

Effect of text messaging on depression in patients with coronary heart disease: A sub study analysis from the TEXT ME randomised controlled trial

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Abstract

Objective We aimed to evaluate the effects on depression scores of a lifestyle-focused cardiac support program delivered via mobile-phone text messaging among patients with coronary heart disease (CHD).

Design Sub-study and secondary analysis of a parallel group, single-blind randomized controlled trial of patients with CHD

Setting A tertiary hospital in Sydney, Australia

Intervention The TEXT ME comprised 4 text messages per week for 6 months that provided education, motivation and support on diet, physical activity, general cardiac education and smoking, if relevant. The program did not have any specific mental health component.

Outcomes Depression scores at 6 months measured using the Patient Health Questionnaire-9 (PHQ-9). Treatment effect across sub-groups was measured using log-binomial regression model for the binary outcome (depressed/not depressed, where depressed is any score of PHQ-9 ≥ 5) with treatment, subgroup and treatment by subgroup interaction as fixed effects.

Results Depression scores at 6 months were lower in the intervention group compared to the control group, mean difference 1.9 (95% CI 1.5-2.4, p-value < 0.0001). The frequency of mild or greater depressive symptoms (PHQ-9 scores ≥ 5) at 6 months was 21/333 (6.3%) in the intervention group and 86/350 (24.6%) in the control group (relative risk 0.26, 95% CI 0.16-0.40, p < 0.001). This proportional reduction in depressive symptoms was similar across groups defined by age, sex, education, BMI, physical activity, current smoking, current drinking, and history of depression, diabetes, and hypertension. In particular, the rates of PHQ-9 ≥ 5 among people with a history of depression were 4/44 (9.1%) vs 29/62 (46.8%) in intervention vs control (RR 0.19, 95% CI 0.07 to 0.51, p < 0.001), and were 17/289 (5.9%) vs 57/288 (19.8%) among others (RR 0.30, 95% CI 0.18 to 0.50, p < 0.001).

Conclusions Among people with CHD a cardiac support program delivered via mobile-phone text messaging was associated with less symptoms of mild-to-moderate depression at 6 months in the treatment group compared to controls.

Trial Registration: Australian New Zealand Clinical Trials Registry Number (ANZCTR):
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Keywords: Text Message; Mobile Phones; Cardiovascular Diseases; Mental Health; Diabetes; Hypertension; Coronary Heart Diseases.

Strengths and limitations of this study

- The strength of this trial is the parallel group, prospective, randomized controlled design
- The trial had a relatively large sample size
- With respect to limitations, it is a single-centre study.
- Depression was measured using the PHQ-9 tool, which is designed as a screening tool.

Introduction

Depression is common among patients with chronic diseases including coronary heart disease (CHD) and often under-recognized and untreated.¹ Comorbid depression affects daily function and is associated with substantial impairment in health-related quality of life and worse clinical outcomes in patients with CHD.²⁻⁴ As well as the direct negative impact of depression on the wellbeing of patients and their carers, depression after myocardial infarction is associated with substantially increased risk of cardiovascular and all-cause mortality.⁵ Patients with depression and CHD need effective treatment and support for both conditions. Attendance at cardiac rehabilitation following a cardiac event decreases morbidity, mortality, depressive symptoms and improves quality of life.^{6,7} Nevertheless, access to cardiac rehabilitation remains difficult, especially for those who are financially disadvantaged, part of an ethnic minority group, older or living far from health centres with limited access to transport.⁸ Also, research suggests some simple interventions delivered in the community/ primary care can improve mental health outcomes and integrating treatments into chronic disease management improves outcomes.^{9,10} Innovation is clearly needed to provide ongoing support for patients with cardiac and other chronic conditions, within limited healthcare resources.

