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Design and development of a self-care application for patients with liver cirrhosis

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ABSTRACT

Aim: Due to the capabilities of the mobile application in the self-care of patients, the present study was conducted to design and evaluate a mobile-based self-care application for patients with liver cirrhosis.

Background: Liver cirrhosis is a progressive and chronic disease that, if left untreated, leads to liver cancer and, finally, the death of the patient.

Methods: This study was conducted in six phases, including determining and confirming the validity of the minimum data set and capabilities for the application, designing a conceptual and logical model and determining the technical capabilities, designing the application, evaluating the prototype usability in a laboratory environment by technical experts, evaluation of the application usability in a real environment by 30 patients with QUIS (Questionnaire of User Interface Satisfaction) questionnaire.

Results: The designed application has capabilities such as calculating the patient's MELD score (Model for End-Stage Liver Disease), medication reminder, location in emergency, and conversation with the physician. The results showed that the patients evaluated the application with a score of 7.94 (out of 9 points) at a good level.

Conclusion: The self-care application can help patients with liver cirrhosis and their families access the necessary information related to the special care of the patient at any time and place; it also helps better manage the patient's life, improve the quality of life, and monitor the patient. These applications can effectively manage chronic diseases by reducing the burden of referrals and costs.

Keywords: Liver cirrhosis, Fibrosis, Self-care, Mobile phones, e-health

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Introduction

Liver cirrhosis is a prevalent chronic disease that can be compensated or uncompensated. It is caused by various liver injuries that lead to inflammation and necrosis (1). Liver cirrhosis is currently the 11th leading cause of death in the world and one of the top 10 causes of death in the United States, accounting for about 3.5% of global deaths. Egypt, Moldova, and Mongolia have the highest cirrhosis mortality rates (4-6). The two most common causes of liver cirrhosis are hepatitis B and alcohol consumption (7, 8). It's the main cause of liver-related death in the world and led to nearly 41·4 million disability-adjusted life-years (DALYs) in 2017 (2). Studies have shown that the prevalence of liver cirrhosis has increased in Iran in recent years. In 2017, the prevalence was 18 million, and 5400 deaths occurred due to chronic liver disease in Iran (3). This disease has complex clinical complications, including hospitalization, impaired quality of life, liver failure, and mortality (9, 10). It also disrupts the patient's social functioning and mental state (11, 12).

Studies have proven the existence of a relationship between the quality of life in patients with liver cirrhosis and disease severity (13). On the other hand, the active role of patients in disease management in controlling and

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preventing chronic disease complications is undeniable (14). Effective education and self-care are important in promoting positive health outcomes and preventing recurrent hospitalizations (15, 16). Traditional methods, such as self-care training through face-to-face meetings, are costly and often do not have the desired results and effects. For this reason, digital devices can provide suitable and cost-effective platforms for patients' empowerment and mutual communication with healthcare providers (17). The IT-based approaches provide a tool for better monitoring patients' treatment process and less dependence on face-to-face care (18, 19). Mobile technologies have been widely used to provide self-care services in recent years. In addition to providing quick and easy access to health information, mobile applications have improved communication with healthcare systems (20, 21). Mobile phones are optimal for maintaining a mobile health (mHealth) program for symptom monitoring because of their portability and easy access. Mobile health programs often include behavioral messages, reminders, disease monitoring, and management programs and are useful for symptom management (22, 23).

According to the mentioned items and the specific problems of patients with liver cirrhosis, such as distance, the spread of COVID-19, problems related to physical activity and nutrition, drug interactions in patients with underlying diseases, and many observed complications and problems, the presence of self-care software can be very effective in solving these problems and provide patients and their families with the possibility of quick location in emergencies, proper nutrition, as well as a great help in the correct use of medications. Therefore, this research aims to design a mobile-based application for the self-care of patients with liver cirrhosis and to help them improve their care.

Methods

Study design

The study was approved by the Tabriz University of Medical Sciences (TUoMS) ethical committee (IR.TBZMED.REC.1399.169). All methods were carried out according to relevant guidelines and regulations. Informed consent was obtained from all participants involved in the study. This study was conducted in 6 phases; their complete explanations are provided below.

Study selection and data extraction process

Databases such as PubMed, Scopus, Web of Science, Science Direct, and Embase were searched from 2000-2021 to identify the components and information elements required for the self-care application program. According to Mesh, the keywords were Cirrhosis Liver, Hepat, Liver, Self-Care, Self-Management, MELD, Ascite, Hepatocellular, Software, Application, Mobile Health, and Telehealth. Also, focus group meetings were held with clinical and technical experts to control and ensure the accuracy of the collected information.

