

Design of a multifaceted strategy based on automated text messaging in patients with recent heart failure admission

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Abstract

Aims To evaluate a telemonitoring strategy based on automated text messaging and telephone support after heart failure (HF) hospitalization.

Methods and results The MESSAGE-HF study is a prospective multicentre, randomized, nationwide trial enrolling patients from 30 clinics in all regions of Brazil. HF patients with reduced left ventricular ejection fraction (<40%) and access to mobile phones are eligible after an acute decompensated HF hospitalization. Patients meeting eligibility criteria undergo an initial feasibility text messaging assessment and are randomized to usual care or telemonitoring intervention. All patients receive a HF booklet with basic information and recommendations about self-care. Patients in the intervention group receive four daily short text messages (educational and feedback) during the first 30 days of the protocol to optimize self-care; the feedback text messages from patients could trigger diuretic adjustments or a telephone call from the healthcare team. After 30 days, the frequency of text messages can be adjusted. Patients are followed up after 30, 90, and 180 days, with final status ascertained at 365 days by telephone. Our primary endpoint is the change in N-terminal pro-brain natriuretic peptide (NT-proBNP) levels after 180 days. Secondary endpoints include changes in NT-proBNP after 30 days; health-related quality of life, HF self-care, and knowledge scales after 30 and 180 days; and a composite outcome of HF hospitalization and cardiovascular death, adjudicated by a blinded and independent committee.

Conclusions The MESSAGE-HF trial is evaluating an educational and self-care promotion strategy involving a simple, intensive, and tailored telemonitoring system. If proven effective, it could be applied to a broader population worldwide.

Keywords Heart failure; Natriuretic peptide; Telemonitoring

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Introduction

Heart failure (HF) remains a prevalent condition and a leading cause of hospitalization worldwide.¹ Despite impressive advances in treatment options in the last three decades, health-related quality of life and overall morbidity continue to be substantially impacted by HF, particularly in the acute setting. Readmissions after an index HF hospitalization are a major contemporary health problem, and programmes that effectively reduce rates of early clinical events are a global unmet need. Several recent international surveys demonstrate that recurrent hospitalizations have not substantially decreased in the last decade.^{2,3} In the United States, the mandatory federal 'Hospital Readmissions Reduction Program' created financial penalties for hospitals with higher re-admission rates, but failed to achieve its objectives, leading to a small reduction in recurrent hospitalizations that was offset by an unintended increase in 30 day and 1 year mortality.^{4,5} In this scenario, a solid body of evidence suggests that preventable and/or treatable precipitating factors are associated with acute decompensated HF (ADHF) hospitalizations.^{6,7} Moreover, a commonly reported cause of recurrent HF admissions is poor adherence to self-care, which is frequently coupled with poor knowledge on the syndrome and its treatment.^{8,9}

Telemedicine is a broad platform of singular strategies with varying complexities that emerged in the medical arena as a promising tool to improve treatment adherence in patients with chronic diseases and to reduce healthcare inequities.^{10,11} Unfortunately, several telemonitoring strategies have been tested in HF with erratic conflicting results.^{12–17} Inconsistent outcomes in these studies are not unexpected, as the effectiveness of telemonitoring is directly influenced by the complex interplay of content and intensity of each intervention, method of communication, environment, and the quality of the underlying model of care. It seems essential that specific strategies be tailored for each healthcare ambience considering social, economic, cognitive, and cultural aspects. The TIM-HF2 trial, for example, recently achieved a significant reduction in the composite endpoint of unplanned cardiovascular admissions or all-cause death in Germany using a multicomponent remote telemonitoring system installed in the patients' home associated with mandatory monthly structured telephone interviews.¹⁸ Unfortunately, this rather complex strategy would not be feasible for most patients with HF in low-income and middle-income countries.

