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ORIGINAL ARTICLE

Impact of Digital Technology Intervention on Medication Compliance, Modification of Risk Factors, and Clinical Outcome in Patients With Acute Coronary Syndrome: A Follow-Up Study

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Abstract

Background: Coronary artery disease (CAD) is prevalent worldwide, presenting significant morbidity and mortality. Despite the advances in the management of CAD, the primary focus continues to be risk factor reduction, lifestyle changes, and medication adherence, all of which contribute considerably to favorable outcomes. Long-term CAD outcomes tend to be poor, especially in developing countries, due to medication non-compliance, a lack of education, and appropriate measures for the modification of risk factors.

Objectives: The present study aims to investigate the use of digital technology in assessing medication compliance, modifying risk factors, and evaluating clinical outcomes in patients with acute coronary syndrome (ACS).

Methods: A prospective, randomized study will be conducted with patients diagnosed with ACS at the Sri Jayadeva Institute of Cardiovascular Disease and Research, Mysore, and JSS Medical College, Mysore, India. A total of 522 patients will be randomized in a 1:1 ratio into either the digital intervention group or the control group. Digital technology registration will be completed during hospitalization, with guidance from the research team. Follow-up assessments will occur every three months for one year. Statistical analysis will be conducted at a 5% significance level. Categorical variables will be analyzed using the Z test for proportions or the Chi-square test, while continuous variables will be assessed using the independent sample t-test.

Results: The results will be presented after data collection and statistical analysis. This study aims to focus on clinical outcomes in patients with ACS, highlighting the importance of lifestyle modification, adherence to medications, and modifications of risk factors by digital technology, bridging the gap between patients and healthcare providers.

Conclusions: We intend for the outcomes of this study to produce an initiative for larger randomized control trials regarding web application in the management of ACS. Favorable outcomes could significantly impact the management of ACS, and web applications can be recommended as part of a routine standard of care established by societal guidelines.

Keywords: digital health; digital technology, risk factors, acute coronary syndrome.

Introduction

Coronary artery disease (CAD) represents as a significant global cause of mortality, particularly prevalent in India, where it constitutes a leading cause of morbidity and mortality. Notably, its prevalence is higher in urban areas as compared to rural regions.[1] Despite efforts in education and knowledge dissemination, approximately 50% of all cardiovascular disease (CVD) cases stem from lifestyle-related risk factors.

Digital technology emerges as a promising solution, offering an alternative to conventional cardiac rehabilitation.[2] It can facilitate improvements in medication compliance, enable regular follow-ups, aid in identifying risk factors,

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Central Illustration: Summary of the study design. The intervention involved digital technology aimed at improving medication compliance, the modification of risk factors, and clinical outcomes

