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Development and Evaluation of a Smartphone Application for Managing Gestational Diabetes Mellitus

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Objectives: The purpose of this study was to develop and evaluate an application (app) that provides tailored recommendations based on lifestyle and clinical data entered by the user. **Methods:** Knowledge and functions required for the gestational diabetes mellitus (GDM) management app were extracted from clinical practice guidelines and evaluated through an online survey. Common and tailored recommendations were developed and evaluated with a content validity index. Algorithms to link tailored recommendations with a patient's data were developed and evaluated by experts. An Android-based app was developed and evaluated by comparing the process of data entry and recommendation retrieval and the usability of the app. After the app was revised, the user acceptance of the app was evaluated. **Results:** Six domains of knowledge and 14 functions were extracted. Seven common and 49 tailored recommendations were developed. Nine lifestyle and clinical data elements were modeled. Eight algorithms with 18 decision nodes presenting tailored recommendations based on patient's data and 12 user interface screens were developed. All recommendations obtained from the use of app concurred with recommendations derived by algorithms. The average usability score was 69.5 out of 100. The user acceptance score with behavioral intention to use was 5.5, intrinsic motivation 4.3, the perceived ease of use score was 4.6, and the perceived usefulness score was 5.0 out of 7, respectively. **Conclusions:** The GDM management knowledge and tailored recommendations obtained in this study could be of help in managing GDM.

Keywords: Individualized Medicine, Gestational Diabetes, Evidence-Based Nursing, Reminder Systems, Medical Informatics Applications

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I. Introduction

Gestational diabetes mellitus (GDM) refers to glucose intolerance with onset or first recognition during pregnancy, and its associated physiological changes [1]. According to the US Centers for Disease Control and Prevention, the prevalence of GDM increased from 8.1% in 2008 to 9.2% in 2010 [2]. Statistics from the Health Insurance Review and Assessment Service demonstrate a similar upward trend in the prevalence of GDM from 6.37% in 2010 to 7.79% in 2011 in Korea [3]. This prevalence is likely to increase owing to increasing childbearing age, higher stress levels due to increased social activities, and excessive body weight due to insufficient physical activity in women of childbearing age [4].

If left untreated, GDM can have negative effects on both mother and infant. Pregnant women with GDM often experience intrauterine fetal death, premature birth, dystocia, birth injury, hydramnios, Caesarean birth, and perinatal complications, such as preeclampsia and pregnancy-induced hypertension [5]. Additionally, women with untreated GDM are at an increased risk of developing type 2 diabetes mellitus (DM) after delivery [6]. The fetus of a woman with GDM has an increased risk of developing several diseases, such as respiratory distress syndrome, fetal macrosomia, neonatal hypoglycemia, jaundice, hypocalcemia, and polycythemia [5].

The goal of GDM management is similar to that of the other types of DM management, that is, to maintain a normal level of blood glucose [7]. For this, DM patients should engage in self-management [8], which involves healthy eating, being physically active, monitoring blood glucose, taking medication, problem solving, healthy coping, and risk reduction [9]. Unlike other forms of DM, GDM remits after childbirth. Therefore, activities such as self-monitoring of blood glucose, medical nutrition therapy, exercise intervention, and medication must be performed intensively for the 3–4 months from initial diagnosis to delivery [10].

In a systematic review, tailored interventions for self-management were modestly effective in self-management behaviors of dietary fat intake, level of physical activity, or screening in patients with chronic diseases [11]. Therefore, if GDM patients are provided with a tailored intervention, they may be able to manage GDM more effectively.

Advances in information and communication technology have made tailored interventions possible for health promotion and management in healthcare. Mobile healthcare, including smartphone applications (hereafter, apps), has recently been introduced in healthcare services. Using smartphones, users can access information on the Internet anytime and anywhere. Furthermore, smartphones have advantages over other types of mobile devices as they provide voice delivery services, location-based services, and camera and recording features useful for healthcare [12]. These characteristics make smartphone apps useful for managing chronic diseases [13]. For example, an app providing tailored feedback on eating behaviors, medication compliance, physical activities, and emotions to patients with DM type 2 had a positive impact on blood glucose levels and self-management [14]. Another app for adults with type 1 DM, providing tailored messages based on blood glucose levels, insulin dosages, medications, diet, and physical activities, improved glycemic control [15].

There are a few Android and iOS apps available for GDM management. Even though they allow users to enter data, these apps provide only general information on GDM management not tailored to the users' data. Therefore, it is necessary to develop and apply a smartphone app that can provide tailored interventions pertaining to the self-management of blood glucose, nutrition, and physical activity for GDM patients.

