Efficacy of an mHealth application (eMOTIVA) in compliance with cardiac rehabilitation guidelines in patients with coronary artery disease: A randomized controlled clinical trial

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Abstract

Background: Cardiac rehabilitation is fundamental among patients recovering from a coronary event, and mHealth technology may constitute a useful tool that provides guidelines based on scientific evidence in an entertaining, attractive, and user-friendly format.

Objective: To compare the efficacy of an mHealth intervention involving the eMOTIVA application and usual care regarding compliance with cardiac rehabilitation guidelines in terms of lifestyle, the control are cardiovascular risk factors and satisfaction among patients that had suffered from an acute coronary syndrome.

Methods: A randomized controlled clinical trial with parallel group design was conducted including 300 patients (150 control group and 150 mHealth group) who underwent a percutaneous coronary intervention with stent implantation after an acute coronary syndrome. Both groups were given an initial evaluation (during hospitalisation) and then after three and six months in a face-to-face consultation. The app incorporates a virtual classroom that provides audio and video information about a healthy lifestyle, a section for the self-recording of cardiovascular risk factors, feedback through personalised messages and gamification to motivate the user. The primary outcome variables were: 1) adherence to the Mediterranean diet and frequency of consumption each food group; 2) level of physical activity, sedentary time, and exercise capacity; 3) smoking cessation and nicotine dependence; 4) adherence to treatment; 4) level of knowledge acquired about cardiovascular risk factors; and 6) app satisfaction and usability.

Results: The study analysed 287 patients, 145 in the mHealth group and 142 in the control group; most were male (69%), with a mean age of 62.53±8.65. Significant improvements were observed in the mHealth group with regard to the control group after six months in terms of: 1) adherence to the Mediterranean diet (11.92±1.70 vs 8.92±2.66, P<.001) and frequency of eating certain foods (red meat ? 1/week: 97.9% vs 68.1%, P<.001; industrial pastries <2/week: 89.6% vs 56.8%, P<.001; oily fish ?2/week: 86.1% vs 41.4%, P<.001; vegetables ?2/day: 90.3% vs 55.3%, P<.001 and fruit ?2/day: 88.9% vs 60.2%, P<.001) 2) physical activity (2112.66±1196.67 MET/week vs 1372.60±944.62 MET/week, P<.001) and sedentary time (8.38±1.88 hours vs. 9.59±2.09 hours (P<.001) 3) exercise capacity (473.49±102.28 metres vs 447.25±93.68 metres, P=.04), 4) adherence to medication (7.94±0.45 points vs 7.49±1.13 points, P<.001) and 5) level of knowledge (117.85±3.83 points vs 111.00±7.11, P<.001). Satisfaction with the app was high (42.53±6.38 points) and its usability was rated as excellent (95.60±4.03 points).

Conclusions: The eMOTIVA app significantly improved the following: adherence to the Mediterranean diet and frequency of eating certain foods, physical activity, sedentary time, exercise capacity, adherence to medication, level of knowledge, systolic blood pressure, heart rate and blood sugar levels. Furthermore, the participants reported a high level of satisfaction with the app

and rated its usability as excellent, so this innovative tool is very promising. Clinical Trial: ClinicalTrials.gov NCT05247606, https://clinicaltrials.gov/study/NCT05247606

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Abstract

Background: Cardiac rehabilitation is fundamental among patients recovering from a coronary event, and mHealth technology may constitute a useful tool that provides guidelines based on scientific evidence in an entertaining, attractive, and user-friendly format.

Objective: To compare the efficacy of an mHealth intervention involving the eMOTIVA application and usual care regarding compliance with cardiac rehabilitation guidelines in terms of lifestyle, the control cardiovascular risk factors and satisfaction among patients that had suffered from an acute coronary syndrome.

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Results: The study analysed 287 patients, 145 in the mHealth group and 142 in the control group; most were male (207/300, 69%), with a mean age of 62.53±8.65. Significant improvements were observed in the mHealth group about the control group after six months in terms of 1) adherence to the Mediterranean diet (11.92±1.70 vs 8.92±2.66 points, *P*<.001) and frequency of eating certain foods (red meat ≤ 1/week: 141/143, 97.9%, vs 96/141, 68.1%, *P*<.001; industrial pastries <2/week: 129/143, 89.6% vs 80/141, 56.8%, *P*<.001; oily fish ≥2/week: 124/143, 86.1% vs 64/141, 41.4%, *P*<.001; vegetables ≥2/day: 130/143, 90.3% vs 78/141, 55.3%, *P*<.001 and fruit ≥2/day: 128/143, 88.9% vs 85/141, 60.2%, *P*<.001) 2) physical activity (2112.66±1196.67 MET/week vs 1372.60±944.62 MET/week, *P*<.001) and sedentary time (8.38±1.88 hours vs. 9.59±2.09 hours (*P*<.001) 3) exercise capacity (473.49±102.28 meters vs 447.25±93.68 meters, *P*=.04), 4) adherence to

medication (7.94±0.45 points vs 7.49±1.13 points, *P*<.001) and 5) level of knowledge (117.85±3.83 points vs 111.00±7.11, *P*<.001). Satisfaction with the app was high (42.53±6.38 points) and its usability was rated as excellent (95.60±4.03 points).

Conclusions: With the use of the eMOTIVA app, significantly favourable results were obtained in the intervention group concerning the control group in terms of: adherence to the Mediterranean diet and frequency of eating certain foods, physical activity, sedentary time, exercise capacity, adherence to medication, level of knowledge, systolic blood pressure, heart rate, and blood sugar levels. Furthermore, the participants reported a high level of satisfaction with the app and rated its usability as excellent, so this innovative tool is very promising.

Trial registration: ClinicalTrials.gov NCT05247606, https://clinicaltrials.gov/study/NCT05247606

Keywords: coronary event; coronary heart disease; eHealth; lifestyle; mHealth.

INTRODUCTION

Cardiovascular disease remains the main cause of death worldwide, responsible for 17.9 million fatalities every year (1). In Europe, about 4 million deaths occur each year due to cardiovascular diseases. Although significant progress has been made in the diagnosis and treatment of acute coronary syndrome (ACS), nearly half of these deaths are due to ischaemic heart disease (2,3). In Spain, coronary heart disease and mainly acute myocardial infarction remain the leading cause of death, causing 29,068 deaths per year. Thus, reducing the prevalence of ACS is still a crucial objective of public health (4,5).

A great deal of evidence has shown that leading a healthy lifestyle and modifying cardiovascular risk factors such as stopping smoking, a healthy diet, weight loss, a suitable level of physical activity (PA), and medication adherence is vital in the prevention of major adverse cardiac and cerebrovascular events and death in people with coronary artery disease (CAD)(6). However, a third of patients with CAD do not follow advice about eating healthily, doing physical activity, and stopping smoking (7).

Thanks to medical advances, the mean hospital stay of patients after a percutaneous coronary intervention (PCI) has decreased greatly in recent years, meaning that less time is

available for providing healthcare education. Health education plays a fundamental role in the process of cardiac rehabilitation following acute coronary syndrome, as it empowers patients to take control of their health, improve treatment adherence, prevent future cardiovascular events, and enhance their overall quality of life (8,9). Providing patients with ongoing support after their hospital discharge may be the key after an ACS. This should include changes in lifestyle, adherence to medication to psychosocial well-being (10). Secondary prevention, which focuses on reducing the risk of recurrent cardiovascular events in individuals who have already experienced an ACS, plays a crucial role in the comprehensive management and ongoing care of these patients. Cardiac rehabilitation (CR) after an AMI is of utmost importance for several reasons: it reduces the risk of suffering another cardiovascular event. Moreover, CR improves cardiovascular health through a structured program of physical exercise, health education, dietary advice, and emotional support designed to improve the quality of life of people who have experienced an ACS. These programmes help to control blood pressure, reduce stress, and promote healthy lifestyle habits, which contribute to better cardiovascular health. It also contributes to functional recovery; after an AMI, many people may experience limitations in their physical and functional ability. Cardiac rehabilitation can help regain muscle strength, endurance and cardiac function, allowing patients to return to daily activities and work. Psychosocial support is also critical; cardiac rehabilitation offers emotional and psychological support, which can be instrumental in helping patients cope with anxiety, depression and stress closely related to coronary heart disease (11). However, despite its benefits, less than 50% of patients with coronary heart disease eligible for a CR program participate in CR after an acute coronary event. This may be due to limited accessibility and availability due to a lack of facilities and long waiting lists. Patients may also experience logistical and transport barriers that make regular participation in face-to-face CR sessions difficult (12). The widespread use of information and communication technology via smartphones may make it easier for healthcare professionals to handle these patients. mHealth technology can provide evidence-based healthcare advice in an entertaining, attractive, and user-friendly format, thereby reducing the cost of healthcare (13). In some cases, it may be a viable alternative or complementary to conventional cardiac rehabilitation. This modality involves participation in distance rehabilitation programs that encompass essential elements such as remote counseling, social interaction, supervision and distance education (14).

