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Original Article

A validation study of questionnaire towards mobile based health applications in uncontrolled diabetic population of India (South)

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ABSTRACT

Background: Mobile applications have the potential to provide needed support for older adults with diabetes. The field of medical application is currently one of the most dynamic in application development and medicine.
Objective: This study was designed to develop and validate a questionnaire to assess knowledge, attitude and practice of uncontrolled diabetic patients towards mobile based health applications.
Methods: A Cross Sectional study was designed and enrolled 78 adult uncontrolled diabetic (≥18 years old DM type 2)patients and clinically validated questionnaire was examined for internal consistency, reproducibility, convergent and discriminant validity using Cronbach's alpha, intra class correlation and CITC scores respectively.
Results: Cronbach's alpha coefficient was 0.97 for Assessment of Knowledge, 0.93 for Assessment of Attitude, and 0.90 for Assessment of Practice in uncontrolled diabetic population.
Conclusion: The final version of questionnaire was found to be statistically internally consistent, reproducible and reliable and could be used to assess the awareness and attitude of patients towards self-management of diabetes mellitus.

1. Introduction

The increased prevalence of type II diabetes and required intensity of disease management programs are straining health care providers who often lack adequate time with patients [1].The self-management of non-insulin requiring type II diabetes deemphasizes frequent blood glucose monitoring and focuses on the modification of lifestyle behaviors [2].Mobile applications have the potential to provide needed support for older adults with diabetes. Preliminary research results for mobile application use suggest great potential for enhancing the outcomes in diabetes patients [3]. Most of the existing diabetes apps support self-management tasks such as blood glucose testing, physical exercise tracking, insulin and other medication administration, diet, and general diabetes education [4]. The field of medical apps is currently one of the most dynamic in app development and medicine with real potential to change the way evidence-based healthcare is delivered [5]. Although there is no evidence-based guideline specifically for diabetes apps targeted for older adults, there is an existing global clinical guideline for managing older people with diabetes and mobile app usability criteria that includes basic usability for interaction processes, interface design, and comprehensibility of content both in general and specifically for the elderly [6,7]. Mobile phones have become an essential communication tool globally; the advances in technology have further increased smart phone reliability in various uses [8]. Mobile applications are tools which provide various functionalities and services ranging from entertainment, business, education, and self-management, including incorporation into chronic disease management and prevention such as diabetes self-care [9]. It has been shown that diabetes self-care can be improved with mobile phone interventions since they offer great potential to support therapy management, to increase therapy adherence, and to prevent disease complications [10]. Valuable features of mobile apps such as simplicity to use, ability to provide specific instructions for better disease management, and ability to share data with other individuals [11]. Overall, as mobile phones are accessible to majority of the global population, use of mobile based applications are to promote medication adherence in patients with uncontrolled diabetes mellitus can have significant effects on the outcomes of pharmacotherapy [12]. Hence this study was designed to develop and validated a questionnaire to assess

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knowledge, attitude and practice of uncontrolled diabetic patients towards mobile based health applications.

2. Methods

2.1. Subjects and procedure

This study was conducted for a period of 3 Months (December 2018 to February 2019) in a General Medicine department of Secondary care hospital Located in Chennai. The protocol was reviewed and approved by the Institutional Ethics Committee before study commencement (Approval No. VISTAS - SPS/IEC/IX/2018/01). Consent from the authorities of the hospital was obtained prior to administration of questionnaires to patients.

2.2. Subject recruitment and confidentiality

Uncontrolled diabetic patients whose HbA1c was greater than 7.5. were requested participation. The study protocol was thoroughly explained to the participants by the investigator. Patients were enrolled into the study only on provision of a written informed consent. All data were documented in specially designed case report forms, and access was restricted to the investigator to ensure non-violation of subject rights and confidentiality.

2.3. Study design

Cross-sectional survey.

2.4. Sample size

Sample size was estimated using the following formula for calculation of sample size for quantitative variable.

$$\text{Sample size} = (Z_{1-\alpha/2})^2\,(SD)^2/d^2$$

$$\text{Sample size} = 78$$

Where $Z_{1-\alpha/2}$ is standard normal variate as mentioned in previous section, where SD is the standard deviation of variable taken from previously done studies, d is the absolute error or precision [13].