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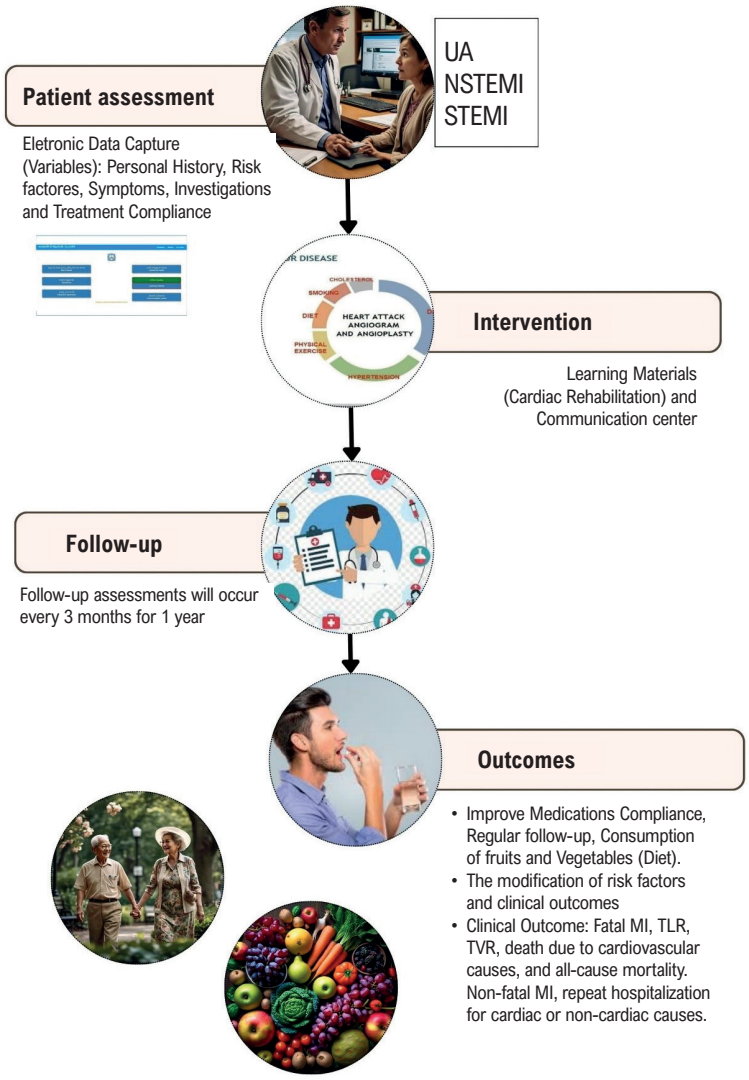

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enable early diagnosis, assist in treatment planning, and enhance treatment adherence. Moreover, its implementation holds the potential to alleviate financial burdens and enhance the overall quality of life.[3] These technologies empower patients to take charge of their health, enabling them to make informed decisions and providing them with the means to monitor and manage their healthcare effectively.[4]

Time constraints, patient overpopulation, and complex guidelines necessitate alternative solutions for real-time patient monitoring.[5] The integration of rapidly evolving digital technology offers an effective solution to address these challenges.[6] There is a growing need for additional research due to the sparse data available to harness the full potential of digital technology.[7] It is also important to maintain privacy and confidentiality when implementing digital interventions into clinical practice.[8]

This study aims to evaluate the impact of digital technology on medication adherence, the modification of risk factors, and clinical outcomes (Central Illustration), including: a) Fatal myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR), cardiovascular mortality, and all-cause mortality and b) Non-fatal MI and repeat hospitalizations for both cardiac and non-cardiac causes.

Methods

This work will be a two-year prospective, randomized study of patients admitted with acute coronary syndrome (ACS), including ST elevation myocardial infarction (STEMI), Non ST elevation myocardial infarction (NSTEMI), and Unstable angina. The sample size powered for the study will be 522 patients, who will be randomized in a 1:1 ratio to either the digital intervention group or the control non-digital intervention group. Informed consent will be obtained from all patients. They will then be randomly assigned to one of two groups: the Digital App Group or the Control Group. Participants will be randomly assigned to case or control groups based on a manual randomization process. Parameters, such as gender, age group, and diagnosis, will be coded, and a unique number will be assigned to each category. Patients will then be randomized into the case or control group according to this unique number, ensuring that the distribution was balanced across these parameters. Both groups will receive standard care before being randomized in the study.

Baseline demographic and clinical data, including age, gender, address, contact information, education, height, weight, and previous medical history, will be recorded. Additionally, risk factors, such as diabetes, hypertension, dyslipidemia, prior history of Ischemic heart disease, prior family history of CAD, alcohol consumption, smoking, and obesity will be documented, and any symptoms that may appear, will be duly documented. Electrocardiogram, Echocardiogram, and Troponin T blood levels will be taken for all patients. Laboratory investigations, including fasting blood sugar (FBS), postprandial blood sugar (PPBS), HbA1C, hemoglobin (Hb), serum creatinine, and lipid profile will be measured for all patients (Figure 1 & 2).

A coronary angiography will be performed at the discretion of the treating physician based on the clinical condition of the patient and if the patient agrees to the procedure. The therapeutic approach and outcome will be updated via digital technology for the Digital App Group (Supplemental Figure 1). Conversely, for the Control Group, all data will be collected at baseline without the use of the app.

