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Diabetes Research
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Effect of lifestyle focused text messaging on risk factor modification in patients with diabetes and coronary heart disease: A sub-analysis of the TEXT ME study

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ARTICLE INFO

Article history:

Received 13 December 2018

Received in revised form

3 March 2019

Accepted 24 April 2019

Available online 4 May 2019

Keywords:

HbA1c

Text messaging

Telemedicine

Type 2 diabetes mellitus

ABSTRACT

Aims: There is potential to provide public health interventions through text messaging for patients with Type 2 diabetes mellitus (T2DM). Our objective was to ascertain if lifestyle focused text messaging addressing cardiovascular risk factors in patients with coronary heart disease (CHD) and T2DM, was more effective than usual care.

Methods: This is a secondary analysis of the TEXT ME study, a randomised clinical trial of a 6-month text messaging intervention in patients with coronary heart disease. The measured outcomes include cholesterol, blood pressure (BP), body mass index (BMI), HbA1c, waist/hip circumference and smoking status. Our objective was to ascertain if lifestyle focused text messaging in patients with T2DM was more effective than usual care, and to determine if the intervention was more effective in patients with T2DM compared to those without.

Results: 229 participants in the TEXT ME study had T2DM (32%), 111 participants in the intervention group and 118 in the control group. At 6 months, the mean difference in systolic BP was -7.6 mmHg (95%CI $-11.8, -3.37$, $p = 0.0003$) and diastolic BP -3.7 mmHg (95%CI $-6.12, -1.24$, $p = 0.0032$). The mean difference in low density lipoprotein in the intervention arm, compared to the control arm, was -0.05 mmol/L (95%CI $-0.27, 0.18$, $p = 0.813$), and in triglycerides was -0.29 mmol/L (95%CI $-0.59, 0.01$, $p = 0.035$) respectively. The mean difference in BMI was -0.89 kg/m² (95%CI $-2.74, 0.95$, $p < 0.0001$) in the intervention group, waist circumference -3.98 cm (95%CI $-8.57, 0.61$, $p < 0.0001$) and hip circumference -3.26 cm (95%CI $-7.67, 1.16$, $p = 0.0006$). Intervention subjects with diabetes were less likely to be smokers at 6 months. The mean difference in HbA1c between the control and intervention group was not significant ($p = 0.126$). The intervention was as effective in patients with diabetes, compared to those without.

Conclusion: Among patients with coronary heart disease with T2DM, lifestyle-focused text messaging resulted in significant risk factor reduction.

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<https://doi.org/10.1016/j.diabres.2019.04.030>

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1. Introduction

Type 2 diabetes mellitus (T2DM) is a growing epidemic in Australia and worldwide. The World Health Organisation (WHO) estimated that the number of people with diabetes in 2014 was 422 million, with the global prevalence being 8.5% [1]. With the large burden of disease caused by diabetes, there is an immense need to develop simple, low cost approaches to encourage patients with diabetes to lead a healthy lifestyle. The Framingham Heart Study revealed that people with diabetes had higher rates of coronary artery disease (CAD) and peripheral arterial disease and this has been confirmed in numerous studies since then [2]. The commonest cause of death in patients with diabetes is cardiovascular disease (CVD), and one study showed that risk of death from CAD was almost three fold higher in individuals with diabetes, compared to those without [3]. Mortality after a first myocardial infarction is also higher among patients with diabetes, compared to those without diabetes [4]. However, for patients with diabetes and established CVD, trials have failed to demonstrate reduced cardiovascular complications with tighter glycaemic control, but there are marked benefits with improved blood pressure and lipid control [5–8]. The ADVANCE Blood Pressure trial demonstrated that during an average follow up of 4.3 years, BP was lowered on average, by 5.6/2.2 mm Hg on those patients on BP lowering therapy. This was associated with a 9% reduction in major adverse cardiovascular events (MACE), 18% reduction in cardiovascular mortality and 15% reduction in all cause mortality. Sub-analysis of patient with diabetes in the ‘4S Simvastatin’ trial demonstrated that use of lipid lowering therapy reduced the risk of major coronary events in patients with T2DM [9].

