Effectiveness of text message based, diabetes self management support programme (SMS4BG): two arm, parallel randomised controlled trial

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ABSTRACT

OBJECTIVE

To determine the effectiveness of a theoretically based and individually tailored, text message based, diabetes self management support intervention (SMS4BG) in adults with poorly controlled diabetes.

DESIGN

Nine month, two arm, parallel randomised controlled trial.

SETTING

Primary and secondary healthcare services in New Zealand.

PARTICIPANTS

366 participants aged 16 years and over with poorly controlled type 1 or type 2 diabetes (HbA1c ≥65 mmol/mol or 8%) randomised between June 2015 and November 2016 (n=183 intervention, n=183 control).

INTERVENTIONS

The intervention group received a tailored package of text messages for up to nine months in addition to usual care. Text messages provided information, support, motivation, and reminders related to diabetes self management and lifestyle behaviours. The control group received usual care. Messages were delivered by a specifically designed automated content management system.

MAIN OUTCOME MEASURES

Primary outcome measure was change in glycaemic control (HbA1c) from baseline to nine months. Secondary outcomes included change in HbA1c at three and six months, and self efficacy, diabetes self care behaviours, diabetes distress, perceptions and beliefs about diabetes, health related quality of life, perceived support for diabetes management, and intervention engagement and satisfaction at nine months. Regression models adjusted for baseline outcome, health district category, diabetes type, and ethnicity.

RESULTS

The reduction in HbA1c at nine months was significantly greater in the intervention group (mean −8.85 mmol/mol (standard deviation 14.84)) than in the control group (−3.96 mmol/mol (17.02); adjusted mean difference −4.23 (95% confidence interval −7.30 to −1.15), P=0.007). Of 21 secondary outcomes, only four showed statistically significant improvements in favour of the intervention group at nine months. Significant improvements were seen for foot care behaviour (adjusted mean difference 0.85 (95% confidence interval 0.40 to 1.29), P<0.001), overall diabetes support (0.26 (0.03 to 0.50), P=0.03), health status on the EQ-5D visual analogue scale (4.38 (0.44 to 8.33), P=0.03), and perceptions of illness identity (−0.54 (−1.04 to −0.03), P=0.04). High levels of satisfaction with SMS4BG were found, with 161 (95%) of 169 participants reporting it to be useful, and 164 (97%) willing to recommend the programme to other people with diabetes.

CONCLUSION

A tailored, text message based, self management support programme resulted in modest improvements in glycaemic control in adults with poorly controlled diabetes. Although the clinical significance of these results is unclear, the findings support further investigation into the use of SMS4BG and other text message based support for this patient population.

TRIAL REGISTRATION

Australian New Zealand Clinical Trials Registry ACTRN12614001232628.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Effective diabetes self management support is vital to address the increase in costly and debilitating long term complications associated with poor diabetes control

Text messages (SMS) are an ideal tool for the delivery of self management support

The effectiveness of SMS for the delivery of diabetes self management support to individuals with poorly controlled diabetes is not known

WHAT THIS STUDY ADDS

Text messaging is well received and has potential to be effective for the delivery of self management support to people with poorly controlled diabetes, warranting further investigation

SMS interventions have the potential to make culturally appropriate and personalised self management support accessible to nearly all people with diabetes, regardless of location

Introduction

The growing prevalence of diabetes is considered to be one of the biggest global health issues.[1] People of ethnic minorities, including Pacific and Māori (New Zealand indigenous population) groups, are particularly vulnerable to the development of diabetes, experience poorer control, and increased rates of complications.[2-6] In New Zealand, 29% of patients with diabetes were found to have HbA1c levels indicative of poor control (≥65 mmol/mol or 8%), putting them at risk for the development of debilitating and costly complications.[7] 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 also will substantially reduce healthcare costs associated with treating or managing the complications.[8-12]

The flexibility of mobile phones and their adoption into everyday life mean that they are an ideal tool in supporting people with diabetes whose condition needs constant management. Mobile phones, which have been used effectively to support diabetes management,[13-16] offer an ideal avenue for providing care at the patient's desired intensity. Additionally, they can provide effective methods of support to patients in rural and remote locations where access to healthcare providers can be limited.[17 18] Although there is growing support for the use of mobile health (mHealth) in diabetes, there is increasing evidence of a digital divide, with lower use of some technologies in specific population groups.[19 20] These groups include people who have low health literacy,[21] have low income,[22-24] and are members of ethnic minorities.[25 26] 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.[27] For mHealth tools to be used to manage poor diabetes control, they need to be designed to the needs and preferences of those people who need the greatest support by considering these factors.

