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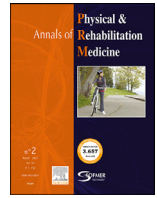
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Original article

Integrated Text Messaging (ITM) for people attending cardiac and pulmonary rehabilitation: A multicentre randomised controlled trial

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ABSTRACT

Background: People living with cardiac and respiratory disease require improved post-hospital support that is readily available and efficient.

Objectives: To 1) test the effectiveness of an automated, semi-personalised text message support program on clinical and lifestyle outcomes amongst people attending cardiac and pulmonary rehabilitation. Also, 2) to evaluate the program's acceptability and utility using patient-reported outcome and experience measures.

Methods: Multicentre randomised controlled trial (3:1, intervention:control) amongst cardiac and pulmonary rehabilitation attendees. Control received usual care (no message program). Intervention also received a 6-month text message lifestyle and support program. Primary outcome was 6-minute walk distance (6MWD). Secondary outcomes included clinical measures, lifestyle, patient-reported outcome and experience measures, medication adherence and rehabilitation attendance.

Results: A total of 316 participants were recruited. They had a mean age of 66.7 (SD 10.1) years. Sixty percent were male (190/316) and 156 were cardiac rehabilitation participants. The cohort's mean baseline 6MWD was higher in the intervention than the control group. At 6 months, 6MWD improved in both groups; it was significantly greater amongst intervention than control participants (unadjusted mean difference of 43.4 m, 95 % CI 4.3 to 82.4; $P = 0.0296$). After adjustment for baseline values, there was no significant difference between intervention and control groups for 6MWD (adjusted mean difference 2.2 m, -21.2 to 25.6; $P = 0.85$), medication adherence, or cardiovascular risk factors. At 6-month follow-up, intervention participants

Abbreviations: 6MWD, 6-minute walk distance; ANCOVA, analysis of covariance; BMI, body mass index; CAT, COPD Assessment Test; CHD, coronary heart disease; CI, confidence interval; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; HREC, Human Research Ethics Committee; ITM, Integrated text messaging; METS, metabolic equivalent; MRC, Medical Research Council; PREMs, patient-reported experience measures; PROMs, patient-reported outcome measures; QOL, quality of life; RCT,

randomised controlled trial; SD, standard deviation; SIM, Subscriber Identity Module; TEXTME, Tobacco, Exercise and Diet Messages trial; WHO, World Health Organisation

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reported significantly lower depression scores (adjusted mean difference -1.3, 95 % CI -2.2 to -0.3; $P = 0.0124$) and CAT scores (adjusted mean difference -3.9, 95 % CI -6.6 to -1.3; $P = 0.0038$), and significantly lower anxiety (adjusted mean difference -1.1, 95 % CI -2.1 to 0; $P = 0.0456$). Most participants (86 %) read most of their messages and *strongly/agreed* that the intervention was easy to understand (99 %) and useful (86 %).

Conclusions: An educational and supportive text message program for cardiac and pulmonary rehabilitation attendees improved anxiety and depression plus program attendance. The program was acceptable to, and useful for, participants and would be suitable for implementation alongside rehabilitation programs.

Trial registration number: ACTRN12616001167459

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Introduction

According to the World Health Organisation (WHO), the top 10 causes of death accounted for 55 % of the 55.4 million deaths worldwide in 2019 [1]. Ischaemic heart disease, stroke and chronic obstructive pulmonary disease (COPD) were the top 3 causes of death globally in 2019 and were responsible for 16 %, 11 % and 6 % of deaths respectively [1]. Despite the COVID-19 global pandemic, heart disease remained the top cause of death in the USA in 2020 [2]. Heart disease and chronic respiratory disease are also 2 of the chronic diseases responsible for high rates of avoidable hospital admissions [3]. Around half of all people admitted to hospital with coronary heart disease (CHD) have experienced a previous acute coronary syndrome [4] and only 1/4 are discharged with the appropriate combination of evidence-based medicines, lifestyle advice (eg, smoking cessation, physical activity, or diet) and referral to rehabilitation [5]. Moreover, the majority do not adhere to lifestyle modification advice or evidenced-based pharmacotherapy [6]. Similarly for COPD, exacerbations result in 700,000 hospitalisations annually in the United States and an estimated 20 % of these are followed by a further readmission within 1 month [7], creating a cost burden of over \$US15 billion each year [8].

Cardiac and pulmonary rehabilitation programs are widely available as a strategy to support ongoing management, lifestyle changes and risk factor management for people with heart and lung disease [9,10]. These programs are commonly delivered by multidisciplinary teams as in-person and group-based programs via local hospitals and community centres [9,10]. The programs usually run over 2–3 months and are based around supervised exercise sessions and education about risk factors. The focus is on quality of life, behaviour change, goal-setting and self-management of the condition/s [9,10]. Both cardiac and pulmonary rehabilitation programs have been shown to be effective in reducing hospital readmissions; improving clinical outcomes, medication adherence and health-related quality of life [10,11]. However, research has consistently reported that enrolment and completion rates are commonly below 30 % for those who have been recommended to attend based on guidelines [12]. This attrition was exacerbated by the COVID-19 global pandemic, resulting in closure of many in-person and group-based services along with increased challenges for face-to-face attendance [13,14]. Therefore, effective and efficient approaches are needed to improve outcomes for people with cardiac and pulmonary disease, along with an increased efficiency of services. Given that both programs follow a similar structure, and have similar goals, it was determined that a similar support program for both forms of rehabilitation could be evaluated in a single study.

