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The Effect of The Mobile Application on Treatment Adherence, Self-Management, and Quality of Life in Patients with Acute Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention

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Background and Aim: Acute myocardial infarction is a clinical condition with high mortality and morbidity rates. Ensuring patient adherence to treatments and lifestyle recommendations after discharge is crucial for effective post-acute myocardial infarction management. This study aimed to determine the impact of the mobile application on treatment adherence, self-management, and quality of life in patients with acute myocardial infarction undergoing primary percutaneous coronary ıntervention.

Study's Methods

Study design and sample

The study was conducted as a prospective (6-month follow-up), two-group (control and intervention), randomized controlled, experimental study.

The universe of the study consisted of patients who had their first time ST segment elevation MI (STEMI) undergoing PPCI in the Cardiology Clinic of a university hospital in Edirne, Turkey, between 01.11.2021 and 10.07.2024. In determining the sample of the study, power analysis was performed with reference to the study of Turan Kavradım and Özer (68). The effect size of the study was found to be 0.92 and considering this effect size, it was determined that it was sufficient to include a total of 54 patients, 27 in each group, at 95% power and 0.05 significance level. However, considering a 20% loss rate during the study period (30), it was aimed to reach a total of 66 patients, 33 patients for each group. Patients who volunteered to participate in the study were determined in accordance with the inclusion criteria. The selection of patients to the intervention and control groups was made using the simple randomization method. According to the randomization list, the groups were matched based on the time of discharge from the clinic of the patients. For patients who were discharged on the same day, the matching was based on their hospitalization times. The inclusion criteria were as follows: the patients who (1) had first time STEMI undergoing PPCI, (2) are over 18 years of age, (3) have a smartphone, (4) have internet access, (5) have orientation to place, time and situation, (6) have no problems with vision, hearing and speech, (7) are at least literate, (8) regularly come in for the doctor's check up, and (9) volunteer to participate in the study. Among the volunteers participating in the study, those who wanted to leave the study (2 patients) and those who didn't come in for the doctor's check up (3 patients) were excluded from the follow-up. Therefore, the study was completed with 61 patients, 30 in the intervention group and 31 in

the control group. The study design and implementation were based on the principles in the CONSORT (Consolidated Standards of Reporting Trials) list (Figure 1).