A recent meta-analysis (15) concluded that mHealth technology has a positive effect on patients who have experienced a coronary event. It analysed the effectiveness of different kinds of mHealth programs in changing lifestyles, promoting treatment compliance, and controlling modifiable cardiovascular risk factors. The analysis found improvements in exercise capacity, physical activity, physical and mental quality of life, and medication adherence. In addition, readmissions for all causes and cardiovascular causes were lower, although no significant improvements were found regarding blood lipids, arterial blood pressure, body mass index (BMI), and waist circumference (WC). Another meta-analysis analysed the effects of mHealth interventions on the risk factors of coronary heart disease, showing that they can lead to significant improvements in BMI, WC, blood lipids, diastolic blood pressure, and levels of depression. However, no improvements were found in systolic blood pressure and anxiety (16)

This clinical trial aimed to assess the efficacy compared with the usual care of an mHealth intervention based on a mobile phone health (eMOTIVA) application (app) in improving compliance with cardiac rehabilitation guidelines and the secondary prevention outcomes in patients that have suffered from an acute coronary syndrome. The following variables were studied: improvements in lifestyle (adherence to the Mediterranean diet, frequency of foods consumed, physical activity, exercise capacity, sedentary time, smoking cessation, adherence to treatment, and level of knowledge); control of cardiovascular risk factors (CVRF) such as BMI, WC, blood pressure, heart rate (HR), total cholesterol level (TC), LDL cholesterol, HDL cholesterol, triglycerides, blood sugar and HbA1c; and usability and satisfaction with the app.

METHODS

Study design

A randomized controlled clinical trial with parallel group design was conducted including 300 patients with coronary artery disease who underwent a percutaneous coronary intervention with stent implantation after an ACS. The trial was conducted in the Cardiology Service of a public reference hospital in the south of Spain in which 1500 percutaneous coronary interventions are conducted every year.

The trial has been developed and reported in agreement with the checklists of the

Consolidated Standards for Reporting Clinical Trials (CONSORT) (17). The trial was registered in ClinicalTrials.gov (NCT05247606). The study protocol has been previously published (18).

Participants

During hospitalisation, patients were considered eligible to participate if they had suffered from a myocardial infarction or angina and had undergone revascularization with stent implantation, were under 75 years of age, had a smartphone or tablet with internet access for the duration of the study, and were able to manage the software. Patients were excluded if their expected survival was less than one year, if they had a physical disability, severe heart failure, severe psychiatric illness, dementia if they did not speak Spanish if they had congenital heart disease with rheumatic etiology, or if they required triple heart bypass surgery.

A total of 150 patients were included in each arm. This sample size is enough to detect a mean effect size, Cohen's d of 0.5 (19) regarding adherence to the Mediterranean diet (8.6±2.0 points) (20), physical activity (210.2 METs-min/week ± 221.8 METs-min/week) (21,22) and a 12% decrease in the prevalence of smokers (prevalence of 21% from the prior pilot study) with a 95% confidence level and a statistical power of 80%.

Recruitment, randomisation, and blinding

Recruitment took place between February 2022 and February 2023, and the follow-up continued until September 2023. The flow diagram of the participants is shown in Figure 1.

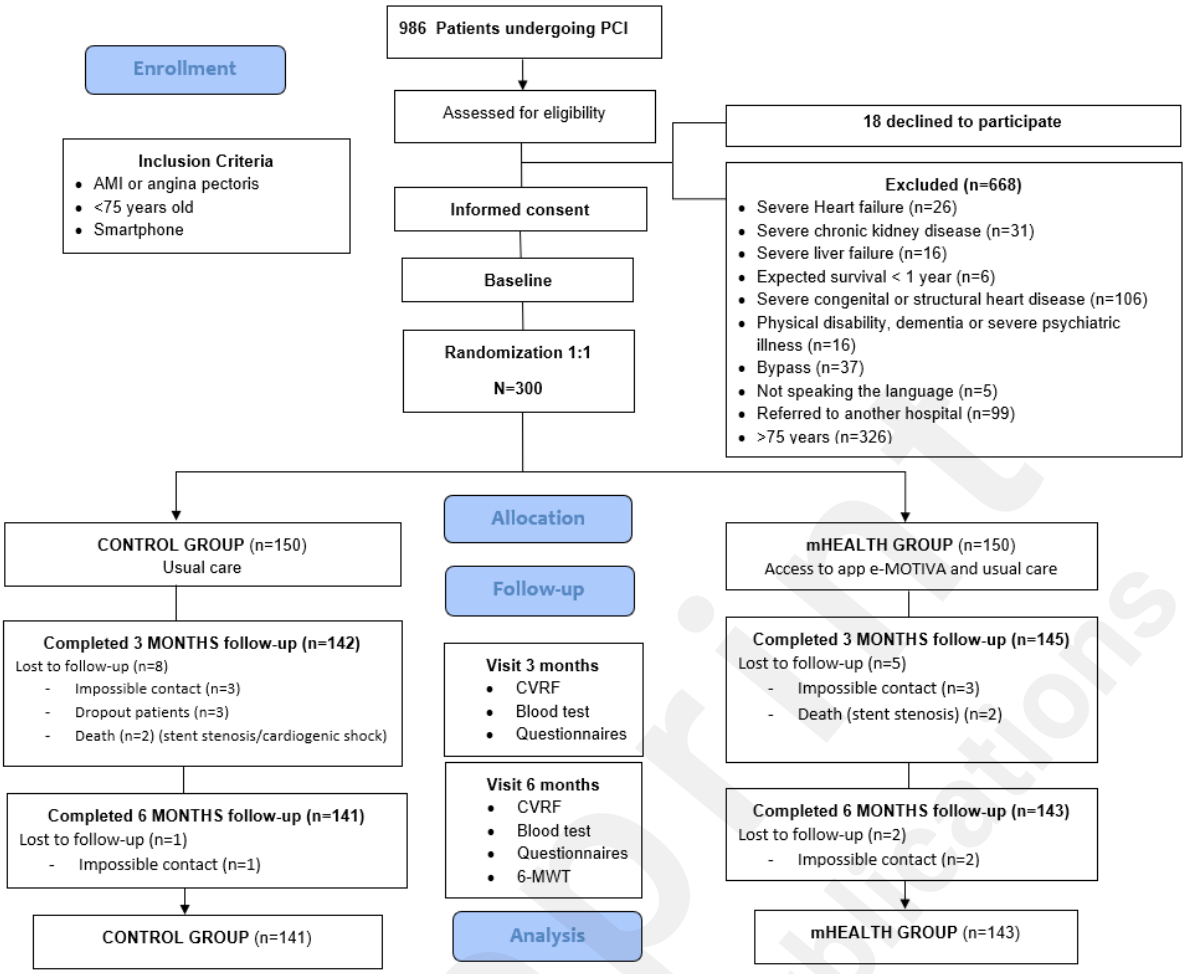

Figure 1. Flow diagram

The participants meeting the inclusion criteria described above were randomly allocated using a computerized random number generator (1:1) to either the mHealth or control group (usual care). The researchers analysing the results were blinded to the allocation of the participants.

Intervention

The intervention began while the patient was in hospital after the coronary event. All the participants in the mHealth group had the eMOTIVA app installed on their mobile phones or tablets. The app incorporates a virtual classroom that comprises a space for participation that guides the user using information based on scientific evidence to reach the treatment goals recommended in the clinical practice guidelines and to maintain a healthy lifestyle. This section addresses four cornerstones of the secondary prevention of cardiovascular diseases. 1) Healthy lifestyle habits: diet, physical activity, and recommendations. 2) Risk factors: high blood pressure, cholesterol, obesity, diabetes, tobacco use, and stress/anxiety.