In recent years, mobile phone technologies such as text messaging interventions comprising health education and reminders have shown promise in improving healthcare service delivery,¹¹ increasing medication adherence,¹² and improving primary prevention of cardiovascular disease – for example improving glycaemic control among diabetes,¹³ and improving smoking quit rates.¹⁴ With respect to mental health, previous trials have reported that automated text messaging offered a feasible and acceptable means of monitoring depression and has the potential to improve outcomes in patients with comorbid depression.^{15,16} A systematic review of 6 trials involving 577 participants with mental health disorders (depression, alcohol dependence, schizophrenia and mood disorders) showed text messaging for health education, therapy goals and medication reminders interventions significantly improved several mental health related outcomes in 5 studies including depression and quality of life scores.¹⁷ However, most of these were pilot studies and little is known about the extent to which text messaging might reduce depressive symptoms in people with CHD. We conducted the Tobacco, Exercise and dieT MESSAGES (TEXT ME) randomized controlled clinical trial in patients with CHD that addressed multiple cardiovascular risk factors.¹⁸ The TEXT ME trial resulted in a modest improvement in LDL-C level and greater improvement in other cardiovascular disease risk factors including blood pressure, body mass index, physical activity and smoking among patient with CHD.¹⁹ The objective of this secondary

and exploratory analysis of the TEXT ME study was to examine if the text message support program had an impact on depressive symptoms at 6 months.

Methods

Study design: The current analyses were a pre-specified secondary analysis of the TEXT ME trial¹⁸. In brief, TEXT ME was a parallel-design, single-blind, randomised controlled clinical trial enrolling 710 patients with CHD from a tertiary hospital in Sydney, Australia between September 2011 and November 2013.¹⁹ The text messaging program and its development process are detailed elsewhere.¹⁹

Participants: Potential participants were identified through screening daily admissions, coronary angiogram case lists, and cardiology outpatient clinic lists from a large tertiary care hospital which serves a diverse population in terms of ethnicity and socioeconomic status in the Western Sydney Local Health District, Sydney, Australia. We included patients older than 18 years, with documented CHD who were able to provide informed consent. CHD was defined as documented myocardial infarction, coronary artery bypass graft surgery, or percutaneous coronary intervention, or proven angiographically and documented before consent. Patients were excluded if they did not have an active mobile phone, sufficient English language proficiency to read text messages, or were referred for evaluation of congenital heart disease or coronary anomalies. Ethical approval was obtained from the Western Sydney Local Health Network Human Research Ethics Committee. Figure 1 displays the study flow chart. A total of 1301 patients with CHD were invited to participate, 591 did not meet all inclusion criteria or declined to participate and 710 were randomized in TEXT ME.¹⁹ Twenty-seven participants (including 12 who were unable to be contacted, 5 who died and 10 with missing data for depression symptoms at 6 months) were excluded from the analysis. Therefore, the current analyses were performed on 683 participants (96%).

Patient involvement: No patients were involved in the design of the study, recruitment and conduct of the study. However, during the process evaluation we shared the results of the study with the participants and collected feedback from the participants. The process evaluation focus group discussions took place after participants completed the intervention and follow-up visit.

Randomization, trial procedure and intervention: Randomization was performed using a computerized randomization program through a secure web interface. The random allocation sequence was in a uniform 1:1 allocation ratio with a block size of 8 and was concealed from study personnel. After recruitment and discharge from hospital, if they were hospitalised, patients

would receive a text message informing them of their allocation.. Data were collected during face-to-face interviews using a structured questionnaire at baseline and 6 months by trained research assistants at the outpatient Cardiology clinic of Westmead Hospital. At study entry all intervention participants were provided brief training on how to read, delete and save the text messages. Data entry was performed by study staff through entering data into the secure web interface. The web-based computer program was set to send messages to patients randomized to the intervention. The message program development was based on behaviour change techniques linked to the theoretical framework reported by Abraham and Michie.^{20,21} In brief, it involved regular semi-personalised text messages providing advice, motivation, and information that aimed to improve general heart health, diet, physical activity and encourage smoking cessation (where relevant).²² Participants randomised to the intervention group received 4 text-messages per week for 24 weeks. Participants received minimum information on depressive symptoms being common in patients with CHD, and were advised to seek further help when needed, which is aligned with the curriculum of secondary prevention. For example, participants were encouraged to seek additional support “Not having support of family and friends can worsen heart disease- if you need help, don’t be afraid to ask”. The design, development and samples of the text messages for TEXT ME have been described in a separate paper.²² Examples of text messages used in the TEXT ME are provided in Supplementary Table S1.

