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Impact of text messages in a middle-income country to promote secondary prevention after acute coronary syndrome (IMPACS)
A randomized trial

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Abstract

Background: Studies that used short message service (SMS) programs as an intervention to promote health care have shown beneficial results in the control of risk factors for ischemic heart disease in patients of high-income countries, but evidence is lacking in low or middle-income countries.

Aims: The purpose of this study is to evaluate whether the use of SMS increases risk factor control within 6 months after discharge by acute coronary syndrome (ACS) in a middle-income country.

Methods: It will be a 2-arm, parallel, double-blind, randomized clinical trial of 160 patients discharged after an ACS from a single center with 6 months of follow-up. The intervention group will receive 4 SMS per week offering advice, motivation and information about medication adherence, increase of regular physical activity, adoption of healthy dietary measures, and smoking cessation (if appropriate). The primary outcome is achieving 4 or 5 points in a risk factor control score, which combines the cluster effect of 5 main modifiable risk factors for ACS [low-density lipoprotein cholesterol, LDL-C <70 mg/dL, blood pressure $<140/90$ mm Hg, regular exercise (≥ 5 days/week $\times$ 30 minutes of moderate exercise per session), nonsmoker status, and body mass index, BMI <25 kg/m^2]. Secondary outcomes are plasma LDL-C level, level of physical activity, blood pressure, medication adherence, proportion of nonsmokers, BMI, rehospitalization, cardiovascular death, and death from any cause. This study, as a randomized clinical trial protocol, followed the recommendations of the Standard Protocol Items (SPIRIT).

Expected outcomes: This study aims to provide evidence of whether SMS interventions are effective in improving cardiovascular disease risk factors control in post-ACS patients in a middle-income country.

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Abbreviations: ACS = acute coronary syndrome, BMI = body mass index, CVD = cardiovascular disease, LDL-C = low density Lipoprotein Cholesterol, Short Message Service, SMS = SAHLPS = Short Assessment of Health Literacy for Portuguese speaking Adults, UFMG's University Hospital = University Hospital of Universidade Federal de Minas Gerais.

Keywords: acute coronary syndrome, mobile health, risk factors, text messages

The authors declare that they have no competing interests.

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1. Introduction

Cardiovascular disease (CVD) remains the leading cause of death and years of life lost worldwide.[1] In addition, since 1990, there has been a 42% [95% confidence interval (95% CI) 36–48] increase in the absolute number of deaths due to ischemic heart disease globally.[2] In Brazil, CVD has also been the leading cause of mortality since the 1960s and has accounted for a substantial percentage of all hospitalizations. In 2011, CVD was responsible for 31% of all deaths, with ischemic heart disease being the leading cause.[3]

Individuals with a prior cardiovascular event have a 5 times greater chance of having another event than people without known CVD.[4] Taking this information into account, a growing body of evidence suggests that adequate management of risk factors substantially reduces unfavorable clinical outcomes, including death, recurrence of ischemic events, and need for revascularization.[5] The World Health Organization estimates that 75% of cardiovascular mortality can be reduced with appropriate changes in lifestyle.[6] When lifestyle interventions are applied to individuals with coronary or other atherosclerotic vascular disease, it is considered secondary prevention.[7]

There is a diversified effort to translate cardiovascular science into guidelines to assist health professionals in the management of CVD, for conditions such as acute coronary syndrome (ACS) and its secondary prevention. Despite the increased use of proven effective therapies, adherence to the available recommendations is still below ideal.[8–10] Several telehealth tools, such as text message services—short message service (SMS), can be simple and inexpensive alternatives to encourage healthy life habits and optimize medication adherence.[11]

Studies that used SMS as an intervention have shown beneficial results in risk factors control for ischemic heart disease in outpatient settings. Martin et al[12] showed a significant short-term increase in the levels of physical activity of cardiac outpatients. Glynn et al[13] demonstrated similar results on patients seen in rural primary care in an Irish municipality and Wald et al[14] showed an improvement on medication adherence in patients taking blood pressure and lipid-lowering therapies for CVD prevention. Corroborating these findings, using an SMS application, Chow et al[11] found modest improvements in cholesterol levels and moderate reductions on blood pressure, body mass index (BMI), and smoking in patients with coronary artery disease.