By summarizing the obtained information, the questionnaire was designed in two clinical and technical sections to confirm the validity of the

Table 1. Extracted Clinical Data Elements for liver cirrhosis self-care application

Main section	Data elements
personal information	Name and surname - father's name - nationality - age - gender - residence (urban-rural) - address - weight - height - type of insurance - family history - record number - drug sensitivity - employment status - marital status - referral date - education level- illness severity- other suggested items
Disease management	Daily measurement of blood pressure - Recording the measured blood pressure values - Daily measurement of body weight - Record the measured weight values - Record time take of medication – Record medication dose- Necessary actions when forgetting to take medications- Expressing the drug interactions of taking medications at the same time- Tests- Sodium- Potassium- Creatinine- Blood Glucose- Cholesterol- Triglyceride- Hemoglobin- Urea- Platelet- Albumin- Bilirubin- Alpha-Phytoprotein- Reducing salt consumption- No smoking- No consuming alcohol- Exercising- Sufficient rest- Observance of meeting time with physician - Providing information about specialized liver and gastroenterology clinics - Education of the patient's family (justification of the patient and his relatives) - Other suggested items
Clinical information	The cause of liver cirrhosis - The number of hospitalizations – Medications- Other diseases (AIDS-diabetes, etc.) - Other medications - History of certain diseases - Proper diet and nutrition - Other suggested items

information elements. The information elements of the questionnaire included 55 and 46 questions in the clinical and technical sections, respectively (Table 1 & 2). These tables are presented in the result section.

The information elements of the questionnaire in the clinical section included demographic information, disease management, and clinical information. In the technical section, the questions were in four sections: security and reliability, user-friendliness, ease of use, and motivational and educational effects.

The validity of the questionnaire was confirmed by 9 clinical and technical experts. The reliability of the questionnaire was calculated as 0.93 by Cronbach's alpha. Also, the data elements of Table 3 were suggested by clinical experts in the "other desired items" section with 98% and were added to the data elements extracted from the first stage and used in the application design.

Table 2. Technical data elements for liver cirrhosis self-care application

Main section	Data elements
Application capabilities (security and reliability)	Registration and login- - Username and password-Change username and password-The possibility of data editing only with admin permission-Confidentiality standards-Control user access to system based on roles-Other suggested items
Application capabilities (user friendliness)	The appropriateness of system pages -Appropriateness of user interfaces to tasks- - The variety of colors -Appropriateness of fonts- Appropriate shape and sign -Ability to register information -Backup option -Admin dashboard-Appropriateness of system response speed -Display the time of data recording (date and time)- Display blood pressure changes as a graph-Display heart rate changes as a graph- Display weight changes as a graph- Recording test images such as echocardiography or ECG- Other suggested items
Application features (ease of use)	Ease of use - Ease of system training-Ease of return to previous pages-Ease of return to the home page-Easy information registration- Communication between system users - Access to information without time and place restrictions- Auto logout - Other suggested items
Application capabilities (motivational and educational effects)	Desire to use the application- Recommending the system to others-Motivating to continue treatment -Motivation for diet and exercise - Providing appropriate educational information - Providing appropriate information about the disease- Providing educational messages- Providing instructions for sending SMS reminders to the patient- Providing motivational messages - Warning of high blood pressure -Notification of increased heart rate - - Notification of heart rate decrease warning- Notice of weight gain - Use of medication reminders - Reminder for in-person visit-Ability to report from the program – Other suggested items

Table 3. Data elements suggested by clinical experts for liver cirrhosis self-care application

Disease management	Clinical information
- BUN - B Hepatitis - C Hepatitis - Blood group & Rh - Liver tests (AST- ALT- ALP) - Personal hygiene - No drug use - Do not take prescribed or over-the-counter medications before consulting a physician - Annual ultrasound according to the physician's opinion - Referral for screening endoscopy with the intervals specified by the physician - Control of blood sugar in diabetics - Weight loss in obese individuals - walking	- Cause of hospitalization - Edema of organs - History of gastrointestinal bleeding - History of ascites - History of hepatic coma - Family history of liver cirrhosis - Family history of liver cancer - The first symptoms of cirrhosis occur

The conceptual model and UML diagrams were designed using IBM Rational Software Architect 9.0, a modeling and development tool for software. The application was designed in two client and server sections. The web service section uses the .NET Core framework with C# programming language. The application programming language was Flutter framework with Dart language and Android Studio programming environment. In the database, the SQL programming language was used in the PostgreSQL database engine.

