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ORIGINAL ARTICLE

3 DEVELOPMENT AND VALIDATION OF ANDROID BASED MOBILE APP FOR DIABETIC FOOT EARLY SELF-ASSESSMENT

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ABSTRACT

³⁵ The most common serious complication associated with diabetes is diabetic foot ulcers. The main problem is the delay in early detection by the patient that is suspected to be the trigger for diabetic foot. For this reason, this condition requires creative, innovative, effective and easy breakthroughs that allow independent detection anytime and anywhere. This study aims to develop and validate mobile app; which is called the Android-based Mobile Diabetic Foot Early Self-Assessment (M-DFEET) app with simple features for self-use among type 2 diabetes patients. ³⁹ The research design used was a non-experimental quantitative study. Two steps were taken: developing mobile app, namely the M-DFEET app, and testing the internal consistency reliability and content validity of the tool. Five experts and thirty patients who had type 2 diabetes and did not have foot ulceration and severe systemic disorders were involved in assessing content validity, and internal consistency. ⁴⁰ The results of statistical analysis showed that the mobile app had acceptable content validity (I-CVI was 1.00) and good internal consistency (Cronbach's alpha = 0.74). The M-DFEET app demonstrates a promising, valid and reliable feature to enable patients with type 2 diabetes to do early self-assessment for their feet. Through this mobile app, patients can perform early detection of diabetes independently anytime and anywhere, in addition to receiving ongoing health education. However, it is necessary to conduct further investigation on the usability and the effectiveness of the mobile app toward patient behaviour in preventing foot ulcers with long-term follow-up.

¹⁷ **Keywords:** Diabetic Foot, Mobile App, Type 2 Diabetes, Health Belief Model

INTRODUCTION

Diabetes is a silent killer disease which in a long run has serious complications ²¹. Its complications have become a significant global public health challenge and a leading cause of deaths ^{1,24,29}. The most common serious and devastating complication associated with diabetes is diabetic foot. Diabetic foot is a consequence of severe complications of chronic diabetes which may result in deep tissue lesions associated with neurological disorders and peripheral vascular disease of the lower limbs ²⁸. The increase in the incidence of diabetic foot is due to the increasing prevalence of diabetes worldwide and the prolonged increase in life expectancy of diabetes patients. The occurrence of diabetic foot in patients with type 2 diabetes was quite high; most patients had type 2 diabetes for more than 10 years, and 60% had disabilities, even leg amputation ^{3,23}.

Indonesia is in the seventh highest position in the world with an estimated case of 10.7 million. ¹⁸ The risk of amputation occurs every 30 seconds and is 15-40 times more common in diabetes patients compared to non-diabetes patients. Of all amputated patients, 85% began with foot ulcerations which then worsen to gangrene or severe ^{6,16}. For this reason, increasing awareness of diabetic foot is very important Patient

awareness in the form of self-initiation in detecting as early as possible complications that arise if the problem is not handled needs to be increased ²². It's expected that the delay in early detection of diabetic foot is the main reason for the incidence of diabetic foot. Previous studies reinforced this assumption ² by showing that diabetic foot complications occur due to delays in early detection and poor case management ^{24,27}. Previous research has also revealed that one way to prevent or delay acute or chronic disease progression is early detection and appropriate patient care ^{10,22,23}. Facts on the ground show that early detection programs and instruments related to the early assessment of diabetic foot ²¹ have already existed. One of the instruments that can be used to screen and assess the risk of diabetic ulcers as prevention and treatment is in low's 60-second diabetic foot screening tool ⁵. This tool has ⁴² also been proven to facilitate early detection of the risk of foot ulcers ^{18,25}.

In addition, this instrument also has drawbacks because it is still conventional and requires the assistance of health workers. innovation is needed to develop a more efficient instrument that can be used independently and is easily accessible. It is hoped that the ease of access can increase the

patient's confidence about healthy behaviour in early detection of diabetic feet.