Despite the promising results, there is insufficient evidence to draw definite conclusions about the effectiveness of SMS interventions for secondary prevention of CVD, particularly in low- and middle-income countries, where mobile health strategies can have a great impact lowering the costs of health care. Although the access to mobile phone is high in countries such as Brazil, with a density of 112.87 phones/100 inhabitants,[15] the understanding of the messages sent by SMS may not be the same as in high-income countries due to the lower educational stratum of the population.

The IMPACS study will be a 2-arm, parallel, double-blind, and randomized clinical trial. The main purpose of this study is to evaluate whether, in patients who are in secondary prevention of CVD, the use of SMS improves control of CVD risk factors during the 6-month follow-up after discharge by ACS, when compared with the usual treatment. The secondary aim is to develop a wide SMS message bank, semi-personalized, which will include information about lifestyle modifications, medication adherence, and CVD risk factor control. This study, as a randomized clinical trial protocol, followed the recommendations of the Standard Protocol Items (SPIRIT).

2. Methods

2.1. Participants (study setting and eligibility)

The study population will include patients of the University Hospital of Universidade Federal de Minas Gerais (UFMG's University Hospital), a public and general hospital in southeast Brazil, who were admitted due to diagnosis of ACS. Patients will be also participants of the "Good Practice Program in Cardiology,"[16] a program of the Brazilian Cardiology Society, Ministry of Health (Brazil), and American Heart Association (United States of America).

Inclusion criteria are as follows:

(1) Consecutive patients admitted at the UFMG's University Hospital with primary or secondary diagnosis of ACS and discharged for outpatient follow-up. Confirmed diagnosis of ACS will be defined based on The Third Universal Definition of Myocardial Ischemia.[17]
(2) Age ≥18 years, of both sexes;
(3) Patients who are able to receive SMS in their own mobile phone.

Exclusion criteria are as follows:

(1) Refusal or inability to sign the informed consent;
(2) Complete illiteracy.

2.2. Interventions

The usual care group (IMPACS control group) will receive standard discharge treatment and standard hospital follow-up. They will monthly receive text messages thanking for their participation in the trial and reminders of trial appointment.

The intervention group (IMPACS intervention group) will receive the usual post-discharge care for ACS, instructions and information, as well as the SMS intervention program. The SMS program will include a variety of topics, such as standard follow-up care reminders and general self-management and healthy habits texts to inform and engage patients in care. The Intervention will run for 6 months and the program will consist of 4 modules, according to baseline characteristics of participants:

(1) Module 1: nonsmokers and free of diabetes;
(2) Module 2: nonsmokers and diabetic patients;
(3) Module 3: smokers and nondiabetic patients;
(4) Module 4: smokers and diabetic patients.

Modules 2 and 4 are subdivided into 2 according to whether or not diabetic patients are in use of insulin. Texts will be sent out 4 times per week for 180 days at pre-established times, with the first SMS being sent immediately after hospital discharge. All participants included in the same module will receive the same texts and in the same order, regardless of the allocation time in the study. No cross-over between groups is expected.

All participants will also be followed by the UFMG's University Hospital Coronary Artery Disease outpatient clinic and rehabilitation program, unless they choose otherwise. IMPACS researchers will be independent of attending physicians and will not interfere with patient care.

Table 1

Text messages according to modules based on characteristics of participants.

Messages	Module 1	Module 2 Noninsulin-dependent DM	Module 2 Insulin-dependent DM	Module 3	Module 4 Noninsulin-dependent DM	Module 4 Insulin-dependent DM
Physical exercise	X	X	X	X	X	X
Healthy diet	X	X	X	X	X	X
Medication adherence	X	X	X	X	X	X
General information*	X	X	X	X	X	X
Smoking cessation				X	X	X
DM management		X	X		X	X
Insulin management			X			X

DM = diabetes mellitus.
* General information on coronary heart disease and its risk factors.

2.2.1. Technological development. Dedicated software was developed by The Telehealth Center of UFMG's University Hospital to send 1-way SMS between server (Windows) and participant's mobile phone.[18] The software has a bank of text messages that allows identification and scheduling for submission of SMS on predetermined dates. To test the software developed and the initial acceptability of text messages sent, a pilot study was conducted and it is described in Appendix 1, http://links.lww.com/MD/D10.