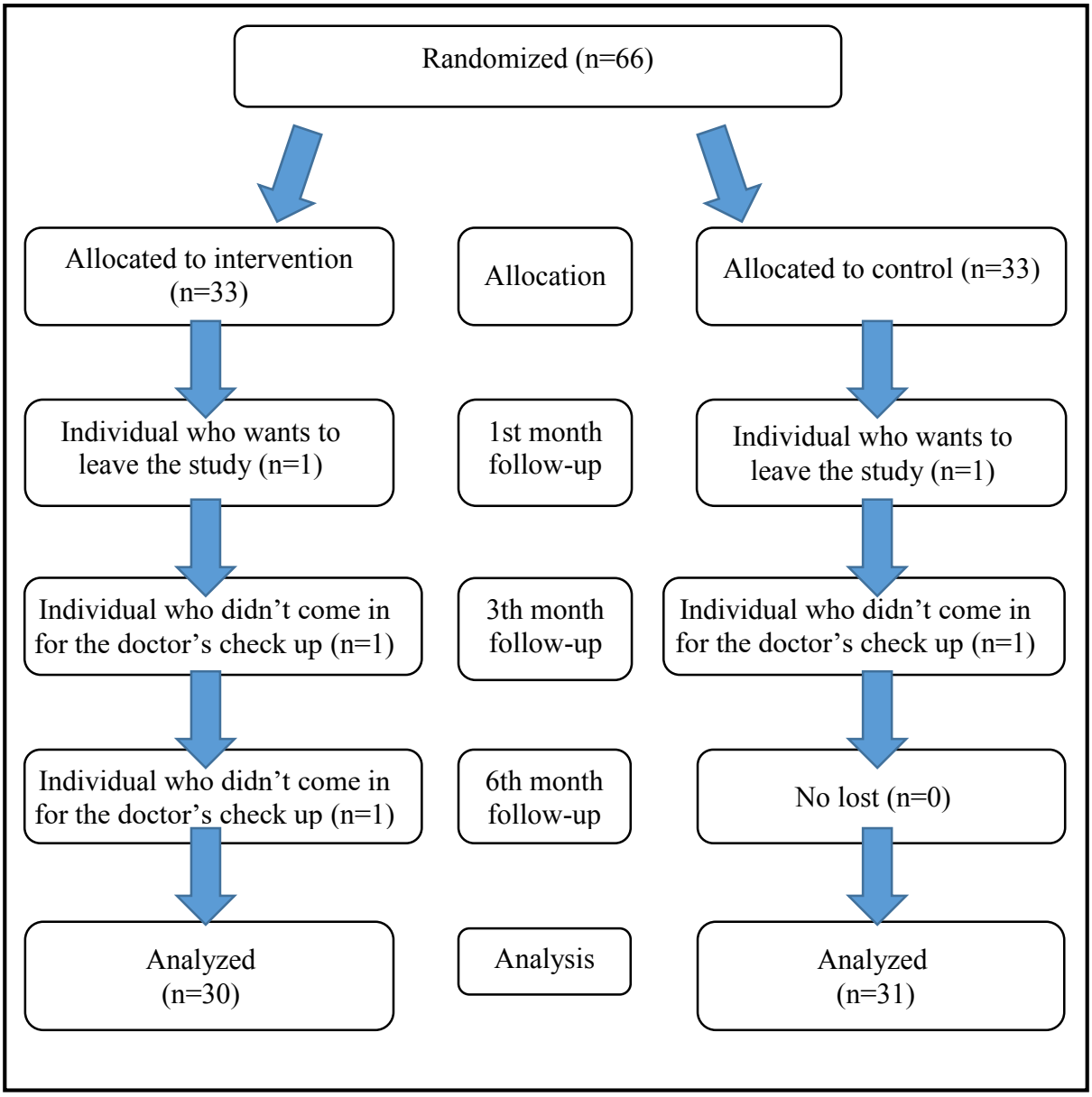


Figure 1. Flow chart of design and recruitment of participants according to CONSORT statement

Study Protocol

Education booklet

In the study, firstly, an education booklet was created by the researchers to be used as an education material to provide self-management in patients with AMI. During the development phase of the education booklet, expert opinions were obtained from a total of 9 people, including 3 cardiologists, 4 academic nurses and 2 cardiology nurses. In line with the expert opinions, the necessary arrangements were made and an 18-page "Education Booklet for Patients Having Heart Attack" was created.

Mobile application and web page control panel

After the creation of the education booklet, the development process of the mobile application began. In the first stage, the content of the application was determined based on the education booklet and sample mobile application studies in the literature (30,66,71,73,74). In order to evaluate the content of the mobile application, expert opinions were obtained from 3 cardiologists, 4 academic nurses and 2 cardiology nurses.

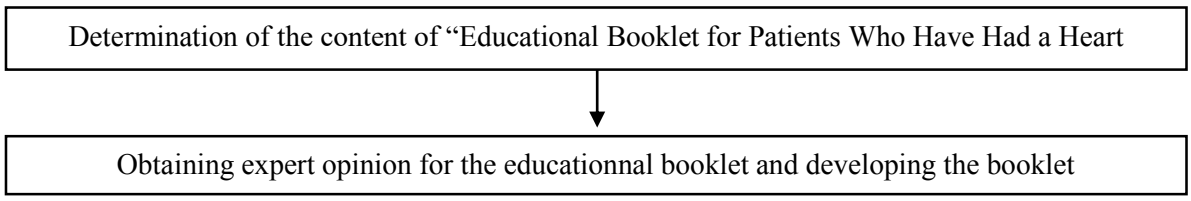
In the second stage, a software company was contacted and the interface and logo of the mobile application called "MEDIFOLL" was designed. The interface of the application includes "Medication Information", Blood P. & Pulse", 'Notifications', 'Lifestyle' and 'Contact' sections. In the "Medication Information" section, medication entries are made. When it is time to take each medication, the mobile application sends a medication reminder notification to the user. "Blood P. & Pulse" section includes the screen where blood pressure and pulse are entered. The "Notifications" section displays personalized reminders sent by the researcher to the users via the web page control panel. Personalized reminders are information provided by the researcher to patients regarding the things to be considered in the post-discharge process, which are included in the education booklet. The "Lifestyle" section has been created for situations where the education booklet is lost or cannot be accessed in their environment where they are located. This section contains the information contained in the booklet under the heading lifestyle changes. The "Contact" section allows users to communicate with the researcher. In this way, patients can send their questions to the researcher via message.

