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Original Article

Protocol for a Randomized Controlled Trial on the Development and Effectiveness of an Educational Mobile Application Using an Integrated Change Model to Prevent Atherosclerotic Cardiovascular Disease Risk Factors

Afsaneh Aein, PhD[1], Mahnaz Solhi, PhD[1*], Ali Vashegani Farahani, MD[2], Mohammad Aljasem, MD[3], Farshid Alaeddini, MD, PhD[2], Leila Janani, PhD[4], Negar Omidi, MD[2,5], Mohammad Hossein Taghdisi, PhD[1]

[1]*Department of Education and Health Promotion, School of Public Health, Iran University of Medical Sciences, Tehran, Iran.*
[2]*Cardiac Primary Prevention Research Center, Cardiovascular Diseases Research Institute, Tehran University of Medical Sciences, Tehran, Iran.*
[3]*School of Medicine, Tehran University of Medical Sciences, Tehran, Iran.*
[4]*Department of Biostatistics, School of Public Health, Iran University of Medical Sciences, Tehran, Iran.*
[5]*Department of Cardiovascular Imaging, Tehran Heart Center, School of Medicine, Tehran University of Medical Sciences, Tehran, Iran.*

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Abstract

Background: *An effective approach to preventing cardiovascular issues is the use of mobile health applications to improve modifiable risk factors. This protocol for a randomized controlled trial aims to evaluate the development and effectiveness of an educational mobile app that employs an integrated change model to reduce risk factors for atherosclerotic cardiovascular disease (ASCVD) among individuals aged 20 to 69 years.*

Methods: *This study will be a parallel, randomized, single-blind clinical trial utilizing the randomized block design involving 430 participants. The participants will be divided into a control group receiving standard clinical care and an intervention group receiving standard clinical care along with app-based education, over approximately 6 months.*

Conclusion: *This application has been designed to enhance motivation, awareness, and positive habits to reduce risk factors in individuals at increased risk of ASCVD. Consequently, the results could improve cardiovascular health knowledge, manage biological risk factors, and modify cardiac behaviors through mobile applications. This research is expected to present a promising approach to utilizing mobile apps for managing cardiovascular health and contribute to the growing body of research on digital health interventions.*

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Keywords: *Atherosclerotic; Education; Mobile app; Cardiovascular disease; Prevention; Risk factor*

[*]**Corresponding Author:** ***Mahnaz Solhi,*** *Professor of Health Education and Promotion, Department of Health Promotion and Education, School of Public Health, Occupational Health Research Center, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran. 1449614535. Tel: +98 21 86704758. Fax: +98 21 88622707. E-mail: solhi.m@iums.ac.ir.*

Introduction

The universal prevalence of cardiovascular disease (CVD), particularly atherosclerotic cardiovascular disease (ASCVD), is significant, with an estimated mortality rate of 23.3 million by 2030. Alarmingly, many patients with ASCVD risk factors remain undiagnosed and poorly managed.[1] Initial preventive measures are crucial, especially as screening tools for assessing cardiovascular risk continue to evolve with advances in risk factor management and medical technology.

In recent years, considerable effort has been focused on the optimal control of cardiovascular risk factors to prevent CVD.[2] The ASCVD risk assessment is often employed in daily clinical practice to determine a patient's 10-year risk of experiencing CVD or stroke. Reducing patients' ASCVD scores has become a common target for intervention. Factors that contribute to ASCVD risk reduction and overall health improvement include adopting a healthy lifestyle, following a heart-healthy diet, engaging in regular physical activity, quitting tobacco use, and maintaining a healthy weight.[3, 4]

While these lifestyle modifications are essential in preventing the progression of atherosclerotic diseases, they are often not effectively implemented and rarely lead to long-term behavioral changes.[5] Potential factors contributing to the rising prevalence of CVD include insufficient patient education, limited health knowledge, and inconsistent screening practices. To effectively prevent CVD in its early stages, it is crucial to screen for ASCVD within the community and provide recommendations based on current guidelines for educational and lifestyle interventions to enhance cardiovascular health, particularly for high-risk individuals.[4, 6, 7] Given the significance of health knowledge and the need for innovative approaches, utilizing modern technologies such as mobile health (mHealth) can play a vital role in preventing ASCVD and managing associated risk factors in individuals.[8] To address this, we have developed an mHealth educational intervention based on an integrated pattern to reduce ASCVD risk factors. Our intervention incorporates personalized visual information, adhering to the European Society of Cardiology (ESC) and American Heart Association (AHA) preventive guidelines, and includes routine in-app tasks that encourage active participation.

Research has demonstrated that long-lasting behavioral changes require the active engagement of participants, leading to increased self-efficacy.[3, 4] The primary objective of this study was to evaluate the development and efficacy of a mobile educational application in promoting a healthy lifestyle among patients with average to high ASCVD risk scores[9] and individuals aged 20 to 69. Our approach was guided by the Integrated Change Model (I-Change Model), which posits that various factors influence an individual's health status.[8]

According to the I-Change Model, these factors include an individual's awareness of the risks associated with specific behaviors, their self-awareness about engaging in such behaviors, and their belief that the proposed intervention can effectively mitigate these health risks. (For further details, refer to Additional File 1.)

