologies for monitoring and managing diabetes: a systematic review. Journal of diabetes science and technology. 2009;3(6):1460.
198. Dobson R, Carter K, Cutfield R, Hulme A, Hulme R, McNamara C, et al. Diabetes Text-Message Self-Management Support Program (SMS4BG): A Pilot Study. JMIR mHealth uHealth. 2015;3(1):e32.
199. Whittaker R, Bramley D, Carter K, Cutfield R, Dobson R, Dorey E, et al. A Comprehensive Approach to Self-management Support for Diabetic Patients and Clinicians. Health Informatics New Zealand Conference, 27-29 November 2013, Rotorua, New Zealand 2013.
200. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Annals of Internal Medicine. 2013;158(3):200-7.
201. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011;13(4).
202. Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-management A Randomized Trial. The Diabetes Educator. 2009;35(4):641-51.
203. Toobert DJ, Hampson SE, Glasgow, RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care. 2000;23(7):943-50.
204. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. The Annals of Family Medicine. 2008;6(3):246-52.
205. Broadbent E, Petrie KJ, Main J, Weinman J. The brief illness perception questionnaire. Journal of psychosomatic research. 2006;60(6):631-7.
206. The EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. Health policy. 1990;16(3):199-208.
207. Janssen M, Lubetkin E, Sekhobo J, Pickard A. The use of the EQ-5D preference-based health status measure in adults with Type 2 diabetes mellitus. Diabet Med. 2011;28(4):395-413.

208. Dobson R, Whittaker R, Jiang Y, Shepherd M, Maddison R, Carter K, et al. Text message-based diabetes self-management support (SMS4BG): study protocol for a randomised controlled trial. Trials. 2016;17(1):179.
209. Minet L, Møller S, Vach W, Wagner L, Henriksen JE. Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials. Patient education and counseling. 2010;80(1):29-41.
210. Gale EAM, Beattie SD, Hu J, Koivisto V, Tan MH. Recruitment to a Clinical Trial Improves Glycemic Control in Patients With Diabetes. Diabetes Care. 2007;30(12):2989-92.
211. Armour TA, Norris SL, Jack L, Zhang X, Fisher L. The effectiveness of family interventions in people with diabetes mellitus: a systematic review. Diabet Med. 2005;22(10):1295-305.
212. Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. 1998.
213. O'Cathain A, Murphy E, Nicholl J. Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. BMC health services research. 2007;7(1):85.
214. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ: British Medical Journal. 2000;321(7262):694.
215. Robson B, Harris R. Hauora: Màori Standards of Health IV. A study of the years 2000–2005. Wellington: Te Ropu Rangahau Hauora a Eru Pomare. 2007.
216. James DC, Harville C, Sears C, Efunbumi O, Bondoc I. Participation of African Americans in e-Health and m-Health Studies: A Systematic Review. Telemedicine and e-Health. 2016;23(5):351-64.
217. McBrien KA, Naugler C, Ivers N, Weaver RG, Campbell D, Desveaux L, et al. Barriers to care in patients with diabetes and poor glycemic control—A cross-sectional survey. PLOS ONE. 2017;12(5):e0176135.
218. Dobson R, Whittaker R, Bartley H, Connor A, Chen R, Ross M, et al. Development of a Culturally Tailored Text Message Maternal Health Program: TextMATCH. JMIR mHealth and uHealth. 2017;5(4).
219. McCool J, Whittaker R, Tanielu H, Umali E, editors. TXTTAOFITAPAA (TEXT STOP SMOKE): A text-based smoking cessation programme adaptation for Samoa. International Journal of Behavioral Medicine; 2016; Melbourne: Springer.
220. Ministry of Health. Living Well with Diabetes: A plan for people at high risk of or living with diabetes 2015 - 2020 Wellington, New Zealand: Ministry of Health; 2015.
221. Ministry of Health. Rural health Wellington, New Zealand: Ministry of Health; 2011. Available from: http://www.health.govt.nz/our-work/populations/rural-health

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