3) Compliance with the treatment and 4) goals to be reached regarding diet, physical activity, body weight, blood pressure, blood sugar, smoking and treatment. Each section includes online interactive videos (about indoor and outdoor physical activity, the correct self-measurement of blood pressure and WC, the treatment of cardiac events, and a guided mindfulness relaxation audio). In addition, the classroom provides documents that can be downloaded and printed such as weekly menus and graphics with information (food pyramid, heart health, characteristics and benefits of physical exercise, and recommendations for a healthy lifestyle, for stopping smoking, and for controlling stress). Each section includes a questionnaire to complete to obtain feedback about the knowledge acquired in the educational sessions. The app includes the use of behavioural strategies to achieve changes in habits using the self-recording of data in the sections related to food consumption, weekly body weight, treatment compliance, physical activity, smoking, and capillary blood sugar in patients with diabetes. To motivate the participants to improve and maintain healthy habits, the app includes the following functions: 1) Reminders about healthy habits are generated at random on a pop-up screen once a week. 2) Personalised messages according to the user's achievements and recommendations adapted to aspects to be improved, by the information recorded during the previous week. These messages may be green (goal reached), yellow (goal partially reached), or red (goal still to be reached). Furthermore, each icon on the home page of the application appears in the colours according to the goals reached and aspects to improve (Figure 2).

The app uses gamification in the form of achievement icons. The users can obtain different medals if they meet the established recommendations for diet and physical activity during the months in which they use the app. These systems with fun rewards, such as awarding digital badges obtained for specific objectives, are related to the participation and motivation of the users in mHealth interventions, and they encourage an initial and sustained commitment among the users to modify CVRF (23,24). What is more, gamification can make the interventions more enjoyable, and this is in line with the theory of self-reliance, which assumes that a key part of intrinsic motivation is enjoyment (25). The application also has fun, colorful warnings and messages, advice, feedback, and self-comparisons using graphics detailing weekly progress (Figure 2).

The application has a messaging section through which the patient can contact healthcare professionals and resolve any queries (Figure 2). The patients from both groups were evaluated using a face-to-face consultation and medical records at the start, and then three

and six months after their hospital discharge.

Figure 2. Contents of the eMOTIVA application

Outcome variables

The primary outcome measures at the end of the intervention in both groups were changes in behaviour regarding: 1) healthy diet; adherence to the Mediterranean diet and frequency of eating each food group; 2) level of physical activity (METs/week and min/week); sedentary time (hours sitting/week) and exercise capacity (six-minute walk test, 6-MWT); 3) smoking cessation in smokers and nicotine dependence; 4) adherence to treatment; 5) level of knowledge acquired about CVRFs; and 6) app satisfaction and usability.

The secondary outcome measures were: 1) BMI and WC; 2) arterial blood pressure and HR; 3) total cholesterol, LDL cholesterol and triglycerides; and 4) HbA1c and blood sugar in patients with diabetes.

Primary outcomes

To evaluate diet, adherence to the Mediterranean diet questionnaire was used (total score:

14 points, <9 points: low adherence, ≥9 points: good adherence) (26). The frequency with which each food group was consumed was measured using a food consumption frequency questionnaire (for each food, the person ticks the box indicating the mean frequency of consumption during the last week) (27). Physical activity time (min/week), intensity (METs/week), and sedentary time (hours seated/week) were analysed using the International Physical Activity Questionnaire (IPAQ) (28) (light physical activity: minimum recommended walking of 150 min/week or 495 METs/week; moderate physical activity: minimum 600 METs/week; vigorous physical activity: at least 3000 METs/week). Exercise capacity was measured with the six-minute walk test (6-MWT) (meters) (29). Generally speaking, healthy people can walk between 400 and 700 meters in six minutes, depending on their age, height, and sex. The greater the distance covered, the higher the exercise capacity. To this end, a change of 50 meters was established as a clinically significant improvement. A distance below 350 meters is a predictor of higher mortality in patients with chronic diseases (30,31). Smoking cessation was self-reported and nicotine dependence was assessed using the Fagerström test (<4 points: low dependence, 4-7 points: moderate dependence, and 8-10 points: high dependence) (32). Medication compliance was assessed using the eight-item scale (total score: 8 points; good/high adherence: 8 points, average adherence: 6-7 points, low adherence < 6 points). Level of knowledge of CVRFs and health lifestyle were analysed using a scale validated by the research team in this kind of patient (maximum score: 120 points. The scale comprises 24 items, each scoring between 1 and 5 points, and respondents were considered to have a high level of knowledge when the correct response was chosen for over 75% of the items (90 points) (33).

Secondary outcomes

During hospital admission and in the physical follow-up visits, the following measurements were taken: body weight and height to calculate their BMI, waist circumference, systolic and diastolic blood pressure, heart rate, lipid values (total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides) and HbA1c and blood sugar.

Finally, satisfaction with the app was assessed using a specific questionnaire developed by the research team (maximum score: 50 points, higher scores mean more satisfaction), and the usability of the app was measured using the System Usability Scale (SUS) questionnaire (total score: 100 points; excellent: >80.3 points; good: 68-80.3 points; poor: 51-67 points; very poor: < 51 points)(34).

Statistical Analysis

A descriptive statistical analysis was performed. Continuous variables were summarized as mean and SD, median, standard deviation, 95% confidence interval, interquartile interval, depending on the distribution of the values, normal or non-normal, and categorical variables were summarized as frequency and percentage. At the end of the 6-month follow-up period, the means of the quantitative primary outcomes of the two groups (mHealth and usual care) were compared using the Student's t-test (normal distribution variables) and the Mann-Whitney U test (variables with non-normal distribution). The Chi-squared/Fisher test was used for the comparison of proportions of qualitative variables between the two groups (mHealth and control). A two-tailed p-value < 0.05 was considered statistically significant in all tests. The SPSS v.24.0 software was used. The researchers analysing the results were blinded to the allocation of the participants to each group.

Ethical considerations

The project was approved by the Research Ethics Committee and was authorized by the hospital. The study complies with Law 14/2007 on Biomedical Research and with the General European Data Protection Regulations and was conducted following the standards and criteria set out in the latest version of the Helsinki Declaration issued in Fortaleza (Brazil) in October 2013. Moreover, all the participants gave their written informed consent to participate in the study.

Concerning the privacy and security of the application, each participant has a private username and password to access the application. Data is stored on a web server and not on a local computer. This web server works with anonymous data and is located in Spain to comply with the regulations for the protection of high-level data. The web server performs daily backups of all the files, as well as backups performed by the software on demand. Thus, the data and the program are doubly protected.

RESULTS

During the recruitment period (February 2022 to February 2023), 986 patients underwent a PCI and were evaluated for inclusion in the study. Among the patients evaluated, 668 were excluded for not fulfilling the inclusion/exclusion criteria, and 18 refused to participate. In the end, 300 were randomized into either the mHealth or control group, 150 in each. There

were nine drop-outs in the control group, eight after three months, and one after six months. In the mHealth group, there were seven drop-outs, five after three months, and two after six months (Figure 1).

The baseline characteristics of the participants are shown in Table 1. Most of them were male (207/300, 69.0%) with a mean age of 62.53±8.65. In general, both groups were homogeneous.

Table 1. Patient baseline characteristics.

	Total (N=300)	mHealth (n=150)	Control (n=150)	*P*
Male, % (n)	69.0 (207)	68.7 (103)	69.3 (104)	0.90
Age, mean±SD (CI 95%)	62.53±8.65 (61.55-63.51)	61,13±8.69 (59.73-62.54)	63.93±8.41 (62.57-65.28)	.005
Educational level, % (n)				
Primary	44.9 (128)	40.7 (59)	49.3 (69)	.11
Middle school	41.1 (117)	41.4 (60)	40.7 (57)	
High school	14.0 (40)	17.9 (26)	10.0 (14)	
Employment status, % (n)				
Employment	32.1 (94)	37.2 (55)	26.9 (39)	.15
Unemployed	11.6 (34)	12.8 (19)	10.3 (15	
Retired	50.9 (149)	45.9 (68)	55.9 (81)	
Occupational disability	5.5 (16)	4.1 (6)	6.9 (10)	
BMI (Kg/m^2), mean±SD (CI 95%)	28.75±4.63 (28.22-29.27)	28.84±4.56 (28.10-29.58)	28.65±4.70 (27.89-29.41)	.72
WC (cm), mean±SD (CI 95%)	103.98±11.49 (102.59-105.38)	104.44±11.91 (102.45-106.43)	103.46±11.02 (101.50-105.42)	.49
Cardiovascular Risk Factors, % (n)				
Overweight	42.3 (127)	42.7 (64)	42.0 (63)	.31
Obesity	35.7 (107)	34.6 (52)	36.7 (55)	
High blood pressure	68.0 (204)	63.3 (95)	72.7 (109)	.08
Diabetes	43.7 (131)	38.7 (58)	48.7 (73)	.08
Dyslipidemia	66.3 (199)	66.7 (100)	66.0 (99)	.90
Smoking	35.7 (107)	37.3 (56)	34.0 (51)	.54
Former Smoker	38.7 (116)	36.0 (54)	41.3 (62)	.34
MORBIDITIES [a]	21.1 (63)	16.8 (25)	25.3 (38)	.07
Personal history CVD, % (n)				
Stable angina	16.0 (48)	14.0 (21)	18.0 (27)	.34
Unstable angina	9.3 (28)	6.7 (10)	12.08 (18)	.11
NSTEMI	9.0 (27)	5.3 (8)	12.7 (19)	.02
STEMI	12.3 (37)	10.0 (15)	14.7 (22)	.21
Arrhythmia	5.7 (17)	6.0 (9)	5.3 (8)	.80

