Mobile App And Digital System For Patients After Myocardial Infarction (AfterAMI); Study Protocol For A Randomized Controlled Trial

Bartosz Krzowski
Medical University of Warsaw https://orcid.org/0000-0001-9987-870X
Michał Peller (michalpeller@gmail.com)
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Maria Boszko
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Paulina Hoffman
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Natalia Żurawska
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Karolina Jaruga
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Kamila Skoczylas
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Gabriela Osak
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Łukasz Kołtowski
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Marcin Grabowski
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Grzegorz Opolski
Medical University of Warsaw: Warszawski Uniwersytet Medyczny
Paweł Balsam
Medical University of Warsaw: Warszawski Uniwersytet Medyczny

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Abstract

Background: Treatment of acute myocardial infarction has been studied and improved over the past years. However, the initial months after myocardial infarction are crucial from the perspective of the patient's prognosis. It is extremely important to take care of all cardiovascular risk factors.

Mobile application 'afterAMI' supported by a web system is a novel telemedical tool developed to support patients and physicians during cardiac rehabilitation. The application has an educational model with a focus on cardiovascular risk factors and lifestyle after myocardial infarction. Moreover, it offers a module that controls vital signs like blood pressure, heart rate, weight, and many others. Additionally, the application will send reminders for better drug adherence.

Methods: A group of 100 patients with myocardial infarction on admission at the 1st Chair and Department and of Cardiology, Medical University of Warsaw, will be recruited into the study. The project aims to assess the impact of the application-supported model of care in comparison with standard rehabilitation. At the end of the study, cardiovascular risk factors will be analysed, along with issues like rehospitalizations, patients' knowledge of risk factors, returning to work, and quality of life. In this prospective, open-label, randomized, single-center study, all 100 patients will be observed for 6 months after discharge from the hospital. Endpoints will be assessed during control visits 1- and 6-months after inclusion into the study.

Discussion: This project is an example of a telemedical solution application embracing everyday clinical practices, conforming with multiple international cardiac societies' guidelines. Cardiac rehabilitation process enhancements are required to improve patients' prognosis. The evidence regarding the use of the mobile application in the described group of patients is limited and usually covers a small number of participants. The described study aims to discuss whether telemedicine use in this context is beneficial for the patients.

Trial registration: ClinicalTrials.gov, NCT04793425, registered 11 March 2022.

Introduction

Background and rationale {6a}

Cardiovascular diseases are the leading cause of death and a focal contributor to disability. Acute myocardial infarction (AMI) treatment has improved significantly over the past years, and the vast majority of patients with the acute coronary syndrome (ACS) can be treated in the cath lab. The mortality rate following AMI varies between countries, but an overall decrease has been observed (1). Nevertheless, 12% of the patients die within one year after AMI (2). Therefore, efforts should be made to optimize the cardiac rehabilitation process. It is crucial to focus on preventing future ischemic events by providing optimal care for patients at-risk (3). Secondary prevention aims to control all cardiovascular disease (CVD) risk factors, which may be challenging in everyday practice. Jankowski *et al.* reported that only

2.9% of patients with coronary artery disease (CAD) have all CVD risk factors controlled corresponding to values recommended in the guidelines (4). Proper CVD risk factor control remains a challenge in the real-world setting.

Several efforts are being made to improve patients' prognosis. The latest approach to improve cardiac rehabilitation is the use of novel telehealth-based solutions. Over 3.2 billion smartphones are used globally, and the mobile applications market is expected to grow by 18.4% between 2018 and 2026. Therefore, enhancing cardiac rehabilitation by mobile application support appears to be a promising tool. Telemedicine has proved to be an effective tool in many clinical scenarios. Widmer *et al.* demonstrated that augmentation of usual cardiac rehabilitation with an online and smartphone-based program improved CVD risk factor management and reduced rehospitalizations or emergency department visits by 40% ($p<0.05$) (5). The educational aspect has also been studied. It appeared that application and virtual-reality-based knowledge compendiums are regarded as user-friendly (6). Coorey *et al.* concluded in the meta-analysis that mobile applications have a beneficial influence on CVD risk factors control, but more scientific evidence is required to enhance the implementation of telemedicine into clinical practice (7).

Although several international cardiac societies recommend telemedicine use (8, 9), evidence-based conclusions are required to adjust specific telemedical tools individually to the patient and improve the prognosis. The influence of mobile application support on cardiac rehabilitation in a European setting is yet to be studied.