Designing user-oriented and knowledge-oriented self-care software for patients with liver cirrhosis

In the user-oriented dimension, the application design was done according to the users' needs. In the knowledge-oriented dimension, scientific evidence and the results of previous studies were used in the design process. The overall design of the software was done in four main parts. The main features of the application were creating profiles for different application users (admin-doctor-patient), the ability to search, the possibility of recording and editing information by different users, medication reminders, providing educational materials in the form of text, photos, and clips, the possibility of patient monitoring by clinical physicians, the possibility of communication and conversation between the patient and the physicians.

In continuing, experts evaluated the software from the technical and clinical aspects to identify bugs and problems. Then, suggestions to modify the software, update the content and finally implement the final version. Then the experts' recommendation was applied to modify the software, update the content, and finally implement the final version. Also the suggestions of several patients with sufficient electronic health literacy were also used.

In the last stage, patients with liver cirrhosis evaluated the software's usability in the real environment. In this phase, the application was installed on the 30 patients' phones, and their companions were selected as samples for one month. Then, the researcher provided the necessary explanations about the application used by the patients and their companions.

For easy interaction and more response to the patients participating in the study, a group was formed in social networks with the membership of patients, researchers, and Specialist physicians, and explanations about application installation and use were provided step by step. The general and technical questions of patients about the application were answered.

Informed consent was obtained from the patients who wanted to participate in the study. And then user accounts were created by the admin for the patients. The patients' opinions after use were collected through the QUIS (The Questionnaire for User Interaction Satisfaction) online questionnaire (24). The survey results were analyzed using descriptive statistics such as mean, variance, and standard deviation. The general steps of research are presented in Figure 1.

Results

The extracted elements of the first stage are presented in Tables 1 and 2 (25-27).

Data elements suggested by clinical experts are presented in Table 3.

In the second step, the UML diagram is used for conceptual design, which class diagram example is presented in Figure 2.

Various modules of the application

The application was designed in 4 main sections, including Introduction to liver cirrhosis, MELD calculator page, Login page, and Location in emergency case.

1. The first part is an introduction to liver cirrhosis. It includes videos to introduce nutrition, physical activities, anatomy and functions of the liver, definition, and symptoms of liver cirrhosis, and general recommendations for patients. The content of this section is designed as text photos and video clips to familiarize the patient with liver cirrhosis.

2. The MELD calculator page: In this section, the patient enters their age, sex, bilirubin, creatinine, and INR values from their most recent laboratory tests. The MELD score is then calculated and displayed to the patient. The results include the patient's general condition and medical recommendations based on their MELD score (Figure 3A).

- If the MELD score is between 0 and 5, the message "body function is normal" is displayed.