The increasing availability and ownership of mobile devices provides an opportunity to provide support to people offered cardiac and pulmonary rehabilitation to improve their self-management and increase participation. Previous clinical trials have reported on the effectiveness of text messaging in improving smoking cessation, [15] and increasing weight loss [16] and physical activity [17]. One example is the Tobacco, Exercise and Diet Messages (TEXTME) trial which found that people with heart disease who received a 6-month semi-

personalised program of text messages achieved significant improvements to their cardiovascular risk factors compared to those who did not [18]. The intervention was also reported to be engaging, useful and helpful [19] as well as being cost effective [20]. A similar program has not yet been used for people with COPD. Therefore, the primary aim of this study was to report on the implementation of an integrated text message (ITM) support program for people with chronic cardiovascular disease (CVD) and/or chronic respiratory disease who were attending cardiac and pulmonary rehabilitation programs following their discharge from hospital [21]. Secondary aims were to determine which factors enhanced their participation, and to explore the acceptability and usability of a text message based self-management and support program in parallel with traditional cardiac and pulmonary rehabilitation.

MATERIALS and METHODS

Study design

This was a multicentre, single-blind randomised controlled trial (RCT) with clinical and patient-reported outcomes at 6 months post-randomisation [21]. The protocol is published elsewhere and was implemented without deviation [21]. Briefly, participants were recruited from hospital sites in Sydney, Australia, and randomised at a ratio of 3:1 into either receiving a 6-month text message support program plus usual care (intervention) or usual care alone (control). Participants were stratified according to whether they were participating in cardiac or pulmonary rehabilitation [21]. Clinical, behavioural, and quality of life (QOL) data were recorded during face-to-face assessments at baseline and 6 months. Written and informed consent was obtained from all participants and the study followed the CONSORT guidelines [22]. Ethical approval was received from the Sydney Local Health District Hospital Human Research Ethics Committee (HREC/16/RPAH/362) and associated Governance committees at each site. The study was sponsored by the University of Sydney.

Participants

Inclusion criteria were: i) adults (≥ 18 years of age); ii) own a mobile phone with an active Subscriber Identity Module (SIM) card; iii) presented to either a cardiac or pulmonary rehabilitation service with a history of either CVD or chronic respiratory disease at a participating hospital. CVD conditions included CHD, cardiomyopathy, peripheral arterial disease, stroke, arrhythmias and aneurysms. Chronic respiratory diseases included chronic bronchitis, bronchiectasis, emphysema, and chronic asthma. Exclusion criteria were i) unwilling to comply with the trial for 6 months or (ii) insufficient understanding of English, the language used in the text messages. Potential participants were consecutively identified by cardiac and pulmonary rehabilitation clinical staff or the research team, then screened for eligibility and invited to participate by the research assistants. Eligible and interested participants were contacted by a study research assistant to obtain written informed consent prior to randomisation and collection of data. All participants were able to

continue with standard cardiac or pulmonary rehabilitation as clinically indicated and attendance was logged in rehabilitation program records.

Randomisation and concealment

Participants were randomised to either usual, usual care (control) or usual and text messaging program (intervention) by computerised randomisation. Randomisation was independent and stratified according to pulmonary or cardiac rehabilitation. Because the study was a pragmatic implementation trial, participants were individually randomised at a ratio of 3:1 (intervention:control). This enabled more participants to receive the text message program. All study personnel, including the study statistician and those recording follow-up measures, were blinded to group allocation. Participants were asked to not discuss if they were receiving the text messages during their follow-up visit.

Study procedures

Once recruited, participants' baseline data were collected, and they were allocated to either the control or intervention group. Participants allocated to the control group received a single introductory text message stating they would be contacted for follow-up at 6 months. Participants allocated to control were offered the messaging program at no cost after their 6-month follow-up.

Participants allocated to the intervention group were digitally registered for the 6-month automated text message program (example messages are provided in Supplemental Material, Table S1). Messages were evidence-based, founded on behavioural psychology, and delivered according to our previously published model [23]. Messages were unidirectional, semi-personalised (preferred name, cardiac/pulmonary, vegetarian, smoker/not) and sent from a purpose-built web-based platform. Participants in the intervention group received 5 messages per week for 26 weeks at random times on random days, to minimise habituation. This approach was chosen in accordance with our previous quantitative and qualitative research [19,24,25]. Although participants were encouraged not to respond to messages, all replies were monitored for safety via a centrally located research assistant with a clinical background.

Messages provided supportive content for 6 months about self-management relating to medication adherence, attendance at rehabilitation, and lifestyle change. Following our previously published process, message content development involved literature reviews, surveys, and information taken from the focus group feedback of people with cardiac and pulmonary diseases who had been recruited from chronic disease programs. For cardiac rehabilitation messages, the primary content concerned general CVD health, smoking cessation, physical activity, and nutrition (Table S1). For the pulmonary rehabilitation messages, content was primarily about general respiratory health, physical activity, smoking cessation, symptom management and symptom monitoring (Table S1). Both the cardiac and pulmonary programs included content supporting medication adherence and participation in rehabilitation. Each week, messages were selected by the software system from the message bank based on prespecified algorithms that varied content about the major areas for each condition. No message was repeated during the study.