Recognizing the importance of awareness in motivating individuals to adopt healthier behaviors, our mHealth app integrates this concept into its design. When people become aware of the health risks associated with specific behaviors, their motivation to change increases, driving them to take action to improve their health.[3] This motivation is crucial in transitioning individuals from the contemplation stage to the action stage, where they actively implement behavioral modifications. Our mHealth app takes these factors into account, focusing on ASCVD risk factors and emphasizing the role of awareness in fostering long-lasting lifestyle changes.

Methods

This study is a parallel, randomized, single-blind trial that aims to investigate how utilizing an educational app for 6 months can motivate individuals to modify their behavior, promote their health knowledge, and manage ASCVD risk factors and treatment adjustments. The Ethics Committee of Tehran University of Medical Sciences (IR.IUMS.REC.1397.932) approved the study protocol, and informed consent will be obtained from the participants. The principal reference used for this protocol is the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement. (See Additional File 2.)

To address the identified needs, we developed a 6-month mHealth intervention in the form of a smartphone application. The content and scope of the program were determined through a comprehensive needs assessment, literature review, and in-depth analysis of existing prevention guidelines.[3, 4] Figure 1 provides an overview of the app's content list. A team of software engineers designed the app with various features and functionalities, including interactive educational videos, user-friendly information on healthy habits (heart health, diet, disease information, ASCVD risk factors), stress management techniques, and customizable reminders for physical activity. The primary goal of this app is to raise awareness of CVD risk factors, motivate individuals to adopt preventive behaviors, and help them monitor key anthropometric indicators such as weight, blood pressure, blood sugar, healthy eating habits, tobacco use, and stress management. By providing users with an engaging and informative platform, we aim to equip them with the knowledge, skills, and tools necessary to effectively manage their ASCVD risk factors and reduce the likelihood of adverse outcomes.