Thus, targeting cardiovascular risk reduction is as important, if not more so, than tight glycaemic control in patients with diabetes who have already developed CVD.

Mobile health is the use of mobile and wireless technology in managing healthcare and has the potential to provide low cost initiatives on a large scale. Mobile phone text messages can remind and motivate patients to adopt a healthy lifestyle and support self-management of their disease. The Tobacco, Exercise and Diet Messages (TEXT ME) study demonstrated that in patients with established CVD, a life-style focussed text messaging intervention for a duration of 6 months improved cardiovascular risk factors such as low density lipoprotein cholesterol (LDL-c), systolic and diastolic blood pressure (SBP, DBP), body mass index (BMI), physical activity and smoking [10]. There is also some evidence that text messaging can be effective in supporting diabetes management. A recent randomised controlled trial conducted among 366 patients with diabetes in New Zealand (SMS4BG), demonstrated that a 9-month text-messaging program resulted in a significant reduction in glycated haemoglobin (HbA1c) [11]. These findings are consistent with other studies on text messaging that have demonstrated favourable outcomes in promoting short-term weight loss and smoking cessation [10,12,13]. Goodarzi et al. and Roghva et al. were both able to demonstrate that a 3–12 month text messaging program in 210 patients with diabetes resulted in a lower total cholesterol and LDL-c level in the intervention arm, in addition to

HbA1c reduction [14,15]. However, not all studies have been able to show the favourable effect of text messaging in diabetes, and there exists a paucity of literature examining text messaging in a larger cohort of patients with T2DM. We conducted this analysis to further explore this topic and add to the current literature available.

The objective of the current analysis was to assess the effectiveness of text messaging on cardiovascular risk factors and HbA1c amongst the subgroup of people with diabetes enrolled in the TEXT ME study and to compare its efficacy between people with and without diabetes.

2. Methods

2.1. Study design

The present study is a sub-analysis of the TEXT ME study, for which the methods and intervention design have been previously described [10–16]. In short, TEXT ME study was a parallel-design, single blind randomized controlled trial of a mobile phone text messaging intervention to improve cardiovascular risk factors among patients with CAD. Participants in the trial were recruited from a large tertiary referral hospital in Sydney. Ethics approval was from the Western Sydney Local Health Network Human Research Ethics Committee. Patients were eligible if they were older than 18 years, had documented CVD and were able to provide informed consent. The criteria for CVD included any one of previous myocardial infarction, previous coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI) or >50% stenosis in at least one major epicardial vessel. Randomization occurred via a computerized randomization program that was accessed through a secure web interface.

The text messaging intervention in TEXT ME involved delivering semi-personalised text messages providing advice, motivation and information directed mainly at improving diet, physical activity levels and encouraging smoking cessation (see Table 1). Participants received 4 messages per week for the duration of 6 months. Messages were sent at random times throughout the day, but during business hours. The content of the messages were based on the ‘Australian Heart Foundation Healthy Living Guidelines’ and were divided into 4 modules: smoking, diet, physical activity and general cardiovascular health [17]. The process and development of message content has been described elsewhere [18]. The general module contained information about secondary prevention, including chest pain action plans and reminders about medication adherence.

Measures of cardiovascular risk factors (LDL-c, triglyceride, blood pressure, BMI, and self-reported measures of physical activity, diet, and medications) were obtained at baseline and after 6 months of the intervention. Research assistants blinded to the treatment allocation undertook the measurements. Demographic information, including education and ethnic origin, was obtained at baseline. The presence of diabetes as a comorbidity was recorded, and was self reported by the participants at baseline visit. As the study was not originally designed to assess the effect of the intervention on glycaemic control, HbA1c was not performed at baseline.

Table 1 – Examples of text messages sent to participants in TEXT ME.

Module	Message
Smoking	[NAME], try identifying the triggers that make you want a cigarette & plan to avoid them.
Diet	Did you know 90% of people don't eat the recommended daily intake of vegetables (5 serves a day)?
Physical activity	Hi [NAME], don't forget physical activity is good for you! It reduces your risk of diabetes, heart attack, stroke, and their complications
General cardiovascular information	Studies show that stress, worry & loneliness can increase the risk of heart disease. Please talk to a health professional if you need help

However, for subjects with diabetes, HbA1c was measured and recorded at the 6-month visit.