Data from the BREATHE registry indicate that Brazil portrays one of the worldwide leading readmission rates after an ADHF hospitalization.¹⁹ In this scenario, the MESSAGE-HF trial was designed to evaluate the safety and feasibility of a tailored telemonitoring strategy based on automated short message service (SMS) text messaging and telephone interviews in the vulnerable period after an HF hospitalization.

MESSAGE-HF is a multicentre, open-label, controlled, randomized clinical trial implemented in HF clinics in Brazil.

Methods

Study design

The MESSAGE-HF study is a prospective multicentre, randomized, nationwide, phase II parallel-group trial designed to evaluate the effectiveness of a self-care promotion strategy primarily based on SMS text messaging and triggered nurse-led telephone interviews. Eligible patients are being recruited from HF clinics in all five geographical regions of Brazil. Most centres are public institutions located in tertiary-care university hospitals. The study protocol complies with the Declaration of Helsinki, was approved by local ethics committees in each centre, and was registered on clinicaltrials.gov (NCT 04062461). Consent forms describing in detail the study intervention, procedures, and risks are being provided to each potential participant, and all enrolled patients must provide written informed consent to participate in the trial. The trial is funded by the Brazilian Ministry of Health (PROADI-SUS research grant).

Eligibility criteria

Heart failure patients older than 18 years old with reduced left ventricular ejection fraction (<40%) and with access to mobile phone are eligible during the vulnerable period after a hospital admission for ADHF. Detailed inclusion and exclusion criteria for the study protocol are described in *Table 1*.

Table 1 Eligibility criteria

Inclusion criteria	
•	Adults (>18 years)
•	HF history irrespective of aetiology
•	Recent ADHF (up to 30 days after hospital discharge)
•	Access to mobile phones
•	Left ventricular ejection fraction < 40% assessed in the last 3 months
Exclusion criteria	
•	Patients on the heart transplant waiting list
•	Surgical or percutaneous (coronary or valvular) interventions up to 3 months prior to randomization
•	Inability to understand or interact with SMS text messages due to cognitive disability or social issues
•	Life expectancy < 1 year
•	Enrolment in another drug or device study up to 30 days prior to randomization
•	Prior randomization in the current protocol

ADHF, acute decompensated heart failure; HF, heart failure; SMS, short messaging service.

Randomization

Patients meeting eligibility criteria are being randomized up to 30 days after hospital discharge by a central randomization system with allocation sequence to one of the two study arms in a 1:1 ratio, in blocks of four patients stratified by centre, using an algorithm embedded in the Research Electronic Data Capture Cloud's Unified Data Management. As per protocol, randomization can be performed on the day of hospital discharge or on the following 30 days. Because of the nature of the intervention, researchers and patients are not blinded to group allocation.

Data collection and management

Research personnel in each centre are responsible for the screening and selection of eligible participants. Baseline data are collected by trained researchers using a structured electronic case report form including sociodemographic and clinical data, health-related quality of life according to the Kansas City Cardiomyopathy Questionnaire (KCCQ),²⁰ satisfaction and acceptability of SMS text messaging, HF self-care assessed by the European Heart Failure Self-Care Behaviour Scale,^{21,22} and HF knowledge evaluated by the Heart Failure Knowledge Questionnaire.^{23,24} All applied scales have been adequately validated for the Portuguese language.^{20,22,24} N-terminal pro-brain natriuretic peptide (NT-proBNP) levels are measured using point-of-care equipment according to the manufacturer's recommendations (Cobas® h 232, Roche Inc., Switzerland).

Feasibility assessment and group allocation

Before randomization, all potentially eligible patients undergo a short feasibility assessment of the text messaging procedure to confirm that technical issues related to the mobile phone brand/model and/or cultural/cognitive features would not interfere with protocol viability. Each participant answers two very simple questions using their own mobile phone: (i) 'What is your name?' and (ii) 'How old are you?' These questions are electronically sent by research personnel, and once the correctness of their answers is secured, the patient is randomized in the trial.