Participants will be recruited from 10 health centers across

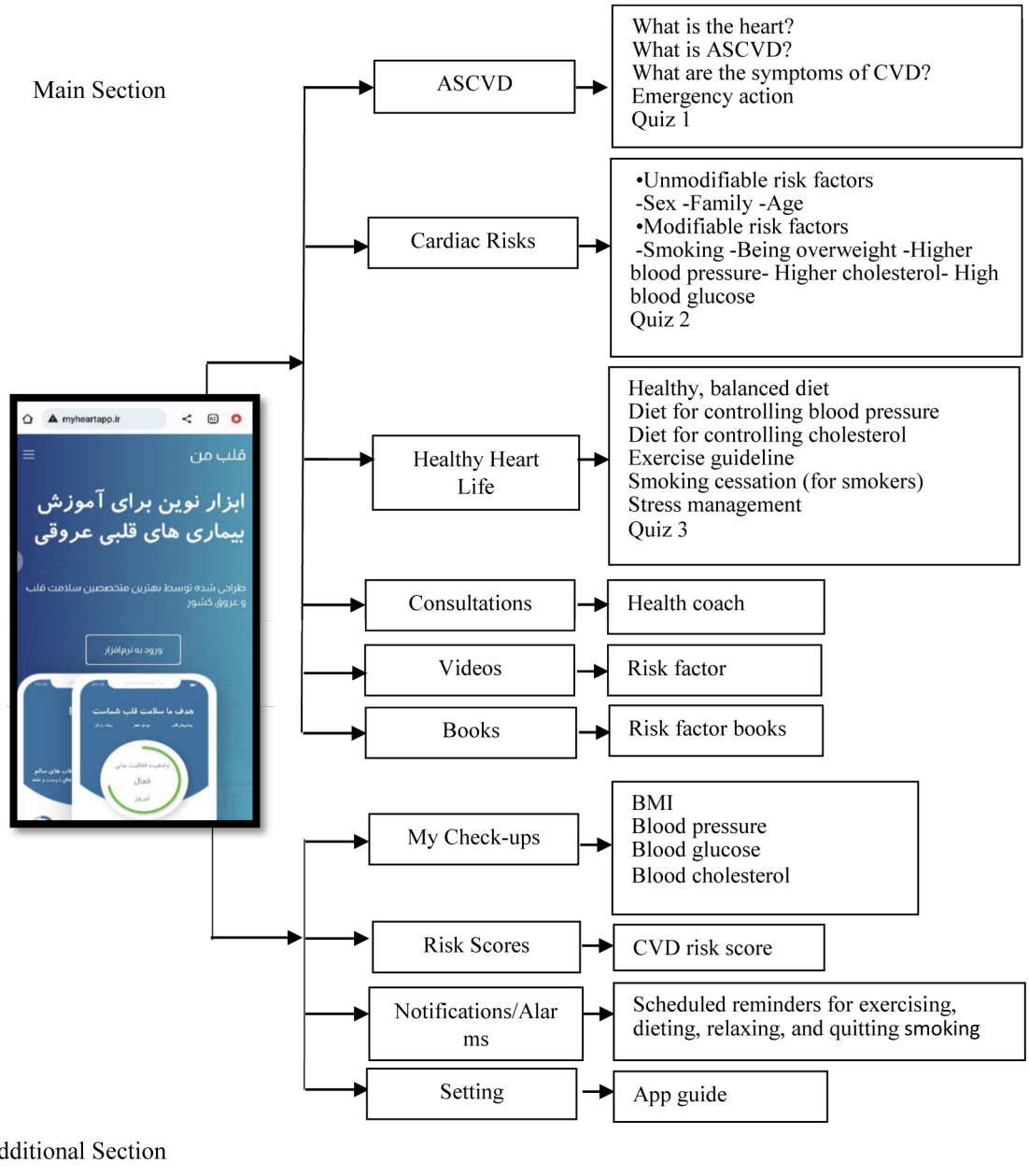

Figure 1. The image showcases the proposed sections of the app, providing an overview of the various features and components. ASCVD, Atherosclerotic cardiovascular disease; BMI, Body mass index

5 regions in Tehran. Eligible individuals will be identified through the European SCORE2 risk assessment tool[4, 9] and have a moderate or high risk of developing ASCVD within the next 10 years. These individuals will be referred to the Department of Primary Prevention of Cardiovascular Diseases at Tehran Heart Center for further evaluation and potential enrollment in the study.

This collaborative effort will involve the Tehran Municipality Health Department, Tehran Heart Center, and the Primary Prevention Research Center of Cardiovascular Diseases. Tehran Heart Center is a highly specialized healthcare facility focusing on CVD treatment, research, and education. This center is a leading institution in the region, renowned for its state-of-the-art facilities and specialized care in the field of CVD. With a capacity of 460 beds, the hospital provides exceptional care to a significant number of patients each year, including approximately 1,300,000 outpatients, 800,000 inpatients, and 55,000 individuals undergoing open heart surgery. In addition to its high patient volume, the hospital also performs a remarkable number of diagnostic and therapeutic procedures, including over 215,000 coronary angiographies, electrophysiology studies, coronary interventions, pacemaker implantations, and ablation procedures annually.[10]

Participants will complete a questionnaire at baseline and 6 months post-intervention to gather data on their knowledge, motivation, and behavior related to ASCVD risk factor prevention. The questionnaire is designed to assess various aspects, including physical activity levels, anthropometric indicators, adherence to a healthy diet, blood pressure, and weight management. Additionally, following the intervention, the degree of app utilization and satisfaction with the mHealth educational app will be evaluated specifically within the intervention group (Figure 2).

Participants in this study are aged 20 to 69 and have at least 2 risk factors for coronary atherosclerosis, such as hypertension or unhealthy eating habits, or had a risk score between 2.5% and 15% based on the European SCORE2 risk assessment tool.[4, 9] All participants will voluntarily enroll in the study and possess a mobile phone or tablet with the ability to operate the mHealth app. Each potential participant will undergo a physician-led evaluation to confirm their eligibility for the study. Once their inclusion criteria are verified, informed consent will be obtained before proceeding with baseline data collection using a structured questionnaire.

Participants will be excluded from the study if they meet any of the following criteria: the presence of uncontrolled chronic diseases, such as renal disease or chronic obstructive pulmonary disease; major depressive disorder or other mental health conditions; and a history of cancer, heart valve replacement, physical disability, myocardial infarction, or cardiac surgery within the preceding 6 months.

The study population will be randomly assigned to either the intervention or control group. The intervention group will receive an educational-supportive program delivered through a mobile phone application, which provides evidence-based information, motivational guidance, and essential skills for recognizing heart disease and managing its risk factors. In addition to standard care, the intervention group will also receive two 30-minute online consultations with a health coach at 1, 3, and 5 months. These personalized consultations aim to help participants develop tailored strategies for managing their risk factors based on their unique circumstances and characteristics. Furthermore, the intervention group will receive daily SMS reminders for 6 months, encouraging them to engage in regular physical activity, maintain healthy eating habits, control weight, manage stress, and quit smoking. The control group will receive standard routine care, which consists of laboratory