Outcomes

Data were collected at baseline and 6 months. At baseline, demographic information, medical history, and clinical measures were collected. After 6 months, outcomes were collected by a research assistant blinded to group allocation. The primary outcome was the 6-minute walk distance (6MWD), a clinically-validated assessment of exercise capacity [26] demonstrated to be reliable for populations

with cardiac or respiratory diseases. The 6MWD test followed a standardised study protocol using the same instructions and equipment between sites [27]. Secondary outcomes (Supplemental Material, Table S2) included clinical and lifestyle measures such as body mass index (BMI) [28], smoking status [29], physical activity [30], and diet [31]. Other measures recorded included patient-reported outcome measures (PROMs), such as quality of life [32], anxiety and depression scores [33], and the impact of COPD on wellbeing [34], patient-reported experience measures (PREMs), such as user satisfaction, and process measures, like software analytical data (for a full list, see Table S2).

Participants attending pulmonary rehabilitation were also asked about their perceived breathlessness and this was classified using the Medical Research Council (MRC) dyspnoea scale [35]. On this scale, a grade of 3, 4, or 5 corresponds to moderate-to-severely disabling COPD; a higher grade represents more severe breathlessness [35]. The COPD Assessment Test (CAT) was also completed for participants with COPD [34]. The CAT score is an externally-validated questionnaire that contains 8 questions covering domains relating to the impact of COPD symptoms [34]. CAT scores range from 0 to 40; higher scores denote a more severe impact of COPD on the person's life [34].

Statistical analysis

As per the study protocol, we estimated a sample size of 310 (150 cardiac, 160 respiratory) people would provide 90 % power and enable observation of a clinically meaningful difference in 6MWD scores in the intervention group compared to controls, for both cardiac (23.3 m) [36] and pulmonary (30.0 m) [37] rehabilitation participants. Calculations allowed for a 20 % drop-out rate. The significance level of the test was 0.05.

Analyses were specified and performed according to the intention-to-treat principle by a statistician blinded to group allocation; full details have previously been published [21]. Baseline data are presented as proportions for categorical data, or as means and standard deviations (SD) for continuous data. Primary and secondary outcomes were summarised as means and corresponding 95 % confidence intervals (CI) for normally distributed continuous outcomes, and as median and interquartile intervals for skewed outcomes. Categorical outcomes were reported as frequencies and percentages. Outcomes were compared using all available data with intervention and control groups compared at 6 months. Normally distributed continuous outcomes were analysed using the analysis of covariance (ANCOVA). The skewed continuous outcome of metabolic equivalents (METs) was categorised into quartiles (<600 min/week, 600–1449 min/week, 1450–2649 min/week, ≥2650 min/week) and analysed using an adjusted ordinal regression. Dichotomous outcomes were analysed using adjusted log-binomial regression. Adjusted analyses were performed when those participating in cardiac and pulmonary rehabilitation were analysed separately, and the baseline value of the outcome variable was included in the models as an independent variable. When analysing the cardiac and pulmonary groups together, an additional independent variable of whether the participants attended cardiac or pulmonary rehabilitation was included.

Pre-specified subgroup analyses of the primary outcome were conducted according to the following baseline data: rehabilitation (cardiac vs pulmonary); sex (male vs female); age (≤65 years vs >65 years); physical activity at baseline (METs<600 min/week vs ≥600 min/week); and participation in rehabilitation (attended <50% vs ≥50 % sessions). Analysis for each subgroup was performed by adding the subgroup variable as well as its interaction with the intervention as fixed effects to the log-binomial regression model used for the primary analysis.