Stroke	4.7 (14)	6.0 (9)	3.3 (5)	.27
Peripheral artery disease	1.7 (5)	2.0 (3)	1.3 (2)	.65
LVEF (%), mean±SD (CI 95%)	56.79±10.41 (55.57-58.00)	56.79±10.10 (55.12-58.46)	56.78±10.74 (55.00-58.56)	.55[b]
Reason for catheterization, % (n)				
Stable angina	36.0 (108)	36.0 (54)	36.0 (54)	.49
Unstable angina	15.0 (45)	12.7 (19)	17.3 (26)	
NSTEMI	19.7 (59)	18.7 (28)	20.7 (31)	
STEMI	29.3 (88)	32.7 (49)	26.0 (39)	
Nº Stents, mean±SD (CI 95%)	2.47±1.67 (2.28-2.66)	2.26±1.60 (2.00-2.52)	2.68±1.70 (2.40-2.96)	.01[b]
Complete Arterial Revascularization, % (n)	81.6 (244)	83.9 (125)	79.3 (119)	.30
Discharge treatment, % (n)				
Anticoagulants	10.0 (30)	12.1 (18)	8.0 (12)	.24
Antiplatelet	98.3 (294)	98.0 (146)	98.7 (148)	.64
Antihypertensives	96.7 (289)	94.0 (140)	99.3 (149)	.01
Insulin	14.4 (43)	9.4 (14)	19.3 (29)	.01
Oral antidiabetics	49.8 (149)	44.3 (66)	55.3 (83)	.05
Statins	93.6 (280)	94.6 (141)	92.7 (139)	.48

[a] Chronic obstructive pulmonary disease, kidney disease, and obstructive sleep apnea syndrome.
[b] U Mann-Whitney [Median (IQR)] mHealth vs control: FEVI [58.0 (64.75-52.00] vs. [60.0 (65.00-54.00)]; Stents numbers [2.00 (3.00-1.00] vs. [2.00 (4.00-1.00)].
BMI: Body mass index; CVD: cardiovascular diseases; LVEF: left ventricular ejection fraction; NSTEMI: non-ST-segment elevation myocardial infarction; STEMI: ST-segment elevation acute myocardial infarction; WC: waist circumference.

Outcome variables

Primary outcomes

The primary outcome variables are shown in Table 2. The score for adherence to Mediterranean diet was significantly higher in the mHealth group after both three months (11.63±1.70 points) and six months (11.92±1.70 points) compared with the control group (9.32±2.55 points; 8.92±2.66 points) (*P*<.001). The percentage of participants with good adherence to the Mediterranean diet (>9 points) was also statistically higher in the mHealth group after three months (136/145, 93.8% vs 96/142, 67.6%, *P*<.001) and after six months (135/143, 94.4% vs 85/141, 60.3%, *P*<.001).

Table 2. Primary outcome variables at baseline, 3 and 6 months.

N baseline	**Total (N= 300)**	**mHealth (n=150)**	**Control (n=150)**	***P***
N 3 months	**(N=287)**	**(N=145)**	**(N=142)**	
N 6 months	**(N=284)**	**(N=143)**	**(N=141)**	

MEDITERRANEAN DIET				
Mediterranean Adherence (score), mean±SD (CI 95%)				
	Baseline	7.85±2.52 (7.56-8.14)	7.78±2.62 (7.36-8.20)	7.92±2.42 (7.53-8.31)	0.48[a]
	3 months	10.48±2.45 (10.20-10.77)	11.63±1.70 (11.35-11.91)	9.32±2.55 (8.89-9.74)	<.001[a]
	6 months	10.43±2.69 (10.12-10.75)	11.92±1.70 (11.64-12.20)	8.92±2.66 (8.48-9.37)	<.001[a]
Good adherence, % (n)				
	Baseline	39.3 (117)	38.7 (58)	40.0 (60)	0.57
	3 months	80.8 (232)	93.8 (136)	67.6 (96)	<.001
	6 months	77.5 (200)	94.4 (135)	60.3 (85)	<.001
FOOD CONSUMPTION				
Red meat ≤1 /week, % (n				
	Baseline	42.5 (127)	42.3 (63)	42.7 (64)	0.70
	3 months	86.7 (249)	97.9 (142)	75.3 (107)	<.001
	6 months	83.2 (237)	97.9 (141)	68.1 (96)	<.001
Blue Fish/ Oily Fish ≥2/week, % (n)				
	Baseline	40.0 (120)	40.3 (60)	40.0 (60)	0.57
	3 months	64.1 (184)	80.0 (116)	47.9 (68)	<.001
	6 months	66.0 (186)	86.1 (124)	45.4 (64)	<.001
Vegetables ≥2/day, % (n)				
	Baseline	32.7 (98)	32.9 (49)	32.6 (49)	0.86
	3 months	70.0 (201)	85.5 (124)	54.2 (77)	<.001
	6 months	73.0 (208)	90.32 (130)	55.3 (78)	<.001
Fruits ≥2/day, % (n)				
	Baseline	48.5 (145)	50.4 (75)	46.6 (70)	0.30
	3 months	74.9 (215)	86.2 (125)	63.4 (90)	<.001
	6 months	74.8 (213)	88.9 (128)	60.2 (85)	<.001
Whole grains ≥1/day, % (n)				
	Baseline	25.6 (76)	26.4 (39)	24.8 (37)	0.76
	3 months	46.0 (132)	61.3 (89)	30.2 (43)	<.001
	6 months	48.4 (138)	66.7 (96)	29.8 (42)	<.001
Industrial pastry <2/week, % (n)				
	Baseline	44.8 (134)	41.7 (62)	47.9 (72)	0.55

	3 months	75.6 (217)	88.2 (128)	62.7 (89)	<.001
	6 months	73.3 (209)	89.6 (129)	56.8 (80)	<.001
PHYSICAL ACTIVITY					
	IPAQ Min/week, mean±SD (CI 95%)				
	Baseline	387.30±342.72 (348.36-426.24)	389.81±355.78 (332.40-447.21)	384.80±330.33 (331.50-438.10)	0.87[a]
	3 months	511.49±310.22 (475.44-547.53)	578.10±326.14 (524.57-631.64)	443.46±278.11 (397.32-489.60)	<.001[a]
	6 months	512.18±321.44 (474.64-549.73)	614.51±332.26 (559.58-669.44)	408.40±274.49 (362.70-454.11)	<.001[a]
	IPAQ METS/week, mean±SD (CI 95%)				
	Baseline	1411.48±1480.98 (1243.21-1579.75)	1457.28±1632.15 (1193.95-1720.61)	1365.68±1316.49 (1153.27-1578.08)	0.89[a]
	3 months	1743.73±1087.58 (1617.37-1870.10)	1991.74±1176.71 (1798.59-2184.90)	1490.48±925.89 (1336.88-1644.09)	<.001[a]
	6 months	1745.24±1139.02 (1612.20-1878.28)	2112.66±1196.67 (1914.84-2310.48)	1372.60±944.62 (1215.32-1529.88)	0.000[a]
	IPAQ H sitting/week, mean±SD (CI 95%)				
	Baseline	9.64±2.40 (9.36-9.91)	9.58±2.44 (9.19-9.98)	9.69±2.37 (9.30-10.07)	0.84[a]
	3 months	8.95±2.04 (8.71-9.19)	8.57±1.89 (8.26-8.88)	9.34±2.13 (8.99-9.69)	0.002[a]
	6 months	8.98±2.07 (8.74-9.22)	8.38±1.88 (8.07-8.69)	9.59±2.09 (9.24-9.94)	<.001[a]
	6-MWT (meters), mean±SD (CI 95%)				
	6 months	460.75±98.87 (448.10-473.41)	473.49±102.28 (455.15-491.82)	447.25±93.68 (429.94-464.55)	0.04
TOBACCO					
	Smokers, % (n)				
	Baseline	35.7 (107)	37.3 (56)	34.0 (51)	0.54
	3 months	42.0 (42)	37.7 (20)	46.8 (22)	0.35
	6 months	43.8 (42)	34.7 (17)	53.2 (25)	0.06
	Smoking cessation, % (n)				
	3 months	58.0 (58)	62.3 (33)	53.2 (25)	0.35
	6 months	56.3 (54)	65.3 (32)	46.8 (22)	0.06
	Nicotine dependence FAGERSTRÖM Fagerstrom (score),				