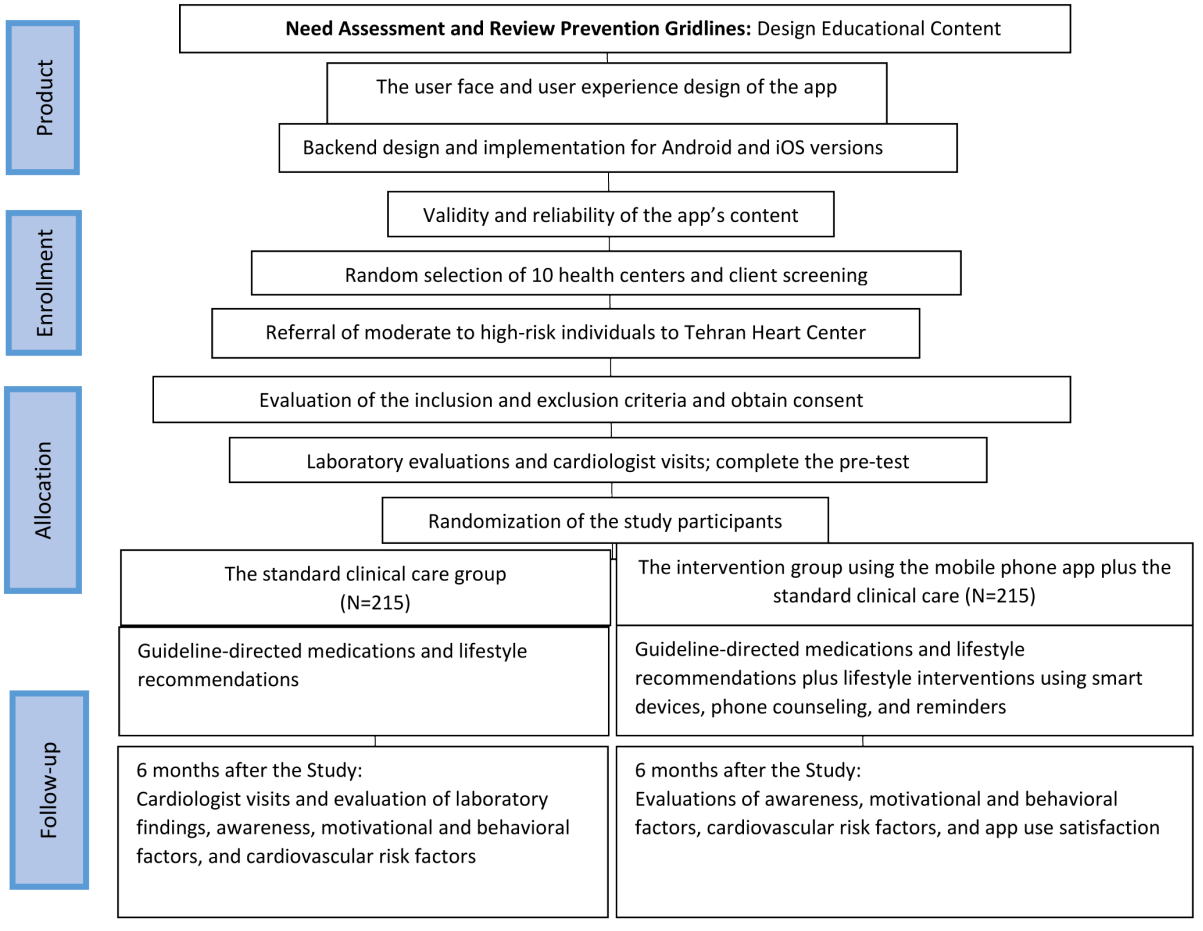

Figure 2. The image presents the study procedure.

evaluations, cardiologist consultations, medication, and other medical procedures at baseline and 6 months. The frequency of appointments and evaluations will be consistent across both the control and intervention groups.

For potential bias and interaction minimization between the groups, the control and intervention groups will be scheduled for separate appointments and will not be in contact with one another. Additionally, all participants will be asked to refrain from engaging in any other educational programs during the study period.

At the outset of the study, municipal health workers at 10 health centers will assess participants' CVD risk scores using the Healthy Heart app (https://delshad.tums.ac.ir), developed by the Healthy Heart Non-Governmental Foundation (registration number: 49185.) This app has been localized to ensure its relevance and applicability to the target population. The risk score will be calculated based on the European SCORE2 risk score chart for participants with available laboratory test results and the World Health Organization (WHO) risk score chart for those without laboratory tests, utilizing body mass index (BMI) as a key parameter.

To facilitate the cardiovascular risk assessment process, a link to the Healthy Heart app will be shared with the municipal health workers. They will access the app via a web-based database and input the participants' basic information, including age, sex, systolic blood pressure, total cholesterol, high-density lipoprotein, fasting blood sugar, HbA1c, height, weight, and smoking history. Using these data, the app will calculate each participant's heart risk score, categorizing it as low, medium, high, or very high risk. The health workers will then communicate these results to participants, enabling them to better understand their current cardiovascular health status and potential ASCVD risk factors.

Participants identified as having moderate to high heart risk scores by the municipal health workers will be referred to the Prevention Department of Tehran Heart Center for further evaluation. There, a researcher and cardiologist will re-examine their eligibility for the study and perform a comprehensive assessment of their cardiovascular health. Prior to the study, health workers at the 10 participating health centers will receive extensive training on using the screening software, ensuring consistency and accuracy in the initial risk assessment process. This standardized approach to participant identification and evaluation helps maintain the study's integrity and enables a more precise comparison of ASCVD risk factors and cardiovascular health outcomes between the intervention and control groups.

The study is to commence with an introductory meeting at the Prevention Department of Tehran Heart Center, where the objectives of the study will be explained to the intervention group. The study team's expectations and the participants' roles will be clearly outlined during this session. Following this, a written consent form will be obtained from each participant, ensuring they are well informed and willing to partake in the study. Subsequently, the participants will undergo a cardiologist consultation on separate days to confirm their eligibility and suitability for inclusion in the study. Once the inclusion criteria are verified, the participants will be randomly assigned to either the control or intervention group by a researcher using a pre-determined, randomized list.