Complications from diabetes can be reduced if confidence in self-care is increased. It is caused more than 95% of treatment for diabetes is observed by the patients themselves based on individual beliefs, abilities, and compliance with health maintenance. Creative, innovative, effective, and easy to do alternatives are needed by patients. One of them is the Mobile Diabetic Foot Early Self-Assessment (M-DFEET). The quality of the instrument is developed based on the user's view on its functionality, reliability, efficiency, usability, and portability. M-DFEET app uses a theoretical approach that builds belief of diabetes patient in early detection to prevent complications. Personal belief is related to vulnerability, severity of a disease, benefits of disease prevention, obstacles in taking an action, and self-efficacy. If a person feels vulnerable to experiencing a serious complication, they will feel threatened and will have a greater chance of taking the most profitable one with the least resistance. Someone will take, early detection of diabetic foot if receiving added cues to action both from within and outside self^{11,13}.

The app has some features which are a login menu, main menu containing patient identity, diabetes screening form regarding patient beliefs, foot assessment items (visual, touch, sensation), conclusions from early foot assessment results, recommendation, health education about foot care, and notification. Visual assessment included analysis of the foot skin condition, toenail condition, pressure of deformity, and footwear. Touch the foot skin temperature and palpate the

pedal pulses. Assessment of sensation was analysed through cotton tip examination.

The aims of this study were to develop and validate a new mobile phone app so called Mobile Diabetic Foot Early Self-Assessment (M-DFEET application) with simple features for self-use by patients with type 2 diabetes.

METHODS

The research design used was a non-experimental quantitative study with two steps were taken: developing mobile app, namely the M-DFEET app, and testing the internal consistency reliability and content validity of the tool. Five experts and thirty patients who had type 2 diabetes and did not have foot ulceration and severe systemic disorders were involved in assessing content validity, and internal consistency.

The instruments used include the title of the instrument, identity with more comprehensive items, early detection of diabetic feet, conclusions from the results of early detection of diabetic feet, and management algorithms according to the results of early detection.

The overall process for developing the M-DFEET application was carried out in two phases. In the first phase, development of a new mobile phone app, namely the M-DFEET application, included patient's belief in forming foot examinations. The design issues that the app must perform, such the functional requirements and the general concept of the app were discussed. This phase was developed in iterative processes until the app was refined. In the second phase, the validity and reliability of app were tested in terms of internal consistency reliability and content validity index.