Variables and outcomes: Data were collected on demographics, medical history and disease factors, including age, sex, years of education, current smoking and drinking status, history of diabetes, history of hypertension and history of depression. The history of depression included questions on prior treatment with medicines, counselling or electroconvulsive therapy (ECT). Physical activity was assessed with the Global Physical Activity Questionnaire.²³ Anthropometric measurements of weight, height, waist circumference and blood pressure were measured according to standardized procedures at baseline and at 6 months. Health-related quality of life was assessed using the SF-12 questionnaire at baseline and 6 months.²⁴

Depressive symptoms were assessed at 6 months using the 9-item Patient Health Questionnaire (PHQ-9). The questionnaire was only administered at the follow-up visit as there were concerns that assessment at baseline while in hospital was not a true reflection of baseline, and that repeating this questionnaire at two-time points may impact responses. The PHQ-9 is a depression screening tool which generates a total score from 0-27. Scores are categorized as 0-4 no depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression,

and 20-27 severe depression.²⁵ The PHQ-9 has been shown to have reasonable sensitivity (81.5) and specificity (80.6) at cut-off score ≥ 5 for patients with CHD²⁵ and has been widely used to detect depression symptoms in clinical settings.²⁶⁻²⁸ The PHQ-9 has showed good reliability (Cronbach's α 0.89 and 0.86) and validity with similar tools to screen depression (i.e PHQ-9 was found to be highly correlated with scores on the Beck Depression Inventory in the general population, $r=0.73$).

Data analysis: Analyses were conducted on data using IBM SPSS version 20.0 (IBM Corporation, USA) and SAS version 9.0 (SAS Institute Inc, Cary, North Carolina, USA). The primary endpoint was the difference in PHQ-9 scores between intervention and control groups at 6 months. Baseline variables were summarised as frequency data, means and standard deviations (SD). The Shapiro-Wilk test of normality was used to evaluate distribution of the PHQ-9 scores. The mean difference in intervention and control group depression scores at 6 months were compared using an independent t-test, and between depression severity categories by Fisher's exact tests. The relative risks were reported with 95% confidence intervals (CIs) for group differences and in people with a history of depression. We conducted a post-hoc analysis with PHQ-9 scores dichotomised at ≥ 5 representing mild symptoms of depression or greater. For the subgroup analysis, we performed a log binomial model for the binary outcome (depressed/not depressed, where depressed is any score of PHQ-9 ≥ 5) with treatment, subgroup and treatment by subgroup interaction as fixed effects. No baseline or any other covariates were included. All tests were two-sided and statistical significance was set at 0.05.

Results

There were no significant differences in the baseline characteristics of the 683 participants included in the analyses and the 27 who were excluded (Figure 1).

The mean age of participants was 58 ± 9 years, 18% were women. 16% had a history of depression of whom 60% reported prior treatment with counselling, 25% medication and 3% electroconvulsive therapy (ECT). Almost two-thirds of the participants (62%) had history of hypertension and one-third (32%) a history of diabetes. Baseline characteristics were similar between the randomised groups (Table 1).