II. Methods

The study was carried out in two phases: development of an app and testing of user acceptance.

1. Development of App

The app was developed following the system development life cycle: analysis, design, development, and evaluation.

1) Analysis

In this stage, the knowledge for GDM self-management and the functions required for a GDM management app were extracted from clinical practice guidelines (CPGs) [7,10,16,17] and related literature [18-20]. After extracting domain knowledge and functional requirements, we surveyed GDM patients on the importance of the knowledge and the usefulness of the functions extracted. We derived common recommendations applicable to all GDM patients as well as tailored recommendations to user's diet, blood glucose, physical activity, ketones, and body weight from the CPGs. A panel of six experts rated the validity of the tailored recommendations using a 4-point Likert scale. The content validity index (CVI) was then calculated. We chose recommendations with an inter-rater agreement over 80% in the content validity test. For the recommendations with CVI scores below 0.80, we revised the recommendations. If all of the experts agreed on their recommendations, we revised the recommendations based on their recommendations. When the recommendations offered by the experts differed, the recommendations were revised based on the CPG published by the Korean Diabetic Association.

2) Design

The functions of the app were presented in a use case diagram. The user interface based on the functions depicted in the use case diagram was designed using Photoshop. The data elements and knowledge required for the app were schematized in an entity relationship diagram (ERD). Then, algorithms linking data and the knowledge were developed. Microsoft Visio was used to draw the use case diagram, ERD, and algorithms.

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3) Development

Databases and knowledge bases were developed using SQLite 3.8.1. The app was developed based on user interface and algorithm design. Java was used as the programming language, and Android Developer Tools were used as the development tool.

4) Evaluation

We evaluated the process of data entry and recommendation retrieval using scenarios. In total, 85 scenarios containing all possible decision nodes of diet, blood glucose, physical activity, ketones, and body weight management were developed and used for the evaluation. Comparisons were then made between recommendations derived by the researcher using algorithms and recommendations obtained by users using the app.

The usability of the GDM management app was evaluated by 5 GDM patients recruited online. Two evaluators were pregnant, and 3 gave a birth in the last 12 months. The patients were provided with an Android application package file and an instruction manual via text message or e-mail. After they used the app for 1 week, they underwent a face-to-face interview (patients 1 and 2), online (patient 3) or telephone survey (patients 4 and 5) for the usability evaluation. The Korean version of the system usability scale [21] was used after verbal approval was obtained for its use [22]. Each of the 10 items was rated on a 0–4 point scale, and the sum was multiplied by 2.5 to convert it to a scale of 100 [21]. If the score was low, we sought additional comments on the functions, ease of use, and contents of the app, and reflected these comments in the revision of the app.

2. Test of User Acceptance

1) Study subjects

Sixty GDM patients were from an online DM community. The inclusion criteria were being pregnant, having a diagnosis of GDM, and possessing an Android smartphone.

2) Measurement tools

Wilson and Lankton's model of patients' acceptance of provider-delivered e-health [23] were used to measure behavioral intention to use (BI), intrinsic motivation (IM), perceived ease-of-use (PEOU), and perceived usefulness (PU) of the app. BI refers to the intention to use the GDM management app in the future, IM refers to the willingness to use the app without any compensation, PEOU refers to the extent to which the app is considered easy to use, and PU refers to the degree to which the user believes that the use of the app would enhance GDM management. BI, PEOU, and PU were measured with the tool developed by Davis et al. [24] and revised by Wilson and Lankton [23]. IM was measured with the tool developed by Davis et al. [25]. BI consisted of 2 items, and IM, PEOU, and PU consisted of 3 items each. The tools were translated into Korean by the research team and back-translated by a nurse fluent in English and Korean. The readability of the tools was tested by 5 doctoral students in nursing informatics. Each item was rated on a 7-point Likert scale (1 = not at all, 4 = average, and 7 = very much). The Cronbach's α of each tool was rated as 0.98 for BI, 0.90 for IM, 0.94 for PEOU, and 0.93 for PU, respectively.

3) Data collection and analysis

The study subjects were provided with a link to the Google Play Store, where they could download the app. The purpose and method of the study were explained both on the Google Play Store's app information screen and on the first screen after the app was launched. Subjects could express their willingness to participate in this study on the first screen of an app. Subjects who agreed to participate in the study were allowed to use the app. After one week's use of the app, the subjects were asked to complete an online questionnaire on user acceptance in a popup window. An online gift certificate was provided as a reward for participation to those who wanted it.