All participants in the study, regardless of group assignment, will receive standard care, which includes initial recommendations for managing cardiac risk factors, additional medical examinations, and medication, if necessary. This ensures that both control and intervention group participants benefit from a baseline level of cardiovascular care and support throughout the study.

For participants in the intervention group, the educational mHealth application will be installed on their mobile devices. They will receive comprehensive instructions on the app's functionality and how to customize it to best suit their individual needs and preferences.

During the initial setup, the intervention group will work with the mHealth application under the guidance of the research team. Any issues or concerns will be addressed promptly, ensuring a smooth onboarding process. This introductory session will last approximately 20 to 30 minutes, during which participants will be provided with an instructional video on the app's usage and guided through the registration of their ASCVD risk factors. To calibrate the blood pressure monitoring feature of the app, participants' personal sphygmomanometers will be synchronized with the application during installation. If significant discrepancies in blood pressure readings are detected or if a participant's sphygmomanometer is found to be faulty, they will be advised to replace their device.

The mHealth application employs scheduled pop-up messages to deliver targeted reminders and recommendations at regular intervals, promoting continuous engagement and sustained behavior change. Furthermore, user data collected on the server will be utilized to monitor compliance and tailor the intervention according to individual needs. A dedicated server has been developed to collect and store user activity data, including the duration and frequency of app usage, specific features accessed, and health-related information such as weight, blood pressure, and test results. The data are automatically uploaded and saved on the server whenever the user's mobile device is connected to the Internet. The information gathered on the server will serve as a valuable resource for tracking participant adherence to the intervention and identifying areas where additional support or adjustments may be required. By leveraging these data, the research team will be able to optimize the mHealth app's effectiveness in promoting positive lifestyle changes and reducing ASCVD risk factors.

The primary objective of this study is to evaluate the impact

of the mHealth intervention on ASCVD risk management by examining factors related to awareness (eg, knowledge), behavior (eg, behavioral barriers), and motivation (eg, attitude) based on the I-Change Model. These factors will be assessed through a researcher-developed questionnaire, which also measures participants' satisfaction with the mobile app experience. The Persian version of the User Experience Questionnaire (UEQ) is administered at baseline, 3 months, and 6 months post-intervention to gauge user satisfaction and evaluate changes in their ASCVD risk management over time.[11, 12] The UEQ provides insights into participants' personal and demographic information, treatment status, and specific health-related behaviors.

Clinical evaluations will be conducted at baseline and 6 months post-intervention to assess changes in various ASCVD risk factors and cardiovascular health indicators. These evaluations include measurements of diastolic and systolic blood pressure, fasting blood sugar, HbA1c, high-density lipoprotein, low-density lipoprotein, total cholesterol, triglycerides, waist circumference, and BMI. The National Survey Questionnaire on Noncommunicable Disease Risk Factors (STEPS) Instrument[13] will be employed to collect and analyze these measurements. The International Physical Activity Questionnaire-Short Form (IPAQ) will be administered to participants at baseline and 6 months post-intervention to assess the impact of health habits on ASCVD risk.[14] Additionally, the WHO STEPS Instrument[13] will be utilized to measure various health behaviors related to ASCVD risk, including healthy diet, treatment adherence, stress management, and smoking cessation.

The sample size for this study was determined using G*Power software (version 3.1.9).[15] To achieve a large effect size (d=0.3) with a statistical power of 0.8 and a significance level of 0.05, a total of 352 participants (n=176 per group) were deemed necessary. Nonetheless, considering an anticipated 15% dropout rate, the sample size was increased to 430 participants (n=215 per group) to ensure sufficient statistical power throughout the study.

Table 1. Procedures performed in each visit
From: "Comparing the effectiveness of a mobile phone application program and usual care in increasing knowledge and creating motivation for cardiovascular health management and preventive behavior of its risk factors in patients aged 20 to 69 years: study protocol for a randomized controlled trial"

	Study Period													
	Enrollment	Allocation	Intervention (time in w= week; m= month)										Study End	
Time point	××××××	0	1m		2m		3m		4m		5m		6m	
			1w	4w	6w	8w	10w	12w	14w	16w	18w	20w	22w	24w
Enrollment:														
Eligibility screening	×													
Informed consent	×													
Allocation		×												
Interventions:														
Physician visits		×												×
Consultation/response to questions				×				×				×		
Self-education by the app			◆	—	—	—	—	—	—	—	—	—	—	◆
Reminder SMS					◆	—	—	—	—	—	—	—	—	◆
Control group (usual care)			◆	—	—	—	—	—	—	—	—	—	—	◆
Assessments:														
Demographic characteristics and predisposing factors		×												
Anthropometry		×												×
Laboratory measurements		×												×
Questionnaires*		×												×
Usability and the level of satisfaction with the app														×

*Questionnaires include items for measuring awareness, motivation, and behavioral factors based on the structures of the I Change Model 2.0.