The SMS4BG (self management support for blood glucose) intervention was developed to address the need for innovative solutions to support self management in adults with poorly controlled diabetes.[28] 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[29] (including extensive formative work and end user engagement to ensure that it met the needs of the population it was designed to reach) is evidence based and theoretically grounded. A previous pilot study found SMS4BG to be acceptable and perceived it as useful.[28] 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.

Methods

Study design

A nine month, two arm, parallel, randomised controlled trial 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[30] and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614001232628). Trial development and reporting was guided by the CONSORT[31] and CONSORT EHEALTH[32] statements.

Participants

Participants were referred to the study by healthcare professionals at their primary and secondary care centres across New Zealand. Additionally, participants could self refer to the study. Eligible participants were English speaking adults aged 16 years and over with poorly controlled type 1 or 2 diabetes (defined as glycated haemoglobin (HbA1c) concentration ≥65 mmol/mol or 8% in the preceding nine months). The initial protocol required HbA1c concentration above the cutoff level within the past three months, but after feedback from patients and clinicians, this period was extended to nine months to ensure a greater reach across those people not having regular tests. Participants required access to a mobile phone and needed to be available for the nine month study duration.

Randomisation and blinding

Eligible participants were randomised to either an 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 and Pacific, or non-Māori/non-Pacific). The randomisation sequence was generated by computer programme using variable block sizes of two or four, and overseen by the study statistician. 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 REDCap randomisation module ensured that treatment allocation was concealed until the point of randomisation. Due to the nature of the intervention, participants were aware of their treatment allocation. Research assistants conducting the phone interviews were also aware of the treatment allocation. However, the objective primary outcome was measured by blinded assessors throughout the study period.

Procedures

Participants who were referred to the study by clinicians or who self referred were contacted by a research assistant via phone to discuss the study and confirm eligibility. All eligible participants completed informed consent followed by baseline assessment over the phone with a research assistant before randomisation. All participants continued with their usual diabetes care including all medical visits, tests, and diabetes support programmes throughout the study. In addition, the intervention group received SMS4BG. Control participants received usual care only. All participants completed a follow-up phone interview nine months after randomisation (within three weeks of the nine month date). HbA1c blood tests (at baseline, three, six, and nine months) were undertaken through standard care and results obtained through medical records.

Intervention

SMS4BG is an automated self management support programme delivered by SMS (short messaging

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service) to motivate and support people to engage in the behaviours needed for successful diabetes management. The programme was tailored by the needs and goals of the individual, and demographic factors. As well as core motivational and support messages (in Māori, Pacific, or non-Māori/Pacific cultural versions), participants could opt to receive additional modules including those for: insulin control, young adult support, smoking cessation, lifestyle behaviour (exercise, healthy eating, or stress/mood management), and foot care (further module details in supplementary table 1).

Participants could choose to receive blood glucose monitoring reminders to which they could reply by sending in their result by text message. They could then view their results graphically over time on a password protected website. If they were identified as not having access to the internet at baseline they were mailed their graphs once a month. All messages were delivered in English although the Māori version included keywords in Te Reo Māori and the Pacific version had keywords in either Samoan or Tongan dependent on ethnicity. Examples of SMS4BG messages can be seen in the box. Participants were able to select the timing of messages and reminders, and identify the names of their support people and motivations for incorporation into the messages. The duration of the programme was also tailored to individual preferences. At three and six months, participants received a message asking if they would like to continue the programme for an additional three months, and had the opportunity to reselect their modules receiving up to a maximum nine months of messages. Participants could stop their messages by texting the word "STOP" or put messages on hold by texting "HOLIDAY."

The message delivery was managed by our content management system, with messages sent and received through a gateway company to allow for participants to be registered with any mobile network. Sending and receiving messages was free for participants. The system maintained logs of all outgoing and incoming messages. Further details of the intervention can be seen in the published pilot study,[28] and protocol.[30]

Primary and secondary outcomes

The primary outcome measure was change in glycaemic control from baseline to nine months' follow-up, measured as HbA1c (in mmol/mol, or equivalently in %). Secondary outcome measures included change in HbA1c at three and six months' follow-up, and the following outcomes at nine months:

- Self efficacy for diabetes management (Stanford self efficacy for diabetes scale (SEDM)[33])
- Diabetes self care behaviours including diet (general and specific), exercise, blood glucose monitoring, and foot care (summary of diabetes self care activities (SDSCA) measure[34])
- Presence of diabetes related distress (two item diabetes distress scale (DDS2)[35])
- Perceptions and beliefs about diabetes (brief illness perception questionnaire (BIPQ)[36])
- Health related quality of life (EQ-5D (index score and visual analogue scale (VAS))[37])
- Perceived social support for diabetes management (measured by use of a four item measure developed for this study assessing overall support, appraisal support, emotional support, and advice/information support; protocol paper provides measure details[30]).