Control group

The research protocol allows each individual institution to provide general instructions (during hospital discharge or at the randomization visit) that are part of their usual HF outpatient care. In addition, the MESSAGE-HF trial provides a specific HF booklet (Supporting Information), developed by Brazilian HF specialists (nurses, nutritionists, and physicians), offering standard recommendations on outpatient care

regarding HF medications, exercise, diet, vaccinations, and basic knowledge on the syndrome. All patients enrolled in the study, including those in the control group, are followed up by face-to-face hospital visits at 30, 90, and 180 days. Vital status and clinical events will also be ascertained at 365 days by a telephone contact. Patients randomized to the control group can have additional follow-up visits if necessary, according to their clinical assessment.

Intervention group

Patients allocated to the intervention group also receive the MESSAGE-HF trial booklet to standardize minimal HF outpatient care in both groups. In addition, detailed written instructions about the self-care promotion strategy are also provided in a specific brochure. All patients enrolled in the study, including those in the intervention group, are seen in protocol face-to-face hospital visits at 30, 90, and 180 days. Similarly, patients can have additional follow-up visits if necessary, according to their clinical assessment, and vital status and clinical events will also be ascertained at 365 days by a telephone contact.

Automated short message service text messages After randomization, patients allocated to the intervention group receive four daily SMS text messages during the first 30 days of the protocol to optimize self-care. Messages can belong to one of the two categories: (i) 'educational SMS messages' with information about HF signs and symptoms, daily activities and lifestyle, correct use of medications, and fluid ingestion (*Table S1*) or (ii) 'feedback SMS messages' inquiring about daily weight (delivered at 7 a.m.), night symptoms (delivered at 10 a.m.), and correct use of medications (delivered at 7 p.m.) (*Figure 1*). Based on the patterns of answers to these messages, the system can automatically generate warnings ('red flags') that trigger automatic diuretic adjustments or a telephone call from the healthcare team (*Figure 2*). These warnings are immediately reported to research personnel in each centre involved in the trial using a web-based system. Both coordinating centres (Hospital Moinhos de Vento, Porto Alegre, RS or Hospital do Coração, São Paulo, SP) will oversee message flow and warnings between patients and HF clinics to ensure adequate compliance with the protocol.

After the first month, the frequency of SMS text messages can be reduced to three times a week in stable patients (without red flags in the first 30 days) and when the patient feels that daily messages would not be necessary (individualized care). After 3 months and up to the end of the protocol (6 months), the frequency of SMS text messages can be further reduced to twice a week.

Primary and secondary endpoints

The primary study endpoint for the study is the change in NT-proBNP levels assessed at baseline and 180 days after

Figure 1 Representative example of daily short message service (SMS) text messages and answers. Weight expressed in kilogrammes.