SPSS was used for descriptive statistics of the participants' general characteristics and user acceptance variables.

III. Results

1. Development of App

1) Analysis

Six domains of knowledge and 14 functions of the GDM management app were extracted from the 4 CPGs and 3 related studies (see Table 1).

The survey on the importance of knowledge and the usefulness of functions showed an average score for the importance of knowledge 4.33 and the usefulness of functions of 4.24. In the open-ended survey, users were requested to add knowledge and functions relating to ketone management, alerting functions on time to enter diet, physical activity, ketone, and body weight information. Based on these requests, we added information on ketone management and a function of displaying recommendations when the ketone level is abnormal [10]. Alert functions on time to enter diet, ketone, physical activity, and body weight information were also added.

Common recommendations for all the users regardless of their input data were classified into 1) What is GDM, 2) Diagnosis of GDM, 3) Implications of GDM, 4) Management

Table 1. Domains of knowledge and functions on gestational diabetes mellitus management

Domains of knowledge	Functions	Source
Risk factors of GDM		NICE (2008) [17]
Importance of GDM management of education		ADA (2012) [7] NICE (2008) [17]
Management of blood glucose	Record blood glucose level daily Alert patients to measure blood glucose levels Recommend calories and physical activity according to gestational age and body weight Alert patients for abnormal blood glucose levels Recommend eating sweets in case of hypoglycemia Recommend hospital visit when blood glucose level is abnormal	ADA (2012) [7] NICE (2008) [17] KDA (2011) [10]
Diet	Display daily recommended calories and carbohydrates per meal Display calories of each food consumed Display carbohydrate content of food consumed daily Recommend calorie consumption based on consumed calories	NICE (2008) [17] KDA (2011) [10] Son & KDA (2011) [20] KDA* (2008) [18]
Physical activity	Record types and length of physical activity Recommend type and length of physical activity based on current physical activity	NICE (2008) [17] KDA (2011) [10] Jang (2000) [19]
Body weight	Input the current body weight Recommend body weight based on current body weight	IOM (2009) [16]

NICE: National Institute for Health and Care Excellence, ADA: American Diabetes Association, KDA: Korean Diabetes Association, KDA*: Korean Dietetic Association, IOM: Institute of Medicine.

of GDM: diet, 5) Management of GDM: physical activity, 6) Management of GDM: self-monitoring, and 7) Management of GDM: insulin injection and hypoglycemia. Detailed contents for common recommendations were extracted from an educational booklet called '*DM Management of Pregnant Women*' published by Seoul National University Hospital.

In total, 49 tailored recommendations were extracted: 4 for diet management, 32 for blood glucose management, 6 for ketone management, 3 for physical activity management, and 4 for body weight management. These tailored recommendations are provided according to the interval of data entry. Detailed recommendations for blood glucose, and physical activity management are provided for each meal. Detailed recommendations for blood glucose management were tailored to not only blood glucose, but also diet and physical activity data. Detailed recommendations for diet and ketone management are provided daily. Detailed recommendations for ketone management are tailored to not only ketone, but also diet and blood glucose data. Detailed recommendations for body weight management are provided weekly.

The CVI for the tailored recommendations rated by 6 experts was above 0.80 for 34 items. They include all recommendations for diet, physical activity, and body weight management, as well as 4 recommendations out of 6 for ketone management and 19 recommendations out of 32 for blood glucose management. However, 15 items had CVI values lower than 0.80. They include 2 remaining recommendations for ketone management and 13 remaining recommendations for blood glucose management. Two recommendations for ketone management and 7 recommendations for blood glucose management were revised based on experts' opinions, and 6 recommendations for blood glucose management were revised based on the CPG published by the KDA.

2) Design

(1) Design of functional requirements

Figure 1 displays the use case diagram describing the functional requirements of the GDM management app extracted at the analysis stage. It shows input of initial assessment and lifestyle data, display of recommendations based on data entered, and management of alerts.