Cost effectiveness as well as healthcare use was assessed during the study period compared with the nine months before randomisation (presented separately). We measured patient engagement and satisfaction with the intervention using semistructured interviews and data from the content management system. The secondary outcomes health related quality of life and perceived social support were not included

Box: Examples of SMS4BG text messages

Core message—Maori version

Kia ora. Control of your glucose levels involves eating the right kai, exercise & taking your medication. Your whānau, doctor & nurse can help you

Young adult message

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 message

[hi] [name]. Good management of your diabetes & your future health includes not smoking, call Quitline on 0800 778 778 for support

Healthy eating message

Healthy eating is an important part of your diabetes treatment and it will help you in controlling your blood glucose levels

Stress and mood management message

[hi] [name]. Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood

Blood glucose monitoring reminder

[hi] [name]. Just a reminder it is time to check your blood glucose. Reply with the result

Foot care message

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

in the initial trial registration but added before commencing the trial.

Statistical analysis

As published in the protocol, a sample size of 500 participants (250 per arm) was estimated to provide 90% power at the 5% significance level to detect a clinically meaningful group difference of 0.5% (5.5 mmol/mol) in HbA1c at nine months, assuming a standard deviation of 1.7% (18.6 mmol/mol). Despite extensive efforts, recruitment for the study was slower than expected, and with the limited overall study period available, 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.

Statistical analyses were performed by SAS version 9.4 (SAS Institute). All statistical tests were two sided at a 5% significance level. Analyses were performed on the principle of intention to treat, including all randomised participants who provided at least one valid measure on the primary outcome after randomisation. Demographics and baseline characteristics of all participants were first summarised by treatment group with descriptive statistics. No formal statistical tests were conducted at baseline, because any baseline imbalance observed between two groups could have occurred by chance with randomisation.

We summarised the primary and secondary outcomes using descriptive statistics at each scheduled visit. A random effects mixed model was used to evaluate the effect of intervention on HbA1c at three, six, and nine months' follow-up, adjusting for baseline HbA1c and stratification factors and accounting for repeated measures over time. Model adjusted mean differences in HbA1c between the 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 intervals and P values were reported. Treatment effects sizes were also compared between important subgroups considered in stratification, including diabetes type (1 and 2), ethnicity (Māori/Pacific and non-Māori/non-Pacific), and region (urban and rural). For other secondary outcomes measured at nine months, we used generalised linear regression models with same covariate adjustment using a link function appropriate to the distribution of outcomes. Model adjusted estimates on the treatment difference between the two groups at nine months were reported, together with 95% confidence intervals and P values. No imputation was considered on secondary outcomes.

Patient involvement

Patients were involved in all stages of the study, including the initial conceptualisation and formative work leading to the development of SMS4BG (for more information, see the development paper[28]). Patient feedback informed the intervention modality, purpose, and structure, and patients reviewed intervention content before it was finalised. Patient feedback on the acceptability of SMS4BG through the pilot study[28] led to improvements to the intervention including additional modules, the option for feedback graphs to be posted, additional tailoring variables, and a longer duration of intervention. Patient feedback also informed the design of this trial—specifically its duration, the inclusion criteria, and recruitment methods. Additionally, patients contributed to workshops of key stakeholders held to discuss interpretation, dissemination of the findings, and potential implementation. We have thanked all participants for their involvement and they will be given access to all published results when these are made publicly available.

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 and control groups (n=183 each; fig 1). The final nine month follow-up assessments were completed in August 2017, with loss to follow-up (that is, no follow-up data on any outcome) low in both groups (overall 7/366=2%). A total of 12 participants (six per group) were excluded from the primary outcome analysis because of no follow-up HbA1c results after randomisation. Baseline characteristics of participants are presented in table 1, and no adverse events were recorded from the study or protocol deviations.

Primary outcome

The main treatment effect on the primary outcome is presented in table 2. The reduction in HbA1c from baseline to nine month follow-up was significantly greater in the intervention group than in the control group (mean −8.85 mmol/mol (standard deviation 14.84) *v* −3.96 mmol/mol (17.02), adjusted mean difference −4.23 (95% confidence interval −7.30 to −1.15), P=0.007). The adjusted mean difference on change in HbA1c at three and six months were −4.76 (−8.10 to −1.43), P=0.005) and −2.36 (−5.75 to 1.04), P=0.17), respectively (table 2).