The application will be accessible in both regional (Kannada) and English languages. In the digital intervention group, patients and their relatives will receive training in the hospital on how to update data and reports, as well as how to access health education materials (Figure 3) related to cardiovascular health. A chat option will be available within the app to address any concerns or queries regarding health status or minor symptoms. Additionally, users will be informed that, in case of emergency or if warning signs of symptoms arise, they should seek medical attention promptly, as the app is not a replacement for a doctor.

Both groups will undergo clinical follow-up at recommended intervals. Telephone follow-up will occur mandatorily every three months to monitor any adverse events in both groups. At the end of the study, a final clinical visit will be conducted at 12 months for both groups.

Figure 1 – Home page.

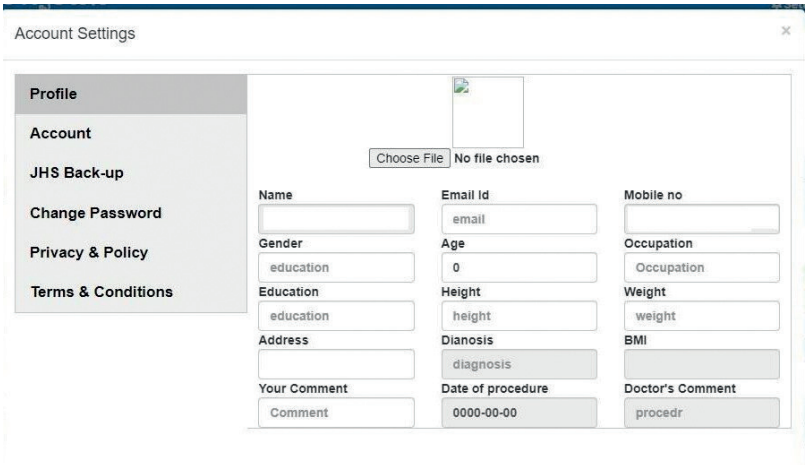

Figure 2 – Demographic Details.

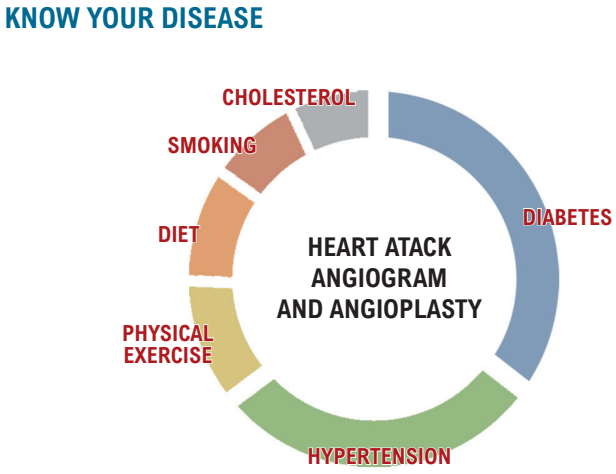

Figure 3 – Learning materials.

Admin Access

The application provides the Investigator with access to promptly check all details and ensure that reports are updated (Figure 4). Data security is maintained with access to data available only to the investigator and is password protected. If any fields are blank or not updated, or reports are missing, the study team will contact the patient for information updates and ensure regular follow-up. Notifications will alert the study team to any patient concerns or queries, which will be promptly addressed in consultation with a cardiologist or relevant specialist. In case of emergencies, patient details and reports are easily accessible (Supplemental Figure 2). Data can be exported to Excel for analysis (Table 1). Access to the admin section is restricted to authorized personnel only in order to maintain privacy and confidentiality.

Sample Size

The sample size for this follow-up study will be determined using the difference of proportion method to ensure adequate power for detecting differences between the groups. A total of 522 participants will be recruited, with 261 to be assigned to the Digital App group and 261 to the Control group.