2.2.2. Text messages. The messages that will be used in this study were developed by the research group, offering advice, motivation and information about medication adherence, increase of regular physical activity, adoption of healthy dietary habits, and smoking cessation (if appropriate). The content of the messages is based on the Brazilian Society of Cardiology Guidelines, available online.[19] Messages will be semi-personalized because the objective is to combine general information with personalized content, using information provided in baseline questionnaires. The bank of text messages, after being developed, was reviewed by individuals not involved in the study to check for language issues and evaluation of understanding. The main goal was to make messages easy to read and understand, for all cultural and social levels. Text messages content according to each module is summarized in Table 1 and examples of text messages sent to the IMPACS intervention group can be seen in Table 2.

At study entry, all participants will be given brief training (three to five minutes) of how to read text messages, save, and delete them, if necessary. The Telehealth Center of UFMG's University Hospital will manage the SMS through a computerized messaging engine, and because of that, participants will be instructed not to respond to them. Interactive communication will only occur via e-mail, if the patient shows an intention to discontinue his/her participation in the study. Messages will be sent at no cost to the participants.

2.3. Outcomes

Participants will have outcomes measured at 6 months (± 1 month) after hospital discharge, in the follow-up appointment pre-scheduled by the study's researchers. Researchers blinded to treatment allocation will collect the data.

(1) Primary endpoint: The primary outcome is achieving 4 or 5 points in a risk factor control score, which combine the cluster effect of 5 main modifiable risk factors for ACS [low-density lipoprotein cholesterol - LDL-C <70 mg/dL, blood pressure $<140/90$ mm Hg, regular exercise (≥ 5 days/week $\times 30$ minutes of moderate exercise per session), nonsmoker status, and BMI <25 kg/m^2].

(2) Secondary endpoints: Plasma LDL-C levels, objective level of physical activity, blood pressure, medication adherence, proportion of nonsmokers, BMI, death from any cause, rehospitalization, and cardiovascular death.

2.4. Sample size

A sample size of 141 patients was estimated, increasing to 160 to allow for a 15% loss to follow-up, 2-tailed and at a 5%

Table 2

Examples of text messages sent to the IMPACS intervention group.

Physical exercise messages
Hi <NAME>, use the stairs. Whenever possible climb stairs instead of using elevators or escalators. Believe in yourself and take care of your health.
Healthy diet messages
Hi <NAME>, reduce the consumption of sweets and sugar, they are not good for your health. Do not forget the sugar "hidden" in juices, coffee, and soft drinks.
Medication adherence messages
Hi <NAME>, have you taken your medications today? Be aware of what your doctor prescribed. Take care of your health.
Basic information messages
Hi <NAME>, angina is a chest pain (in burning or tightening) that arises with physical exertion or stress. If you get angina again, do not wait, talk to your doctor, or seek emergency care.
Smoking cessation messages
Hi <NAME>, in moments of fissure, rest easy. The sensation goes away in less than 5 minutes. Always avoid the first smoke. Talk to your doctor about it.
DM management messages
Hi <NAME>, take care of your feet daily. If cracking, calluses or wounds appear, seek medical attention.

Table 3

Flow chart of study design.

Study setting, eligibility, and allocation

   Daily visits to the coronary intensive care for recruitment and allocation of eligible patients.

   Checking inclusion and exclusion criteria:

Inclusion criteria	Exclusion criteria
Consecutive patients admitted with diagnosis of	Refusal or inability to sign the informed consent;
ACS and discharged for outpatient follow-up;	Complete illiteracy.
Age ≥18 years, of both sexes;	
Patients who are able to receive SMS in their	
own mobile phone.	

Signing written informed consent.

Hospitalization (baseline)

Demographic, educational, socioeconomic, and clinical characteristics of the study participants will be collected at baseline.

Data collected during hospitalization:

ACS type and severity criteria, diagnostic and therapeutic procedures performed in the in-hospital phase, and prescribed medications at hospital discharge;

   Patient weight, height, heart rate, and blood pressure will be measured;

   Total cholesterol and fractions, triglycerides, troponin, creatinine;

   Level of physical activity - Measured by IPAQ-SF and "short question."

   Health Literacy Questionnaire (SAHLPA-18)

Patient brief training (3–5 minutes) - how to read SMS.

Randomization and intervention

Blocking randomization (blocks of 4 patients).

Researchers, data collectors, and attending physicians will be blind to the treatment allocation (double blinding).

IMPACS control group	IMPACS intervention group
The usual care group will receive standard	The intervention group will receive standard discharge treatment and
discharge treatment and standard hospital	standard hospital follow-up, as well as the SMS intervention program.
follow-up.	