Objectives {7}

This study will aim to determine the effect of mobile application-supported cardiac rehabilitation on CVD risk factors control, rehospitalization, and emergency department visits, quality of life, and the ability to return to work. We hypothesized that cardiac rehabilitation enhancement with the mobile application would improve prognosis by CVD risk factors management. Moreover, we expect that the intervention will improve patients' quality of life.

Trial design {8}

This protocol is a randomized, open-label, interventional study with two arms. Participants will be randomized to (1) a control group (CG) with standard cardiological care or (2) a mobile application-supported interventional group (IG). The anticipated number of participants is 100.

Methods: Participants, Interventions And Outcomes

Study setting {9}

This single-center study will be carried out at the 1st Department of Cardiology at the Medical University of Warsaw, an academic, public hospital in the capital of Poland. Cardiologists and fellows of cardiology will conduct all study-related procedures. The Department ensures all treatment options for patients with

AMI and during their cardiac rehabilitation process. It is regarded as the leading Department of Cardiology in Poland.

Eligibility criteria {10}

Inclusion Criteria:

- signing the informed consent to participate in the study
- hospitalization due to myocardial infarction
- owning a mobile device with Internet access and the Android/iOS operating system
- age >17 years old
- positive results of a test verifying the basic skills of using mobile applications

Who will take informed consent? {26a}

After screening a list of patients admitted to the department of cardiology, a staff member will check the reason for admission. A study team member will approach every patient presenting with AMI, and the inclusion criteria will be assessed. The study design will be thoroughly described to the patient, including all potential benefits, harms, and ethical implications. Each eligible patient will be proposed to enter the study. If the patient agrees to participate in the research, the informed consent will be signed in 2 copies: one for the participant and one for the research archives. Every participant will receive a note with a summary of the study design.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable; this trial does not have biological specimens.

Interventions

Explanation for the choice of comparators {6b}

Participants will be randomly assigned to one of the two groups (1) a control group with standard cardiological care or (2) a mobile application-supported interventional group.

Intervention description {11a}

The rehabilitation process of patients in the intervention group will be supported by the mobile application (afterAMI) with a synchronized, dedicated web page.

Patients in the intervention group will also be given access to educational data regarding their diseases. Every educational chapter was prepared by a cardiologist experienced in managing patients after MI.

Additionally, every patient will regularly (at least 2 per week) receive messages with notifications about lifestyle interventions and adherence to therapy.

Another essential feature of the application is the possibility to report patients' vital signs (blood pressure, heart rate, weight, and other), which will be daily analyzed and if necessary, a short message will be sent to the patient, advising to present to the primary healthcare clinic or emergency department. A possible clinical scenario is an alarming rapid bodyweight increase, which might foreshadow incoming heart failure exacerbation.. Another potential use of the application lies when the patients report rapid pulse. In this case, new-onset atrial fibrillation might be suspected. In every case requiring confirmation, the patient will be referred to the nearest emergency room. However, all patients will be informed that they should immediately present to the nearest emergency unit or contact the emergency services in case of recurring angina or any other acute complaints.

Additionally, the application will send notifications with reminders to take drugs. This solution has been previously evaluated in many studies and proved to be a successful tool in increasing adherence to the therapy (10).

Moreover, the application includes a module with air pollution parameters measured amidst the localization setup. If they exceed the alarming levels, the patients will be notified, and outdoor physical activities will be minimized.

Moreover, every patient will have a medical history card created based on the discharge documents from the hospital. This solution aims for the patient always to have brief information about underwent coronary interventions. This knowledge might be crucial for the physicians performing the subsequent percutaneous coronary intervention (PCI) and might decrease time-to-balloon.

Finally, the application offers a possibility to text message and call the physician and the hospital. We believe that this will translate into better work organization, better time management (as fewer consultations are likely to be missed by patients), and patient safety.

Criteria for discontinuing or modifying allocated interventions {11b}

The only criterion for discontinuing is the participants' request.

Strategies to improve adherence to interventions {11c}

Not applicable; this trial does not have strategies to improve adherence.

Relevant concomitant care permitted or prohibited during the trial {11d}

Not applicable; this trial does not have concomitant care permitted or prohibited.

Provisions for post-trial care {30}

Not applicable; participants will continue with traditional care after the trial is finished. Trial participation is beneficial for the patients due to more intense medical care. Every patient included in the study will have two additional cardiological consultations.