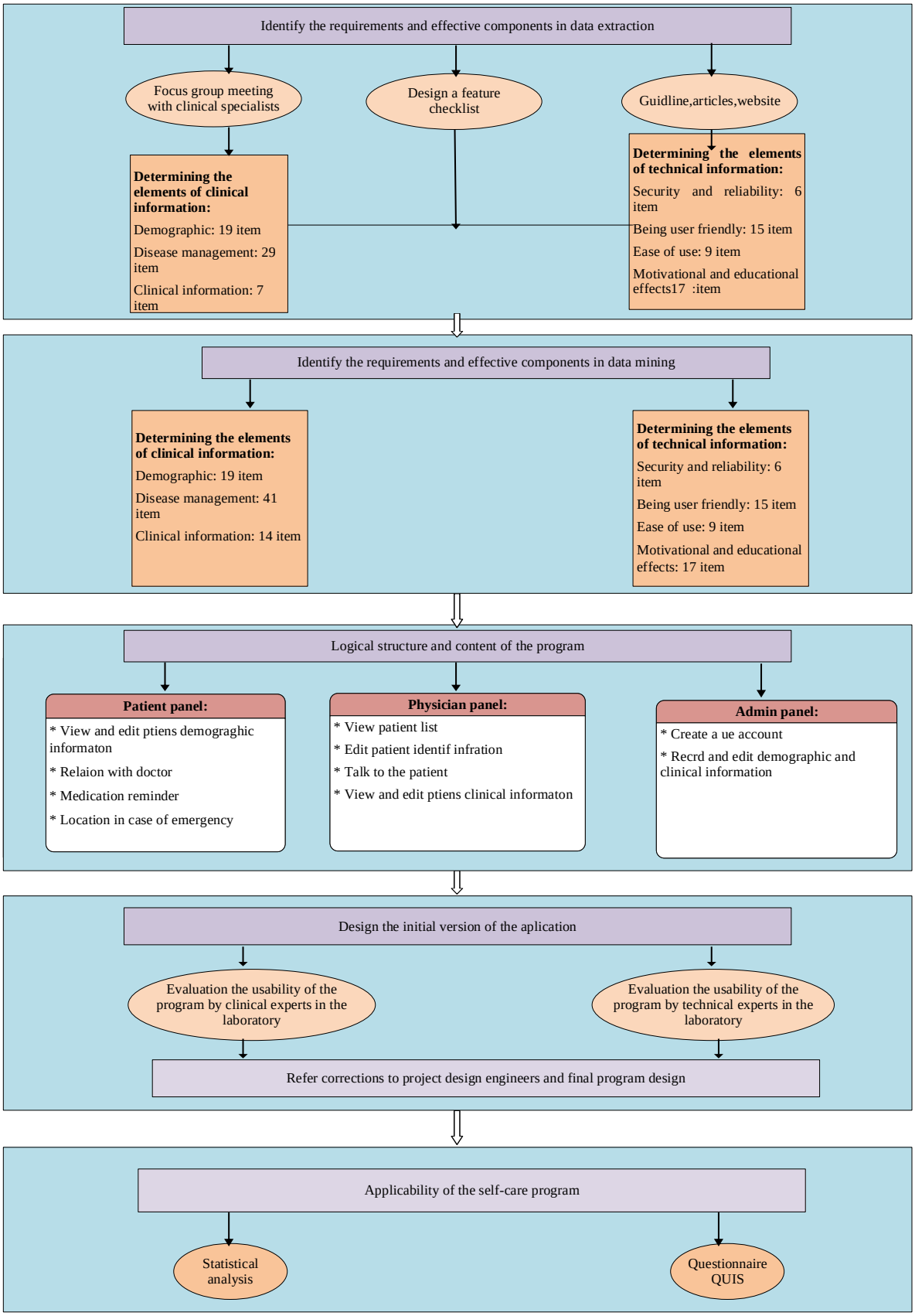

Figure 1. The general steps for developing liver cirrhosis self-care application

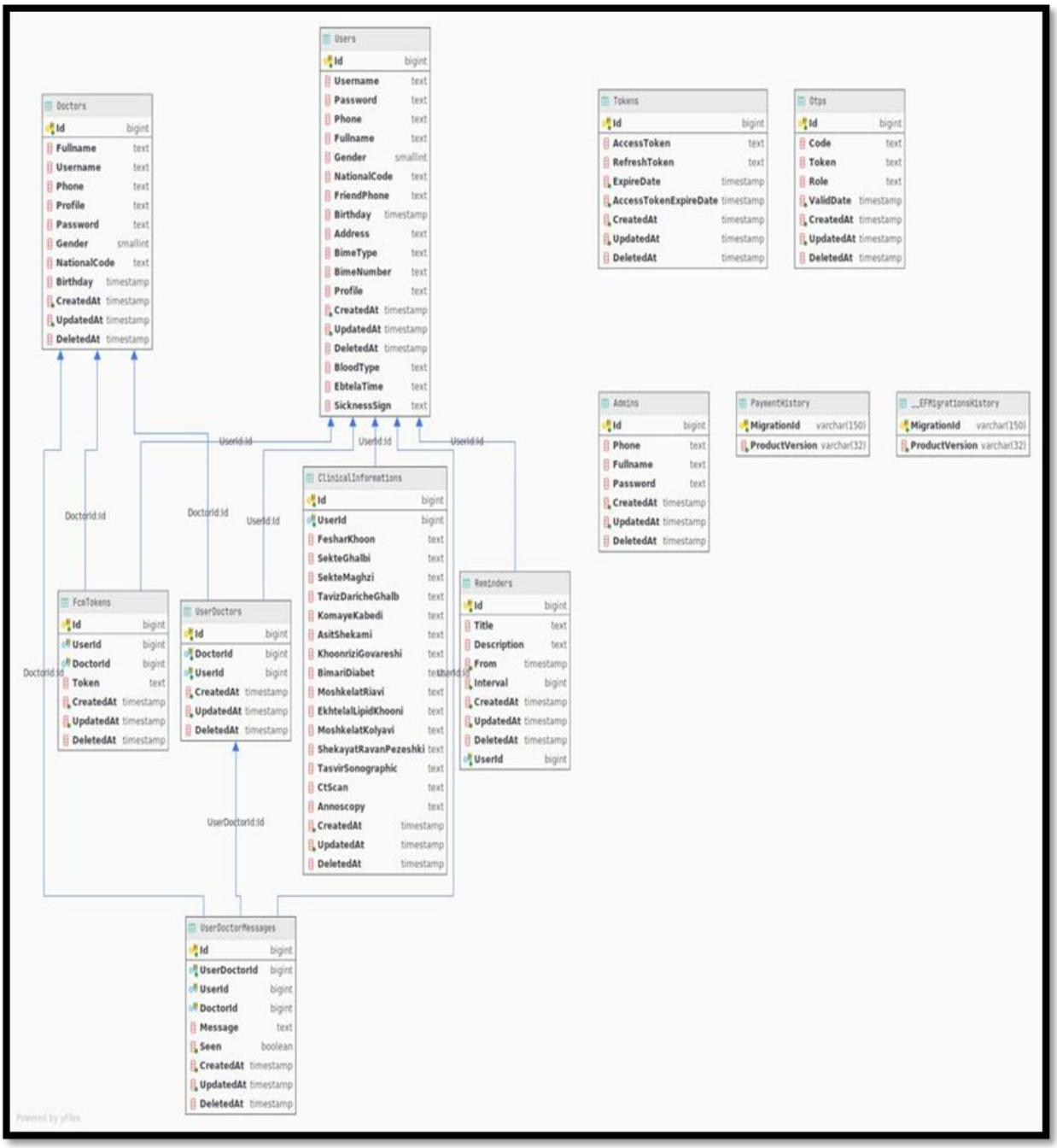

Figure 2. UML diagram of liver cirrhosis self-care application

- If the MELD score is between 5 and 10, the message: “Take pharmaceutical recommendations regularly and avoid painkillers and hypnotics, as there is a possibility of coma" is displayed.
- If the MELD score is between 10 and 15, the message "Comply with medical and nutritional orders and file a transplant file. Filing a medical record is not an emergency." is displayed.

3. The third part is the login page, designed with different access levels of Admin, physician and patient (Figures 3 B, C, D).
- Nutritional information: This part is designed as a text and video clip.
- Information about physical activities: This part is designed as a text and video clip.