DAILY SMS TEXT MESSAGES & ANSWERS

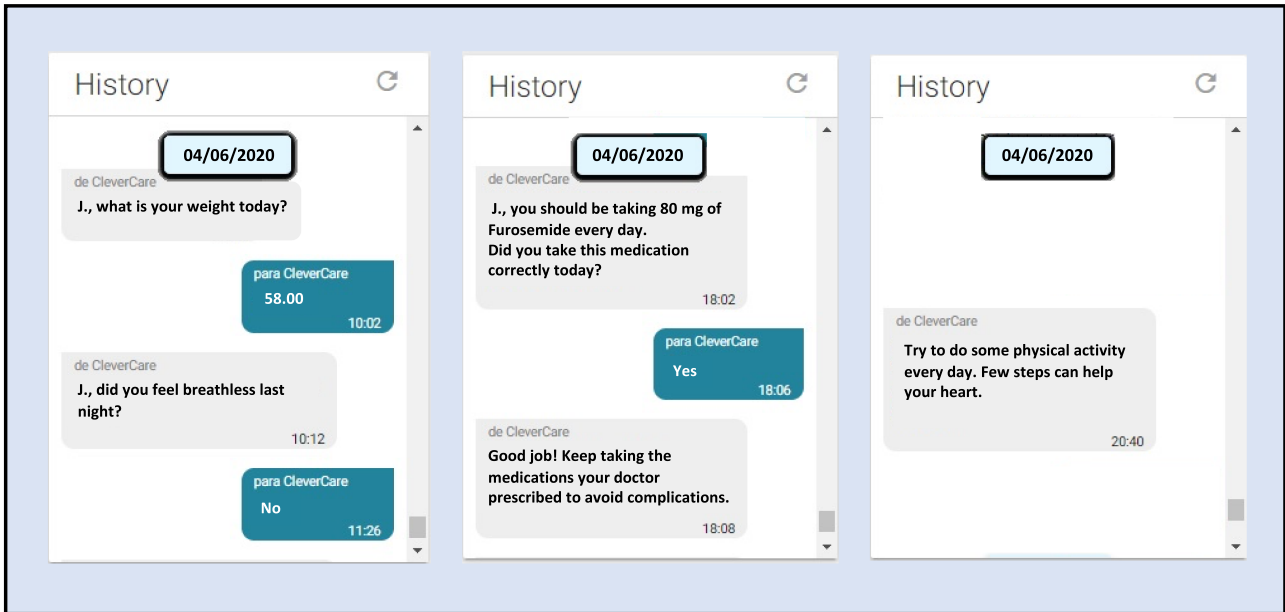
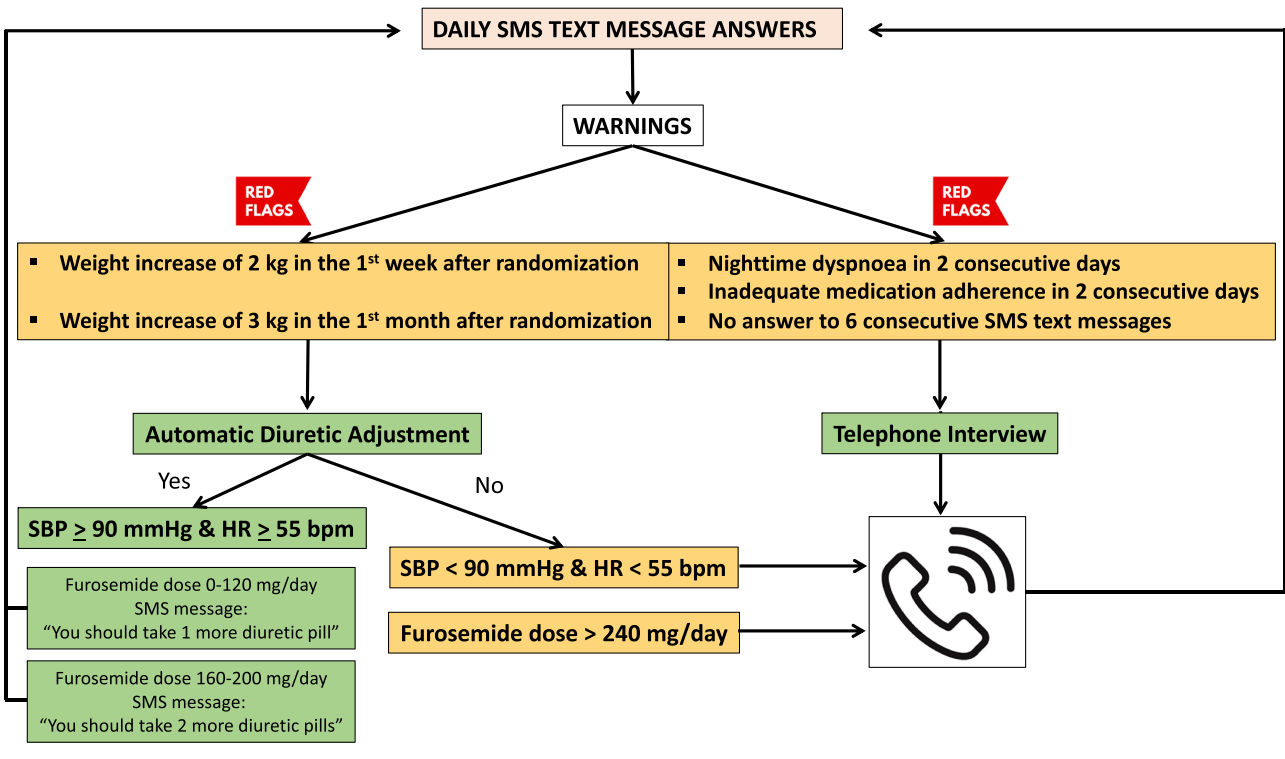