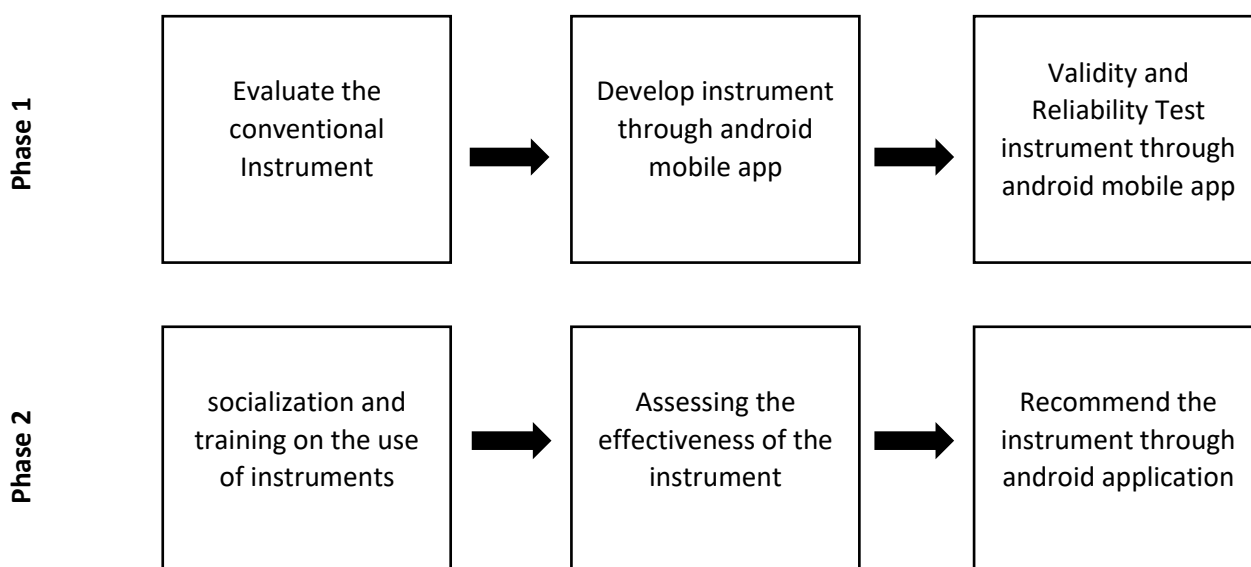


Figure 1: Flow of M-DFEET APP development and the testing

Phase 1: The development of the M-DFEET application was carried out from December 2020 to September 2021 based on

diabetic foot screen tool⁵. It began with assessing some requirement and usage modules of the app generating some alternatives for implementation

and prototyping, testing, and implementations. It was developed in Indonesian language using the Android platform. The Android platform permits broad distribution through Google Play.

Phase 2: Validity and reliability test. The validity of the application is carried out by evaluating the Content Validity Index (CVI). The CVI assessment of the app was carried out by five experts. The experts were two specialists' doctors in diabetes and three nurse educators specialized in diabetes patients and diabetic foot from Indonesia. The validity test was carried out by assessing the I-CVI (Individual Content Validity Index) score. The measurement scales used were as follows: 1: Irrelevant, 2: Somewhat relevant and requires significant changes, 3: Relevant enough, but needs a little change or modification, 4: Very relevant. In addition, to assess to what extent each instrument item is understood, the scales used were 4: good/ very good, 3: needs a little improvement, 2: need major repair, and 1: requires replacement or repair. The item would be accepted if the I-CVI was 1.00. Moreover, reliability was tested using internal consistency reliability (*Cronbach's alpha*). A value greater than 0.7 was generally taken to indicate good internal consistency. In this study, 30 samples were used for internal consistency.

The ethical clearance of this study was obtained from the health research ethics commission of Institute of Health Science with the protocol number: 085/EC-KEPK-SB/IX/2021. The respondents were informed about the aim of the study and requirement to sign an informed consent form for participation agreement.

RESULTS

Starting app development in July 2021. First step is instrument development in the form of paper based through Focused group discussion and expert consultation, Repair of instruments according to the results of FGDs and the results of expert consultations, and validity and reliability testing. The second step is app development by android app developer on August 2021. The next step is app socialization on September 2021 and the last step is app trial among community in October 2021.

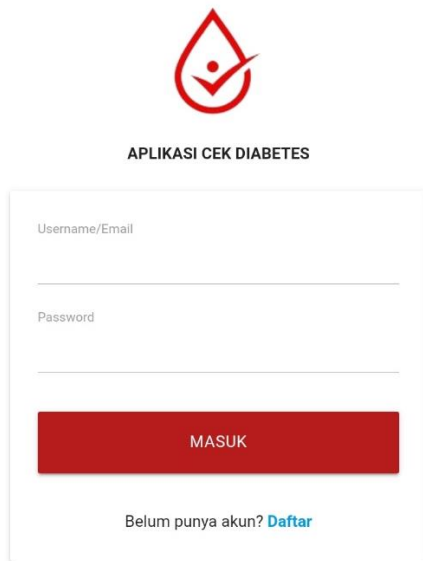
Phase 1: The development of the application. The development of the M-DFEET application started from creating modules that support simple features. The features include a login menu, main menu (dashboard) containing patient identity, diabetes screening form about patient beliefs in performing foot examinations, foot assessment items (visual, touch, sensation), conclusions,

recommendation, health education about foot care, and notification. The theoretical foundation of the health belief model was applied. Before logging in, users had to register first to get a username and password. After successful registration, there would be a notification to their email, and then the user relogged in by entering the username and password that they already had. The system then performed a query process. If the username and password entered were correct, then the process would continue to the dashboard. On the dashboard, there are features about patient identity, diabetes screening form, foot care education, and logout. In the patient identity menu, the users filled in their name, date of birth, gender, duration of diabetes, address, smoking status, comorbidities, and username.