mean±SD (CI 95%)					
	Baseline	5.32±2.77 (4.79-5.85)	5.39±2.93 (4.61-6.18)	5.24±2.62 (4.50-5.97)	0.77
	3 months	3.26±2.78 (2.39-4.13)	2.30±2.27 (1.24-3.36)	4.14±2.96 (2.82-5.45)	0.031
	6 months	3.05±2.84 (2.16-3.93)	2.18±2.37 (0.95-3.40)	3.64±3.02 (2.39-4.89)	0.10
CARDIOVASCULAR RISK FACTOR					
CVRF KNOWLEDGE (score), mean±SD (CI 95%)					
	Baseline	108.26±9.34 (107.20-109.32)	108.15±7.39 (106.95-109.34)	108.37±10.97 (106.60-110.14)	0.40[a]
	3 months	113.61±6.27 (112.88-114.34)	116.14±4.23 (115.45-116.84)	111.02±6.94 (109.87-112.17)	<.001[a]
	6 months	114.45±6.64 (113.67-115.22)	117.85±3.83 (L117.21-118.48)	111.00±7.11 (109.81-112.19)	<.001[a]
MEDICATION ADHERENCE					
MMAS-8 (score), mean±SD (CI 95%)					
	Baseline	7.18±1.85 (6.95-7.40)	7.16±1.70 (6.86-7.46)	7.19±1.98 (6.85-7.52)	0.049[a]
	3 months	7.78±0.79 (7.68-7.87)	7.96±0.25 (7.92-8.01)	7.59±1.06 (7.41-7.76)	<.001[a]
	6 months	7.72±0.88 (7.61-7.82)	7.94±0.45 (7.87-8.02)	7.49±1.13 (7.30-7.68)	<.001[a]
SATISFACTION APP (score), mean±SD (CI 95%)					
	3 months	-	42.32±5.96 (41.34-43.30)	-	-
	6 months	-	42.53±6.38 (41.47-43.59)	-	-
USABILITY APP (score), mean±SD (CI 95%)					
	3 months	-	95.75±4.04 (95.08-96.41)	-	-
	6 months	-	95.60±4.03 (94.93-96.27)	-	-

[a] U Mann-Whitney. [Median (IQR)] mHealth vs control: Mediterranean diet adherence baseline [7.00 (9.00-6.00)] vs. [7.00 (9.00-5.25)], 3 months [11.00 (12.00-9.25] vs [8.00 (10.00-5.00)], 6 months [11.00 (13.00-8.50)] vs [7.00 (9.00-5.00)]; Physical activity min/week baseline [245.00 (630.00-105.00)] vs. [210.00 (420.00-113.75)], 3 months [420.00 (210.00-622.50] vs [420.00 (198.75-647.50)], 6 months [630.00 (840.00-210.00)] vs [420.00 (795.00-245.00)]; Physical activity METS/week baseline [808.50 (2079.00-346.50)] vs. [693.00 (1386.00-272.25)], 3 months [1386.00 (2279.25-693.00)] vs. [1386.00 (2136.75-674.25)]; 6 months [2079.00 (2799.00-693.00)] vs. [1386.00 (2665.50-808.50)]; Physical activity hours sitting/week baseline [10.00 (12.00-8.00)] vs. [11.50 (8.00-12.00)], 3 months [9.50 (10.00-8.00)] vs. [10.00 (12.00-7.00)], 6 months [8.00 (10.50-7.00)] vs. [9.00 (12.00-7.00)]; CVRF knowledge baseline [109.00 (113.00-101.50)] vs. [105.50 (111.50-101.00)], 3 months [117.00 (118.00-113.00)] vs. [106.50 (112.75-98.75)], 6 months [118.00 (120.00-113.00)] vs. [108.50 (112.75-101.00)]; Medication adherence baseline [7.75 (8.00-5.75)] vs. [7.75 (8.00-4.18)], 3 months [8.00 (8.00-8.00)] vs. [8.00 (8.00-7.75)], 6 months [8.00 (8.00-8.00)] vs. [7.75 (8.00-7.50)].

6-MWT: six-minute walk test; CVRF: cardiovascular risk factor; IPAQ: International Physical Activity Questionnaire; MD: Mediterranean diet; MMAS-8: 8-item Morisky Medication Adherence Scale.

Regarding the frequency food was eaten, a significant decrease is observed in the

consumption of red meat in the mHealth group compared with the control group (≤ 1/week: 142/145, 97.9% vs 107/142, 75.3%, *P*<.001, 3 months) and (141/143, 97.9% vs 96/141, 68.1%, *P*<.001, 6 months). The mHealth group also ate fewer industrial pastries (<2/week: 128/145, 88.2% vs 89/142, 62.7%, *P*<.001; 3 months) and (129/143, 89.6% vs 80/141, 56.8%, *P*<.001; 6 months). In addition, the consumption of the following foods was significantly higher in the mHealth group: oily fish (≥2/week: 116/145, 80.0% vs 68/142, 47.9%, *P*<.001; 3 months) and (124/143, 86.1% vs 64/141, 41.4%, *P*<.001; 6 months), vegetables (≥2/day: 124/145, 85.5% vs 77/142, 54.2%, *P*<.001; 3 months) and (130/143, 90.3% vs 78/141, 55.3%, *P*<.001; 6 months), fruit (≥2/day: 125/145, 86.2% vs 90/142, 63.4%, *P*<.001; 3 months) and (128/143, 88.9% vs 85/141, 60.2%, *P*<.001; 6 months) and wholemeal cereals (≥1/day: 89/145, 61.3% vs 43/142, 30.2%, *P*<.001; 3 months) y (96/143, 66.7% vs 42/141, 29.8%, *P*<.001; 6 months).

Regarding the time spent doing physical activity each week (min/week), the mHealth group did significantly more after three months compared with the control group (578.10±326.14 min/week vs 443.46±278.11 min/week, *P*<.001). Likewise, after six months, physical activity increased in the mHealth group and decreased in the control group (614.51±332.26 min/week vs 408.40±274.49 min/week, *P*<.001). Regarding the intensity of physical activity (METs/week), that of the mHealth group was significantly greater than that of the control group after three months (1991.74±1176.71 METs/week vs 1490.48±925.89 METs/week, *P*<.001) and after six months (2112.66±1196.67 METs/week vs 1372.60±944.62 METs/week, *P*<.001), considered to be physical activity of moderate intensity in both groups.

The control group had a significantly more sedentary lifestyle, with a mean number of hours seated of 9.34±2.13 (*P*=.002) after three months and 9.59±2.09 hours (*P*<.001) after six months, compared with the mHealth group (8.57±1.89 hours, *P*=.002, after three months; 8.38±1.88 hours, *P*<.001, after six months).

Exercise capacity, assessed using the distance covered in metres during the six-minute walk test (6MWT), was significantly higher in the mHealth group than in the control group (473.49±102.28 metres vs 447.25±93.68 metres, *P*=.04).

Regarding smoking cessation, although more participants gave up smoking in the mHealth group, the difference was not significant. However, the scores for nicotine dependence after three months decreased significantly in the mHealth group compared with those receiving usual care (2.30±2.27 points vs 4.14±2.96 points, *P*=.03).

Medication adherence was significantly higher in the mHealth group after both three months (7.96±0.25 points, *P*<.001), and six months (7.94±0.45 points, *P*<.001), compared with the control group (3 months: 7.59±1.06 points, *P*<.001; 6 months: 7.49±1.13 points; *P*<.001).

The level of knowledge of CVRF and healthy lifestyle was significantly higher among the patients from the mHealth group than among those receiving usual care, after both three months (116.14±4.23 points vs 111.02±6.94 points, *P*<.001) and six months (117.85±3.83 points vs 111.00±7.11 points, *P*<.001).

Finally, the participants in the mHealth group expressed a high level of satisfaction with the app (42.32±5.96 points, 3 months) and (42.53±6.38 points, 6 months), and rated it as excellent (>80.3 points) for usability (95.75±4.04 points; 3 months) and (95.60±4.03 points; 6 months).

Secondary outcomes

The secondary outcome variables are shown in Table 3. The anthropometric variables (BMI and WC) improved slightly in both groups, with no significant differences being found between the groups.

Table 3. Secondary outcome variables at baseline, 3 and 6 months.