Figure 2 Algorithm of red flags during the MESSAGE-HF trial protocol and the expected responses. HR, heart rate; kg, kilogrammes; SBP, systolic blood pressure; SMS, short message service.



randomization (Table 2). Secondary endpoints include changes in (i) NT-proBNP levels assessed at 30 days; (ii) health-related quality of life evaluated by the KCCQ at 30 and 180 days; (iii) HF self-care assessed by the European Heart Failure Self-Care Behaviour Scale at 30 and 180 days; (iv) HF knowledge evaluated by the Heart Failure Knowledge Questionnaire at 30 and 180 days; as well as (v) a composite clinical outcome (HF hospitalization and cardiovascular death). Other clinical outcomes are also blindly adjudicated: overall hospitalizations, total mortality, and emergency department visits (<24 h). Finally, satisfaction and acceptability of SMS text messaging will also be assessed during follow-up. During the trial, predefined clinical outcomes are adjudicated against standardized criteria by a blinded and independent clinical endpoint committee at Hospital do Coração (São Paulo, SP) consisting of physicians trained on adjudication of clinical events.

Training and monitoring

Professionals in all centres are trained (in person or virtually) before the enrolment of the first patient and are periodically monitored by research personnel of the coordinator centres (Hospital Moinhos de Vento, Porto Alegre, RS and Hospital

do Coração, São Paulo, SP) to ensure (i) compliance to the research protocol; (ii) that data reported in case report forms are accurate, complete, and verifiable; (iii) that participants' rights and well-being are in accordance with good clinical practices in research; (iv) that the documentation of clinical endpoints is adequate; and (v) that written informed consent forms are correctly signed. Monitors also check adequate storage of NT-proBNP equipment and supplies. All visits are recorded in a monitoring report.

Current status and COVID-19 impact on the study

The MESSAGE-HF trial has 30 active centres in Brazil and 377 patients (54% of total sample) randomized by May 25, 2021. During the COVID-19 pandemic randomization was substantially reduced and on-site follow-up visits had to be restricted. Monthly enrolment rates returned to pre-pandemic level after September 2020. From March to August 2020, institutional restrictions directly impacted measurement of NT-proBNP at 180 days in some centres. The Steering Committee strongly suggested that research personnel made any possible effort to avoid missing data on natriuretic peptides levels, allowing follow-up measurement to be made up to 3 months after the expected day.

Table 2 Design, data, and outcomes of the MESSAGE-HF study

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation (days)			Final
		Baseline	30	90	180	360
TIMEPOINT**						
ENROLMENT:						
<i>Eligibility screening</i>	✓					
<i>Informed consent</i>	✓					
<i>Allocation</i>		✓				
INTERVENTIONS:						
<i>Control group</i>			←————→			
<i>Intervention group</i>			←————→			
ASSESSMENTS:						
<i>Sociodemographic data</i>		✓				
<i>Clinical data</i>		✓	✓	✓	✓	
<i>NT-proBNP</i>		✓	✓		✓	
<i>Clinical events</i>			←————→			
<i>Dyspnoea score</i>		✓	✓	✓	✓	
<i>Satisfaction and acceptability of SMS</i>			✓	✓	✓	
<i>KCCQ, EHFSBs, HF knowledge</i>		✓	✓		✓	
<i>Telephone contact</i>						✓

EHFSBs, European Heart Failure Self-Care Behaviour Scale; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; NT-proBNP: N-terminal pro-brain natriuretic peptide.