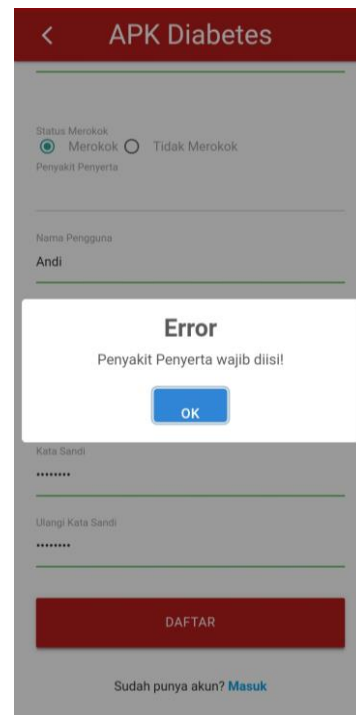
M-DFEET app contains questions about patient beliefs in performing foot examinations: perceived susceptibility, perceived seriousness, perceived benefits, and perceived barriers. The belief instrument was prepared based on the theory of the health belief model. After answering all the questions, users would get conclusions according to their beliefs in the categories of high confidence, medium confidence, and low confidence in a foot self-examination. The next feature is the early detection of diabetic feet which contains 12 questions including visual, touch, and sensation. After completing the foot examination feature, the user would get conclusion score of the assessment which varies from high risk, low risk, and moderate risk of experiencing foot injuries. Based on the final assessment score, the user would get two recommendations. The first recommendation is to carry out routine screening every day through the M-DFEET application and simple self-care at home if the results of the examination are in a low category. The second recommendation is to refer to the nearest health service facility to get further therapy if the results of the examination are in the medium and high categories. Screenshots of the splash screen and main feature before login is shown in Figure 2a, and Figures 2b, 2c, and 2d show screenshots of the registration menu, login menu, and dashboard, respectively.

Based on the figure 2 above, the display of this application is: a. Splash screen and main feature, b. Registration feature, c. Login feature, and d. Dashboard

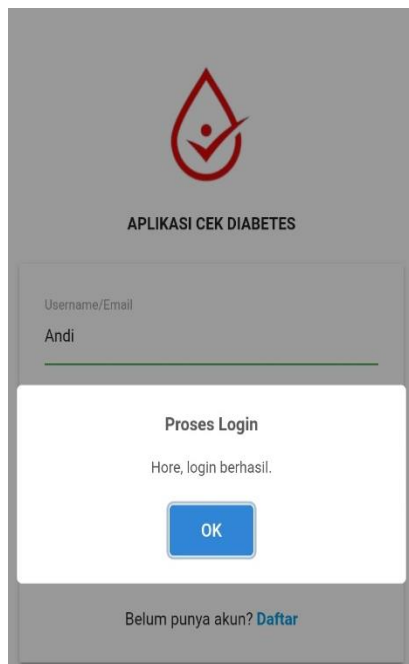
Phase 2: Validity and reliability test. The statistical analysis result showed that the content validity of the M-DFEET application was acceptable (I-CVI was 1.00), and the app had good internal consistency (*Cronbach's alpha* = 0.74). Detailed results of the I-CVI are shown in Table 1



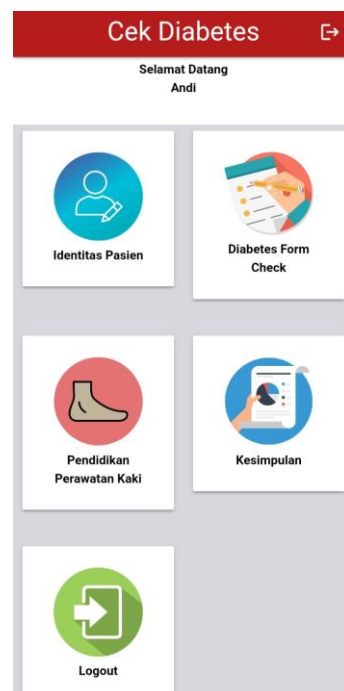
(a)



(b)



(c)



(d)

Figure 2: M-DFEET application user interface

Table 1: Content validity of the M-DFEET application

M-DFEET items	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	I-CVI
Patient identity	4	4	4	4	4	1
Patient belief	4	4	4	4	4	1
Diabetes screening form (visual, touch, sensation)	4	4	4	4	4	1
Conclusion	4	4	4	4	4	1
Recommendation	4	4	4	4	4	1
Health education about foot care	4	4	4	4	4	1

Based on the Table 1 above, result of statistical analysis showed that main menu containing Patient identity, Patient belief, Diabetes screening form (visual, touch, sensation), Conclusion, Recommendation, and Health education about foot care have 4 score from each expert.