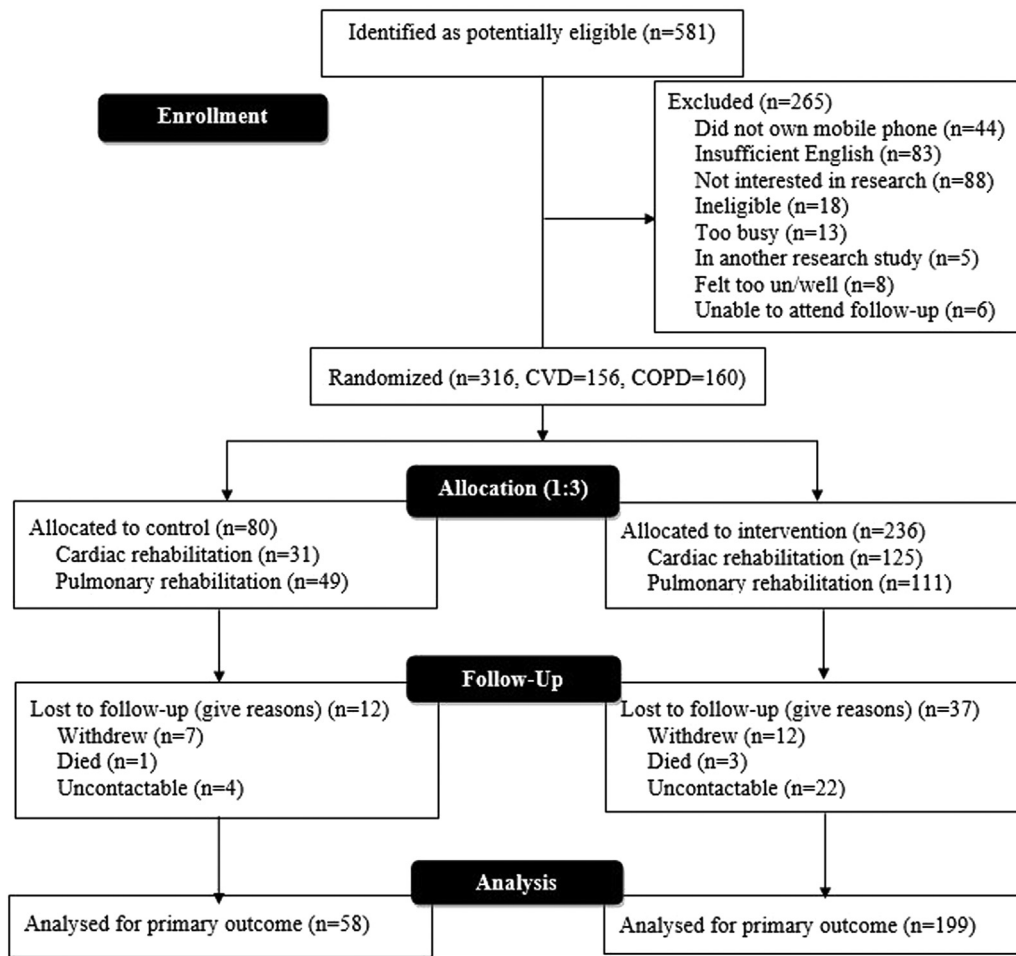


Fig. 1. Details of a 6-month trial to investigate the integration of text messages into cardiovascular and pulmonary rehabilitation programs. Intervention participants received the messages; control participants did not.

Figure Legend: COPD, Chronic obstructive pulmonary disease
CVD, cardiovascular disease.

After discounting the estimated 20 % dropout, primary outcome data were missing in 6 % of the total cohort (0.5 % in cardiac and 11 % in pulmonary). As there were missing primary outcome measurements at follow-up and data were likely to be missing at random, sensitivity analysis was performed using multiple imputation of 20 iterations. The auxiliary variables to estimate missing data were 6MWD at follow-up, and age, sex, education, employment, CVD, COPD, sleep apnoea, Type 2 diabetes, hypertension, high cholesterol, depression, BMI and 6MWD at baseline. A *P*-value <0.05 was considered statistically significant. Analysis was performed using SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA).

RESULTS

The first participant was recruited to the study in May 2017 and the final follow-up was completed in June 2019. In total, 581 potential participants were screened and, of these, 265 were not eligible for inclusion or declined participation, and 316 were enrolled (Fig. 1). Recruitment closed when the sample size target was reached. At the end of the study, 19 participants had withdrawn, 26 were unable to be contacted and 4 (1 cardiac and 3 pulmonary) had died (Fig. 1).

Demographic characteristics of the participants along with clinical and lifestyle measures are summarised in Table 1. At baseline, the mean age of the cohort was 66.7 years (63 years for those receiving cardiac rehabilitation, and 69 years for those in the pulmonary

group), 60 % were men, 49 % (156) participated in cardiac rehabilitation and 51 % (160) in pulmonary rehabilitation, 35 % had experienced a prior myocardial infarction, 18 % were diagnosed with type 2 diabetes, and 14 % were current smokers. Of the 125 who provided ethnicity data, 98 (78 %) were Caucasian, 13 (10 %) were Asian. In addition, 58 % (111/191) were either married or living with a partner, 25 % (72/285) were working and 41 % (117/285) were retired. Anxiety and depression scores were comparable between the control and the intervention groups at baseline: mean anxiety scores were 6.3 (SD 3.8) vs 5.7 (SD 4.2) and mean depression scores were 5.6 (SD 3.9) vs 5.1 (SD 3.3). Similarly, mean CAT scores were similar between the 2 groups at 21.1 (SD 7.8) vs 21.2 (SD 7.3).

Of those attending cardiac rehabilitation, more participants in the intervention group 42 % (52/123) had previously had a myocardial infarction compared to 29 % (9/31) of the control group, although a similar proportion had received diagnoses of either cardiomyopathy (9/123, 7% vs 4/31, 13%), peripheral vascular disease (3/124, 2% vs 1/30, 3%) although slightly fewer in the intervention group had a prior transient ischaemic attack or stroke (4/122, 3% vs 2/31, 6%). Of those attending pulmonary rehabilitation, a similar proportion in the intervention and control groups required oxygen (8/107, 7% vs 3/49, 6%) or had a chest condition in the past 12 months that required antibiotics or steroids (37/46, 80% vs 76/102, 74%). For participants attending pulmonary rehabilitation, the mean MRC dyspnoea scale scores indicated that breathlessness was similar for the intervention (3.0, SD

Table 1
Baseline characteristics of all people who were receiving either cardiac or pulmonary rehabilitation and who participated in a 6-month trial of text messages integrated into their rehabilitation program. Intervention participants received the messages; control participants did not.