2.5. Study methodology

2.5.1. Validation of questionnaire

Reliability analysis. Internal consistency of individual items in each domain of the questionnaire was examined to assess the overall reliability. The homogeneity of questions in each domain was determined in terms of Cronbach's alpha (α) coefficient, whose value of 0.7 or above was considered for the questionnaire to be internally consistent. Reproducibility of answers was also examined through administration of the questionnaire to mentally stable patients on day 1 (test arm) and day 15 (re-test arm: wash out period of 14 days) and computation of intraclass correlation coefficient (ICC). An ICC of 0.7 or above was considered significant for test-rest reproducibility.

Construct validity. Corrected-Item to Total Correlation (CITC) scores and Average Variance Extracted (AVE) were computed to examine convergent and discriminant validity of the construct respectively.

2.5.2. Inclusion criterion

Uncontrolled diabetic patients (HbA1C > 7.5) of either gender, who express willingness to participate in the study by providing a written informed consent.

2.5.3. Exclusion criterion

- Patients with underlying psychiatric or cognitive dysfunctions and diabetic patients whose HbA1C is less than 7.5.
- Patients who do not undersign the written informed consent.

2.6. Statistical methods

Descriptive summary of demographic and clinical variables is presented either as mean ± SD or as median (minimum and maximum). Choice of descriptive and inferential statistical method was based on distribution normality as determined through normal probability plot and Shapiro-Wilk test. Statistical analyses were performed using International Business Machines – Statistical Package for the Social Sciences (IBM – SPSS) 20.0 and Graph Pad Prism 6.0.

3. Results

Patients with type II diabetes mellitus who visited the hospital were requested participation. The printed version of questionnaire was issued to 78 patients. 62 patients filled independent responses to the questions and returned the questionnaires back to the investigator. Hence the response rate was 79.5%. Descriptive summary of demographical parameters of the studied population is shown in Table 1.

Reproducibility of responses was examined through computation of intraclass correlation coefficient. Two sets of answers from the patients in the test-retest arm were obtained and examined. A coefficient of 0.7 or higher was considered as a measure of significant reproducibility were shown in Table 2 & Table 3.

Purification of items was not carried out because the CITC of all individual items were above 0.5 and the Cronbach's alpha of all the individual constructs were above 0.8 suggesting the constructs to be consistent before purification itself. Table 4 &Table 5.

Factor structures were accepted as the composite reliabilities and average variances extracted for individual constructs were above acceptable limits as shown in Table 6.

Discriminant validity

Empirical distinction of individual constructs was examined through discriminant validation. The squared correlation of each pair was less than the variances extracted suggesting significant empirical distinction between the constructs as shown in the Table 7.

Table 1
Summary of demographics (n = 62).

S. No	Demographic	Category		Number of Patient (%)
1.	Age (in years)	*Range*	*Summary Statistics*	08 (12.9)
		18–35	34 (24, 35)	
		36–65	52 (41, 64)	54 (87.1)
2.	Gender	Male		39 (62.9)
		Female		23 (37.1)
3.	Literacy rate	Literate		51 (82.3)
		Illiterate		11 (17.7)
4.	Location	Urban		52 (83.9)
		Rural		10 (16.1)
5.	Smoking History	Smokers		20 (32.3)
6.	Alcoholism	Alcoholics		24 (38.7)
7.	Obesity	Normal		40 (58.1)
		Overweight		03 (4.8)
		Class I obesity		09(14.5)
		Class II obesity		05 (8.1)

Table 2
Reliability analysis: Summary of tests for reproducibility.

Domain	Maximum Score	Median Scores[a]		P-value[b]	ICC
		Day 1	Day15		
Knowledge	5	2 (0, 3)	2 (0, 3)	0.217	0.91
Attitude	5	0 (−2, 2)	0 (−2, 2)	0.558	0.94
Practice	5	−2 (−3, 2)	−2 (−3, 2)	0.999	0.98

[a] Data represented as median (minimum, maximum).
[b] P-value retrieved through Wilcoxon matched pairs signed rank test, ICC: Intraclass-correlation coefficient.