Sample size and data analysis

A sample size of 292 patients per group will ensure at least 90% power to detect a 20% reduction in the logarithm of the ratio between 180 day and baseline NT-proBNP levels when comparing the intervention and control groups using a two-tailed *t*-test with an α level of 0.05. In this calculation, we assumed a common standard deviation of 0.83 for the log scale of the ratio.²⁵ Assuming a dropout rate of approximately 20%, the final estimated total sample size was 700 patients (350 per group).

All analyses will be based on the intention-to-treat principle. Logarithmic transformation will be used for biomarker data, including NT-proBNP, to address their skewed distribution. Analysis of the primary endpoint will be performed in pre-specified subgroups: age strata, gender, educational levels, New York Heart Association functional classes, left ventricular ejection fraction strata, NT-proBNP levels, HF aetiology, baseline KCCQ scores, and baseline HF self-care and knowledge scores. The primary treatment comparison will be reported as the ratio of the geometric means of NT-proBNP between groups, as previously reported in the PARAMOUNT trial,²⁵ incorporating the proportional change over time in the two groups. The primary 180 day analysis was pre-specified as the last observation carried forward and included all patients randomly assigned to treatment groups who had a baseline assessment and at least one post-baseline assessment (the carryover method of imputation). We will perform additional analyses of the primary endpoint for sensitivity, including a completer-only analysis, and a multiple imputation analysis to account for patients without a 180 day follow-up assessment. Statistical testing will be performed with a two-sided significance level of 0.05 and estimated geometric means for the ratios, estimated effect sizes, and their 95% confidence intervals. Secondary endpoints will be compared between groups using Kaplan–Meier curves and the log-rank, Student's *t*, or Mann–Whitney–Wilcoxon tests, as well as χ^2 or Fisher's exact tests, as appropriate.

Discussion

Hospital readmissions are a recurrent and common event in the first 90 days after an ADHF index hospitalization despite persistent efforts to develop effective strategies to thwart this phenomenon worldwide.^{1–3} The reason for this continuous burden is certainly multifactorial but involves the complex interplay of masked and/or unresolved clinical congestion coupled with poor adherence to self-care and poor knowledge on the syndrome and its treatment. This disturbing situation seems to be particularly prevalent in low-income and middle-income countries.¹

The MESSAGE-HF trial is testing an educational and self-care promotion strategy involving a simple, intensive, and tailored telemonitoring system based on SMS text messaging associated with triggered nurse-led telephone interviews (*Table 3*). Our protocol proposes a unique methodology based on minimal human interaction in this vulnerable period, particularly for HF patients without early HF symptoms after discharge and who demonstrate weight stability. Moreover, the proposed strategy also plans to tackle the fundamental elements related to readmissions in patients with warning signs of decompensation or non-compliance using a technologic framework that could be applied in a global perspective.

Current telemedicine HF concepts are comprehensive strategies that include telemonitoring and telemedical interventions, guideline-based outpatient care, and structured patient education grouped together and known as remote patient management.¹¹ Conceptually, telemedicine represents an opportunity of ensuring the achievement of public health policies, especially in large continental countries in which these are not fully met due to the existence of unassisted or remote areas. Unfortunately, the use of telemedicine has been considered unreliable in Latin America and most parts of the world given the logistical struggles of establishing supportive technological structures that are efficient and viable for a large number of patients.¹⁰