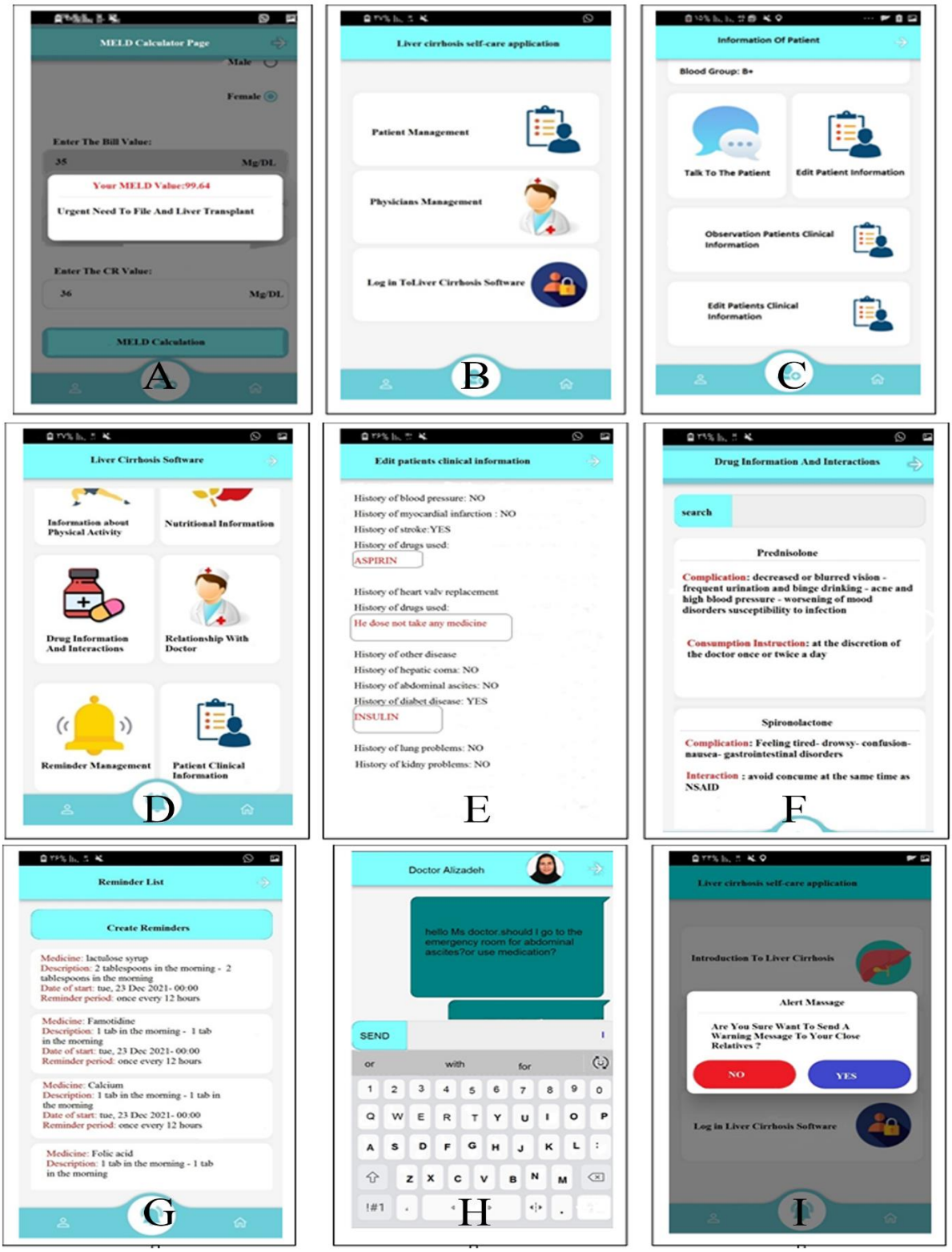

Figure 3. The screenshot of application multiple pages

- Information about disease clinical management: If a patient has an underlying disease, they should specify the disease and record their medications and any possible allergies. This will help the physician

prescribe medications and treatments with the knowledge of these conditions to prevent drug interactions and side effects (Figure 3 E).

- Drug interactions: In this section, a list of all drugs used for liver cirrhosis, as well as drugs related to underlying diseases that a person may be suffering from, has been compiled. Also, consumption instruction, drug interactions and drug warnings can be seen in this section. Frequently asked questions (FAQ) about the side effects of drugs are also written in red to inform and reassure the patient that the side effects are normal (Figure 3 F).
- Reminder management: Patients can enter all their medications in the reminder creation section (reminder title, reminder text, start date, start time, and consumption period). So that application sends a reminder (warning) at the set hours for patients (Figure 3 G).
- Communication with the physician: The patient and physician can exchange messages (Figure 3 H).

4. Location in emergency case: Since muscle cramps are a common side effect of liver cirrhosis that can limit the patient's ability to move (28), a bell-shaped warning section has been designed on all pages due to the critical nature of this complication. In such a situation, the application can connect to Google Maps and send a message to the patient's companion regarding the patient's condition and location, if the patient's GPS is turned on. This will inform the patient's companion of the patient's condition and location (Figure 3 I & Figure 4).

After the application was piloted with a small group of patients, necessary modifications and adjustments were made based on their suggestions, the opinions of physicians, and the research team's feedback. For example, some educational content, especially about diet, was changed from text to video. Based on user feedback, some drug information was added. Additionally, some information was prioritized over other subsections based on the needs of patients and user usage patterns.

Figure 4. Sending coordinates of the patient's location in emergency situations

Some people had difficulty installing the software or receiving reminders. During project implementation, communication was established with patients through a WhatsApp group. If patients had any problems installing or using the software, they were guided. The problems and bugs were fixed in the final version.

Finally, the satisfaction level was measured using QUIS in the sample, as shown in Table 4 and Figure 5.

The demographic information of participants in the study is presented in Table 5.