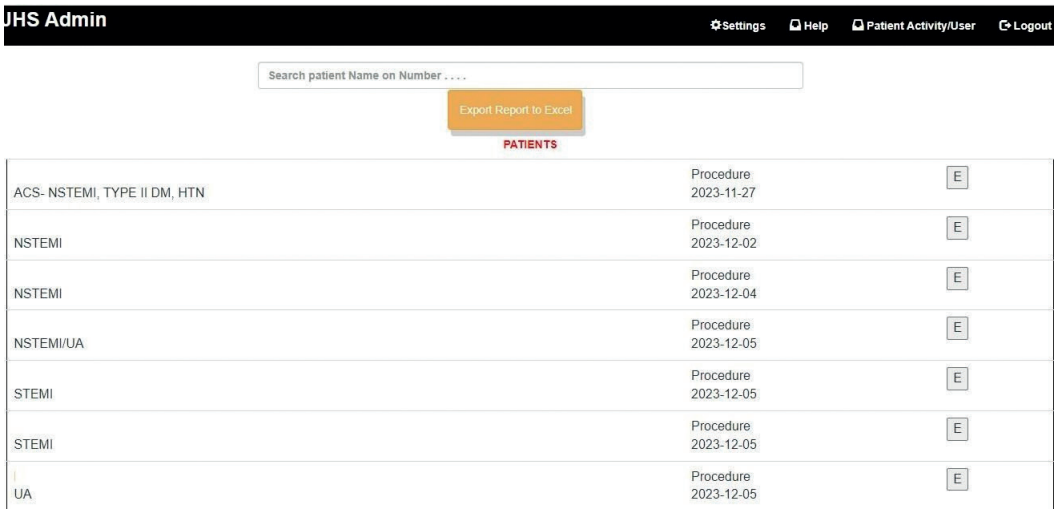

Figure 4 – Home page.

Sample Size Determination:

Assumptions made:

1. The type 1 error (α) of the study is considered as 5%
2. The type II error (β) of the study is considered as 20%

Formula Used

$$n = \frac{\left(z_{\frac{\alpha}{2}} + z_{\beta}\right)^2 \left(p_1(1-p_1) + p_2(1-p_2)\right)}{(p_1 - p_2)^2}$$

Where,

n = Sample size.

$z_{\frac{\alpha}{2}}$ = Z score adjusted for the level of significance.

p_1 = proportion of individual possessing the attribute from case group.

p_2 = proportion of individual possessing the attribute from control group.

Key Parameters of the study – titled "The Effect of Mobile Application-Based Technology Use on Medication Compliance and Modification of Risk Factors in Post PTCA Cohort of Patients".

Data Analysis Plan

The collected data will be analyzed using MS Excel, R software, or Python, with a significance level of 5% and a 95% confidence interval (95% CI). Statistical tools, such as descriptive statistics and parametric tests (including t-tests and ANOVA) will be employed. The objective is to determine if there are significant differences in the proportions of key variables between the Digital App Group and the Control Group (Figure 5). These variables include medication

Table 1 – Variables included in the study (Electronic Data Capture)

1) Demographic details: Age, Gender, Occupation, Education, etc.
2) ACS diagnosis: Unstable angina, NSTEMI, and STEMI
3) Risk Factors: Diabetes, Hypertension, Physical activity, Alcohol consumption, Smoking, and Obesity (Body Mass Index)
4) Medication Compliance, Regular follow-up, Consumption of fruits and Vegetables (Diet).
5) Serious Adverse Events: a) Fatal MI, TLR, TVR, death due to cardiovascular causes, and all-cause mortality. b) Non-fatal MI, repeat hospitalization for cardiac or non-cardiac causes.
6) Laboratory and other investigations: FBS, PPBS, HbA1C, Hb, EF, serum creatinine, and lipid profile, as well as electrocardiogram, echocardiographic assessment, and coronary angiogram with treatment approaches and outcomes.

ACS: acute coronary syndrome; MI: myocardial infarction; TLR: target lesion revascularization; TVR: target vessel revascularization; NSTEMI: Non ST elevation myocardial infarction

compliance, adverse events, or serious adverse events, regular follow-up, diabetes, hypertension, lack of physical activity, smoking, alcohol consumption, and consumption of vegetables and fruits.