Outcomes {12}

All 100 patients will be observed for 6 months after discharge from the hospital. We will assess the Endpoints during two control visits, in 1- and 6-months, after inclusion in the study. Primary outcomes encompass rehospitalization or urgent outpatient visit and cardiovascular risk factors control (blood pressure, body mass, nicotinism, dyslipidemia). Secondary outcomes will include quality of life and depression severity assessment (MacNew, EQ-5D-5L, and DASS-21 questionnaires), cardiovascular risk factors' knowledge, and return to work in case of professionally active patients.

Moreover, data collection will include sex, age, laboratory tests, and prescribed pharmacotherapy.

Rehospitalization or urgent outpatient visit

The number of admissions to hospital or urgent outpatient visits will be assessed between baseline and control visits.

Cardiovascular risk factors

Blood pressure

All patients at discharge from the hospital are asked to measure and note blood pressure values daily. The mobile application-obtained mean blood pressure values covering 5 days prior to their visits will be averaged for the IG patients. The mean blood pressure values of CG-comprised patients will also be averaged but based only on the presented notes. Additionally, meeting guidelines-based recommended values will be checked in both groups. Hypertension is one of the main cardiovascular risk factors, with a significant prevalence of 1.13 billion worldwide (11). Hypertension control in patients after MI is crucial and correlates with patients' prognosis (12).

Body mass

All patients will be weighed at admission to the hospital and during control visits 1- and 6-months after discharge. Weight change will be measured. Maintaining healthy body weight is one of the fundamental aspects of preventing cardiovascular diseases and an essential treatment element after an MI.

Nicotinism

All patients will be asked about smoking at admission and during control visits 1- and 6-months after discharge. Smoking cessation is one of the main goals of patients after MI. Quitting smoking is necessary to reduce the risk of another ischemic incident. It has been documented that patients who stopped smoking have reduced the risk of another MI by 50% (13).

Dyslipidemia

All patients after MI will have their cholesterol levels measured during hospitalization. Subsequent cholesterol level measurements will be performed during control visits. According to ESC guidelines, different groups of patients have different LDL cholesterol target values, which should be met during the rehabilitation process (14). Lowering LDL cholesterol levels correlates with a better prognosis after MI (15).

Secondary Outcome Measures:

Quality of life – MacNew (16)

Quality of life will be assessed with the MacNew questionnaire containing 27 questions. The scoring of the MacNew is as follows, the maximum score in every domain is 7 [high quality], and the minimum is 1 [poor quality]. The quality of life is assessed in the context of physical, emotional, and social aspects.

Quality of life - descriptive profile of the respondent's health state (17)

Quality of life will be assessed with the help of the EQ-5D-5L questionnaire, gauging 5 aspects: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Every segment is assessed based on a 5 level scale:

LEVEL 1: indicating no problem; LEVEL 2: indicating slight problems; LEVEL 3: indicating moderate problems; LEVEL 4: indicating severe problems; LEVEL 5: indicating an inability to/extreme problems

DASS 21 - Depression, anxiety and stress assessment (18)

Depression, anxiety, and stress assessment will be assessed with DASS 21 scale. The DASS is a quantitative measure of distress along the 3 axes of depression, anxiety, and stress.

There are 21 questions; each has 4 possible answers:

0 Did not apply to me at all - NEVER

1. Applied to me to some degree, or some of the time - SOMETIMES
2. Applied to me to a considerable degree, or a good part of the time - OFTEN
3. Applied to me very much, or most of the time - ALMOST ALWAYS

Seven questions are assigned to every aspect: depression, anxiety, and stress.

Higher result in each section contributes to higher severity in depression, anxiety, and stress.

Cardiovascular risk factors knowledge

Cardiovascular risk factors knowledge will be assessed with a previously prepared questionnaire (10 questions).

Return to work

In the cases of previously working patients, the likelihood of returning to work will be assessed, and the timing of returning to work will be counseled.

Participant timeline {13}

Figure 1 shows the recommended SPIRIT figure with the participant timeline.

Sample size {14}

Currently, the data regarding the reduction of rehospitalizations or urgent visits impacted by mobile applications is limited. Previous studies were conducted on smaller populations. This calculation was based on Widmer and colleagues' (5) study, considering rehospitalization and urgent ambulatory visits — comparing the effects of an online and smartphone-based program with standard rehabilitation on the mentioned endpoint. There was a 40% decrease in the primary endpoint. 50% of patients in the control group and 20% in the interventional arm were rehospitalized or visited the emergency department.