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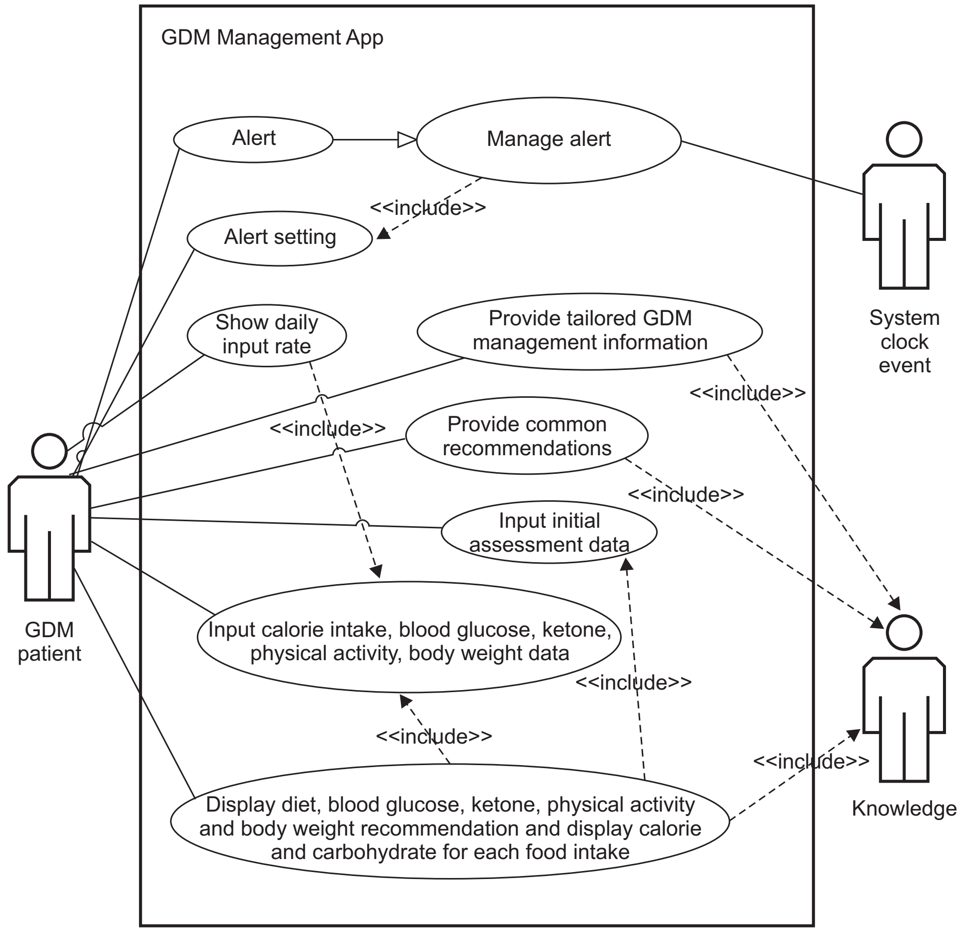

Figure 1. Use case diagram. GDM: gestational diabetes mellitus.

(2) Development of database

The data necessary for GDM management are classified into initial assessment data and lifestyle data. Initial assessment data includes pre-pregnancy body weight, height, expected date of delivery, and past history of hypoglycemia; and lifestyle data includes calorie intake, blood glucose level, physical activity, ketone level, and body weight. In total, 9 data dictionaries were created with the attributes and value sets of the data elements.

In total, 18 decision nodes for providing common recommendations and tailored recommendations based on lifestyle and clinical data (calorie intake, blood glucose level, ketone level, physical activity, and body weight) were developed. Table 2 shows an example of decision node recommending duration of physical activity.

The relationship between the data and the tailored recommendations for the GDM management app is presented as an ERD in Figure 2. Ten tables of the database include tables for initial assessment data, diet, blood glucose, physical activity, ketone, body weight, tailored recommendations, common recommendations, calories and carbohydrate by food, and metabolic equivalent tasks by physical activity.

(3) Development of algorithms

The process of presenting tailored recommendations based on patient's lifestyle and clinical data was developed as algorithms. In total, 8 algorithms were developed, 1 main algorithm and 7 sub-algorithms. The main algorithm includes the overall process of GDM management. The 7 sub-algorithms include algorithms for displaying tailored normal ranges based on initial assessment data, alert setting and alerting, diet management, blood glucose management, physical activity management, ketone management, and body weight management. Figure 3 shows the flowchart for the body weight management sub-algorithm.