A decrease in HbA1c from baseline to nine month follow-up was observed in 75% (132/177) of intervention participants compared with 59% (105/177) of control participants (χ^2 test, P=0.01). At nine months, 27% (48/177) of intervention and 17% (30/177) of control participants had HbA1c levels dropping to below 65 mmol/mol (P=0.024).

We saw no significant interaction between the treatment group and any of the prespecified subgroups: type 1 versus type 2 diabetes (P=0.82), non-Māori/non-Pacific versus Māori/Pacific ethnicity (P=0.60), high urban versus high rural/remote region (P=0.38). Adjusted mean differences on change in HbA1c from baseline to nine months for patients with type 1 and type 2 diabetes were −5.75 mmol/mol (95% confidence interval −10.08 to −1.43, P=0.009) and −3.64 mmol/mol (−7.72 to 0.44, P=0.08), respectively. Adjusted mean differences for non-Māori/non-Pacific

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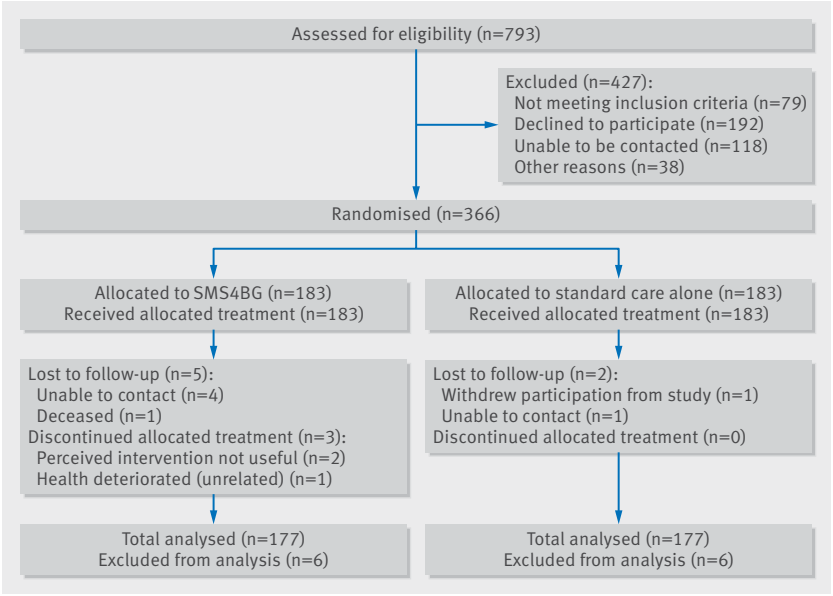

Fig 1 | Trial registration flowchart

and Māori/Pacific people were −4.97 mmol/mol (−8.51 to −1.43, P=0.006) and −3.21 mmol/mol (−9.11 to 2.70, P=0.28), respectively. Adjusted mean differences for participants living in high urban and high rural/remote areas were −4.54 mmol/mol (−8.40 to −0.68, P=0.02) and −3.94 mmol/mol (−9.00 to 1.12, P=0.13), respectively (table 3).

Table 1 | Baseline characteristics of participants. Data are number (%) of participants unless stated otherwise

Characteristic	Intervention group (n=183)	Control group (n=183)
Male sex	92 (50)	97 (53)
Ethnicity		
Māori	37 (20)	46 (25)
Pacific	29 (16)	20 (11)
Asian	8 (4)	12 (7)
New Zealand European	93 (51)	88 (48)
Other	16 (9)	17 (9)
Ethnicity category		
Māori/Pacific	66 (36)	66 (36)
Non-Māori/non-Pacific	117 (64)	117 (64)
Diabetes type		
Type 1	65 (36)	64 (35)
Type 2	118 (65)	119 (65)
Location		
High urban	125 (68)	117 (64)
High rural/remote	58 (32)	66 (36)
Smoking status		
Smoker	29 (16)	35 (19)
Non-smoker	154 (84)	148 (81)
Treatment: insulin	142 (78)	145 (79)
Referral source		
Primary care	72 (39)	77 (42)
Secondary care	106 (58)	105 (57)
Self referred	5 (3)	1 (1)
Age group		
16-24 years	25 (14)	21 (12)
25-49 years	66 (36)	65 (36)
50-64 years	73 (40)	77 (42)
≥65 years	19 (10)	20 (11)
Age (years), mean (SD)	47 (15)	47 (15)
Time since diagnosis (years), mean (SD)	13 (11)	12 (9)

SD=standard deviation.