Effects of text messaging on depression: Depression scores at 6 months were significantly lower (better) in the intervention group compared to the control group, with a mean difference of 1.9 (95% CI 1.5 to 2.4, p-value <0.0001) on the PHQ-9. The difference between the different categories of depression symptoms (mild, moderate, moderately severe and severe depression) reported by the participants was significantly lower in the intervention group compared to the control group (p<0.001). The frequency of mild to moderate depressive symptoms (PHQ-9 scores 5-14) at 6 months was 6% in the intervention and 25% in the control group, (Relative Risk 0.26, 95% CI 0.16 to 0.40, p <0.001, unadjusted). The number of participants reporting any depression (PHQ-9 \geq 5) was significantly higher in the control group compared to the intervention group (86 vs 21). (Table 2)

Table 3. reports the difference in the distribution of the PHQ-9 items at 6 months between the intervention and control groups. The differences were significantly different between groups for PHQ-9 item 1-7 at 6 months and fairly consistent across all items. The frequency of participants endorsing PHQ-9 item 9 relating to suicidality was 0.6% in the intervention group vs 0.9% in the control group (RR 0.70, 95% CI 0.12 to 4.17, p=0.696). (Table 3)

Figure 2 reports the treatment effect on PHQ-9 scores at 6 months by patient subgroup. The relative risk of being depressed after treatment compared to not being treated was consistent across patient sub-groups: age, sex, education, BMI, physical activity, current smoking, current drinking, and history of depression, diabetes, and hypertension (Figure 2 and Supplementary Table S2). The mental health component score of the SF-12 was significantly lower in the intervention group compared to the control group at 6 months (Supplementary Table S3). The rates of PHQ-9 \geq 5 among people with a history of depression were 4/44 (9.1%) vs 29/62 (46.8%) in intervention vs control (RR 0.19, 95% CI 0.07 to 0.51, p<0.001), and were 17/289 (5.9%) vs 57/288 (19.8%) among others (RR 0.30, 95% CI 0.18 to 0.50, p<0.001).

Discussion

In the TEXT ME trial, we found that a lifestyle-focused cardiovascular secondary prevention program delivered via text-message, and not specifically targeting depression or other abnormal mood symptoms, resulted in fewer symptoms of depression at 6 months in participants receiving the texting intervention. There were 75% fewer patients reporting PHQ-9 scores over 5 in the intervention groups and this proportional reduction was similar across different patient groups and somewhat unexpected given the lack of therapeutic content provided in the intervention. This size of difference is consistent with one depressive symptom that occurred nearly every day now only

occurring several days a week, or reducing from more than half the days of the week to not at all; or alternatively the cessation of two symptoms that previously occurred several days a week.

A recent systematic review assessing the impact of text messaging interventions in individuals with mental health disorders suggested that the interventions might be effective in improving mental health outcomes.¹⁷ However, the evidence for mHealth interventions in lowering depressive symptoms in CHD patients, or in patients with other chronic health conditions is limited. The Care Assessment Platform for Cardiac Rehabilitation (CAP-CR)²⁹ smart-phone based intervention conducted in 120 post-myocardial infarction patients, in 2009, included a comprehensive package of health and exercise monitoring, motivational and educational material delivery via text messaging, and weekly mentoring consultations. It demonstrated reductions in psychological distress at six-weeks (measured by Kessler 10 Psychological Distress Scale³⁰ K10, mean difference 1.85, 95% CI -0.11 to 3.8, $p=0.1$ and DASS-depression score, mean difference 0.90, 95%CI -0.77 to 2.57, $p=0.3$). Attendance in cardiac rehabilitation programs have been shown to be associated with decreased symptoms of depression, and improved psychological well-being.³¹ Internet-based cognitive behavioural therapy support programs have also been shown to have potential in reducing depressive symptoms.^{32 33} With increasing use of mobile phones, text messaging has the potential to support cardiac rehabilitation and reduce the burden of cardiovascular diseases and depression.³⁴