An online calculator (https://clincalc.com/) was used to determine the sample size, assuming the power of 80% and significance of 5%. A total of 76 patients (38 per group) were required. However, considering a possible lost-to-follow-up group and possible dropouts, a decision to recruit 100 patients was made.

Recruitment {15}

Participant recruitment will occur daily from Monday to Friday. Patients eligible for the study and willing to participate will be provided with complete and detailed information on the study protocol. Lastly, patients will sign two copies of the informed consent.

Assignment of interventions: allocation

Sequence generation {16a}

Concealment mechanism {16b}

Implementation {16c}

Randomization will be performed with an online tool available at https://www.randomizer.org. A hundred sets will be generated, each with a number (1 for CG and 2 for IG). All allocations to CG and IG will be executed before the study begins. The list of subsequent allocations will not be visible for the recruiting physician until the initial eligibility assessment of the patient and obtaining the patient’s consent for study participation. After collecting the initial documentation, the physician will be unblinded and receive the group allocation information from the principal investigator. Figure 2 shows the study design flow chart, describing all the steps of the study (Fig. 2).

Assignment of interventions: Blinding

Who will be blinded {17a}

This is an open-label study. The only blinded study participants will be physicians who will check the patients' will to participate in the study. After obtaining agreement, the randomized group will be unblinded.

Procedure for unblinding if needed {17b}

This is an open-label study. The recruiting physicians will be unblinded after obtaining agreement from the patient.

Data collection and management

Plans for assessment and collection of outcomes {18a}

The assessments will be carried out at the 1st Department of Cardiology, Medical University of Warsaw, and the rehabilitation will follow a scheduled program. The intervention involves installing the afterAMI mobile application on patients' smartphones. Control visits will take place in the cardiac ambulatory clinic. Blood samples will be sent to the local laboratory. Patients will be asked to fulfill the MacNew, EQ-5D-5L, and DASS21 questionnaires. An experienced cardiologist familiar with the study protocol will conduct all the control visits.

Plans to promote participant retention and complete follow-up {18b}

Patients will be called to schedule the control visit's date after discharge. Additionally, patients in the IG will receive a notification in their mobile app reminding them about the upcoming ambulatory visits.

Data management {19}

All data collected during the study and medical documents will be protected and stored in a room dedicated to clinical trials' records. All electronic materials will be duly stored in the principal researcher's computer protected with a password known only to the principal researcher. Additionally, a backup in the cloud will be performed after new data collection.

Confidentiality {27}

The highest level of confidentiality will be applied. The participants' data will be kept separately from any identifying information. According to good clinical practice, all investigators will make every effort to keep the sensitive data confidential.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable; all blood samples will be tested in the laboratory according to the locally implemented standards and subsequently utilized. There are no plans for future blood use. No other biological specimen will be tested during this trial.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The distribution of continuous variables will be estimated using the Shapiro-Wilk test. In the case of variables with a normal and non-normal distribution, the groups will be compared using the Student's t-test and the non-parametric Mann-Whitney U test. The comparison of qualitative variables between the groups will be performed using the Fisher exact test. In order to compare changes in the values of continuous variables over time, the analysis of variance will be performed. To compare the outcome of the patients, the Kaplan-Meier estimators will be utilized.

Interim analyses {21b}

Not applicable; interim analyses will not be performed in the present study.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Not applicable; additional analyses are not planned in the present study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

A per-protocol analysis will be performed after completing all of the follow-up visits. In the analysis, we will include all patients who meet inclusion criteria and sign informed consent regardless of the follow-up completion. Statistical calculations will be performed twice; after obtaining data from the first follow-up visit from all patients and after the final follow-up, 6 months after discharge. In case of missing data, patients will be excluded from the particular analysis.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Not applicable; access to the data sets and statistical code are not planned for this study. However, this material might be available upon an adequately justified request to the corresponding author while maintaining participants’ anonymity.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The research center is coordinated and managed by GO and the researcher MG. The principal investigator-BK will direct the trial. There is no additional steering committee considered for this study. All researchers will meet monthly to discuss the recruitment progress and solve possible issues.