Secondary outcomes

The main effect of the intervention on secondary outcomes are presented in table 4. No significant differences were observed between the two groups for self efficacy (SEDM). A significant improvement in foot care behaviour was seen in the intervention group compared with the control group (adjusted mean difference 0.85 (95% confidence interval 0.40 to 1.29), P<0.001) but no significant group differences were observed for diet (general or specific), exercise, blood glucose testing, and smoking behaviours (SDSCA). No significant group differences were observed for diabetes distress (DDS2).

In relation to perceptions and beliefs about diabetes, a significant reduction in illness identity (how much patients experience diabetes related symptoms) on the BIPQ was observed in favour of the intervention (adjusted mean difference −0.54 (95% confidence interval −1.04 to −0.03), P=0.04). However, we saw no significant group differences for perceptions of consequences, timeline, control, concern, emotions, and illness comprehensibility. A significant improvement in health status on the EQ-5D VAS was observed in favour of the intervention (4.38 (0.44 to 8.33), P=0.03) but no significant differences were observed between groups for the quality of life index score. Finally, the measure of perceived support for diabetes management showed a significant improvement between the groups in how supported the participants felt in relation to their diabetes management overall (0.26 (0.03 to 0.50), P=0.03) but no significant group differences on appraisal, emotional, and informational support.

Participant satisfaction and acceptability

Among the intervention participants, 169 (92%) completed questions at follow-up about satisfaction and acceptability of the intervention (table 5). Participants reported high levels of satisfaction with SMS4BG, and all but two participants thought that text messaging was a good way to deliver this type of support. Ten participants reported technical issues while receiving the intervention, most commonly issues replying to the messages (n=4), issues accessing graphs (n=2), and mobile reception issues (n=2).

Participant engagement

Owing to individual tailoring, participants in the intervention group received varying numbers of messages. Half the participants (92/183) received messages for three months, an additional 18% (33/183) chose to continue the messages for six months, and the remaining 32% (58/183) chose to continue the messages to the maximum nine months. Only three participants chose to stop their messages early. A total number of 76 523 messages were sent by the system to participants (median number of messages per participant 242 (interquartile range

Table 2 | Treatment effect on primary outcome (HbA1c (mmol/mol)). Data are mean (standard deviation) unless stated otherwise

	Intervention (n=177)	Control (n=177)	Unadjusted mean difference (95% CI)*	P for difference	Adjusted mean difference (95% CI)*	P for difference
Baseline	86.37 (17.83)	83.30 (14.80)	—	—	—	—
Change from baseline at 3 months	−8.70 (14.61)	−2.73 (15.07)	−5.89 (−9.41 to −2.36)	0.001	−4.76 (−8.10 to −1.43)	0.005
Change from baseline at 6 months	−7.16 (14.14)	−4.93 (13.97)	−3.05 (−6.63 to 0.54)	0.10	−2.36 (−5.75 to 1.04)	0.17
Change from baseline at 9 months	−8.85 (14.84)	−3.96 (17.02)	−5.24 (−8.52 to −1.97)	0.002	−4.23 (−7.30 to −1.15)	0.007

*Random effects mixed model without and with adjustment for baseline outcome, diabetes type, ethnicity, and region. Both treatment group and visit were included in the model with their interaction term. A random participant effect was added to account for repeated measures on same participant.

122-511; range 14-2050)), and 16 251 messages of blood glucose results were sent into the system by participants receiving the reminders (68 (1-169; 0-917)).

Discussion

This study found that a tailored, theoretically based, SMS based, diabetes self management support programme led to modest improvements in glycaemic control. The effects of intervention were also seen in four of 21 secondary outcomes, including foot care behaviour and ratings of diabetes support. The programme showed a high level of acceptability with the overwhelming majority of participants finding the intervention useful and willing to recommend it to others.

It is well documented that any reduction in HbA1c is likely to be associated with a decrease in the risk of diabetic complications.[38] Reductions in HbA1c are much more clinically important at higher levels, given that the association between vascular complications and HbA1c is non-linear and that similar reductions at lower HbA1c levels have much less effect.[38-40] In a less ethnically diverse population of people with type 2 diabetes who had levels of HbA1c higher than 6.5% (53 mmol/mol), a decrease of 1% (11 mmol/mol) has been found to result in reduced microvascular complications by 37%, myocardial infarction by 14%, and risk of

Table 3 | Treatment effect on primary outcome (HbA1c (mmol/mol)), by key subgroups. Data are mean (standard deviation) unless stated otherwise