N baseline[a] **N 3 months** **N 6 months**	**Total (N=300)** **(N=287)** **(N=284)**	**mHealth (n=150)** **(N=145)** **(N=143)**	**Control (n=150)** **(N=142)** **(N=141)**	***P***
BMI (Kg/m2), mean±DE (IC95%)				
Baseline	28.75±4.63 (28.22-29.27)	28.84±4.56 (28.10-29.58)	28.65±4.70 (27.89-29.41)	0.72
3 months	28.29±4.43 (27.77-28.80)	28.33±4.48 (27.59-29.07)	28.24±4.40 (27.51-28.97)	0.86
6 months	28.27±4.71 (27.72-28.82)	28.22±4.69 (27.44-28.99)	28.33±4.74 (27.53-29.12)	0.69[a]
WC (cm), mean±DE (IC95%)				
Baseline	103.98±11.49 (102.59-105.38)	104.44±11.91 (102.45-106.43)	103.46±11.02 (101.50-105.42)	0.49
3 months	102.40±10.97 (101.06-103.74)	102.56±11.53 (100.62-104.51)	102.22±10.35 (100.36-104.08)	0.80
6 months	101.82±11.36 (100.43-103.21)	101.59±11.87 (99.58-103.59)	102.09±10.80 (100.14-104.03)	0.72
SBP (mmHg), mean±DE (IC95%)				
Baseline	132.93±20.18 (130.65-135.23)	133.53±19.94 (130.31-136.75)	132.34±20.47 (129.04-135.64)	0.94[a]
3 months	131.11±15.50 (129.29-132.92)	128.96±15.87 (126.32-131.59)	133.27±14.85 (130.80-135.74)	0.01
6 months	132.88±19.67 (130.57-135.19)	130.00±21.90 (126.35-133.65)	135.78±16.73 (132.99-138.58)	0.01
DBP (mmHg),				

mean±DE (IC95%)					
	Baseline	75.41±11.52 (74.10-76.72)	75.17±12.53 (73.14-77.19)	75.65±10.45 (73.96-77.33)	0.71
	3 months	74.86±10.66 (73.61-76.11)	73.68±9.76 (72.06-75.30)	76.05±11.42 (74.15-77.95)	0.06
	6 months	77.78±10.92 (76.50-79.07)	76.84±11.00 (75.00-78.67)	78.74±10.79 (76.93-80.54)	0.14
HR (beats/min), mean±DE (IC95%)					
	Baseline	73.07±13.94 (71.48-74.65)	72.63±12.99 (70.53-74.72)	73.51±14.85 (71.11-75.90)	0.70[a]
	3 months	69.33±9.73 (68.19-70.47)	66.75±8.91 (65.27-68.23)	71.93±9.86 (70.29-73.57)	<.001[a]
	6 months	69.31±10.51 (68.07-70.54)	68.20±10.13 (66.51-69.89)	70.43±10.80 (68.62-72.23)	0.07[a]
Glucose (mg/dl), mean±SD (CI 95%)					
	Baseline	122.27±51.12 (116.46-128.08)	116.48±45.55 (109.13-123.83)	128.06±55.69 (119.07-137.05)	0.02[a]
	3 months	111.51±35.10 (107.00-116.02)	110.58±35.92 (104.03-117.13)	112.44±34.38 (106.15-118.74)	0.48[a]
	6 months	108.10±31.36 (103.78-112.42)	101.10±18.57 (97.51-104.70)	115.44±39.46 (107.61-123.27)	0.007[a]
HbA1C (%), mean±DE (IC95%)					
	Baseline	6.32±1.35 (6.14-6.49)	6.17±1.32 (5.92-6.42)	6.45±1.38 (6.20-6.70)	0.01[a]
	3 months	6.43±1.20 (6.06-6.79)	6.61±1.40 (6.03-7.19)	6.19±0.84 (5.78-6.60)	0.25
	6 months	6.57±1.01 (6.30-6.84)	6.44±1.01 (6.04-6.84)	6.69±1.02 (6.30-7.08)	0.36
TC (mg/dl), mean±DE (IC95%)					
	Baseline	168.83±46.18 (163.52-174.17)	171.97±47.11 (164.29-179.65)	165.66±45.16 (158.27-173.05)	0.24
	3 months	116.68±29.83 (112.95-120.82)	117.23±29.39 (111.71-122.76)	116.54±30.39 (110.85-122.23)	0.86
	6 months	116.34±30.79 (112.04-120.63)	113.89±26.35 (104.71-119.06)	118.89±34.77 (111.92-125.86)	0.25
HDL-C (mg/dl), mean±DE (IC95%)					
	Baseline	42.35±10.95 (40.92-44.33)	42.63±10.34 (40.92-44.33)	42.08±11.57 (40.16-43.99)	0.67
	3 months	42.35±12.67 (40.65-44.05)	42.41±9.67 (40.58-44.25)	42.29±15.18 (39.38-45.20)	0.49[a]
	6 months	44.02±11.27 (42.39-45.65)	43.80±11.22 (41.54-46.07)	44.26±11.38 (41.87-46.64)	0.78
LDL-C (mg/dl), mean±DE (IC95%)					
	Baseline	101.15±42.90 (96.18-106.11)	104.39±43.20 (97.30-111.49)	97.88±42.48 (90.88-104.87)	0.19
	3 months	54.94±23.15 (51.85-58.04)	54.42±23.05 (50.04-58.80)	55.47±23.34 (51.04-59.90)	0.79[a]
	6 months	54.63±24.14 (51.17-58.09)	50.42±18.67 (46.66-54.19)	59.07±28.23 (53.22-64.91)	0.10[a]
TG (mg/dl), mean±SD (CI 95%)					
	Baseline	142.98±77.80 (134.02-151.94)	141.62±76.87 (129.09-154.15)	144.36±78.99 (131.39-157.32)	0.96[a]

3 months	112.61±56.35 (105.17-120.05)	109.06±56.86 (98.37-119.76)	116.13±55.88 (105.66-126.59)	0.12[a]
6 months	107.16±55.10 (99.45-114.86)	108.81±61.69 (96.70-120.93)	105.41±47.47 (95.84-114.98)	0.93[a]

[a] U-Mann Whitney. [Median (IQR)] mHealth vs control: BMI 6 months [27.30 (31.22-24.97)] vs. [27.14 (30.45-24.97)]; SBP baseline [129.00 (142.00-120.00)] vs. [130.00 (146.00-122.00)]; HR baseline [70.00 (79.75-65.00)] vs. [72.00 (83.00-62.00)], 3 months [67.00 (72.00-60.00)] vs. [70.00 (80.00-65.00)], 6 months [67.00 (74.50-67.00)] vs. [70.00 (80.00-70.00)]; Glucose baseline [103.50 (129.50-90.25)] vs. [114.00 (158.50-96.00)], 3 months [93.00 (166.00-88.50)] vs. [125.00 (127.00-96.00)], 6 months [90.00 (111.50-83.50)] vs. [104.00 (123.00-88.00)]; HbA1c baseline [5.70 (6.37-5.40)] vs. [5.90 (7.15-5.60)]; cHDL 3 months [45.50 (51.50-42.25)] vs. [41.00 (51.00-33.00)]; cLDL 3 months [61.00 (84.50-54.25)] vs. [54.00 (91.00-35.00)], 6 months [54.00 (67.50-45.50)] vs. [55.00 (77.50-42.75)]; TG baseline [123.50 (174.75-95.25)] vs. [128.00 (173.00-97.00)], 3 months [130.50 (204.25-100.25)] vs. [100.00 (118.00-57.00)], 6 months [100.00 (132.00-78.00] vs. [112.50 (123.00-78.75].

App: application; BMI: body mass index; DBP: diastolic blood pressure; HbA1c: glycosylated hemoglobin; HDL-C: low-density lipoprotein cholesterol; HR: heart rate; LDL-C: high-density lipoprotein cholesterol; SBP: systolic blood pressure; TC: total cholesterol; TG: triglycerides; WC: waist circumference.

Systolic blood pressure was significantly lower in the mHealth group after both three months (128.96±15.87 points, *P*<.001) and six months (130.00±21.90 points, *P*<.001), compared with the control group (3 months: 133.27±14.85 mmHg, *P*=0.019; 6 months: 135.78±16.73 mmHg, *P*=0.014). However, no significant differences were found in diastolic blood pressure (DBP) between the groups. HR was significantly lower in the mHealth group after three months compared with the usual care group (66.75±8.91 bpm vs 71.93±9.86 bpm, *P*<.001), but not after six months.