(4) Design of user interface

In total, 12 screens were designed. They include screens for the main menu, initial assessment data entry/modification, displaying recommended range, displaying common recommendations, alert setting, diet management, blood glucose management, physical activity management, ketone management, body weight management, monitoring lifestyle data entry rate, and app information. Figures 4 and 5 show the

Table 2. Examples of tailored recommendations

Node	Recommendations
If "physical activity input value after a meal" does not exist	Physical exercise is important for blood glucose management. Please press "no exercise" if you did not exercise.
If "physical activity input value after a meal" is 0–19	You are not exercising enough. Please exercise for 20 minutes after a meal. If exercising is difficult for you, you should take a break and exercise for 10 minutes at a time.
If "physical activity input value after a meal" is 20	You have exercised the recommended duration.
If "physical activity input value after a meal" is 21–30	You have exercised a little bit more than recommendation. If your lower abdomen contracts more than 4 or 5 times during exercise, it is recommended that you drink a cup of water, lie down on your left side, and breathe from the abdomen. Please exercise for 20 minutes after a meal.
If "physical activity input value after a meal" is ≥31	You have exercised excessively. Too much exercise can lead to pregnancy complications such as uterine contractions. Please exercise for 20 minutes after a meal. If your lower abdomen contracts more than 4 or 5 times during exercise, it is recommended that you drink a cup of water, lie down on your left side, and breathe from the abdomen. If your lower abdomen contracts continuously, you need to see your doctor.

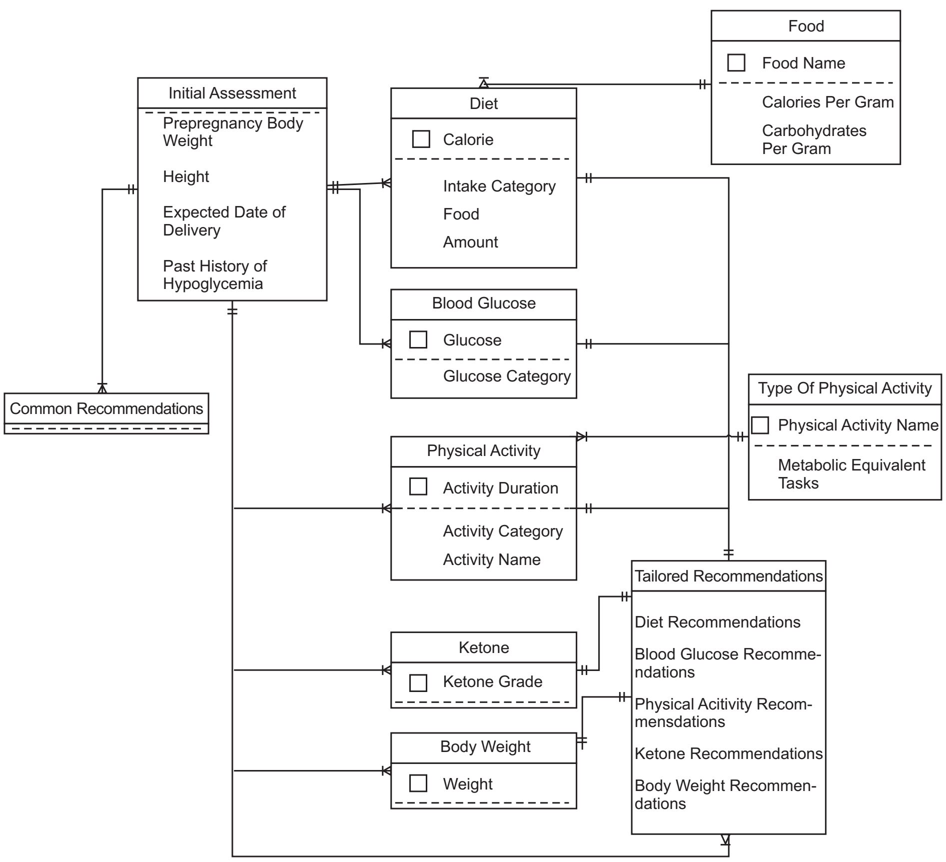

Figure 2. Entity relationship diagram.