Follow-up appointment (6 months after hospital discharge)

   Data collected during the follow-up appointment:

     Plasma LDL-C level, blood pressure, body mass index;

     Proportion of nonsmokers (self-report and Carbon Monoxide Meter Breath Test);

     Level of physical activity (IPAQ-SF, "short question," and accelerometers);

     Medication adherence ("Medida de Adesão aos Tratamentos" – MAT);

     Hospital readmissions, cardiovascular death, and death from any cause.

   Follow-up questionnaire (acceptability and understanding)

ACS = acute coronary syndrome, IPAQ-SF = International Physical Activity Questionnaire Short Form, SMS = short message service.

significance level, would have 80% power to detect a difference of at least 19% between the intervention and the control groups in achieving 4 or more of the 5 modifiable risk factors listed above (Risk Factor Control Score), based on the findings of the study by Chow et al.[11] An interim analysis before the end of the patient allocation will be done to evaluate the follow-up losses with the objective of reassessing the sample size initially considered.

2.5. Allocation and blinding

After obtaining written informed consent, the data of each patient will be entered into an online database. To reduce predictability of a random sequence, a blocking randomization will be provided in blocks of 4 patients following the date of patient enrollment. The computerized randomization program is only accessible to administrators of the Telehealth Center of the UFMG's University Hospital. The random allocation sequence will follow a uniform 1:1 ratio and the researchers, data collectors, and attending physicians will be blind to the treatment allocation (double blinding).

2.6. Data collection methods

The eligible patients will be identified by daily assessment in the Coronary Intensive Care Unit of UFMG's University Hospital and followed up throughout the hospitalization for data collection. All data collectors will undergo specific training for understanding and systematically applying the study protocol.

Demographic, educational, socioeconomic, and clinical characteristics of the study participants will be collected at baseline. At this stage, ACS type and severity criteria, diagnostic and therapeutic procedures performed in the in-hospital phase, and prescribed medications at hospital discharge will also be collected. Before hospital discharge (up to 48 hours before discharge), patient weight, height, heart rate, and blood pressure will be additionally measured for future analysis.

The participant timeline is described in Appendix 02, http://links.lww.com/MD/D10 and the flow chart of study design in Table 3.

The data collection protocols are briefly summarized in the following:

(1) Plasma LDL-C level: measured at baseline and 6 months after hospital discharge (before the outpatient appointment), after 12 hours of fasting, in the same laboratory. Measurement of total cholesterol, triglycerides, and high-density lipoprotein cholesterol will be done with CHOL VITROS Chemistry Products slides from Ortho Clinical Diagnostics (VITROS 5.1 and VITROS 5.600/colorimetric method). For LDL-C dosage, the value is generally

calculated. When triglycerides value >400 mg/dL, we will perform direct dosing of LDL-C using the reagent LDL VITROS Chemistry Products from Ortho Clinical Diagnostics (VITROS 5.1 and VITROS 5.600/ End point Method).

(2) Level of physical activity: measured by the International Physical Activity Questionnaire Short Form (IPAQ-SF) [20] at baseline and 6 months after hospital discharge. The measure will be validated in one-fifth of the participants by using accelerometers (Actigraph wGT3X-BT; Pensacola, FL). A question about whether the patient is performing scheduled physical activity following the recommendation of the Brazilian Society of Cardiology will also be included in the follow-up questionnaire.[21]

(3) Blood pressure: measured at baseline and 6 months after hospital discharge by the same automatic blood pressure device (OMRON model HEM-705 CP Intellisense) and OMRON blood pressure cuffs up to 48 hours before hospital discharge and in the follow-up visits. Three resting measurements will be made, with the patient in the seated position, with the arm supported. The mean of the last 2 readings will be considered for data analysis.

(4) Medication adherence: measured at 6 months after hospital discharge via "Medida de Adesão aos Tratamentos" – MAT,[22] a validated instrument composed of 6 items that evaluate the behavior of the individual in relation to daily use of medicines. The answers are obtained by means of a 6-point ordinal scale that varies from "always" [1] to "never" [6]. The values obtained with the answers to the 6 items are summed and divided by the number of items (values vary from 1 to 6). Subsequently, values 5 and 6 are computed as 1 (adherent) and the others are computed as 0 (nonadherent).