DISCUSSION

The M-DFEET application was proven valid and reliable. This application is specially designed to make users especially people with type 2 diabetes easier to carry out foot examinations independently from anywhere and anytime. The development of the M-DFEET app began with the discovery of data about the complexity of foot injuries and their complications. A literature review, field studies on the need for early detection of diabetic foot applications and discussion with doctors and nurses who are experts in the field of diabetic foot were conducted. The delay in preventing the onset of wounds on the diabetic feet is caused by the delay in self-detection. The data showed that many instruments and applications have been developed and published previously on the prevention of diabetic foot injuries^{19,7,9}.

Previous research also revealed that the developed mobile application can prevent the occurrence of diabetic foot^{8,4}. However, these instruments and applications can only be used by health workers and require patients to come to a health service centre. These two reasons are suspected to trigger patients to delay examinations, and thus finally wounds appear or even feet must be amputated. This assumption is also agreed¹⁴ who revealed that the developed mobile application needs to be improved, especially by integrating patient's needs. Previous research has also revealed that mobile applications have proven to be useful in supporting self-care of diabetic patients, but it does not consider the user's need, and thus the users stop using the application². The facts show that the successful control of complications due to diabetic foot will depend on the patient's self-care independently, because more than 95% diabetes mellitus treatment relies on individual beliefs, abilities, and compliance with health maintenance. The quality of the instrument to be

developed depends on the user's view on the app's, functionality, reliability, efficiency, usability, and portability.

The M-DFEET app also identifies the patient confidence in performing routine and independent foot examinations. The Health Belief Model (HBM) theoretical approach, the most widely used theory to explain health behaviour, was used in this study²⁰. This theory explains the effect of a perceived belief or individual belief in disease and health behaviour. Personal beliefs consist of beliefs about vulnerability, severity of a disease, benefits, obstacles in acting and considering self-efficacy or self-confidence in taking an action. If a person feels vulnerable to experiencing a serious complication of the illness they are suffering from, they will feel threatened and have a greater chance of taking health actions that are considered necessary. The chosen course of action is the most profitable one with the least resistance. Health actions e.g., early detection of diabetic foot are taken if there are cues to action both from within and or outside the individual^{11,13}. The M-DFEET application uses a theoretical approach that builds belief of type 2 diabetes patient in early detection of diabetic foot, and it is expected to prevent complication of diabetic foot and reduce causes of mortality.

The limitation identified in this study is that the application was developed in Indonesian language and only for Android users. Affordability of the internet network, especially for those who live in remote area, which makes them unable to use the application properly. Another obstacle is this app had technical problems in the form of the application not responding when socialization was carried out. But this problem can be solved and back to normal in one week. This research does not ask users the level of ease of use because it only aims to testing of usability and effectiveness of the application on the preventive behaviour from diabetic foot has also not been carried out.

CONCLUSION

The purpose of this study was achieved, especially in terms of the development and validation of the application. The M-DFEET application provides simple, promising, valid, and reliable features for diabetic foot self-assessment of type 2 diabetic

patients. With the application, patients can perform ³² early detection of diabetic foot independently from anywhere and anytime. The use of this application is projected to contribute to evidence-based nursing practices and to reduce diabetes-related disability and mortality.

Recommendations

The M-DFEET application can still be developed by adding features regarding the diabetic foot assessment and foot care of diabetes patients. In addition, the automatic chat bot feature needs to be considered to add the benefits for users. Further work is still needed to investigate the usefulness and effectiveness of the application on patient behaviour in preventing foot ulcers with long-term follow-up among larger number of populations.

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