In this scenario, clinical trials^{12–17} that investigated the impact of remote patient management in patients with HF have produced inconsistent results. The lack of conclusive efficacy results may be explained by differences in the actual content and intensity of each intervention and the heterogeneous nature of the patient populations included in different studies. Most reports demonstrating beneficial effects of telemedicine strategies in HF enrolled unstable and vulnerable patients with a recent index hospitalization. An overview of 15 systematic reviews on the effectiveness of home telemonitoring interventions for patients with HF suggests reduction in the relative risk of all-cause mortality (0.60 to 0.85) and HF-related hospitalizations (0.64 to 0.86) compared with usual care. Reductions in risks of mortality and all-cause hospitalizations appeared to be greater in patients who had been recently discharged (≤ 28 days) from an acute care setting after a recent HF exacerbation.²⁶

Table 3 Objectives of triggered telephone contacts

Nurse-led telephone interview
<ul style="list-style-type: none"> ▪ Assessment of new or worsening heart failure signs & symptoms ▪ Review of medications the patient should be taking ▪ Evaluation of side effects and barriers to medication adherence ▪ Guidance on options for acquiring medications ▪ Review of daily weight control and causes of weight gain ▪ Assessment of diet, fluid intake, and physical activity ▪ Review of any clinical events that occurred since the last visit

Mobile text messaging using SMS technology is a simple and low-cost approach that can be delivered to any mobile phone and be applicable to a broader group of patients in under-assisted regions. In Brazil, for instance, recent surveys suggest that approximately 50% of the population send and receive SMS text messages at least a few times a month.²⁷ The effectiveness of SMS-based strategies on enhancing management support and patient-provider communication has been suggested particularly for chronic diseases such as diabetes mellitus and human immunodeficiency virus infections.²⁸ Few studies, however, have evaluated strategies using SMS text messages in HF patients. Nundy *et al.* assessed the feasibility and acceptability of an SMS intervention in a small study with a predominantly African American population and preliminarily explored the effects of this intervention on self-management. Patients hospitalized with ADHF were included in an automated SMS programme for 30 days after hospital discharge, receiving reminders of self-care and patient education on diet, symptom recognition, and management of the syndrome. Participants strongly agreed that the programme was easy to use, reduced missed pills, and decreased salt intake. The intervention was associated with significant improvements in HF self-care management and maintenance.²⁹ A recent Chinese study investigated whether SMS would improve self-care behaviour and clinical outcomes in patients with ADHF, irrespective of left ventricular ejection fraction. Patients were randomized to receive one structured telephone contact within 30 days of discharge, educational SMS text messages within the first 10 days of discharge and then weekly messages for a month, or usual care. In a short-term follow-up (30 days), there were no difference in clinical outcomes among the three groups, but the 180 day composite event rate was significantly lower in the SMS and structured telephone support groups compared with the usual care, with no significant difference between the two phone-based interventions.³⁰

The design of the MESSAGE-HF trial has several unique features. We are testing an intensive telemonitoring and educational strategy based on four daily automated SMS messages in the vulnerable period after an ADHF admission. The system allows interaction with a robotic platform and enables programmed furosemide adjustment based on individual weight variation. This strategy is intrinsically coupled with selective nurse-led structured telephone support for a subset of the enrolled patients, triggered by specific red flags such as night symptoms, non-compliance with medications, or insufficient response to the text messages. In addition, an individualized and tailored aspect of the intervention is that patients will have the option to modulate the intensity of the telemonitoring strategy after 30 days, reducing the number of messages if they feel such rigorous supervision is no longer needed. This integrated and multifaceted approach will allow minimal human interaction for a substantial subgroup of participants—patients with weight and clinical stability who comply with the prescribed drug treatment. As the required technological framework is simple and self-educational, we believe that the nature of this interaction, particularly in specific patients at a susceptible stage of the HF syndrome, will have the greatest chance to translate into significant clinical benefits. Finally, if proven effective, this strategy can be easily applied to a broader population worldwide.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Educational SMS.

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