Variable	Cardiac		Pulmonary		Total cohort	
	Control (n = 31)	Intervention (n = 125)	Control (n = 49)	Intervention (n = 111)	Control (n = 80)	Intervention (n = 236)
Age (years), mean (SD)	64.3 (8.9)	61.6 (11.7)	71.1 (8.0)	68.7 (9.2)	68.5 (9.0)	64.9 (11.2)
Male sex, n (%)	23 (74)	92 (74)	25 (51)	50 (45)	48 (60)	142 (60)
Medical history						
Type 2 diabetes, n (%)	4/31 (13)	22/125 (18)	12/47 (25)	15/109 (14)	16/78 (20)	37/234 (16)
Sleep apnoea, n (%)	6/31 (19)	11/125 (9)	7/48 (15)	16/110 (14)	13/79 (16)	27/235 (11)
Hypertension, n (%)	20/31 (64)	86/125 (69)	29/48 (60)	54/109 (49)	49/79 (62)	140/234 (60)
High cholesterol, n (%)	19/31 (61)	82/125 (66)	19/48 (40)	39/109 (36)	38/79 (48)	121/234 (52)
Prior MI, n (%)	9 (29)	52 (42)	5 (28)	11 (35)	14 (29)	63 (41)
Depression, n (%)	6/31 (19)	14/125 (11)	6/47 (13)	17/108 (16)	12/78 (15)	31/233 (13)
Clinical Measures						
SBP (mmHg), mean (SD)	122.7 (14)	120.7 (13.4)	122.2 (17.0)	127.6 (18.7)	122.4 (15.7)	123.5 (16.1)
SBP >130 mmHg, n (%)	6/30 (20)	25/123 (20)	9/41 (22)	37/85 (43)	15/71 (21)	62/208 (30)
DBP (mmHg), mean (SD)	66.4 (9.4)	68.3 (9.4)	72.9 (8.7)	75.9 (10.9)	70.1 (9.5)	71.4 (10.7)
DBP >80 mmHg, n (%)	0/30 (0)	10/123 (8)	7/40 (17)	32/84 (38)	7/70 (10)	42/207 (20)
HR (bpm), mean (SD)	74.8 (13.2)	73.8 (12.0)	80.4 (14.0)	83.2 (14.8)	78.2 (13.9)	78.2 (14.2)
BMI (kg/m ²), mean (SD)	30.2 (7.3)	28.4 (5.0)	27.2 (6.7)	27.7 (6.6)	28.4 (7.1)	28.1 (5.8)
BMI > 30 kg/m ² , n (%)	13/31 (42)	37/124 (30)	12/44 (27)	30/89 (34)	25/75 (33)	67/213 (31)
Waist circumference (cm), mean (SD)	105.4 (15.3)	99.4 (12.5)	110.3 (51.2)	95.6 (14.3)	106 (21.5)	99.1 (12.6)
Lifestyle factors						
Current smoker, n (%)	1/13 (8)	6/65 (9)	7/39 (18)	11/79 (14)	8/52 (15)	17/144 (12)
Former smoker, n (%)	12/30 (40)	60/122 (49)	32/49 (65)	69/109 (63)	44/79 (56)	129/231 (56)
Drink alcohol ≥ once/week, n (%)	10/28 (36)	60/116 (52)	19/45 (42)	47/107 (44)	29/73 (40)	107/223 (48)
Number of standard drinks of alcohol consumed/week, mean (SD)	6.8 (5.0)	6.7 (9.5)	9.9 (9.0)	10.6 (13.3)	8.8 (7.9)	8.5 (11.5)
Exercise ≥5 days/week x 30 mins, n (%)	16/28 (57)	89/121 (74)	28/49 (57)	60/107 (56)	44/77 (57)	149/228 (65)
6-minute walking distance (m), mean (SD)	434.5 (122.0)	477.3 (98.1)	350.5 (92.2)	370.9 (117.9)	383.5 (112.0)	427.8 (120.0)
Servings of fruit/day, mean (SD)	2.1 (0.9)	2.0 (1.2)	1.7 (1.4)	1.7 (1.1)	1.8 (1.2)	1.8 (1.1)
Servings of raw vegetables/day, mean (SD)	1.3 (1.1)	1.7 (1.4)	1.3 (1.3)	1.4 (1.7)	1.3 (1.2)	1.5 (1.5)
Servings of cooked vegetables/day, mean (SD)	2.2 (1.6)	2.4 (1.5)	2.3 (1.4)	2.3 (1.4)	2.3 (1.5)	2.4 (1.5)
Number meals/week dining out, mean (SD)	2.8 (2.3)	2.5 (3.6)	1.8 (2.6)	1.9 (2.8)	2.2 (2.5)	2.2 (3.2)

BMI, body mass index; bpm, beats per minute; DBP, diastolic blood pressure; HR, heart rate; MI, myocardial infarction; mins, minutes; m, meters; n, number of participants; SBP, systolic blood pressure; SD, standard deviation.

1.1) and control groups (2.7, SD 1.0). For the total cohort, mean oxygen saturation was also similar for the intervention and control groups before (96.5, SD 2.4 vs 95.9, SD 2.3) and after (93.3, SD 8.5 vs 92.1, SD 5.9) the 6MWD test was completed. Similarly, Borg scale results immediately after the 6MWD were similar for the intervention (2.4, SD 1.6) and control (2.8, SD 1.8) groups.

Primary and secondary outcomes

The mean 6MWD increased from baseline to 6-month follow-up in both the intervention (from 427.8 m, 95 % CI 412.6 to 442.9 at baseline to 477.9 m, 95 % CI 458.5 to 497.4 at 6 months) and control groups (from 383.5 m, 95 % CI 357.3 to 409.6 at baseline to 434.5 m, 95 % CI 400.7 to 468.4 at 6 months). At 6 months, 6MWD was significantly greater in intervention than control participants (unadjusted mean difference 43.4 m, 95 % CI 4.3 to 82.4; *P* = 0.0296). However, this difference did not remain; adjusted analyses revealed no significant differences between the intervention and control groups in the primary outcome of 6MWD at 6 months (adjusted mean difference 2.2 m, 95 % CI -21.2 to 25.6). Similarly, sensitivity analysis using multiple imputation showed no difference in 6MWD between the 2 groups (5.2 m, 95 % CI -19.1 to 29.6).

There were also no statistically significant differences at 6 months between the intervention and control groups for secondary outcomes of mean blood pressure, BMI, waist circumference, proportion of current smokers, physical activity, or nutrition (Table 2) nor differences in QOL scores and METS. Scores for anxiety and depression were significantly lower (ie, better) for those in the intervention group, compared to the control group, at 6 months (Table 2).

Subgroup analyses for the primary outcome

Subgroup analyses by sex, age, level of activity at baseline, and attendance at rehabilitation are shown in Table 3. While there was no difference in the primary outcome based on sex, age, and attendance for at least 50 % of their rehabilitation program, those who were less active at baseline had significantly greater 6MWD improvements at 6-month follow-up than those who had been initially more active at baseline (Table 3).