The levels of the lipid variables (TC, HDL-c, LDL-c, and triglycerides) presented large decreases in both groups, with no significant differences found between the groups.

Blood sugar levels were significantly lower after six months in the mHealth group than in the control group (101.10±18.57 mg/dl vs 115.44±39.46 mg/dl, *P*=.007). The improvements were not reflected in the level of HbA1c, however.

DISCUSSION

Main results

The present clinical trial evaluated the efficacy compared with the usual care of an mHealth intervention based on an eMOTIVA app about secondary prevention outcomes in patients who had suffered from acute coronary syndrome. The following variables were studied: improvements in lifestyle (adherence to the Mediterranean diet, frequency of foods consumed, physical activity, exercise capacity, sedentary time, smoking cessation,

adherence to treatment, and level of knowledge); control of CVRF (BMI, WC, blood pressure, heart rate (HR), total cholesterol level (TC), LDL cholesterol, HDL cholesterol, triglycerides, blood sugar, and HbA1c). Our results show that the eMOTIVA app, achieved significantly more favorable results in the intervention group with respect to the control group in terms of: adherence to the Mediterranean diet, the frequency of consumption of foods, the time and intensity of physical activity, sedentary time and exercise capacity, adherence to medication, level of knowledge about CVRF, systolic blood pressure (SBP), HR and blood sugar. Moreover, the participants reported being very satisfied with the app, rating its usability as excellent.

Primary outcome variables

Healthy diet

A healthy diet plays a very important role in both the prevention and treatment of CAD. Strong evidence exists about the efficacy of the Mediterranean diet in managing cardiovascular risk factors in patients in secondary prevention (35,36). In our trial, adherence to the Mediterranean diet increased significantly in the mHealth group after both three and six months compared with the control group. Moreover, an increase was observed in the consumption of healthy food such as fruit, vegetables, wholemeal cereals, and oily fish, and a decrease in the consumption of red meats and industrial pastries in the mHealth group. In a study that analysed a cardiac telerehabilitation program with a mobile care monitoring strategy after an acute coronary syndrome, significant improvements were obtained in adherence to the Mediterranean diet in the intervention group (37). By contrast, other authors did not report significant differences between groups about healthy eating with the use of a support program based on text messages for patients with coronary artery disease, type 2 diabetes, or both (38). Given our results, mHealth technology involving an app may be useful for improving eating behaviour and maintaining a healthy diet in these patients, compared with interventions based on text messages alone. The clinical benefits of these improvements in diet have been reported. For example, studies state that eating fish that is rich in omega-3 polyunsaturated fatty acids such as oily fish at least once a week is associated with a 16% decrease in the risk of cardiovascular disease (39). Likewise, increases in fibre consumption of 7 g/day are associated with a 9% decrease in the risk of cardiovascular disease (40).

Physical activity

Physical activity (PA) is a modifiable factor that plays a crucial role in decreasing recurrent coronary events and mortality. The cardiovascular benefits of PA are well known, with recent meta-analyses reporting that it is significantly associated with a decrease in cardiovascular and all-cause mortality in patients with CAD (41–43). Our results are promising because the participants who used the eMOTIVA app did more physical activity and were less sedentary. Although physical activity was self-reported in our trial, an objective test was conducted to measure exercise capacity using the 6-MWT, and the participants in the mHealth group were found to have significantly better exercise capacity. Our results are in line with those obtained in other trials in which the effectiveness of mHealth with CAD patients was analysed (44–47). Recent meta-analyses also revealed that the use of interactive mobile applications with self-recording and feedback achieves an increase in the amount of physical activity performed by the participants and improvements in their functional capacity (15,48).

Tobacco

Stopping smoking is one of the most effective secondary prevention measures after suffering from acute coronary syndrome (49). The EUROASPIRE study (50), which assessed smoking cessation rates in patients with coronary artery disease in the whole of Europe, with a 2-10-year follow-up, stated that individuals who stopped smoking presented a reduction of nearly 50% in general mortality. In our study, although no differences were observed between the groups regarding smoking cessation, nicotine dependence after three months, measured by the Fagerström test, was significantly lower in the mHealth group compared with the usual care group. A recent meta-analysis (49) that analysed smoking cessation and risk factors to continue smoking after an ACS concluded that the smoking cessation rate after an ACS was 45%. These results are similar to ours, where we observed that 46.8% (22/51) of the control group stopped smoking, while in the mHealth group, this figure was higher (65.3%, 32/56), suggesting that our interactive tool helped the participants to maintain the willpower to change, possibly thanks to the support and motivation they perceived. Another recent meta-analysis (51) found that telehealth interventions had a significant effect on smoking cessation in patients with CAD. By contrast, other meta-analyses did not find significant differences in smoking cessation between groups using telehealth interventions, but these interventions did not use

interactive tools with recording, feedback, or gamification(48,52,53).

Medication adherence

There is evidence that several drugs such as platelet antiaggregants or angiotensin-converting enzyme inhibitors improve the prognosis of patients who have suffered from an acute myocardial infarction (AMI). After their discharge from the hospital, patients are prescribed a great deal of medication, and good treatment compliance is an important challenge for the outcome of these patients (54). Medication adherence a year after an AMI is usually around 65%, although some studies show that this figure is as low as 50% in the last three months of the first year (55,56). In our trial, significant improvements were achieved in the mHealth groups using the eMOTIVA app after both three and six months. Failure to adhere to treatment can be explained by factors such as not understanding that the treatment is necessary or a lack of knowledge. Thus, mobile phone healthcare apps with medication reminders or notifications, the self-recording of treatment taken, and interactive information such as videos can be of great use for improving treatment compliance among patients (6,38,44).

Knowledge of CVRF

Patients' level of knowledge of CVRF and health lifestyle is not adequately addressed in trials analysing the efficacy of mHealth. In our study, the level of knowledge was significantly higher among the patients in the mHealth group compared with those receiving usual care. These results are in line with those obtained by other authors who report that the use of a social media platform with learning modules significantly increased knowledge and awareness of coronary artery disease (44). Therefore, interactive and innovative mHealth tools can play a part in increasing knowledge of a healthy lifestyle. In our study, the virtual classroom incorporated in the app may have been responsible for the increase in knowledge observed.

Secondary outcome variables

BMI and WC

A recent meta-analysis (16) that analysed the efficacy of mHealth at decreasing risk factors related to coronary artery disease found significant decreases in both BMI and WC in the intervention group. However, other recent meta-analyses are in agreement with our results

in that no significant reductions were obtained in these anthropometric values with the use of the app (15,48,52,53). The participants in the mHealth group in our study consumed more vegetables, fruit, wholemeal cereals, and fish, and less red meat and industrial pastries. Moreover, they complied with the recommendations to perform at least 150 minutes of physical activity per week. Our application, however, was not specifically designed with weight loss in mind, although it did include dietary advice, and losing weight is known to involve more than merely eating healthier food; it is also necessary to limit calorie intake and increase energy expenditure through physical activity (57).

Blood pressure and HR

In our study, SBP was significantly lower among the patients using the app compared with those in the control group. Our results are in agreement with other studies that analysed the use of healthcare applications in patients with coronary artery disease (44,58,59). This clinical benefit is of note because one meta-analysis (60) concluded that a 10 mmHg decrease in SBP reduces the risk of major cardiovascular events by approximately 20%, coronary artery disease by 17%, and all-cause mortality by 13%. However, no significant improvements were found in DBP, possibly due to the intensive drug treatment prescribed after a coronary event that had a similar effect on the patients in both the mHealth and usual care groups. On the other hand, the significant decrease in SBP found in our study could be explained by the greater compliance with the antihypertensive treatment among the participants using the application, or by the greater adherence to the Mediterranean diet and the increase in physical activity performed. The recent prevention guidelines for cardiovascular diseases state that lifestyle interventions among patients with high blood pressure involving a healthy diet and physical exercise may be enough to control blood readings and even reduce the amount of medication required to control them (56). Regarding HR, several trials found that mobile technology did not result in significant differences between groups (24,47,61). By contrast, Dorje et al. (2019) (44) managed to significantly decrease HR after six months through the use of a WeChat platform. In our study, decreases in HR to below 70 bpm were found after both three and six months in the intervention group, but only the decrease three months into the follow-up was significant. This higher HR decrease in the intervention group compared to the control group may be because the mHealth group performed more physical activity, which has been related to a decrease in resting heart rate (62). Increases in heart rate have a direct correlation with cardiovascular events. Several kinds of medication, including beta blockers, have been

shown to help with the treatment aim of reducing HR in patients with CAD. Thus, a heart rate below 80 bpm and close to 70 bpm is a treatment goal in hypertensive patients with CAD (63).