Composition of the data monitoring committee, its role and reporting structure {21a}

No additional external monitoring committee is considered for this study. The principal investigator will meet monthly with all the researchers involved in this study via an online platform (Zoom) to discuss the research progress and solve possible issues. Researchers are instructed to immediately report any issues to the principal investigator, who will subsequently organize an additional committee meeting and inform the board review committee from the Medical University of Warsaw and the Ethics Committee of the Medical University of Warsaw, Warsaw, Poland, when appropriate.

Adverse event reporting and harms {22}

Serious adverse events of mobile application usage have not been described so far. However, any adverse events will be reported and thoroughly documented and presented in the study summary.

Frequency and plans for auditing trial conduct {23}

The principal investigator will continuously monitor the trial conduct. Monthly reports regarding any potential adverse events and protocol violations will be prepared. Additional auditing will be conducted on request from the Ethics Committee of the Medical University of Warsaw.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any protocol amendments will be reported to and approved by the Ethics Committee of the Medical University of Warsaw. All modifications will be updated at clinicaltrials.gov by the principal investigator (BK).

Dissemination plans {31a}

The participants will receive a full report with the results of their assessments after the data is analyzed. At the end of the study, the principal investigator will contact the participants to provide them with final educational materials and information regarding secondary cardiovascular prevention. Study outcomes will be reported at both local and international cardiological conferences. The final study results will be submitted to a peer-reviewed indexed scientific journal within the 3 years after the last patient's enrollment.

Discussion

This study aims to investigate the effects of mobile application-assisted cardiac rehabilitation after MI on rehospitalization rate, cardiovascular risk factors control, and patients' quality of life. Considering the alarmingly high percentage of deaths within the first year after MI, there is a real need for improving the rehabilitation process by intensifying cardiovascular risk factors' control. Standard schemes consisting of pharmacotherapy and lifestyle changes have been thoroughly studied and recommended in the

guidelines (3). Novel methods of increasing the patient's involvement and adherence are of the highest importance.

Telemedicine is a rapidly growing branch of the diagnostic, therapeutic, and rehabilitation process. Cardiology is one of the primary beneficiaries of the newly implemented tools. Several cardiac guidelines recommend enhancing everyday clinical practice with mHealth solutions, which seem to prove this assumption (9, 19, 20). Even though there are various mobile applications available for patients, only a few were validated in clinical settings, focusing on mentioned endpoints. Additionally, many of them were not developed by clinicians or experts in their fields of interest. It is crucial to establish whether such digitally supported rehabilitation may translate into a better prognosis through cardiovascular risk factors control improvement. In previous studies, mobile applications proved to reduce the rehospitalization rate after MI, but the data were collected only in a smaller sample of patients and different healthcare systems (5). Johntson et al. reported that a simple, dedicated mobile application results in better self-reported drug adherence and may correlate with lifestyle changes and quality of life (21). However, the discussion regarding the use of mobile applications in cardiac patients is still ongoing.

Despite several strengths, this study also has some limitations. Firstly, we will be unable to assess the mortality rate due to a short observation period and small sample size (both due to organizational issues). However, we do not expect this parameter to differ between groups. Additionally, this single-center analysis might be biased due to internal protocols, which might differ in other clinics.

Nonetheless, our project stands as a practical example of implementing modern solutions to improve patients' prognoses. If our assumptions regarding the potential beneficial effects of using the afterAMI application appear trustworthy, this study will provide a stronger voice in discussing broader telemedicine usage in everyday clinical practice.

Trial Status

Recruiting.

Version 1. April 11, 2021.

Date recruitment began: December 1, 2020. Approximate date when recruitment will be completed: March 31, 2022.

Abbreviations

AMI: Acute Myocardial Infarction

ACS: Acute Coronary Syndrome

CVD: Cardiovascular Disease

CAD: Coronary Artery Disease

CG: Control Group

IG: Interventional Group

PCI: Percutaneous Coronary Intervention

Declarations

Acknowledgements

We thank all the participants for their involvement in the study.

Authors' contributions {31b}

B.K. is the principal investigator**. B.K., M.P., P.B., Ł.K.** and **G.Op.** were responsible for the concept and the design of the study. **M.B. P.H., K.J., K.S., N. Ż.** and **G. Os.** were involved in data collection. **B.K. and M.P**, are responsible for statistical analysis. **B.K., M.P and P.B.** wrote the first version of the manuscript. All authors edited and approved the final version of the manuscript.