Subgroup analysis of participants in cardiac rehabilitation found a non-significant increase in 6MWD at 6 months in the intervention group compared to the controls (unadjusted mean difference 18.9 m, 95 % CI -29.2 to 67.1). In addition, for the cardiac rehabilitation subgroup, no significant differences were found between intervention and control group data for either systolic blood pressure (adjusted mean difference -1.3 mmHg, 95 % CI -8.4 to 5.8) or diastolic blood pressure (adjusted mean difference 3.1 mmHg, 95 % CI -1.0 to 7.2) at 6 months.

Subgroup analysis of participants in pulmonary rehabilitation found a non-significant difference between intervention and control data for 6MWD (unadjusted mean difference 38.6 m, 95 % CI -10.6 to 87.8). For those in the pulmonary rehabilitation subgroup, the mean CAT score at 6 months was also significantly lower in the intervention than control group (adjusted mean difference -3.9, 95 % CI -6.6 to -1.3; *P* = 0.004).

Patient reported experience measures

Of the 236 participants allocated to the intervention group, 185 (78 %) completed the end-of-study user feedback survey. The

Table 2

Primary and secondary outcomes at 6 months for the whole total cohort of people who participated in a 6-month trial into the integration of text messages within cardiac or pulmonary rehabilitation programs. Intervention participants received the messages; control participants did not.

Variable	Control	Intervention	Adjusted effect size* (95 % CI)
Primary Outcome			
Mean 6MWD (m), mean (95 % CI)	434.5 (400.7 to 468.4)	477.9 (458.5 to 497.4)	2.2 (−21.2 to 25.6)
Secondary Outcomes			
SBP (mmHg), mean (95 % CI)	124.6 (120.7 to 128.5)	126.8 (124.5 to 129.1)	0.8 (−3.9 to 5.5)
SBP >130 mmHg, n (%)	21/63 (33)	71/178 (40)	0.95 (0.65 to 1.38)
DBP (mmHg), (95 % CI)	74.5 (72.1 to 76.8)	78.7 (77.3 to 80)	2.9 (0.2 to 5.5)
BMI (kg/m ²), mean (95 % CI)	28.5 (27 to 30.1)	28 (27.1 to 29)	0.0 (−0.4 to 0.5)
BMI >30 kg/m ² , n (%)	22/63 (35)	61/175 (35)	1.12 (0.9 to 1.38)
Waist circumference (cm), mean (95 % CI)	101.1 (97.3 to 104.8)	100.4 (98.2 to 102.6)	−2.5 (−5.6 to 0.7)
>80 % medication adherence, n (%)	64/67 (95)	190/194 (98)	1.03 (0.97 to 1.09)
Current smoker, n (%)	6/67 (9)	13/194 (7)	1.01 (0.64 to 1.61)
Heart rate (bpm), mean (95 % CI)	75.7 (71.9 to 79.4)	74.6 (72.4 to 76.7)	0.5 (−3.2 to 4.1)
METS (min/week), median (IQR)	960 (400 to 2640)	1500 (720 to 2660)	0.93 (0.49 to 1.75) [^]
Active ≥5 days/week x 30mins, n (%)	44/80 (55)	96/236 (41)	0.85 (0.67 to 1.08)
Sedentary time (min/day), mean (95 % CI)	480.5 (430.4 to 530.6)	422.6 (393.2 to 452)	−47.3 (−101.7 to 7.1)
Drink alcohol ≥ once/week, n (%)	32/67 (48)	100/195 (52)	0.91 (0.69 to 1.2)
Number of standard drinks of alcohol consumed/week, mean (95 % CI)	7.9 (4.8 to 11)	8.2 (6.4 to 10)	0.3 (−3.3 to 3.9)
Servings of fruit/day, mean (95 % CI)	1.6 (1.3 to 2)	1.8 (1.6 to 2)	0.2 (−0.2 to 0.5)
Servings of raw vegetables/day, mean (95 % CI)	0.9 (0.7 to 1.1)	0.9 (0.8 to 1)	0 (−0.2 to 0.2)
Servings of cooked vegetables/day, mean (95 % CI)	1.7 (1.4 to 2.1)	2 (1.7 to 2.2)	0.2 (−0.2 to 0.6)
Number of meals dining out per week, mean (95 % CI)	1.9 (1.2 to 2.5)	1.8 (1.4 to 2.2)	−0.1 (−0.8 to 0.7)
Number of rehabilitation sessions attended, mean (95 % CI)	14 (12.5 to 15.6)	13 (12.2 to 13.8)	−0.2 (−1.8 to 1.3)
Attended ≥1 session of rehabilitation, n (%)	61/67 (91)	203/207 (98)	1.08 (1.0 to 1.16)
SF12 V2 Physical Health Summary score, mean (95 % CI)	39 (36.2 to 41.8)	41.3 (39.7 to 43)	−0.2 (−2.9 to 2.5)
SF12 V2 Mental Health Summary score, mean (95 % CI)	45.3 (42.7 to 48)	50.6 (49 to 52.1)	2 (−0.8 to 4.8)
HADS anxiety score, mean (95 % CI)	7 (6 to 7.9)	5.4 (4.9 to 6)	−1.1 (−2.1 to 0)
HADS depression score, mean (95 % CI)	6.2 (5.3 to 7.1)	4.1 (3.6 to 4.7)	−1.3 (−2.2 to −0.3)
CAT ⁺ score, mean (95 % CI)	21.1 (18.6 to 23.6)	17.8 (16.1 to 19.5)	−3.9 (−6.6 to −1.3)

6MWD, 6-minute walk test distance; BMI, body mass index; CI, confidence interval; DBP, diastolic blood pressure; HADS, Hospital Anxiety and Depression Scale; IQR, interquartile interval; m, meters; METS, metabolic equivalents; mins, minutes; n, number of participants; SBP, systolic blood pressure; SF-12, short-form 12 health survey.