	Intervention (n=177)	Control (n=177)	Adjusted mean difference (95% CI)*	P for difference
Diabetes type				
Type 1				
Baseline	87.55 (18.95)	82.64 (12.34)		
Change from baseline at 3 months	−8.84 (11.15)	−1.28 (12.33)	−7.67 (−12.45 to −2.88)	0.002
Change from baseline at 6 months	−3.76 (12.41)	−3.02 (9.66)	−1.05 (−5.92 to 3.82)	0.67
Change from baseline at 9 months	−7.70 (12.05)	−1.66 (11.92)	−5.75 (−10.08 to −1.43)	0.009
Type 2				
Baseline	85.73 (17.24)	83.65 (15.98)		
Change from baseline at 3 months	−8.62 (16.23)	−3.53 (16.41)	−3.42 (−7.82 to 0.98)	0.13
Change from baseline at 6 months	−9.13 (14.78)	−5.90 (15.70)	−3.32 (−7.80 to 1.16)	0.15
Change from baseline at 9 months	−9.49 (16.19)	−5.24 (19.21)	−3.64 (−7.72 to 0.44)	0.08
Ethnicity				
Māori/Pacific				
Baseline	91.08 (19.95)	85.17 (13.56)		
Change from baseline at 3 months	−8.42 (15.84)	−1.87 (17.20)	−5.36 (−11.80 to 1.07)	0.10
Change from baseline at 6 months	−6.11 (14.86)	−5.00 (14.69)	−0.77 (−7.31 to 5.78)	0.82
Change from baseline at 9 months	−7.91 (18.11)	−3.29 (17.22)	−3.21 (−9.11 to 2.70)	0.28
Non-Māori/non-Pacific				
Baseline	83.73 (16.02)	82.24 (15.38)		
Change from baseline at 3 months	−8.85 (13.98)	−3.13 (14.04)	−4.50 (−8.33 to −0.67)	0.02
Change from baseline at 6 months	−7.64 (13.88)	−4.88 (13.64)	−3.29 (−7.19 to 0.61)	0.10
Change from baseline at 9 months	−9.39 (12.70)	−4.33 (16.99)	−4.97 (−8.51 to −1.43)	0.006
Location				
High rural/remote				
Baseline	85.21 (18.91)	83.12 (17.13)		
Change from baseline at 3 months	−5.38 (14.13)	−2.07 (15.05)	−1.34 (−6.89 to 4.21)	0.63
Change from baseline at 6 months	−7.52 (13.88)	−6.38 (15.77)	0.14 (−5.53 to 5.80)	0.96
Change from baseline at 9 months	−9.72 (16.32)	−5.42 (17.21)	−3.94 (−9.00 to 1.12)	0.13
High urban				
Baseline	86.92 (17.37)	83.39 (13.35)		
Change from baseline at 3 months	−10.20 (14.66)	−3.06 (15.17)	−6.53 (−10.69 to −2.37)	0.002
Change from baseline at 6 months	−7.01 (14.34)	−4.15 (12.95)	−3.62 (−7.84 to 0.60)	0.09
Change from baseline at 9 months	−8.40 (14.07)	−3.18 (16.95)	−4.54 (−8.40 to −0.68)	0.02

*Random effects mixed model 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 participant effect was added to account for repeated measures on same participant.

Table 4 | Treatment effect on secondary outcomes. Data are mean (standard deviation) unless stated otherwise