Funding {4}

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Availability of data and materials {29}

After the final study is published, the materials and data will be available upon a reasonable request to the corresponding author.

Ethics approval and consent to participate {24}

The study has been developed in accordance with the declaration of Helsinki guidelines and was approved by the Scientific Ethics Committee of the Medical University of Warsaw (KB 150/2020). All participants will be asked to provide written informed consent before inclusion. Please see the annexing "Ethical Approval."

Consent for publication {32}

Please see the annexing "Informed Consent."

Competing interests {28}

None declared

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Figures

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
TIMEPOINT	$-t_1$	0 *(during hospitalization due to MI)*	t_1 *(30 days after discharge from hospital)*	t_2 *(6 months after discharge from hospital)*
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
AfterAMI group			←	→
Control Group			←	→
ASSESSMENTS:				
Laboratory test		X		
Rehospitalization or urgent outpatients visits			X	X
Cardiovascular risk factors control			X	X
Quality of life - MacNew		X	X	X
Quality of life – EQ-5D-5L		X	X	X
Depression – DASS21		X	X	X
Cardiovascular risk factors knowledge		X	X	X
Return to work			X	X

Figure 1

Recommended SPIRIT figure with participant timeline.

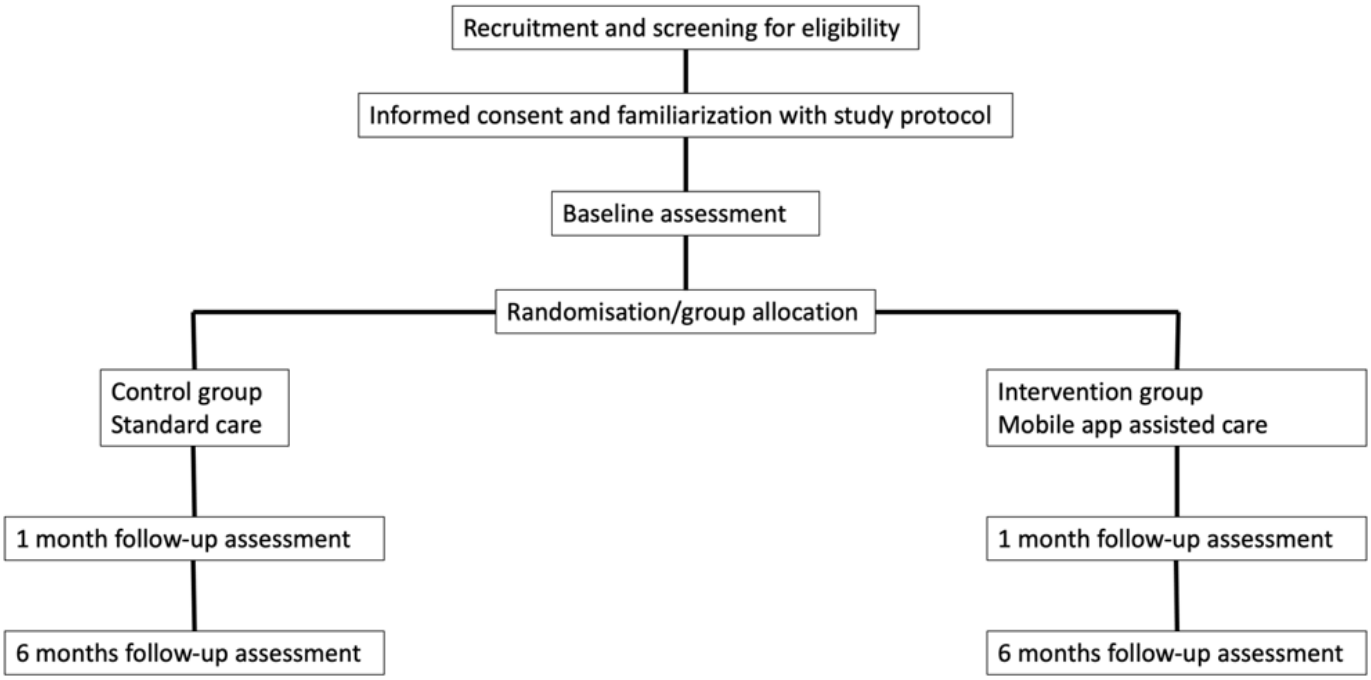

Figure 2

Study flow chart.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORTafterAMI.doc