2.2. Outcomes

The primary outcomes of the TEXT ME study were LDL-c, triglycerides, SBP, DBP, BMI, waist and hip circumference, smoking status at 6 months. We have added the outcome of HbA1c at 6 months to the current sub-analysis. The proportion of subjects who achieved guideline targets of modifiable risk factors (LDL-c < 2 mmol/L, blood pressure < 140/90 mm Hg, exercising regularly [≥ 5 d/week \times 30 min of moderate exercise per session], nonsmoker status, HbA1c < 7% [53 mmol/mol] and BMI < 25) at 6 months was examined. The proportion of patients achieving multiple risk factor targets was also assessed.

2.3. Statistical analysis

We followed a pre-specified statistical analysis plan that was prepared for this sub-analysis and all intervention evaluations were performed on an intention to treat basis. The primary analysis used was analysis of covariance (ANCOVA),

adjusting for the baseline values of the primary outcomes between the intervention and control group at the end of the study. The same method was applied for all the continuous secondary outcomes.

For each continuous outcome, the raw mean difference and the corresponding 95% confidence interval (CI) were reported with the adjusted p-value from ANCOVA. However for HbA1c, baseline levels were not measured and therefore could not be adjusted for. For the binomial outcome, the log binomial regression model, adjusting for the baseline measure of the outcome was used to compare the effect of the intervention. The relative risk (RR) and the corresponding 95% CI with the adjusted p-value from the regression model were reported. To compare the effect of the intervention on outcomes in the cohort of patients with diabetes and without diabetes, an interaction term between intervention and diabetes status was added to the models.

Summaries of continuous baseline variables are presented as means and standard deviations unless skewed, and then presented as medians and interquartile ranges. Categorical variables are presented as frequencies and percentages. Analyses were conducted using SAS version 9.4 (SAS Institute

Table 2 – Baseline characteristics of subjects with and without diabetes in the TEXT ME Study.

Characteristic	Participants with diabetes			Participants without diabetes Overall (n = 481)
	Intervention (n = 111)	Control (n = 118)	Overall (n = 229)	
Age (years)	60.2 \pm 9.0	58.5 \pm 8.8	59.3 \pm 9.0	56.8 \pm 9.2
Men	92 (83)	98 (83)	190 (83)	392 (81)
Women	19 (17)	20 (17)	39 (17)	89 (19)
European Ethnicity	68 (61)	20 (17)	132 (58)	341 (71)
Years of education	10.6 \pm 2.8	10.8 \pm 3.5	10.7 \pm 3.2	11.7 \pm 3.6
LDL-c (mmol/L)	2.3 \pm 0.8	2.4 \pm 0.8	2.4 \pm 0.8	2.8 \pm 1.0
SBP (mm Hg)	131.0 \pm 12.9	131.3 \pm 13.4	131.2 \pm 13.1	127.6 \pm 11.6
BMI (kg/m ²)	31.5 \pm 6.7	31.0 \pm 6.8	31.2 \pm 6.7	29.9 \pm 5.4
Waist circumference (cm)	107.7 \pm 17.4	107.6 \pm 19.8	107.6 \pm 18.7	102.0 \pm 14.6
Hip circumference (cm)	108.2 \pm 17.9	105.6 \pm 19.5	106.8 \pm 18.7	102.2 \pm 14.3
Total cholesterol (mmol/L)	4.3 \pm 1.1	4.4 \pm 1.0	4.4 \pm 1.1	4.7 \pm 1.2
Triglycerides (mmol/L)	2.0 \pm 1.0	2.0 \pm 1.0	2.0 \pm 1.0	1.9 \pm 1.0
SBP \geq 140 mm Hg	22 (20)	27 (23)	49 (21)	48 (10)
DBP \geq 90 mmHg	17 (15)	25 (21)	42 (18)	61 (13)
BMI \geq 25 (kg/m ²)	97 (87)	100 (85)	197 (86)	356 (74)
Current smoker	51 (46)	71 (60)	122 (53)	255 (53)

Data presented as mean \pm SD or number (%). There were no significant differences between the intervention and control subjects with diabetes, and no significant differences between the diabetes subjects and the non-diabetic subjects.