Secondary outcome	Intervention (n=169)		Control (n=172)		Adjusted mean difference (95% CI)*	P for difference
	Baseline	9 months	Baseline	9 months		
Self efficacy (SEDM)	6.94 (1.48)	7.55 (1.33)	6.93 (1.68)	7.44 (1.46)	0.11 (−0.13 to 0.36)	0.36
Diabetes self care behaviours (SDSCA)						
General diet	4.33 (1.98)	4.91 (1.78)	4.37 (2.06)	4.99 (1.79)	−0.10 (−0.45 to 0.25)	0.58
Specific diet	3.84 (1.44)	4.25 (1.39)	3.89 (1.59)	4.19 (1.38)	0.09 (−0.18 to 0.36)	0.50
Exercise	3.11 (2.15)	3.45 (2.03)	3.27 (2.32)	3.48 (2.19)	0.06 (−0.35 to 0.48)	0.76
Blood glucose testing	4.38 (2.63)	4.85 (2.57)	4.24 (2.72)	4.85 (2.54)	−0.12 (−0.58 to 0.33)	0.59
Foot care	1.93 (2.19)	2.75 (2.51)	1.97 (2.17)	1.92 (2.13)	0.85 (0.40 to 1.29)	<0.001
Diabetes distress (DDS2)	3.37 (1.50)	3.03 (1.48)	3.44 (1.54)	3.26 (1.56)	−0.18 (−0.45 to 0.10)	0.21
Perceptions and beliefs about diabetes (BIPQ)						
Consequences	5.38 (2.72)	5.24 (2.76)	4.92 (2.79)	5.42 (2.78)	−0.34 (−0.86 to 0.18)	0.20
Timeline	9.06 (1.72)	9.05 (1.99)	8.61 (2.37)	8.72 (2.18)	0.22 (−0.19 to 0.62)	0.29
Personal control	5.84 (2.23)	6.84 (2.10)	6.09 (2.39)	6.81 (2.10)	0.10 (−0.30 to 0.50)	0.62
Treatment control	8.15 (1.81)	8.62 (1.56)	8.08 (2.03)	8.45 (1.68)	0.15 (−0.18 to 0.49)	0.37
Identity	5.05 (2.74)	4.62 (2.70)	4.56 (2.78)	4.97 (2.60)	−0.54 (−1.04 to −0.03)	0.04
Concern	7.23 (2.78)	6.55 (2.98)	6.99 (2.88)	6.47 (2.99)	−0.04 (−0.57 to 0.50)	0.89
Emotions	5.36 (3.02)	4.74 (3.17)	4.70 (3.34)	4.90 (3.06)	−0.37 (−0.97 to 0.23)	0.23
Illness comprehensibility	7.65 (2.14)	8.36 (1.60)	7.73 (2.15)	8.24 (1.78)	0.15 (−0.18 to 0.48)	0.38
Health related quality of life (EQ-5D)						
Index	0.83 (0.17)	0.84 (0.17)	0.84 (0.18)	0.84 (0.17)	0.00 (−0.03 to 0.04)	0.81
Health status VAS	66.24 (19.02)	73.22 (19.88)	70.03 (19.87)	70.03 (19.51)	4.38 (0.44 to 8.33)	0.03
Perceived support for diabetes management						
Overall support	4.75 (1.42)	5.14 (1.11)	4.89 (1.30)	4.94 (1.25)	0.26 (0.03 to 0.50)	0.03
Appraisal	5.13 (1.29)	5.30 (1.13)	5.20 (1.23)	5.21 (1.17)	0.11 (−0.13 to 0.35)	0.38
Emotional	5.14 (1.31)	5.30 (1.19)	5.20 (1.18)	5.20 (1.21)	0.11 (−0.13 to 0.35)	0.36
Advice/information	5.39 (1.05)	5.57 (1.03)	5.33 (1.11)	5.54 (0.89)	0.01 (−0.18 to 0.20)	0.90

*Linear regression model adjusted for baseline outcome, diabetes type, ethnicity, and region.
SEDM=self efficacy for diabetes management; SDSCA=summary of diabetes self care activities; DDS2=diabetes distress scale 2 item; BIPQ=brief illness perceptions questionnaire; VAS=visual analogue scale.

death by 21%.[38] A total of 75% of participants in the intervention group experienced a decrease in HbA1c at nine months, with a mean reduction in HbA1c of 8.9 mmol/mol (0.8%) from baseline, and a significant group difference of 4.2 mmol/mol (0.4%) in favour of the intervention. Therefore, the results in this study have potential to be clinically relevant in reducing the risk of vascular complications and death, although further investigation is needed.

The average reduction of 4.2 mmol/mol (0.4%) in HbA1c seen in this study did not reach the level chosen to signify clinical significance in the initial power calculation (5.5 mmol/mol (0.5%) reduction in HbA1c). Therefore, this study is unable to conclude that the effects of the SMS4BG intervention are clinically significant. Although further investigation is needed, we believe the results have the potential to still be clinically relevant in practice, particularly among individuals with high levels of HbA1c, such as the participants with poorly controlled diabetes in this study. The unadjusted group difference on change in HbA1c from baseline was −5.89, −3.05 and −5.24 mmol/mol at three, six, and nine months, respectively. The main analysis, with adjustment for baseline value and stratification factors, showed a smaller treatment effect, although both results were significant at three and nine months. Similar results were found across major subgroups of interest despite the fact that these analyses were not specifically powered. These consistent findings led us to believe that the intervention shows promising effects on treating people with poorly controlled diabetes and warrants further investigation.