Majority of the patients possess inadequate knowledge, attitude and practice towards use of mobile based health applications.This necessitates the need to promote awareness and attitude of patients towards mobile based health applications.

4. Discussion

Diabetes self-management mobile apps that are designed and developed to manage diabetes may support self-management in diabetes [13]. There are various free or paid apps for diabetes yet their use by patients necessitates supervision as the health benefits of mobile apps in managing diabetic conditions are unknown. Thus, the use of mobile medical apps which can assist diabetes mellitus management is limited [14]. Before mobile apps are promoted to increase their use in managing diabetes among patients, a systematic evaluation of selected mobile medical apps for diabetes mellitus self-management is important to guide diabetic patients or care givers in choosing suitable mobile medical apps for diabetes self-management [15]. The evaluation of the contents and features of mobile medical apps for diabetes self-management would allow to rank the usability and completeness of the mobile apps [16]. Quality and consistency of the questionnaire was determined by

Table 3
Mean Score, Cronbach's alpha, and Intraclass Correlation Coefficient.

Constructs	Items	Mean Score (n = 62)	Cronbach's alpha coefficient (n = 62)	Intraclass correlation coefficient (n = 62)
	Assessment of Knowledge	62.9	0.90	0.86
	Assessment of Attitude	14.9	0.89	0.86
	Assessment of Practice	29.0	0.87	0.89
Knowledge	Do you own an android or iOS or Windows based smart device?	80.6	0.84	0.81
	Do you have access to good internet connectivity?	72.6	0.87	0.92
	Does any of your activity of daily living requires your smart device?	48.4	0.94	0.87
	Do you use mobile applications frequently?	33.8	0.88	0.82
	Do you feel easy and comfortable to use your smart device?	79.0	0.95	0.89
Attitude	Are you aware of mobile based health applications?	24.2	0.86	0.80
	Do you feel that mobile based heath applications can promote your medication adherence?	16.1	0.80	0.94
	Do you feel that mobile applications can keep a good track of your blood sugar profile?	8.1	0.89	0.83
	Are your aware that mobile based health applications can help in planning your diet?	6.5	0.93	0.81
	Do you feel the information you receive via the mobile health application trust worthy?	19.4	0.95	0.92
Practice	Do you feel safe for your personal health data to be available on servers and to be accessed (ONLY) by health care professionals?	24.2	0.82	0.87
	Have you ever used a mobile health application before for diabetic management?	0	0.87	0.89
	Do you feel it is possible to adopt the life style interventions suggested by the mobile application?	21.0	0.91	0.90
	Are your aware that mobile based applications are not a replacement for clinic visits?	43.5	0.83	0.95
	Do you feel that mobile based health applications can enhance your knowledge of diabetes and its management?	56.5	0.94	0.86

Table 4
Reliability analysis: Tests for internal consistency.

S. No	Questions	Factor loading	Corrected item-to-total correlation	Construct wise Cronbach's Alpha
Domain I – Assessment of Knowledge				
1.	Do you own an android or iOS or Windows based smart device?	0.677	0.634	**0.97**
2.	Do you have access to good internet connectivity?	0.832	0.781	
3.	Does any of your activity of daily living requires your smart device?	0.768	0.834	
4.	Do you use mobile applications frequently?	0.845	0.825	
5.	Do you feel easy and comfortable to use your smart device?	0.751	0.697	
Domain II – Assessment of Attitude				
1.	Are you aware of mobile based health applications?	0.678	0.658	**0.93**
2.	Do you feel that mobile based heath applications can promote your medication adherence?	0.767	0.861	
3.	Do you feel that mobile applications can keep a good track of your blood sugar profile?	0.811	0.739	
4.	Are your aware that mobile based health applications can help in planning your diet?	0.708	0.794	
5.	Do you feel the information you receive via the mobile health application trust worthy?	0.794	0.678	
Domain III – Assessment of Practice				
1.	Do you feel safe for your personal health data to be available on servers and to be accessed (ONLY) by health care professionals?	0.627	0.716	**0.90**
2.	Have you ever used a mobile health application before for diabetic management?	0.648	0.775	
3.	Do you feel it possible to adopt the life style interventions suggested by the mobile application?	0.812	0.817	
4.	Are your aware that mobile based applications are not a replacement for clinic visits?	0.644	0.685	
5.	Do you feel that mobile based health applications can enhance your knowledge of diabetes and its management?	0.736	0.752	