Abbreviations: LDL-c: Low density lipoprotein cholesterol; SBP: systolic blood pressure; BMI: body mass index; DBP: diastolic blood pressure.

Inc.). All statistical tests were 2-tailed, and a 5% significance threshold was maintained.

3. Results

Of the 710 patients recruited in the TEXT ME study, 229 (32%) identified as having diabetes at baseline visit. 111 of these were in the text messaging intervention group, and 118 in the control group. The mean age for participants with diabetes was 59.3 ± 9.0 years, compared to 56.8 ± 9.2 years. The majority of participants in both groups were men and of European ethnicity. The patients with diabetes had similar baseline characteristics compared to those without (see Table 2). The participants with diabetes in the intervention group were well matched to those in the control group.

3.1. Effect of intervention on measures of cardiovascular risk and glycaemic control

Among diabetes patients, at six months, the mean difference in SBP was -7.6 mmHg (95%CI $-11.8, -3.37$, $p = 0.0003$) and DBP -3.7 mmHg (95%CI $-6.12, -1.24$, $p = 0.003$). The mean difference in LDL-c in the intervention arm, compared to the control arm, was -0.05 mmol/L (95%CI $-0.27, 0.18$, $p = 0.813$) and in triglycerides it was -0.29 mmol/L (95%CI $-0.59, 0.01$, $p = 0.035$). The mean difference in BMI was -0.89 kg/m² (95%CI $-2.74, 0.95$, $p < 0.0001$) in the intervention group, waist circumference -3.98 cm (95%CI $-8.57, 0.61$, $p < 0.0001$) and hip circumference -3.26 cm (95%CI $-7.67, 1.16$, $p = 0.0006$), compared to control (Table 3). The mean difference in HbA1c between the control group and intervention group was -0.39% (95%CI $-0.88, 0.11$, $p = 0.126$). At 6 months, there were more non-smokers in the intervention group, compared to the control (RR 1.27, 95% CI 1.06, 1.51, p -value 0.0041).

3.2. Patients achieving guideline targets for cardiovascular risk factors

We found that within the cohort of participants with diabetes, the intervention participants were more likely to have a BP within target range ($<140/90$ mmHg), exercising regularly, and to be non-smokers. In addition, of the 6 guideline-targets we had pre-specified, the intervention participants were more likely to be achieving 3 or 4 of the guideline targets (Fig. 1).

3.3. Difference between participants with diabetes, compared to those without

When comparing the effectiveness of the intervention in participants with diabetes and those without, we found that the intervention was equally effective in both groups.

The p -value for interaction for all measured parameters was not significant ($p > 0.05$), suggesting that the intervention was not more effective in participants without diabetes, compared to those with diabetes. The intervention effects did not differ between the group with diabetes, compared to the group without for LDL-c ($p = 0.01$), SBP ($p = 0.86$), DBP ($p = 0.539$) or BMI ($p = 0.302$).

Table 3 – Outcomes at 6 months amongst subjects with diabetes who received the intervention, compared to the control.