In addition to the main effects on clinical outcomes of TEXT ME,¹⁹ the additional benefit of TEXT ME in reducing depressive symptoms at 6 months make it a very appealing low-cost strategy for patients with CHD. Depression is associated with worse health outcomes in patients with CHD.^{35 36} Poor health behaviours, such as smoking, non-adherence to prescribed medications and lifestyle changes are observed in patients with depression.³⁷ Previous studies have suggested association of depression with quality of life³⁸. In our trial, quality of life- mental component summary scores were significantly lower in the intervention group compared to control group. These results should be interpreted cautiously because medication use can be a marker of depression, and our trial did not collect information on dose and duration of medication use for depression. It is possible that the improvements in behavioural risk factors in TEXT ME may have been in-part mediated by improvements in psychological well-being. From our qualitative evaluation,²¹ participants in TEXT ME felt supported and engaged, and this is likely to contribute to the mechanisms that explain the reduction in depressive symptoms. It is also possible that the focus on improving lifestyle behaviours in TEXT ME contributed to the fewer depressive

symptoms as maintaining a healthy lifestyle is a key component of many depression management programs.³⁹

The strengths of this trial is the parallel group, prospective, randomized controlled design and a relatively large sample size. With respect to limitations, it is a single-centre study, and the findings need to be replicated in other centres and populations. The analysis is a sub-study and secondary analysis of the main TEXT ME trial and baseline measures of PHQ-9 were not included. The PHQ-9 was designed as a screening tool for depression and depressive symptoms. We did not confirm the presence of depression in trial participants using the gold standard semi-structured psychiatric interview. However, self-reported depression scores are highly correlated with the diagnosis of clinical depression and the PHQ-9 ≥ 5 cut point has good sensitivity (82%) and specificity (81%) when used with CHD patients.²⁶ While we did not assess depressive symptoms at baseline, randomization ensured that most patient characteristics were distributed evenly between groups.

A previous study in Denmark, of 19, 520 acute coronary syndrome patients reported the prevalence of depression 15 – 20%.⁴⁰ A meta-analysis in patients with heart disease reported that, the risk of mortality was two times higher in people with a history of depression.³⁸ Our trial showed that the prevalence of depressive symptoms was lower in the intervention group compared to control group among those with a history of depression. While depression is recognised as important to manage in patients with chronic disease, there are few mechanisms available to help prevent the development of depression in patients at risk. The findings of this study indicate exciting potential of a simple and potentially scalable text-message based intervention to support mild to moderate depressive symptoms in this population. Addressing depressive symptoms early may be key to supporting patients in achieving multiple lifestyle risk factor behavioural change.

In summary, this study demonstrates that provision of a text-messaging based intervention focused on lifestyle change among people with CHD was associated with fewer symptoms of mild to moderate depression at 6 months in the intervention group compared to controls. These results suggest that text messaging might be a low-cost and scalable intervention to address the development of depression in patients with cardiovascular diseases. Further research is needed to determine whether a text-messaging program can prevent the development of depression in patients with CHD.

Panel: Research in context**Systematic review**

Systematic reviews of randomized controlled studies of mobile phone technologies for health behaviour change and diseases management suggest that text messaging interventions might be useful for self-management of chronic diseases.¹¹ Another systematic review of seven studies measuring the impact of text messaging in mental health reported that five studies had significant improvements in a variety of psychiatric and social functioning assessments.¹⁷ These studies suggest mobile phone text messaging program has potential to support management of patients with mental illness.

Interpretation

The results of the TEXT ME trial suggest that provision of a text-messaged based intervention focused on lifestyle change among people with coronary heart disease was associated with less mild to moderate depressive symptoms at 6 months. These results suggest that text messaging might be a low-cost and scalable intervention to address the development of depression in patients with cardiovascular diseases.

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Author contribution: CC and SMSI had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analyses. Study concept and design: CC, MH, JR, AR. Analyses and interpretation of data: SMSI, CC, SS, MH. Drafting of the manuscript: SMSI, CC, MH, CK, SS, KR. Critical revision of the manuscript for important

intellectual content: All authors. The first and the corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Transparency declaration: The first and corresponding authors (the manuscript's guarantor) 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, if relevant, registered) have been explained.