(5) Proportion of nonsmokers: measured at 6 months after hospital discharge by self-report. The participant will answer the following question: "Are you smoking after hospitalization?", for which he/she could answer "Yes" or "No." The answer will be also confirmed by a Carbon Monoxide Meter Breath Test (piCO Smokelyzer, Kent, UK). This is an indirect and noninvasive measure of blood carboxyhemoglobin. The device directly measures carbon monoxide (ppm) and carboxyhemoglobin is a calculation based on clinical evidence. The values obtained by the device are 0 to 6 (nonsmoker range), 7 to 19 (light smoking range), and 20 or more (heavy smoking range).[23,24]

(6) BMI: measured at baseline and 6 months after hospital discharge. BMI will be calculated by weight measured in kilograms divided by height in square meters.

(7) Rehospitalization: measured at 6 months by means of self-report and medical discharge records.

(8) Cardiovascular death and death from any cause: measured at 6 months by report of relatives and confirmed by death certificate or medical records.

(9) Health literacy questionnaire: measured at baseline. A version consisting of 18 items of The Short Assessment of Health Literacy for Portuguese speaking Adults (SAHLPA-18) [25] will be applied to participants at the baseline.

(10) Follow-up questionnaire: a follow-up questionnaire with self-report of reading messages will be applied as well as questions about acceptability and understanding (Appendix 3, http://links.lww.com/MD/D10).

2.7. Data management and monitoring

Data management will be done by the Telehealth Center of UFMG's University Hospital. Data entry will be made through a password-protected, web-based interface by a registered team and double-checking for verification of data consistency will be performed. The study's steering committee (LGP, LCCB, ALPR) has the overall responsibility for the conduction and periodic monitoring of the study.

2.8. Statistical methods

Analysis will be performed according to the intention-to-treat principle. For the baseline characteristics, continuous variables will be summarized as mean $\pm$ SD or as median and first and third quartiles (Q1, Q3), and groups compared using Student t tests or Mann–Whitney test, based on the distribution pattern. Categorical variables will be expressed as proportions and 95% CIs and groups compared by Chi-square test. The primary outcome will be compared between groups using Chi-square test. We will also analyze effects across subgroups, such as sex, age, or other covariates of interest, using logistic regression models. The criterion for statistical significance will be set at $\alpha = 0.05$ and SPSS Statistics for Windows (Version 20.1; IBM Corp., Armonk, NY) will be used for the analysis.

2.9. Ethics and dissemination

Patients will be asked if they wish to participate in the study while hospitalized. After screening for inclusion and exclusion criteria, eligible patients will receive written an oral information about the study. Written and informed consent will be obtained from all participants before allocation. The ethical approval for this study has been obtained from The Medical Ethics Committee of the Universidade Federal de Minas Gerais (Number: 2,054,294 dated August 03, 2017). Any changes in the protocol during the trial that may affect the conduct of the trial, safety, and the benefit to patients will require a formal amendment to the initial protocol and be immediately communicated to The Medical Ethics Committee. The findings of this study will be published and disseminated via scientific forums, with no restrictions.

3. Discussion and conclusion

The "IMPACS" study is an innovative study, as it evaluates the implementation of an effective and simple strategy in the secondary prevention of CVD in a middle-income country. Two important issues make this study different from others who used SMS as a telehealth tool: the range of approaches and the measurement of health literacy.

The messages address several essential conditions for CVD prevention at the same time: medication adherence, regular physical exercise, healthy dietary habits, smoking cessation (if appropriate), diabetes management (if appropriate), and general information on coronary heart disease, all of them with a language adapted to cultural and social level of the target population. In order to compare the results of the IMPACS study with those found in previous studies of SMS intervention in high-income countries, the assessment of health literacy is a crucial factor.

In conclusion, the IMPACS study aims to provide information, by randomized controlled data, whether SMS interventions is

effective in increasing CVD risk factors control in patients post-ACS in a middle-income country.

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Author contributions

LGP, ALPR, and LCCB have participated in study design. LGP is responsible by the collection and management of data. All of them will be responsible by analysis and interpretation of data. All of them have seen and approved the submitted manuscript, which reports unpublished work not under consideration elsewhere. LGP and LCCB have done the literature review, article selection, and designed the scope of the article. All authors contributed in the writing of the manuscript. ALPR and BRN reviewed the final version. All authors have read and approved the manuscript.

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