* Adjusted for outcome measures at baseline and participation in cardiac vs pulmonary rehabilitations; Mean difference (95 % confidence interval) for continuous variables; Relative risk (95 % confidence interval) for categorical variables, unless otherwise stated.

[^] Adjusted for outcome measures at baseline and participation in cardiac vs pulmonary rehabilitations; proportional odds ratio (95 % confidence interval).

* Only assessed in participants attending pulmonary rehabilitation.

majority, 160 (of 185, 86 %) read 90–100 % of the text messages and 159 (86 %) *agreed* or *strongly agreed* that the messages were useful. In addition, 184 (99 %) found the messages easy to understand, and 106 (57 %) were motivated to change their lifestyle, including increasing their physical activity (84/185, 45 %). For 89 (48 %) people the messages helped remind them to take their medication. Most (145/185, 78 %) participants reported that a program length of 6 months was *just right*; comparative minorities stated that the program was either *too short* (25/185, 13 %) or *too long* (13/185, 15 %).

Almost all participants said the style of language used in the messages was *just right* (170/185, 92 %); although 8 (4 %) stated they found it *too casual* and 6 (3 %), *too formal*. Furthermore 160 (86 %) participants said that the number of messages received per week was *just right*, while a minority stated there were either too many (21/185, 11 %), or too few (3/185, 2 %). Most participants (134/185, 72 %) saved the messages, and around half (99/185, 54 %) shared them with family/friends.

Process outcomes

Although the message program was one-way, from the hospital to the participant, some people did reply. These replies were monitored for safety and content evaluation. In total, 410 replies (from 92 unique numbers) were received. Evaluation of the reply content was summarised into the following categories: to say *thank you* (157/410, 38 %); to confirm adherence to diet, physical activity, smoking or other health advice in the message (117/410, 28 %); to advise the message was *received* or to say *ok* (32/410, 7.8 %); to comment on medications (24/410, 6 %); for administrative reasons, such as a name

change or wrong number (9/410, 2 %); to make a comment unrelated to the study (9/410, 2 %); or the reply was blank (62/410, 15 %). The message sending software did not identify any issues with sending messages. There were also no messages received that triggered a safety issue such as reports of chest pain or mental health concerns.

In terms of attendance and completion of rehabilitation, there was no significant difference in terms of number of rehabilitation sessions attended between the intervention and control groups (13 sessions, 95 % CI 12.2 to 13.8 vs 14 sessions, 95 % CI 12.5 to 15.6) per week. Nevertheless, after 6 months more participants in the intervention than control group said they had attended rehabilitation (203/207, 98% vs 61/67, 91 %).

Discussion

Cardiac and pulmonary rehabilitation recommended guidelines are evidence-based but their reach, completion and sustained behaviour change is suboptimal. Results from this RCT trial of ITM, a lifestyle-focussed text message program, for people attending cardiac and pulmonary rehabilitation were mixed. For both the intervention and control group, 6MWD increased between baseline and 6 months; the addition of the ITM did not significantly improve 6MWD performance, or the difference between the groups after adjustment for baseline values. We also found that the ITM program did not significantly improve other cardiovascular risk factors or participant QOL. Nevertheless, people in the intervention group who received ITM messages had improved depression and anxiety scores. They were also more likely to attend their rehabilitation sessions and reported that they found the message contents to be both easy to understand

Table 3

Subgroup analyses of the 6-minute walk distances (in meters) of people receiving either cardiac or pulmonary rehabilitation and who participated in a 6-month trial of text messages integrated into their rehabilitation program. Intervention participants received the messages; control participants did not. Distances are divided by gender, age, level of physical activity at baseline and rehabilitation attendance at 6-month follow-up.

Subgroups	Control (95 % CI)	Intervention (95 % CI)	Mean difference (95 % CI)	P-value for interaction	
Sex	Male	462.3 (436.4 to 488.3)	474.0 (459.1 to 488.9)	11.6 (−18.3 to 41.6)	0.328
	Female	466.2 (434.0 to 498.3)	454.2 (434.7 to 473.6)	−12.0 (−49.2 to 25.1)	
Age	≤65 years	492.5 (457.4 to 527.6)	471.9 (454.5 to 489.2)	−20.7 (−59.5 to 18.2)	0.179
	>65 years	449.9 (425.2 to 474.6)	462.3 (446.3 to 478.4)	12.4 (−16.8 to 41.5)	
Active at baseline	METS ≥600 min/week	499.2 (473.3 to 525.2)	471.1 (458.3 to 483.9)	−28.2 (−57.2 to 0.8)	0.011
	METS <600 min/week	431.8 (388.1 to 475.6)	484.8 (450.7 to 518.9)	53 (−2.2 to 108.1)	
Rehabilitation sessions attended	≥50 %	471.1 (447.8 to 494.4)	471.3 (457.9 to 484.7)	0.2 (−26.7 to 27.2)	0.768
	<50 %	447 (402.1 to 491.9)	455.9 (430.9 to 480.9)	8.9 (−42.5 to 60.3)	

CI, Confidence Interval; min, minutes; METS, metabolic equivalents.

and useful. Participants with COPD who received the intervention also had significantly lower mean CAT at 6 months compared to those in the control group.