Table 5
Factor structure analysis of individual constructs and convergent validity.

Kaiser-Mayer-Olkin Sampling Adequacy Measure = 0.881				
Item	Assessment of Knowledge	Assessment of Attitude	Assessment of Practice	Construct wise Cronbach's Alpha
K_1	0.748			**0.97**
K_2	0.819			
K_3	0.798			
K_4	0.745			
K_5	0.702			
A_1		0.684		**0.93**
A_2		0.708		
A_3		0.793		
A_4		0.788		
A_5		0.845		
P_1			0.817	**0.90**
P_2			0.742	
P_3			0.628	
P_4			0.793	
P_5			0.844	
Eigen value	3.215	2.742	2.885	
% of Variance	6.1%	8.7%	11.1%	25.9% (Total)

Table 6
Acknowledgment of factor structure for individual constructs.

S.No	Construct	No. of Items in Construct	Composite Reliability	Convergent Validity (AVE)
1.	Assessment of Knowledge	5	0.857	0.635
2.	Assessment of Attitude	5	0.926	0.715
3.	Assessment of Practice	5	0.908	0.642

AVE: Average Variance Extracted.

Table 7
Discriminant validity and squared correlation between the constructs.

	Assessment of Knowledge	Assessment of Attitude	Assessment of Practice
Assessment of Knowledge	0.54[b]		
Assessment of Attitude	0.71[a]	0.48[b]	
Assessment of Practice	0.30[a]	0.28[a]	0.59[b]

[a] Denotes significant empirical distinction at 99% confidence interval (P value < 0.01).
[b] Denotes the average variance extracted of the constructs.

reliability analysis. Overall consistency of the questionnaire and individual domains was determined through Cronbach's alpha while the magnitude of contribution of individual question towards Cronbach's alpha was determined through CITC scores. As the CITC score of all individual questions was above 0.5 and the Cronbach's alpha of all the domains was above 0.8, the questionnaire on the whole was found to be consistent. Hence, no question in the construct was dropped and the questionnaire as such was subjected to further statistical validation. CITC scores were also interpreted to determine the convergent validity as they quantify the relationship between each of the questions and the total score of the individual domains. On the whole, the questionnaire exhibited acceptable internal consistency with overall Cronbach's alpha above 0.8 and sufficient reproducibility with intraclass correlation coefficients above 0.75 [17]. In addition, we determined the empirical distinction of individual domains through discriminant analysis. The squared correlation of each pair was found to be less than variances extracted suggesting that each domain is empirically distinct from each other. This method of determining empirical distinction between the domains of the questionnaire was adopted from a previous literature [18].

5. Conclusion

A 15-item containing, three domain questionnaire was developed and validated to assess the knowledge, attitude and practice of uncontrolled diabetic patients towards usage of mobile based health applications. To the best of our knowledge this is first kind of study to develop and quantify the knowledge, attitude and practice of uncontrolled diabetic patients towards usage of mobile based health applications by using questionnaire and thereby arrive at outcomes to develop systematic strategies for promotion of medication adherence. Medication adherence plays a crucial role in the pharmacotherapy of diabetes mellitus and aids in achieving target blood glucose level. Hence, promotion of medication adherence through use of mobile based health applications is a promising approach for better diabetic care. This Questionnaire is recommended to be assessed in Uncontrolled Diabetic population who utilize mobile application for selfmanagment with a larger sample size to achieve the medication adherence and Management Goal.

Conflict of interest

Authors declare that they have no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.dsx.2019.04.037.

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