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Data sharing statement: Patient level data and statistical code available from the corresponding author at reasonable request. Consent for data sharing was not obtained but the presented data are anonymised and risk of identification is low.

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Figure legends:

Figure 1. Flow Chart

Figure 2. Treatment effects on PHQ-9 scores ≥ 5 at 6 months, by patient subgroup

Table 1. Baseline characteristics of the study participants

Characteristics	Intervention Group	Control Group
	(n=333)	(n=350)
	n (%)	n (%)
Age, mean (SD) years	57.9 (9.0)	57.3 (9.2)
Women	61 (18.3)	61 (17.4)
Education, mean (SD), years	11.4 (3.5)	11.5 (3.5)
Body Mass Index, BMI, kg/m ² mean (SD)	29.7 (6.0)	29.6 (5.9)
Physical activity- regular exercise	32 (9.6)	35 (10.0)
Current drinker	86 (25.8)	116 (33.1)
Current smoker	174 (52.3)	189 (54.0)
History of diabetes	105 (31.5)	114 (32.6)
History of hypertension	212 (63.7)	212 (60.6)
History of depression	44 (13.2)	62 (17.7)
Prior medication	14/44 (31.8)	13/62 (21.0)
Prior psychological counselling	25/44 (56.8)	41/62 (66.1)
Prior electroconvulsive therapy	3/44 (6.8)	0/62 (0.0)

SD Standard deviation;

Table 2. Depression scores (PHQ-9) at 6 months

Variables	Intervention	Control	Mean Difference (95% CI)	P-value
	(N=333)	(N=350)		
	n (%)	n (%)		
PHQ-9 total score, mean (SD)	1.0 (2.2)	2.9 (3.3)	1.9 (1.5 to 2.4)	<0.0001*
No depression [score 0-4]	312 (93.7)	264 (75.4)		
Mild depression [score 5-9]	16 (4.8)	68 (19.4)		
Moderate depression [score 10-14]	4 (1.2)	16 (4.6)		
Moderately severe [score 15-19]	1 (0.3)	1 (0.3)		
Severe depression [score 20-27]	0 (0)	1 (0.3)		
Any depression [score 5-27]	21 (6.3)	86 (24.6)		<0.001^

SD Standard Deviation; * Independent t-test; ^ Fisher's Exact test

Table 3. Difference in PHQ-9 items at 6 months

Variables	Intervention (N=333) n (%)	Control (N=350) n (%)	P-value
PHQ-9 item 1: Little interest or pleasure in doing things	26 (7.8)	85 (24.3)	<0.001
PHQ-9 item 2: Feeling down, depressed or hopeless	43 (12.9)	132 (37.7)	<0.001
PHQ-9 item 3: Trouble falling or staying asleep, or sleeping too much	44 (13.2)	119 (34.0)	<0.001
PHQ-9 item 4: Feeling tired or having little energy	67 (20.1)	187 (53.4)	<0.001
PHQ-9 item 5: Poor appetite or overeating	25 (7.5)	60 (17.1)	<0.001
PHQ-9 item 6: Feeling bad about yourself — or that you are a failure or have let yourself or your family down	17 (5.1)	35 (10.0)	0.016
PHQ-9 item 7: Trouble concentrating on things, such as reading the newspaper or watching television	10 (3.0)	23 (6.6)	0.030
PHQ-9 item 8: Moving or speaking so slowly that other people could have noticed? Or so fidgety or restless that you have been moving a lot more than usual	4 (1.2)	8 (2.3)	0.281
PHQ-9 item 9: Thoughts that you would be better off dead, or thoughts of hurting yourself in some way	2 (0.6)	3 (0.9)	0.694
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PHQ-9 item 9 relating to suicidality			