Participants referred to Tehran Heart Center from 10 health centers in 5 districts of Tehran Municipality will be randomly assigned to either the intervention or control group following the assessment of their initial ASCVD risk score and confirmation of meeting inclusion criteria. The randomization sequence will be generated using the online sealed envelope website, ensuring unbiased group allocation. A random sequence generation file was created by a statistician using the block method for 6 variables. Based on a block size of 4 participants, all individuals will be divided into 2 equal groups (n=108 blocks). A statistical expert, who is not a part of the research team, will then create a random sequence. The data will be subsequently entered into SPSS and provided to the data analyst in coded form, ensuring that the data analyst remains blinded to the group assignments.

According to Table 1, the intervention group will be followed up through 2 visits and 3 phone consultations, while the intervention group will go through 3 phases: pre-test, instructing, and post-test stages.

During the first visit for the intervention and control groups, the researcher will administer an initial evaluation questionnaire to assess participants' knowledge, motivational factors, and behavioral factors related to ASCVD. The questionnaire will also gather information on participants' predisposing factors, and laboratory tests and clinical parameters will be evaluated before the start of the intervention. For the intervention group, the educational content will be activated immediately after completing the pre-test form. The intervention group will have access to the tailored instructional content through the mHealth app for a duration of 6 months. This content will be based on the needs assessment results and recommendations from the primary prevention of ASCVD guidelines, specifically focusing on classes AI, IIA, and IB.

Following the initial visit, the intervention group will receive telephone consultations at 1, 3, and 5 months after receiving the mHealth app. These consultations will be conducted by a health coach, who will guide participants in finding tailored solutions for managing ASCVD risk factors based on their individual characteristics and living conditions. The health coach will also gather feedback on the implementation of the educational program and address any issues that may arise. Should any problems be reported, the research team and application specialists will work together to resolve them promptly. After the first consultation, the intervention group will receive a reminder SMS to ensure continued engagement with the app and the adoption of recommended lifestyle changes.

It is important to note that the control group will not receive reminder messages or telephone counseling during the study.

After 6 months, the intervention and control groups will attend a second visit. At this point, access to the educational materials will be discontinued for the intervention group. During the second visit, both groups will complete the initial questionnaire again, allowing for the evaluation of changes in awareness, motivational, and behavioral factors following the intervention. Laboratory tests will be repeated, and a cardiologist will perform clinical reevaluations for all participants. The intervention group will receive an online questionnaire to assess its satisfaction with the mHealth app and its usability. This feedback will provide valuable insights into the app's effectiveness and user-friendliness, allowing for potential improvements in future iterations of the application.

Throughout the study, various health indicators will be monitored for all participants at each visit, including heart rate, weight, height, blood pressure, blood sugar, waist circumference, hip circumference, and lipid profile. Participants in the intervention group will also measure their heart rate, blood pressure, and fasting blood sugar daily at home while tracking their weight, waist circumference, and hip circumference weekly.

Two sources will be used to collect the participants' information: 1) digital data gathered on the server and 2) the WHO STEPS, a UEQ questionnaire, and an I-Change Model and questionnaire, to be filled out by the researcher. The data will be analyzed via an SPSS database according to a predefined data dictionary. Data validity will be verified by using double entry for data inclusion.

Frequency and percentage frequency will be used to analyze the descriptive findings, while mean and standard deviation will be employed for quantitative findings. The analysis of covariance (with a 95% confidence interval) will be applied to evaluate the effectiveness of the principal variables. This procedure will be repeated for all quantitative variables, and the remaining qualitative variables will be compared using the $\chi 2$ test between the 2 groups. The outcomes will be assessed for each protocol, and any missing data will be handled through multiple imputation methods to ensure the integrity and robustness of the study findings.

Discussion

The rising prevalence of ASCVD, attributed to unhealthy lifestyles and an aging population, necessitates the development of novel approaches within healthcare systems.[7] In response to this challenge, the proposed study aims to investigate and compare patients' ASCVD risk scores to assess the efficacy of a mobile phone-based, theory-driven educational intervention in promoting health and reducing risks. The study incorporates 3 innovative elements to evaluate the impact of health interventions in preventing primary CVD: 1) Social partnership: Collaboration with the Tehran city municipality to identify and monitor high-risk groups within the community. 2) Mobile phone technology: Utilizing an accessible and continuous educational tool,

the mHealth app, for delivering targeted interventions. 3) Personalized guidance: Health coaches will provide tailored solutions for managing risk factors based on individual characteristics and living conditions.

Previous systematic review studies on behavioral interventions in the general adult population have demonstrated their positive effects on CVD risk factors.[16] Consequently, this research has the potential to offer a groundbreaking approach to managing cardiovascular health through mobile apps, thereby contributing to the growing body of evidence on the efficacy of digital health interventions.

Addressing ASCVD risk factors through education and promoting healthy lifestyle choices is crucial for effective prevention.[8] In order to boost motivation and education among high-risk groups, it is necessary to explore innovative approaches that go beyond conventional clinical methods. Mobile technologies, such as mHealth applications, present a promising opportunity to tackle this challenge.[2] Several studies have compared mobile technology-supported healthcare with traditional medical care, yielding positive results in various areas, such as weight control,[17] hypertension management,[18, 19] physical health,[20] smoking cessation,[1, 20-22] and HbA1c levels among diabetic patients. Despite these promising findings, the number of studies examining the impact of mobile tools on controlling CVD risk factors remains limited. To address this research gap, our study focuses on a community-based intervention, leveraging mobile technology to assess its potential in managing and reducing ASCVD risk factors within a real-world setting.