	Participant with diabetes				Participant without diabetes				P-value for interaction
	Intervention		Control		Intervention		Control		
	Mean difference (95% CI)	P-value	Mean difference (95% CI)	P-value	Mean difference (95% CI)	P-value	Mean difference (95% CI)	P-value	
LDL-c (mmol/L)	2.0 ± 0.8	0.8133	2.0 ± 0.9	0.8133	2.1 ± 0.8	0.8133	2.2 ± 0.8	0.8133	0.0998
HbA1c % (mmol/mol)	7.3(56) ± 1.7 (18)	0.1260	7.7(61) ± 1.9 (21)	0.1260	127.6 ± 13.6	0.0003	134.6 ± 15.2	0.0003	<0.0001
SBP (mmHg)	130.1 ± 14.1	0.0003	137.7 ± 17.1	0.0003	80.6 ± 17.8	0.0032	83.3 ± 9.7	0.0032	0.5393
DBP (mmHg)	80.4 ± 8.0	0.0001	84.1 ± 10.0	0.0001	28.2 ± 5.1	0.0001	29.4 ± 5.8	0.0001	0.3023
BMI (kg/m ²)	31.1 ± 6.1	<0.0001	32.0 ± 7.6	<0.0001	97.5 ± 12.7	<0.0001	103.5 ± 15.8	<0.0001	0.4433
Waist circumference (cm)	105.6 ± 14.8	0.1472	109.6 ± 17.2	0.1472	99.5 ± 11.5	0.0351	105.2 ± 13.2	0.0351	<0.0001
Hip circumference (cm)	106.0 ± 12.8	0.0351	109.3 ± 16.8	0.0351	1.5 ± 0.9	0.0351	1.6 ± 1.0	0.0351	0.3115
Triglyceride (mmol/L)	1.8 ± 0.9	0.0351	2.1 ± 1.3	0.0351	-0.29 (-0.59, 0.01)	0.0351	-0.1 (-0.27, 0.06)	0.0351	0.3581

Values are reported as mean ± SD. All variables were adjusted for baseline level except for HbA1c. The failure of the p -value for interaction to reach significance indicates that there was no interaction between diabetes and treatment allocation, i.e. intervention was as effective in participants with diabetes, compared to those without.

Abbreviations: LDL-c: low density lipoprotein cholesterol, HbA1c: glycated haemoglobin; SBP: systolic blood pressure, DBP: diastolic blood pressure, BMI: body mass index.

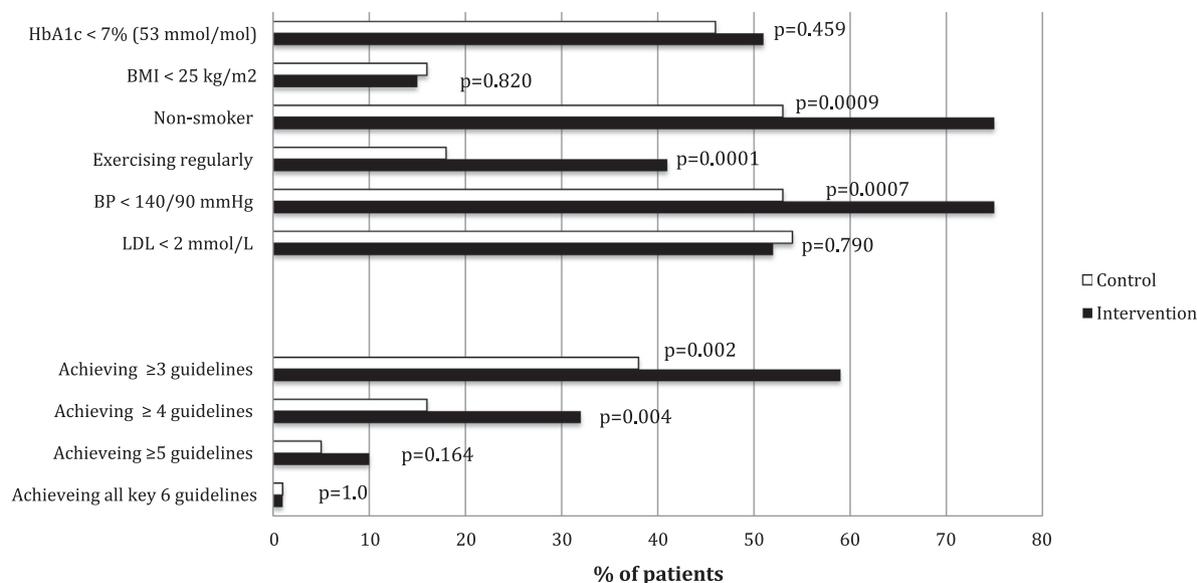


Fig. 1 – Effect of text messaging on achieving guideline targets in patients with both T2DM and CAD. Abbreviations: HbA1c: glycated haemoglobin; BMI: body mass index, BP: blood pressure, LDL: low density lipoprotein.