Lipid, HbA1c and blood sugar values

Keeping blood lipid levels under control is a very important aim in the secondary prevention of cardiovascular disease (57). The meta-analysis conducted by Cholesterol Treatment Trialists' Collaboration (64) reported that the risk of major vascular events decreased by 21% for each 1 mmol/L reduction in LDL cholesterol achieved with statin treatment. In our study, as in other clinical trials on the efficacy of mHealth in patients with coronary disease, blood lipid values decreased drastically but no significant differences were found between the groups due to the powerful drug treatment that all patients are submitted to after a coronary event (38,47,65). Likewise, a high blood sugar level is also an important risk factor leading to the onset and development of CAD. Diabetes mellitus is an important risk factor for acute myocardial infarction and a common comorbidity among patients hospitalized with AMI, present in approximately 30% of cases (66). Our study did not find a significant decrease in HbA1c. However, blood sugar levels decreased significantly in the mHealth group after six months. These results for HbA1c may also be a result of the intensive drug treatment followed by the patients in both the mHealth and usual care groups.

Satisfaction and usability

High levels of satisfaction and acceptance with the healthcare received have been observed to have positive implications for health outcomes and the patient's experience, thereby reducing healthcare costs and the use of emergency services (67). In our study, satisfaction after six months of using the application reached 42.53±6.38 points out of 50, considered a high level of satisfaction, while the score for usability was 95.60±4.03 points out of a possible 100, considered to be excellent. The self-recording of physical activity, diet, and clinical variables along with the positive personalised feedback were likely factors contributing to the high level of satisfaction and usability reported by the participants who used the eMOTIVA app. Other studies that have used mHealth interventions with these patients have also reported high levels of usability of 80.4 points out of 100 (37) and 87.3 points out of 100 (68). These findings highlight the potential of mobile health applications as useful tools for improving recovery and supporting secondary prevention after a coronary event. They are particularly relevant for populations in which access to a medical center to

take part in cardiac rehabilitation is difficult, either due to living in remote areas or economic reasons.

Limitations

This study presents some limitations. First, one of the inclusion criteria was that patients had to have a smartphone. However, the ever-increasing use of these devices in the lives of people all over the world would suggest that this limitation seems of little importance. Due to the nature of the study, as in most trials with digital tools, it was impossible for either the patients or healthcare staff to be blinded. However, the staff analysing the data were indeed blinded to the allocation of each participant to a group. Some variables were self-reported by the patients (adherence to the Mediterranean diet, physical activity, medication adherence), which could have resulted in them overestimating their health-promoting behaviour. However, the results were confirmed by other variables that were measured by healthcare professionals, such as exercise capacity using the six-minute walk test or blood pressure. Another possible limitation is that the control group was two years older than the intervention group, and the proportion of patients receiving insulin, oral antidiabetics, and antihypertensive treatment was slightly higher.

Strengths

A strength of the study that stands out is the number of participants taking into account that it was a voluntary intervention study using mHealth and that there were very few drop-outs. This might imply that the app was easy to use and that the patients were motivated to change their habits. The use of validated questionnaires specific to this population is another strength. In addition, the hospital where the intervention was conducted is a public reference hospital that treats patients from urban and rural areas, so the sample is representative for the generalisation of the results. Finally, the educational sessions and app design were designed taking into consideration validated psychological theories. Likewise, our eMOTIVA application included setting objectives, self-monitoring of diet and physical activity, feedback, and gamification, which are resources that have been shown to improve the results obtained with these mHealth tools.

CONCLUSIONS

With the use of the eMOTIVA app, significantly favourable results were obtained in the intervention group concerning the control group in terms of: adherence to the Mediterranean diet, the frequency of eating certain foods, physical activity, sedentary time, exercise capacity, adherence to medication, level of knowledge of CVRF, SBP, heart rate and blood sugar levels. This trial highlights the potential of mHealth as a complement or alternative to the cardiac rehabilitation programmes conducted in medical centres, which are often overburdened. In addition, the participants reported high levels of satisfaction with the application, and it presented excellent usability. Thus, it could be a promising new tool for the cardiac rehabilitation of patients with coronary artery disease in general, and in particular, for those for whom attending a health center or hospital is difficult.

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Conflicts of Interest

The authors declare no conflict of interest.

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Supplementary Files

Tables.
URL: http://asset.jmir.pub/assets/a1f0adab0058169259b870741d375af6.docx

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Tables_ 27_05_24.
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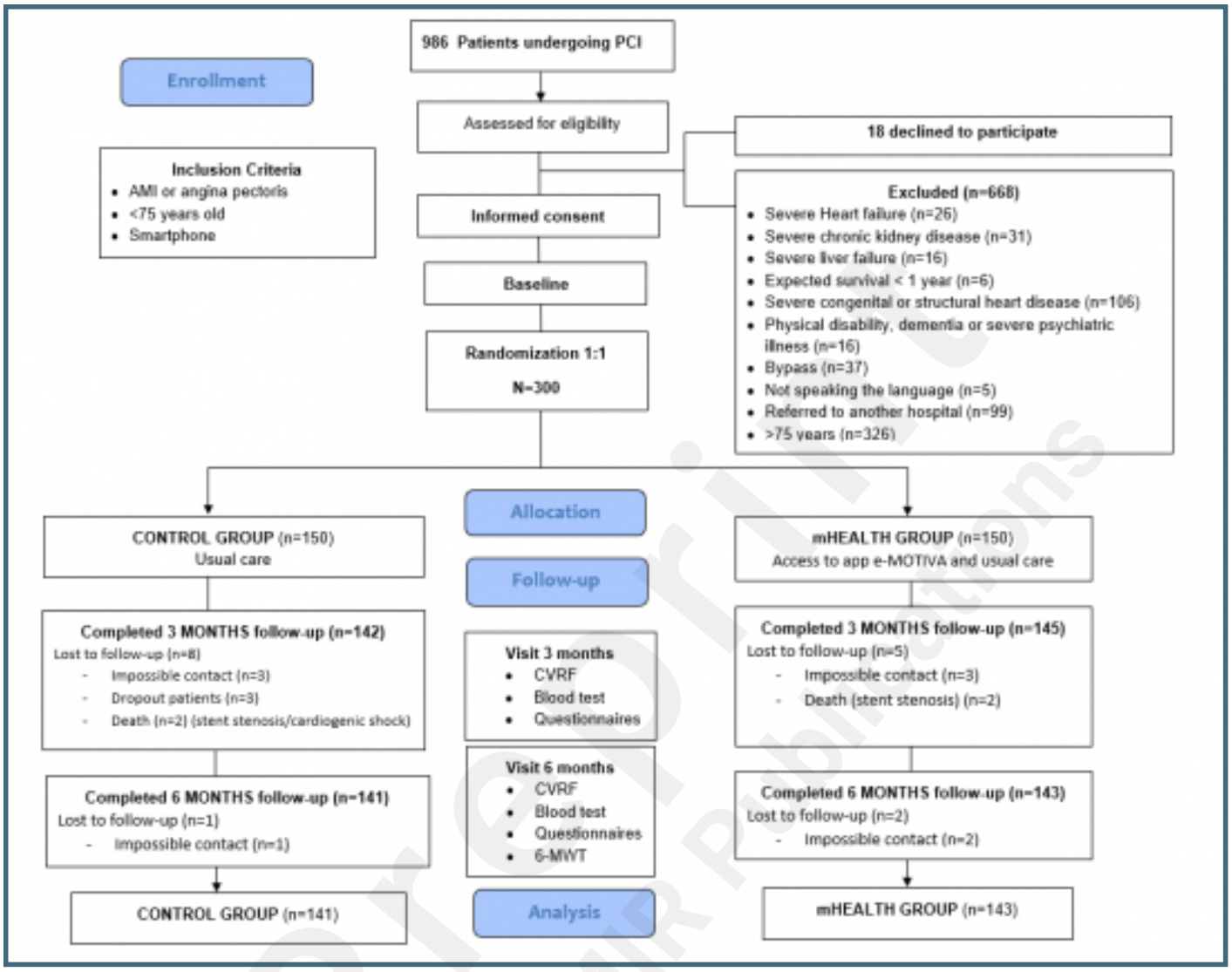
Figures

Flow diagram.



Contents of the eMOTIVA application.

Multimedia Appendixes

Satisfaction questionnaire prepared by the research team.
URL: http://asset.jmir.pub/assets/565ee579c70e8b74cc7497c72040f995.pdf

CONSORT (or other) checklists

Consort.
URL: http://asset.jmir.pub/assets/bf0519344ba52b5097c8e218b97fc523.pdf