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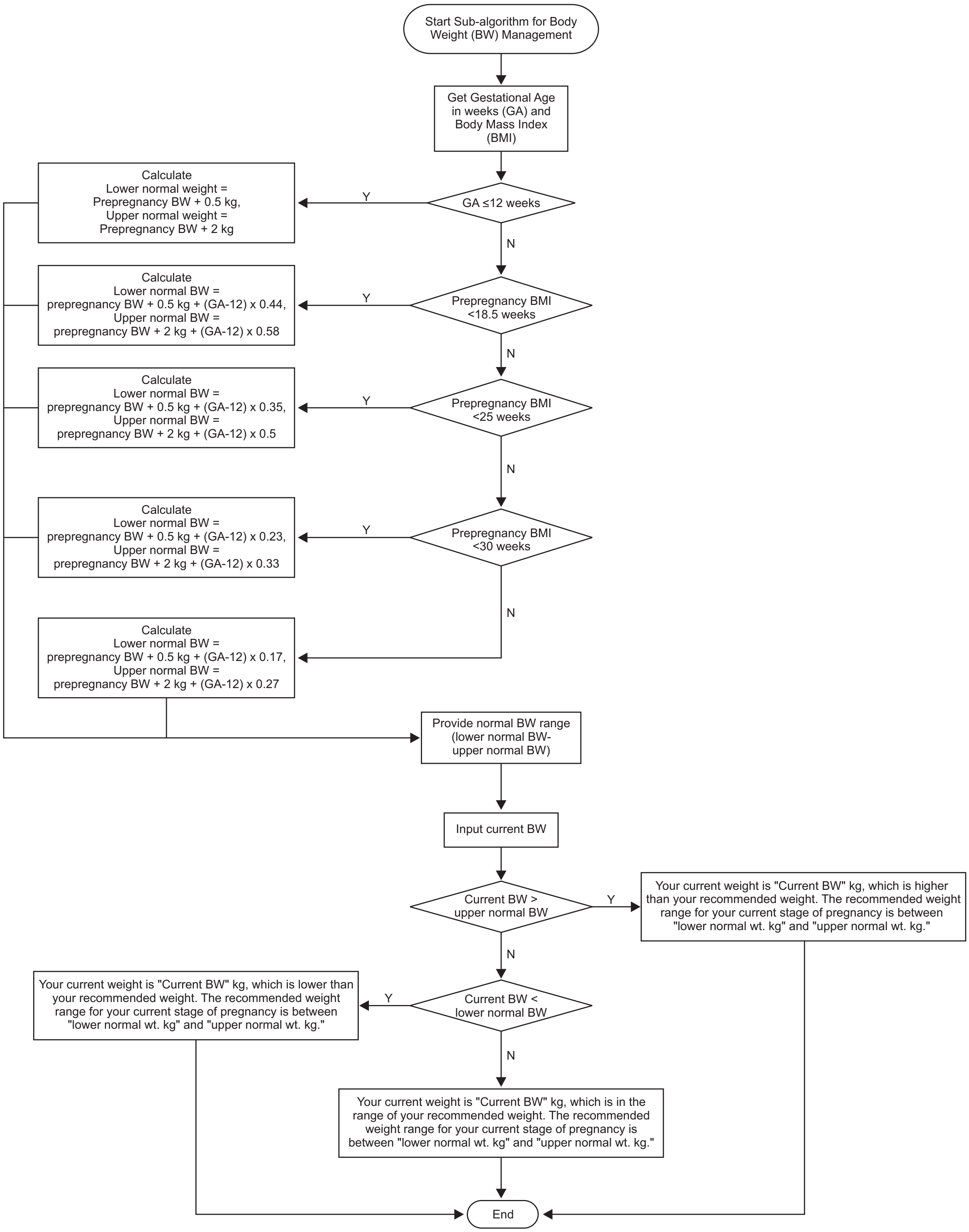

Figure 3. Flowchart for body weight management sub-algorithm.

screens for ketone management and body weight management, respectively.

3) Development

The GDM management app was developed on a PC with the Windows 7 (64-bit) OS. Android Developer Tools were

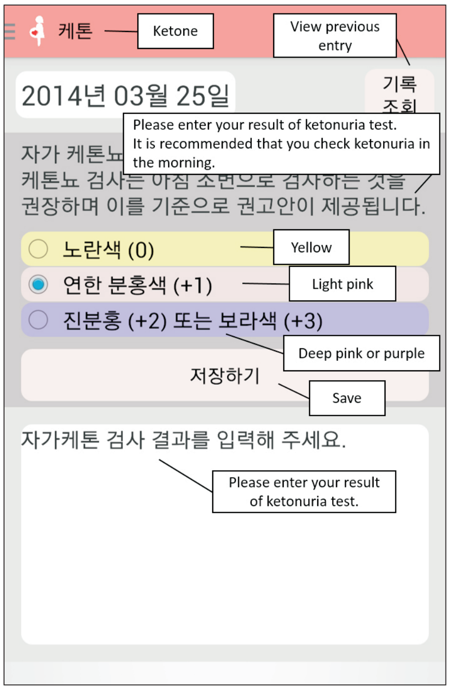

Figure 4. Screen for ketone management.