Thus, participants with diabetes were just as likely to benefit from the intervention, compared to those without (Table 3).

4. Discussion

Our analysis found that a simple, low cost customised program of lifestyle focused text messaging in patients with diabetes and coronary artery disease led to an improvement in some cardiovascular risk factors, including systolic and diastolic blood pressure, BMI, hip and waist circumference and triglyceride levels. However it did not significantly improve HbA1c or LDL-c, presumably due to the smaller sample size and reduced power. The intervention was as effective in participants with diabetes, compared to those without. Our analysis was the first of its kind to be performed in a cohort of patients with diabetes and established CVD, where the focus of the text messaging intervention was to improve cardiovascular risk factors rather than glycaemic control.

In the UK prospective diabetes study (UKPDS), 49% of deaths within 10 years of diagnosis of diabetes were due to cardiovascular disease. In another study, atherosclerosis was found to be more frequent and more extensive and had an earlier onset among people with diabetes mellitus than in people without the condition [19]. Therefore, better control of cardiovascular risk factors has the potential to significantly impact morbidity and mortality in patients with diabetes. The UKPDS demonstrated a linear relationship between HbA1c and both micro and macro-vascular disease [20]. This has led to the expectation that a reduction in HbA1c would reduce adverse cardiovascular outcomes. However, studies have since failed to demonstrate that tight glycaemic control is effective for the secondary prevention of cardiovascular complications. This was evident in the ‘Action to Control Cardiovascular Risk in Diabetes’ (ACCORD) Study, which

demonstrated that when compared to standard therapy, intensive therapy did not reduce major cardiovascular events, and even resulted in increased mortality ([6]. Similarly, the ‘Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation’ (ADVANCE) study, demonstrated that within the short term, tightening glycaemic control from moderate to tight levels of HbA1c (6.5% or 48 mmol/mol) had no significant effect in reducing macrovascular disease [8]. More recently, the ‘Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes’ (LEADER) and ‘Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes’ (EMPAGREG) trials have demonstrated reduction in major adverse cardiovascular events, but these results have been independent of improvement in glycaemic control, suggesting other factors may be responsible for the reduced cardiovascular morbidity associated with these medications.

In contrast, studies focusing on intensive cardiovascular risk factor reduction in patients with diabetes and existing CVD or multiple risk factors have shown that this reduces cardiovascular mortality. The UKPDS Blood Pressure study demonstrated a reduction in mortality and complications related to diabetes with tight control of blood pressure [21]. The ADVANCE Blood Pressure Trial demonstrated the benefits of blood pressure reduction on both micro- and macrovascular events in patients with T2DM [22]. The Steno-2 trial also demonstrated that a long term, multifactorial intervention targeting risk factors in patients with T2DM reduced the risk of cardiovascular events [23]. In a post hoc analysis of the Scandinavian Simvastatin Survival Study (4S), a significant reduction in major coronary events and revascularization was observed in simvastatin-treated patients with diabetes [24]. Thus, controlling cardiovascular risk factors may be more important than tighter glycaemic control, in improving cardiovascular outcomes for patients with T2DM who already have established cardiovascular disease.

Whilst the evidence suggests that an improvement in glycaemic control may not be effective in secondary prevention of cardiovascular disease in patients with diabetes, it is still important for the prevention of micro-vascular complications. The reduction in HbA1c in the group of participants with diabetes who received the intervention was not statistically significant in our study but it was not designed to improve HbA1c or adequately powered for this endpoint. A few studies in the past have examined the effect of text messaging in improving outcomes in diabetes mellitus. The SMS4BG study enrolled 366 participants and administered an individually tailored, bidirectional 9-month text messaging intervention in cohort of patients with diabetes [11]. They found an adjusted mean difference in HbA1c of -4.23 mmol/mol (95% CI: -7.30 , -1.15 , $p = 0.007$) as a result of the intervention. Additionally, Islam et al were also able to show a mean difference in HbA1c in the text messaging intervention group of -0.66% , as a result of a 6-month text messaging intervention in a cohort of 236 participants [25]. Another randomized, non-blinded, parallel-group clinical trial allocated 126 individuals in California with T2DM to receive text messaging, and found a significant reduction in HbA1c as a result of the intervention [26]. A meta-analysis of the impact of text messaging on HbA1c, performed before the SMS4BG Study was published, demonstrated an overall reduction of -0.60% (p -value < 0.001) in the cohort of participants who received a text messaging intervention [27].