Discussion

Management of chronic diseases requires interaction between healthcare providers and patients to track the patient's condition and ensure adherence to treatment regimens. Digital tools and mobile-based

Table 4. Evaluation of usability and patients' satisfaction with self-care application

Phrase	Average	Standard deviation	Variance
Overall application performance	7/98	1/77	1/31
Screen	8	1/73	1/30
Terminology and information	7/69	2/41	1/55
Learning	8/04	1/41	1/12
General impressions	8/10	1	1
Average	7/94	1/67	1/26

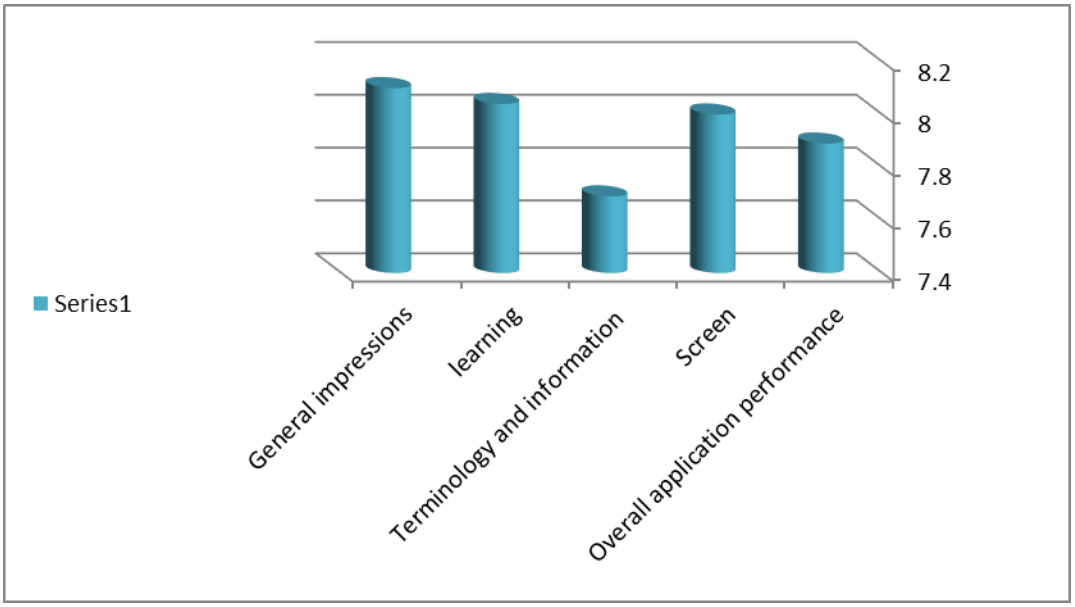

Figure 5. Average level of self-care application usability

Table 5. The demographic information of participants

Item		Abundance	Average
Gender	Female	11	36/67%
	Male	19	63/33%
Age	20-30	11	36/67%
	30-40	11	67/67%
	40-50	4	13/33%
	50-60	4	13/33%
Education	High school	3	10%
	Diploma	6	20%
	Associate	2	6/67%
	Bachelor	15	50%
	Master of science	4	13/33%
Residence	Urban	22	73/33%
	Rural	8	26/67%
Users	Patient	15	50%
	Patients' family	15	50%

software can help providers and patients facilitate this process and improve the quality of healthcare delivery (29). For example, in a study that developed a mobile patient management system for HIV/AIDS and TB patients, the system has the capabilities to set and remind appointments, send drug reminders, and send motivational and educational messages to patients. (30). Other studies have shown that patients who used mobile self-care systems for asthma self-management experienced improvements in pulmonary function (forced expiratory volume and peak expiratory flow rate), quality of life, decreased exacerbation episodes, and unscheduled visits (31).

In this context, self-care applications can potentially improve the self-management and well-being of cirrhosis patients by providing education, symptom tracking, medication management, and lifestyle guidance. This study aimed to develop and evaluate a self-care application for patients with liver cirrhosis.

Similar to our study, various studies have confirmed the role of digital systems in improving the care of patients with liver disorders. For example, Khademzadeh developed an intelligent recommender system for people who are prone to non-alcoholic fatty liver disease. The technical design steps of their system were similar to our study. However, for the system

evaluation, they used the System Usability Scale (SUS) with 30 patients (32). A study aimed at managing the dietary intake of patients with nonalcoholic fatty liver disease using AI (Artificial Intelligence)-based software (Calomeal) automatically analyzed images of meals of 29 patients. The patients received nutritional counseling and were followed up for 6 months. After this period, significant decreases were observed in laboratory test levels and body weight. The Calomeal software increased the patients' dietary awareness, and 75.1% expressed satisfaction with the software (33). In addition to reviewing guidelines and articles, patients and physicians participated in this study to determine the application requirements. This is consistent with the findings of studies highlighting the importance of patient and healthcare provider participation in developing such programs to achieve long-term use and improve patient care and research (34).