The statistical analysis for this study will be conducted as follows:

1. **Normality Test**: The normality of data distribution will be verified using Shapiro's test.
2. **Presentation of Variables**: This will be done after data collection and statistical analysis have been completed.
3. **Analysis of Continuous Variables**: An independent (unpaired) sample t-test will be used to assess continuous variables between the Digital (App) group and the Control group.
4. **Analysis of Categorical Variables**: A Z-test for proportions or Chi-square test will be applied to assess categorical variables between the Digital (App) group and the Control group.
5. **Follow-up Data Analysis**: Since this is a follow-up study, repeated measures by one-way ANOVA will be used to evaluate changes over time. In cases where significant differences are observed, Bonferroni tests will be used as a post-hoc analysis to test for critical differences.

Ethics and dissemination

Patients will be informed about the study, and written informed consent will be obtained prior to any study procedures. The study has been approved by the Institutional Ethics Committee of Sri Jayadeva Institute of Cardiovascular Sciences, Mysore (SJICS&R/IEC07/2023/01), and the Institutional Ethics Committee of JSS Medical College (JSSMC/IEC/27102023/06 NCT/2023). Key findings will be published in leading academic journals and will be presented at conferences. Additionally, a thesis will be prepared.

Study Outcome

This study aims to evaluate the impact of digital technology on medication compliance, the modification of risk factors, and clinical outcomes, including:

a) Fatal MI, TLR, TVR, death due to cardiovascular causes, and all-cause mortality.

b) Non-fatal MI, repeat hospitalization for both cardiac or non-cardiac causes.

Study status

The recruitment stage has been concluded, with a total of 522 patients diagnosed with ACS, equally randomized into two groups: 261 patients in the digital group and 261 patients in the control group. Data collection is scheduled to be concluded by May 2025.

Discussion

The present study aims to assess the effectiveness of digital technology intervention in enhancing regular follow-up, remote monitoring, medication compliance, the modification of risk factors, reductions in recurrent cardiovascular events, and improving disease self-management and health outcomes among patients diagnosed with ACS.[9]

Digital technology has the potential create awareness about cardiovascular health.[10] These technologies, including web applications (cloud computing application) can disseminate educational materials and educate the individual about the effect of risk factors,[11] such as diabetes, cholesterol, lack of physical activity, smoking, excessive alcohol consumption, and unhealthy dietary habits. It underscores the importance of the consumption of fruits and vegetables, as well as highlights the importance of physical activity, such as walking, jogging, and swimming. Additionally, it promotes healthy behavioral habits.[3]

Digital technology interventions for cardiac rehabilitation have demonstrated comparable impacts on health outcomes to conventional clinic-based programs,[12] particularly in reducing recurrent cardiovascular events and improving one's quality of life. These interventions aim to bridge the gap between hospital-based care and patient home care, enhancing the quality of care and reducing disparities associated with geographic and financial constraints.[5,13]

This digital technology was quite useful during the COVID-19 pandemic when patients found it extremely difficult to approach hospitals[14] and seek medical care due to lockdowns and the stigma attached to healthcare facilities[4].The burden of CVD is rapidly increasing in developing countries. However, access to cardiovascular rehabilitation and secondary prevention continues to be limited in these regions.[6] Digital technology offers low-cost[15] and easily accessible models to bridge the gap between health-based care and home care.