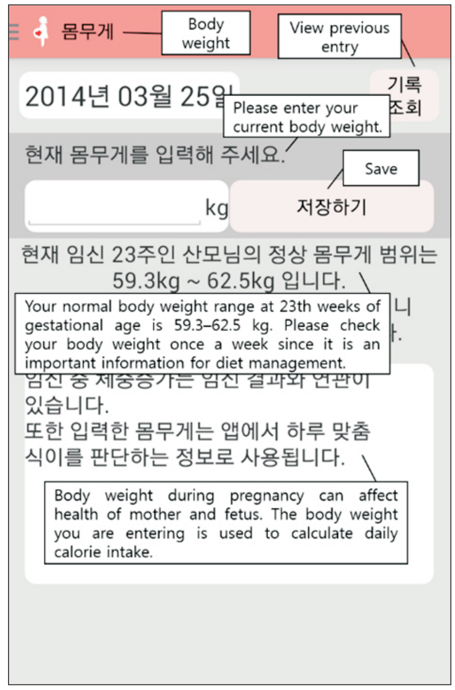

Figure 5. Screen for body weight management.

used in the Eclipse development environment and ActionBarSherlock was used as a library for the user interface. Java was used as the programming language. The smartphone app supports Android 2.2 (code name: Froyo, API level: Android 8) through Android 4.4 (code name: Kitkat, API level: Android 19).

4) Evaluation

Regarding the evaluation of data entry and recommendation retrieval process using scenarios, all recommendations obtained from the use of the app by 2 users concurred with recommendations derived from algorithms by the first author using 85 scenarios.

Regarding the usability of app, usability scores ranged from 52.5 to 87.5 with the average of 69.5. The participants requested the addition of more food items to the food database, a function to modify input data, a function to display the previous input when entering calorie intake, and extra slots for them to enter more snack intake. Additionally, they requested changes of displaying calories in the food database from calories per portion to calories per 100 g, and for a louder alert sound. The app was modified to incorporate all of these requests except the addition of extra slots to enter more snack entries based on the CPGs recommendation of three meals and three snacks per day.

2. Test of User Acceptance

Out of 60 GDM patients who downloaded the app, 36 participated in the acceptance survey. Fourteen out of 36, five using the same IP, five using the same cellphone number, and four with no GDM, were excluded from the study. In total responses of 22 were analyzed.

The average age of the participants was 32.2 years, and the average gestational age was 32.7 weeks. Among the participants, 12 (54.5%) replied that it was their first pregnancy, 8 (36.4%) their second, one (4.5%) her third, and one (4.5%) her fourth. Fourteen (63.6%) of them had a normal body mass index, and eight (36.4%) were overweight. For 20 (90.9%), it was the first time they had been diagnosed with GDM, and two (9.1%) had had GDM before. Eight (36.4%) had received education on GDM, and the remaining 14 (63.3%) had received no previous education on GDM (see Table 3).

The average scores for BI, IM, PEOU, and PU were 5.5, 4.3, 4.6, and 5.0 out of 7, respectively. Out of 11 items, “I will find the GDM app enjoyable” of IM had the lowest score (4.2), and 2 items of BI showed the highest score (5.5) (see Table 4).

IV. Discussion

In this study, we developed an app to provide tailored recommendations to initial assessment data and lifestyle data entered by the user based on CPGs, and we then evaluated

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Table 3. Demographic characteristics of respondents

Characteristic	Frequency (%)
Age (yr), mean	32.2
25–29	6 (27.3)
30–34	12 (54.5)
35–39	4 (18.2)
Gestational age (wk), mean	32.7
25–29	7 (31.8)
30–34	6 (27.3)
35–39	9 (40.9)
The number of pregnancy	
1	12 (54.5)
2	8 (36.4)
3	1 (4.5)
4	1 (4.5)
BMI (kg/m^2)	
Normal (18.5–24.9)	14 (63.6)
Overweight (25.0–29.9)	8 (36.4)
GDM before pregnancy	
Yes	2 (9.1)
No	20 (90.9)
Previous education on GDM	
Yes	8 (36.4)
No	14 (63.3)
Experience of health management app use	
Yes	6 (27.3)
No	16 (72.7)
Contents of the apps used before	
Pregnancy	5 (83.3)
Weight management	2 (33.3)
DM management	4 (66.7)
Frequency of app use per week	
1	1 (16.7)
5	2 (33.3)
>7	3 (50.0)

GDM: gestational diabetes mellitus, DM: diabetes mellitus.

the user acceptance of the app.