This study contributes to the evidence around the use of SMS to support diabetes management.[13-15] 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.[14 16 41] Unlike previous studies that typically focus on 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, enhancing potential reach and generalisability. The only limit on the population was the requirement that participants had to have poor diabetes control. This criterion was particularly important given associated costs and debilitating complications of poorly controlled diabetes. Although few trials so far have examined the effectiveness of mHealth interventions in this population,[42] this study provides evidence to support the use of this modality to provide diabetes education and support to individuals with poor control.

Table 5 | Intervention satisfaction and acceptability results (n=169)

Question	No (%) of yes responses
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)

The control group also experienced a decrease in HbA1c from baseline to the nine 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,[43] but it is not expected that these improvements would be sustainable past the initial few months without intervention.

Study strengths

Strengths of the current study included its sample size, diverse population, very 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 participants 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 individuals with poor control. Considering poorer outcomes are experienced by ethnic minority groups, a strength of this study was its high proportion of participants representing these groups.

Strengths of the intervention were that it was theoretically based, the information reinforced messages from standard care, and it was system initiated, personally tailored, and used simple technology. These strengths result in high relevance to diverse individuals, increasing the intervention's reach and acceptability. Unlike SMS4BG, previous diabetes SMS programmes have largely focused on specific groups—for example, limiting their generalisability. Furthermore, the SMS4BG intervention was tailored and personalised to the individual. Although this specificity results in a more complex intervention in relation to its delivery, it appears to be a worthwhile endeavour with high satisfaction and the majority of participants happy with their message dosage.

Study limitations

The biggest study limitation was the difficulty with recruitment, which resulted in a sample size smaller than initially planned. One reason for the low recruitment was the required time needed by clinicians to identify and refer patients to the study, which was not always available. Furthermore, many referred patients who did not meet the HbA1c inclusion criteria were still referred because clinicians had thought these individuals would benefit from the programme. This limitation highlights the difference between research and implementation where strict criteria can be relaxed. Alternative methods of recruitment could be explored, such as through laboratory test facilities to ensure access to the intervention regardless of clinician availability.

Owing to time restrictions, longer term follow-up of participants was not feasible within the current study, although it is hoped that a two year follow-up of the present study's participants is possible. The significant group difference seen at three months, dropping slightly at six months, but reaching significance again at nine 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.

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 could provide greater benefit. It is likely that some people were not referred to the study, or were unable to take part, due to the criteria that they must be able to read English. SMS health programmes have been translated into other languages such as Te Reo;[44] thus, further research needs to look at whether such translations would be of benefit in SMS4BG.

Implications

This study shows the potential of SMS4BG to provide a low cost, scalable solution for increasing the reach of diabetes self management support. It showed that a text messaging programme can increase a patient's feelings of support without the need for personal contact from a healthcare professional. Half of the intervention group reported sharing the messages with others. Traditional education for diabetes self management is delivered to individual patients, but there is benefit of support from other people being involved.[45] This is particularly pertinent to ethnic populations such as Māori groups, in whom family have an important role in supporting diabetes self management.[46]

With technology advancing rapidly, there is a call for mHealth to move towards more complex technology. However, this study has shown that text messaging—available on any mobile phone—although simple, is still potentially effective for improving glycaemic control. Equally, this study had very few technical difficulties, which probably contributed to the high satisfaction with the intervention. The individual tailoring of the intervention, and ability for participants to choose varying components and dosages, means that questions remain around 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 inform the development of future interventions. With participants highly satisfied with the intervention and largely happy with their intervention dosage, but great variance in the modules, durations, and dosages, SMS4BG may need to remain individually tailored in this way, resulting in a more complex intervention for delivery until further investigation on this can be made.

Conclusions

This study showed that a tailored and automated SMS self management support programme has potential

for improving glycaemic control in adults with poorly controlled diabetes. Although the clinical significance of these results is unclear, and the full duration of these effects is yet to be determined, exploration of SMS4BG to supplement current practice is warranted.

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Contributors: RW obtained funding for this trial. All coauthors had input into the study protocol. RD, RW, RMu, and MS contributed to the development of the intervention content. RD managed the day-to-day running of the trial and delivery of the intervention. RD and RW collected the data. YJ and RD did the data analyses. All coauthors were involved in the interpretation of the results. RD wrote the article with input from all coauthors. All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. All authors approved the final version of this manuscript. RD is guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethical approval: The study received ethical approval from the New Zealand Health and Disability Ethics Committee (14/STH/162). All participants provided informed consent to take part in the trial.

Data sharing: The research team will consider reasonable requests for sharing of deidentified patient level data. Requests should be made to the corresponding author. Consent for data sharing was not obtained but the presented data are anonymised and risk of identification is low. The original protocol[30] is available from the corresponding author on request.

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

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Web appendix: Supplementary table 1