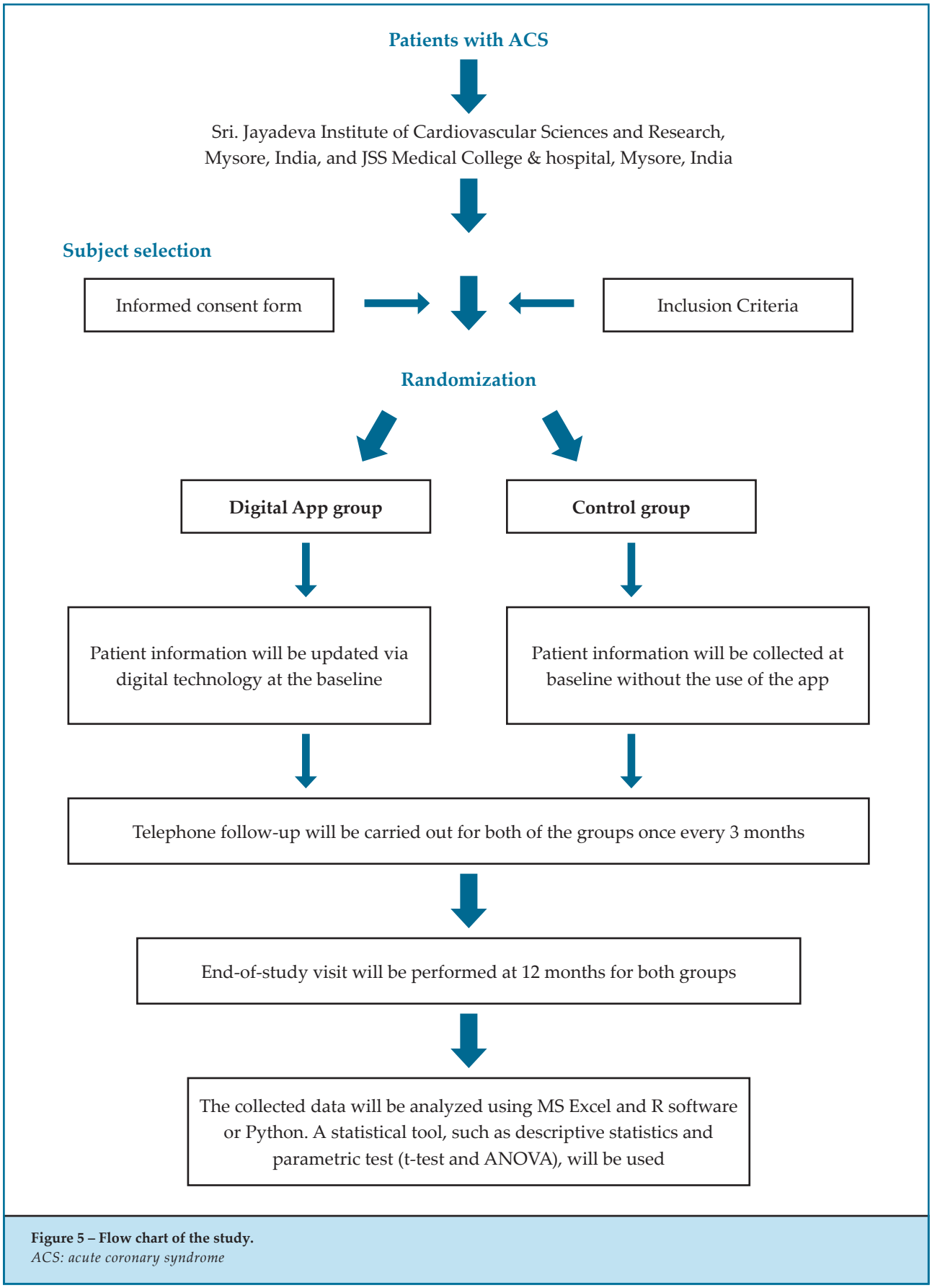

Figure 5 – Flow chart of the study.
ACS: acute coronary syndrome

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Author Contributions

Conception and design of the research, writing of the manuscript and critical revision of the manuscript for intellectual content: CJ Devaraju, Kumar S, Sadananda KS, Kumar V, Nanjappa V, Rajith KS, Ravindranath KS; acquisition of data: CJ Devaraju.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

This article is part of the thesis of PhD submitted by Devaraju C. J., from JSS Academy of Higher Education and Research.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Sri Jayadeva Institute of Cardiovascular Sciences and Research under the protocol number SJLCS&R/2EC0J/2023/01 and JSSMC/LEC/27/02023/06/2023. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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