According to the system development cycle, we reviewed published CPGs [7,10,16,17] and three research articles on GDM [18-20] and extracted domains of GDM knowledge and functions for GDM management in the analysis stage. An online survey was conducted with GDM patients on the importance of the knowledge and the usefulness of the functions. The results showed high scores for importance and usefulness. Sometimes there were no detailed recommendations for GDM management available in the CPGs, for example, daily maximum amount and time of physical activity or hyperglycemia management in a situation of low calorie intake and high exercise levels. In such cases, we developed tailored recommendations based on the expert knowledge of nurses caring for GDM patients. As Sonnenberg and Hagerty [26] observed, CPGs cannot cover all possible clinical scenarios.

Data elements and knowledge for GDM management were identified and the relationship between the data and the knowledge was designed as a database in the design stage. Algorithms linking data and knowledge to provide tailored recommendations were developed. This study is the first attempt to provide tailored recommendations for GDM management based on data entered by patients.

An app was developed for the Android operating system which had the highest penetration rate in the smartphone market in 2011 [27]. Unfortunately, this limits the iPhone users' access to the app.

It was found that all recommendations obtained from the use of the app concurred with the recommendations derived from algorithms using scenarios in the evaluation stage. The average score for app usability was relatively low at 69.5 out of 100. Even though this score is above average and in the acceptable range according to Bangor et al. [28], the low score reflects the number of requests made by the users during the usability evaluation. The app was modified to reflect most of these users' requests.

The user acceptance of the app was evaluated after one week of use. Acceptance scores were relatively low compared to the evaluation results of Guo et al.'s DM management smartphone app [29]. The low average scores are likely because this study only provided an app service; however, the study of Guo et al. [29] provided not only app service but also nurse-led consultation service. If the subjects in the study of Guo et al. [29] had questions or concerns arose, they were encouraged to call or meet the care manager in person. In addition, because GDM is related to fetus outcomes, the anxiety of GDM patients is higher than that of general DM patients. This may lead GDM patients to have higher expectation for a GDM app. However, some positive comments were made by the users. For example, some commented that a free and easy access to GDM educational materials and providing tailored normal ranges of various self-management variables on the app was of great help.

The GDM management knowledge and tailored recommendations obtained in this study could be helpful in man-

Table 4. Results of app acceptance survey

Construct	Item	Item Mean ± SD	Construct Mean ± SD
Behavioral intention to use	I intend to use the GDM app.	5.5 ± 1.1	5.5 ± 1.1
	I predict I will use the GDM app.	5.5 ± 1.2	
Intrinsic motivation	I will find the GDM app to be enjoyable.	4.2 ± 1.7	4.3 ± 1.6
	The actual process of using GDM app will be pleasant.	4.4 ± 1.8	
	I will have fun using the GDM app.	4.4 ± 1.7	
Perceived ease of use	My interaction with the GDM app will be clear and understandable.	4.7 ± 1.7	4.6 ± 1.7
	The GDM app will be easy to use.	4.5 ± 1.9	
	I will find it easy to get the GDM app to do what I want it to do.	4.5 ± 1.9	
Perceived usefulness	Using the GDM app will support critical aspects of my healthcare.	4.6 ± 2.0	5.0 ± 1.7
	Using GDM app will enhance effectiveness in managing my healthcare.	5.2 ± 1.7	
	Overall, the GDM app will be useful in managing my healthcare.	5.2 ± 1.7	

GDM: gestational diabetes mellitus, DM: diabetes mellitus.

aging GDM in the future. Nevertheless, this study has the following limitations.

First, in this study, we created an app only for the Android users excluding iPhone users. Thus, we recommend the development of an iPhone-based app in the future.

Second, this study did not include insulin treatment and stress management of the GDM self-management elements because there were no detailed recommendations available on these domains. However, if the disease cannot be controlled by lifestyle management, it is necessary for patients to take insulin treatment [7,10]. Also, the blood glucose levels of patients with GDM can also be affected by stress [30]. Therefore, we recommend inclusion of insulin treatment and stress management in the future.

Finally, in this study, we evaluated acceptance level but did not evaluate the clinical effects of the app, such as reductions in blood glucose levels. Therefore, we recommend a study to evaluate the clinical impact of the app on the blood glucose levels of patients with GDM in the future.

Conflict of Interest

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

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