In the third stage, a web page control panel was created that allows the mobile application to be controlled remotely, patient information to be viewed, data to be monitored, lifestyle information to be uploaded and viewed in the mobile application, personalized reminders to be sent to patients, and to becommunicated with patients (https://www.medifoll.com/, https://www.medifoll.com/brave/login).

In the fourth phase, the application was purchased from Google Play Store and App Store. In the fifth stage, the mobile application and website were tested by experts for 1 week to determine usability of them and errors. Finally, a pilot study was conducted with 4 patients and the patients were allowed to use the application for a month. Patients who participated in the pilot study were not included in the study.

After the pilot study was completed, the Patient Information Form was filled out with all patients in the patient room before discharge. The researcher provided training to the patients in both groups in line with the educaiton booklet and it was delivered to the patients. MEDIFOLL application was downloaded to the mobile phones of the patients in the intervention group and user registration was made. Information was provided to them on how to use the application and how to enter data such as blood pressure and pulse rate. The times of the use of medications prescribed during discharge were planned together with the patients and they were provided with the opportunity to enter their medications into the application.

Patients in the intervention and control groups were interviewed in the outpatient clinic 1 month, 3 months and 6 months after discharge, and the Patient Information Form, İUBÖ ve MIDAS scales were filled out. The flow chart of the research is presented in Figure 2.