A study by Ha et al. was conducted for the remote monitoring of abdominal ascites in outpatients with liver cirrhosis; patients communicated information for managing this complication by sending their weight to their physicians and healthcare providers. Twenty-seven patients used the remote monitoring system (RMS) for 6-week. They answered questions about weight, abdominal pain, fever, abdominal distension, peripheral edema, and jaundice every second day. They could also interact with the treatment team through the software if needed. The results indicated that designed software can provide care for outpatients (35). In the designed application in our study, the "Weight" and "Gender" fields are included in the "MELD" section to manage this complication and prevent abdominal ascites. According to their most recent laboratory test results, the MELD calculation formula is also included so patients can enter their bilirubin, creatinine, and INR in the relevant boxes. Based on the calculated MELD score, recommendations are displayed for the patient's self-care. Additionally, video clips on "nutritional information" and "physical activity" have been designed to provide patients with nutrition and physical activity information to prevent liver ascites' complications.

Some studies have confirmed the effectiveness of using interactive voice response (IVR) to report the main indicators of health status instead of face-to-face visits for patients with liver cirrhosis. For example, one study used IVR to monitor patients and predict their risk of hospitalization and mortality. The 79 patients in the study were followed until they died or received a liver transplant. The study followed up on the patients' jaundice, abdominal/leg swelling, weakness, need for paracentesis, medication changes, and weight changes. The results showed that IVR can effectively manage cirrhosis and identify patients who require serious care and interventions (36). In our study, we designed a "conversation with patient" section in the physician's panel and a "communication with physician" section in the patient's panel. Since most questions are about side effects, medicine consumption, drug interactions in patients with underlying diseases, and necessary measures in case of forgetting to take the medicine, we also designed an "Information & drug interactions" section and a "Reminder management" section in the application. The "Information & drug interactions" section provides information on side effects, drug interactions, and medicine consumption to help patients better understand their medications.

In the reminder management section, the patient can enter their medications and the time of each reminder in the relevant box. The application will then send a reminder (warning) at the set times to prevent the patient from forgetting to take their medication.

According to the results of some studies, using the SCAN-ECHO (Specialty Access Network-Extension of Community Healthcare Outcome) program to manage chronic diseases can be useful and effective if the consultations are done by phone between the primary care physician and specialist (37). In the present study, the "Conversation with Patient" and "Communication with Physician" sections allow patients to communicate directly with their attending physicians. In the "Patient Clinical Information" section, patients can upload laboratory images, ultrasounds, endoscopies, and CT scans for their physicians' advice and dietary and medicinal recommendations. The blood group item is also included in the "Patient Information" section for use in blood transfusions in cases of emergency bleeding. Additionally, the "Information Related to the Clinical Patient Management" section has been designed to record the patient's underlying disease, medications, and drug sensitivities for the best possible management of this chronic disease. Based on the features above, the designed application appears to

have more information and capabilities for managing the disease and its complications.

Our study's major limitations were a small sample size and a short patient follow-up time. These limitations were due to the unwillingness of more patients to participate in the study, or the lack of familiarity of elderly patients with mobile technology to use the software. The strength of our study was the active participation of patients and providers in determining the software requirements and the consideration of all the items specified in other studies in its design.

Conclusion

An educational web-based self-care mobile application was designed and evaluated by patients and their families. The application has six parts, each divided into subparts that provide users with practical information in text and images. It also includes a medication reminder to help users manage the correct and timely use of medications, which is especially important for health recovery.

Liver cirrhosis is a complex disease with various complications and problems for patients and their families. This research focused on developing a self-care application to manage these complications. The evaluation results suggest that this application can help patients with liver cirrhosis and their families access the necessary information about the patient's special care at any time and place. It can also help them better manage the patient's life, improve their quality of life, and monitor their treatment more simply and affordably. Therefore, self-care applications are expected to play a significant role in improving the quality and effectiveness of patient care and ultimately reducing the workload of healthcare providers.

Self-care applications offer many advantages, but there are also some considerations when using them. These include usability and accessibility, data privacy and security, integration with other information systems for effective care, and providing appropriate content and personalization based on individual patient needs. Liver cirrhosis self-care programs can improve self-care in cirrhotic patients by providing education, symptom tracking, medication management, and lifestyle guidance. Overall, these applications help empower patients to actively participate in their care and improve their quality of life.

Ethical statement

The study was approved by Tabriz University of Medical Sciences (HUMS) ethical committee (IR.TBZMED.REC.1399.169).

All methods were carried out in accordance with relevant guidelines and regulations.

Informed consent was obtained from all participants involved in the study.

Conflict of interests

The authors declare no conflict of interest.

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