Scalable strategies that support people with chronic disease and improve attendance and completion of rehabilitation programs are needed. The widespread availability and convenience of mobile devices offer a contemporary form of health communication. Previous research has demonstrated the benefit of text message programs in reducing cardiovascular risk [18], but we are unaware of the evaluation of such an intervention in the context of cardiac and pulmonary rehabilitation. While this trial did not replicate the results of TEXTME [18] in terms of a reduction in cardiovascular risk factors, it did provide evidence that a texting program alongside cardiac and pulmonary rehabilitation is both engaging and useful for participants, and that it reduces anxiety, depression and improves attendance at rehabilitation sessions. Some factors which may have led to no improvement in the intervention group may include limited health literacy, lack of motivation to change behaviour, a lack of carer support or possibly a lack of self-efficacy [38]. Potential opportunities for improvement to an ITM service could be to create content with more engagement with health providers, to synchronise messages with digital sensors and health trackers, and also to create more individualised content [19,39,40]. The current intervention did improve CAT scores, suggesting that the text message program may have reduced the impact of COPD symptoms on participants' lives [34]. A 2021 systematic review [38] identified only 1 other study that evaluated a text message program for people with COPD [41]. That study was a pilot of 17 participants and the text message component of the intervention was mainly to provide reminders to participants about entering symptom information, rather than to provide support and advice [41].

Our qualitative findings align with results from other studies of text message programs involving people with heart disease [19,39], breast cancer [25], and diabetes [42], where participants consistently reported that messages had high usefulness and provided support. Furthermore, the pilot study by our group of people with COPD also found that the text reminders served as an effective prompt for exercise, provided a sense of accountability and served as positive motivation for participants [41]. Taken all together, these studies suggest that text message programs offering regular reminders and positive and practical tips are well accepted by participants, easy to implement and can be delivered in an automated, yet monitored, way. We suggest that these programs offer a valuable adjunct to further reinforce the content and education in-between sessions of traditional cardiac and pulmonary rehabilitation programs. These trials have also highlighted the importance of qualitative evaluation of implementation alongside clinical trials to understand the participant perspective, beyond clinical measures [43]. Such evaluations also facilitate continuous review and improvement of message content and ongoing optimisation of engagement strategies [39].

Importantly, we found that participants in both cardiac and pulmonary rehabilitation groups improved their 6MWD after receiving

the 6-month ITM program. Specifically, at 6 months the mean 6MWD recorded for cardiac rehabilitation participants was 19 m farther in the intervention group than in the control group; for pulmonary rehabilitation participants this increase was 39 m more in the intervention than control group. Neither of these values reached a statistical significance level of $P < 0.05$, but those participating in pulmonary rehabilitation reached clinical significance and those participating in cardiac rehabilitation almost reached clinical significance. A previous study of cardiac rehabilitation participants concluded that a 6MWD improvement of 23 m would be considered clinically significant [36]. For pulmonary rehabilitation participants, a 6MWD improvement of over 30 m would be classed as a clinically significant minimally important difference [37,44]. The improvements in 6MWD observed in our groups represent an improvement to a level that would then make increased physical activity more viable for people with cardiac and respiratory disease, a facilitation that would, in turn, improve exercise tolerance and lead to ongoing improvements beyond 6 months since the duration and effectiveness of physical activity continues to be improved as exercise capacity increases. Of course, it is acknowledged that the 6MWD test has limitations; it is considered a functional assessment rather than a gold standard [45]. Importantly, our text message program also successfully facilitated attendance at in-person rehabilitation sessions something that is important based on previous work that has shown that increased attendance at cardiac rehabilitation [46] and pulmonary rehabilitation [47] also improves physical and psychosocial outcomes.

There are several limitations associated with this pragmatic trial. Firstly, the study was conducted in 1 state of Australia and was not powered to detect changes in hospitalisation rates and other hard outcomes. Secondly, inclusion and exclusion criteria were intentionally broad because the focus of the study was ITM implementation within the context of cardiac and pulmonary rehabilitation, rather than its effectiveness within robust clinical parameters and under strict control of external variables. Thirdly, baseline data was collected by local rehabilitation clinicians as part of routine care, leading to potential inter-site variation although primary analyses compared between groups at the 6-month follow-up were from data collected by research assistants blinded to baseline results and group allocation. It is also important to note that, for pragmatic reasons (due to the implementation nature of this trial), randomisation was at a ratio of 3:1. This favoured the intervention and allowed more participants the opportunity to receive ITM.

In conclusion, the provision of an educational, supportive, text-based message program for people attending cardiac and pulmonary rehabilitation to encourage behaviour change as part of rehabilitation did not have a significant impact on adjusted 6MWD results for all participants, although it did reach clinical significance for those in the pulmonary rehabilitation group only. In addition, the intervention was well-received by participants: it improved their anxiety and depression scores and increased rehabilitation session attendance rates. We have shown that ITM is suitable for delivery alongside

formal rehabilitation programs and offers a scalable strategy that is a useful adjunct to reinforce the content and educational information provided to participants in-between their sessions of traditional, face-to-face cardiac and pulmonary rehabilitation programs. Future text message programs could be individually tailored to deliver physical activity messaging content based on person-centred need using sensor devices. A text message program in this context may also provide additional support after completion of a formal program and be highly relevant within the context of the COVID-19 pandemic.

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Data availability

Data will be made available on request.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.rehab.2023.101800](https://doi.org/10.1016/j.rehab.2023.101800).

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