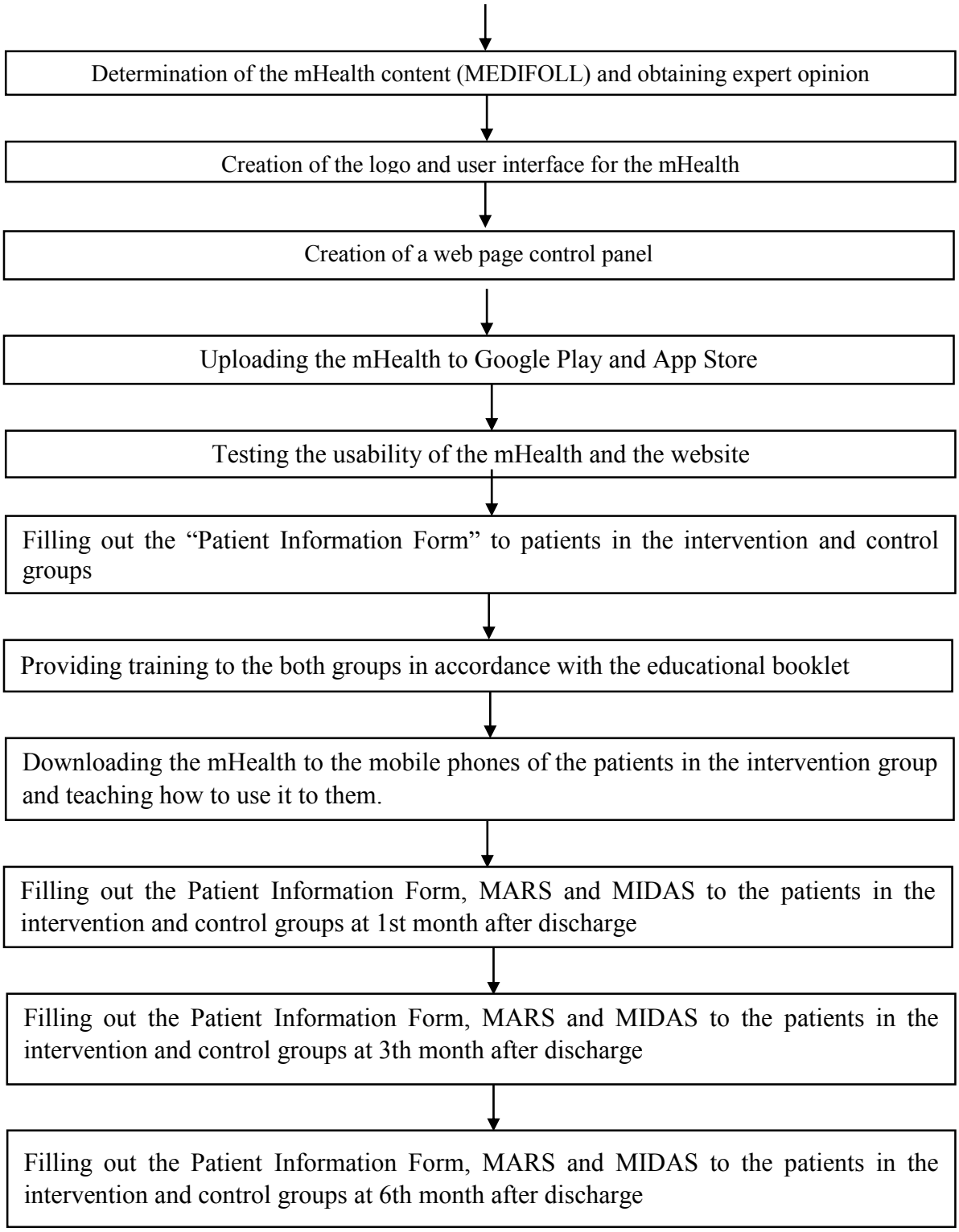


Figure 2. The flow chart of the research

Data collection tool

Patient Information Form: It, developed by the researcher through a literature review (15,18,30,36,59,67), consists of questions about the socio-demographic, the lifestyle, and the disease characteristics of the participants.

Medical Adherence Report Scale (MARS): The scale was developed by Horne and Hankins to determine medication adherence in individuals with chronic diseases. The Turkish validity and reliability of the scale was performed by Şen et al. (21). The scale has 5 items, one sub-dimension and 5-point Likert type. The total score obtained from the scale varies between 5 and 25. A high total score indicates adherence to medication treatment, while a low score indicates non-adherence to medication treatment. The Cronbach alpha value of the scale was found to be 0.78 in the study of Şen et al. (21) and 0.68 in this study.

Myocardial Infarction Dimensional Assessment Scale (MIDAS): The Turkish validity and reliability of the scale, developed by Thompson et al., was performed by Yılmaz et al. (71). The scale is used to determine the HRQoL of individuals with MI and consists of 35 items and 7 sub-dimensions (physical activity, insecurity, emotional reaction, dependency, diet, concerns over medication, and medication side effects). This 5-point Likert-type scale is scored between 0-4. Scores that can be obtained from the scale and its sub-dimensions vary between 0-100. The score is calculated with the formula: (Total score obtained from the sub-dimension/highest score that can be obtained from the sub-dimension) x100. As the scores obtained from the scale increase, the perceived HRQoL worsens. In the study of Yılmaz et al. (71), the Cronbach alpha value of the sub-dimensions of the scale was found to be between 0.79-0.90. In this study, it was found to be 0.93.

Ethical Consideration

The study was conducted in accordance with the Declaration of Helsinki. The study protocol was approved by the Scientific Research Ethics Committee of XXX University Faculty of Medicine (xxx), and written permission was obtained from the institution where the study was to be conducted (xxx). Necessary written consents were obtained from the patients.

Data Analysis

The data were evaluated using the IBM SPSS 22.0 (Statistical Package for Social Sciences 22.0) package program. The data to a normal distribution was examined by the Kolmogorov–Smirnov test. The number and percentage distribution were used to evaluate categorical data, and meanstandard deviation was used to evaluate continuous data. In the analysis of the data, Mann Whitney U test was used to compare the mean scores that did not show normal distribution between the groups and Student's t test was used to compare the mean scores that showed normal distribution. Pearson chi-square test and Fisher-Freeman-Halton Exact test analysis

were used to determine the relationship between groups for nominal variables. The statistical significance limit value was accepted as $p<0.05$.