The development and implementation of the educational content were guided by a needs assessment based on the behavioral structures of the I-Change Model.[23] This model identifies 3 key factors (awareness, behavioral, and motivational) that contribute to successful behavior change. The I-Change Model postulates that for genuine behavior change to occur, enabling factors, including motivation, awareness, and predisposing factors, must be present within the individual. In essence, the I-Change Model seeks to promote future behavior change by cultivating awareness of current behaviors. The model's emphasis on addressing various factors influencing behavior, such as motivation, awareness, and predisposing factors, supports the efficacy of theory-based interventions in targeting diverse health-related outcomes.[24-27] Educational research highlights the importance of incorporating theory or a combination of theories to effectively address the complex nature of health-related issues.[27]

Although many social cognitive models recognize the significance of motivational factors in health behavior, fewer models emphasize the importance of individuals' self-awareness regarding their current behavior. In contrast, the I-Change Model not only prioritizes self-awareness about current behavior but also postulates that behavior change evolves through cognitive stages – from lack of awareness about behavioral consequences to active engagement in health behavior modification.23 Consequently, it is crucial for an individual to first acknowledge their unhealthy behavior and understand the steps they can take to alter it before forming motivation and intention to change. Given the I-Change Model's distinct focus on self-awareness and its staged approach to behavior change, the study leverages these unique features in the design of the mHealth app's content. By integrating the model's principles into the educational intervention, the study aims to enhance the effectiveness of the app in promoting awareness, motivation, and, ultimately, positive behavioral changes among participants at risk for ASCVD.

Despite the potential benefits of this study, there are some limitations to consider: 1) Participant dropout: There is a risk of participants dropping out or not cooperating in attending the training sessions at the Department of Prevention. To mitigate this, incentives such as free visits for participants or their family members will be offered. 2) Technical difficulties: Issues with installing and using the mobile app might arise. To address this, face-to-face meetings, telephone counseling, and open communication with the researcher will be available to provide support. 3) Language constraint: The app is available only in the Persian language, which may limit its accessibility to non-Persian-speaking populations.

However, the study also possesses several notable strengths. 1) Evidence-based content: The app's content is grounded in evidence-based practices approved by cardiology experts, ensuring its applicability to diverse ethnic, cultural, and social populations. 2) Privacy protection: The app prioritizes user privacy, securely recording, storing, and providing feedback on participants' health data. 3) Urban population sampling: The study includes participants from urban settings, enhancing the generalizability of findings to similar populations. 4) Cost-effectiveness: The educational intervention is designed to be cost-effective, allowing for broader accessibility and potential scalability.

By acknowledging these limitations and capitalizing on the study's strengths, the potential impact of the mHealth intervention on promoting cardiovascular health and reducing ASCVD risk factors among urban populations can be more accurately assessed.

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Additional File 1

Content design, questionnaire, and application theory

This study comprises 2 components: 1) the development of educational content for a mobile app program and 2) an educational intervention based on the integrated behavior change model and the behavior change-evaluation model, which aims to promote primary prevention of risk factors for coronary atherosclerotic diseases. In the first part of the study, the mobile phone program's content will be developed using a qualitative approach, based on the needs assessment of classes I, II, and IIa of the primary prevention of risk factors in the guidelines for the prevention of atherosclerotic diseases of the coronary arteries. To collect data for the model's construction, patient interviews will be conducted. A questionnaire, based on the knowledge acquired from these interviews, will be provided to 12 physicians and health education professionals to assess its validity using the content validity ratio (CVR) and the content validity index (CVI). A reliability study will be conducted by administering the questionnaire to 30 patients, followed by the calculation of the Cronbach's α index to confirm its reliability.

The second part of the study will adopt a randomized controlled clinical trial with a parallel design to develop a smart mobile phone training program based on the structures of the integrated behavior change model (I-Change Model). The intervention's effectiveness in promoting primary prevention of disease risk factors will then be evaluated.

In this study, the integrated behavior change model will assess the prevention behavior of coronary atherosclerotic disease risk factors based on the following constructs:

Information factors:

1. Message (eg, level of discrepancy between message and target group's beliefs)
2. Channel (eg, mass media strategies)
3. Source (eg, trustworthiness of source)

In this study, face-to-face training during the 2 initial and final visits, counseling, and health coaching via phone calls, text messages, and a smart mobile phone application will be the selected information factors.

Predisposing factors:

1. Behavior (eg, lifestyle and prior experiences)
2. Psychological (eg, traits and personality)
3. Biology (eg, sex, age, and genetic predisposition)
4. Social culture (eg, socioeconomic status and policies)

Demographic questions will be asked of the participants to identify the predisposing factors that affect their behavior. These factors include the history of health problems, family numbers, income, employment status, level of education, family status, and health insurance coverage.