With the ubiquitous ownership of mobile phones in current times, text messaging has far reaching potential to be used as a public health initiative. It can be delivered at a relatively low cost per person and allows the option of being personalised to suit the individual's needs. A systematic review of reviews performed by Hall et al examining the use of text messaging in health improvement and behaviour change found that the majority of published interventions were effective when addressing diabetes management, weight loss, physical activity and smoking cessation [28]. The messages may be perceived as a continuation of care beyond just the hospital or clinical encounter, and encourage greater patient engagement. Text messaging is a powerful tool in population health, as the cost is relatively low, its use is widespread and it requires minimal technological expertise. Messages can be accessed at any time according to personal convenience and can be stored for review later. Given such ease of use and application, text messaging that results in lifestyle and behavioural change has immense potential to be an important population health initiative, particularly for people with diabetes, and this is supported by our study.

The main limitation of this study was that our randomised control trial was not powered to detect a difference in HbA1c and it was only examined as a post-hoc analysis in a trial that was primarily targeted at patients with CAD. Furthermore, intervention messages were not designed to improve glycaemic control. It is possible that a larger sample size and diabetes-specific messages might demonstrate an improvement in HbA1c with a text messaging intervention. A power calculation based on the Text Me data indicates that a total of 754 participants (377 each in the intervention and control

group) would be required to achieve difference in HbA1c of 0.26% with 90% power and 5% significance.

Secondly, our study identified patients as having diabetes through self-reported measures and there is a possibility that some participants had undiagnosed diabetes. The HbA1c data was only collected at 6 months, and we did not have a baseline value to assess the degree of improvement with the intervention, from baseline. Thirdly, our study was not designed to specifically target education on diabetes. While the messages provided lifestyle advice, primarily on diet, exercise and smoking cessation, there were no messages aimed at directly educating patients on how to improve glycaemic control. Fourthly, our study was conducted in a single centre in Western Sydney and our follow up period was limited to 6 months. As a consequence, the results of our study may not be generalizable in different contexts and our results may be limited only to the period in which the intervention was applied, with no results available on how sustained this effect was. Lastly, while an objective reduction in cardiovascular risk factors through lifestyle focused text messaging may be possible, this does not necessarily correlate with improved clinical outcomes, and this requires further exploration.

5. Conclusion

In summary, we found that lifestyle-focussed text messaging was effective in improving some cardiovascular risk factor levels in participants with coronary heart disease and diabetes in the TEXT ME study. The intervention led to a reduction in systolic blood pressure, BMI, waist circumference and triglyceride levels. The intervention was as effective in patients with diabetes, compared to those without. There is the potential for such a program to be scaled up to support improvements in cardiovascular health and diabetes management at a population level.

Acknowledgements

We thank the staff at Westmead Hospital for supporting the recruitment and TEXT ME program development at Westmead Hospital. We would also like to thank Laura De Keizer and Tony Barry for their assistance with this program.

Funding source

We received the ICPMR Jerry Koutts Scholarship at Westmead Hospital to assist with this project. Additionally, this work was supported by peer-reviewed grants from the National Heart Foundation of Australia Grant-in-Aid (G10S5110) and a BUPA Foundation Grant. Dr. Chow is funded by a Career Development Fellowship, and co-funded by the National Health and Medical Research Council (NHMRC) (1033478) and National Heart Foundation (11S6016) and Sydney Medical Foundation Chapman Fellowship. Dr Redfern is funded by an NHMRC Career Development Fellowship (1061793) and co-funded with a National Heart Foundation Future Fellowship (G160523).

Conflicts of interest

There are no conflicts of interest to declare.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2019.04.030>.

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