The pre-motivational stage, or awareness stage:

1. Knowledge,
2. Risk perception
3. A guide to action

Pre-motivational factors will be addressed via the mobile phone program menus by providing information about cardiovascular disease, heart physiology, prevalence, signs, and symptoms, prevention strategies, and reframing positive and negative thoughts and beliefs about atherosclerotic diseases. To address the pre-motivational factors, the mobile phone program will provide information about the coronary arteries, modifiable and non-modifiable risk factors of coronary atherosclerotic diseases, and how to prevent them. Benefits and obstacles of preventive behavior, as well as healthy lifestyle tips (including healthy diets, physical activity, smoking cessation, blood lipid control, blood sugar control, obesity/overweight control, blood pressure control, and stress management), and video clips on how to control risk factors, will be presented.

The motivational stage:

1. Attitudes: cognitive and emotional benefits and drawbacks of behavior
2. Social influences: social norms and expectations
3. Self-efficacy: expectations about one's ability to engage in a given behavior

Motivational factors will be addressed via mobile phone app menus, face-to-face motivational interviews during 2 visits, and text messages to reinforce positive behaviors aimed at achieving proper personal management of risk factors. The app will include quotes from credible sources to support the validity and reliability of the information provided. A technical service and technical communication will be available in the "Settings" tab to provide technical support. Moreover, a video tutorial will guide users on how to use the program effectively. Additionally, SMS warnings and notifications will be sent to

the phone number of one of the participant's family members in case of emergencies, thus providing further support to the participant.

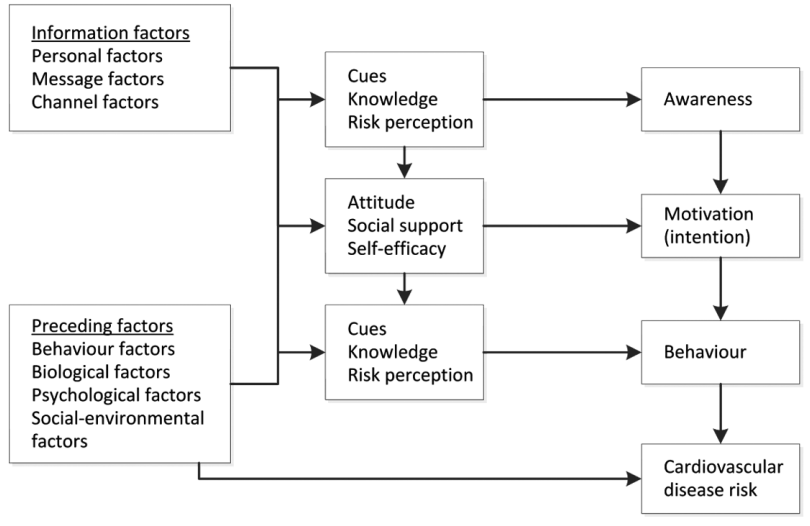
The post-motivational or behavioral phase:

1. Functional skills
2. Intention
3. Behavioral barriers

The following will be evaluated in the behavior phase:

1. Body mass index (BMI) calculation, height, weight, and abdominal girth monitoring (weekly feedback in the form of graphs and progress/regression displayed to the software user)
2. Blood pressure and heart rate monitoring (monthly feedback provided)
3. Heart disease risk assessment
4. Self-assessment section
5. Coronary atherosclerotic disease risk factors

Telephone counseling and guidance videos will be provided to assist users in overcoming behavioral barriers.



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Additional File 2

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	First page
Trial registration	2a	Trial identifier and registry name. If not yet registered, the name of the intended registry	Page 3
	2b	All items from the World Health Organization Trial Registration Data Set	Page 3
Protocol version	3	Date and version identifier	Page 3
Funding	4	Sources and types of financial, material, and other support	Page 11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 11
	5b	Name and contact information for the trial sponsor	Page 11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Investigator-initiated trial (PhD dissertation)
	5d	Composition, roles, and responsibilities of the coordinating center, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Page 11
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including a summary of relevant studies (published and unpublished) examining the benefits and harms for each intervention	Page 3
	6b	Explanation for choice of comparators	Page 4-6
Objectives	7	Specific objectives or hypotheses	Page 3-5
Trial design	8	Description of trial design including the type of trial (eg, parallel-group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	Page 3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where a list of study sites can be obtained	Page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centers and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 8-9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 8-9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6-7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 7
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 8-9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 8
Recruitment	15	Strategies for achieving adequate participant enrolment to reach the target sample size	Page 8

Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce the predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	Page 8-9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 8-9
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions?	Page 8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Page 8
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of the outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 10
	18b	Plans to promote participant retention and complete follow-up, including a list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	-
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 9
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomized analysis), and any statistical methods to handle missing data (eg, multiple imputations)	Page 9
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent of the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent of investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 11
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	-
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	Page 3
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained to protect confidentiality before, during, and after the trial	Page 11
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 11

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data-sharing arrangements), including any publication restrictions	Page 12
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	Persian language
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.