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Original Article

Design, developing and validation a questionnaire to assess general population awareness about type II diabetes disease and its complications

Ali Reza Soltanian, PhD, Associate Professor^{a,*}, Shiva Borzouei, MD, Assistant Professor^b, Mohammad Afkhami-Ardekan, MD, Professor^c

^a Department of Biostatistics and Modeling of Noncommunicable Diseases Research Center, School of Public Health, Hamadan University of Medical Sciences, Hamadan, Iran

^b Department of Internal Medicine, School of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran

^c Department of Endocrinology, Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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ABSTRACT

Background: Timely prevention of type 2 diabetes decrease socio-economic burden of disease in a society. To measure people's knowledge, the existence of valid and accurate tool such as questionnaires is very important. In the study we tried to make a comprehensive questionnaire to measure knowledge of apparently healthy individuals.

Material and methods: In this study a questionnaire to assess general population awareness about type II diabetes disease and its complications was Design, developing and validation based on 10 experts' panel and statistical inferences.

Results: Initially 67 questions designed and according to the experts' panel 16 questions were removed and 11 questions were edited. Finally, content validity of 51 questions has been approved by the experts' panel. According to Lawshe's score if CVRs were at least 0.8, items will be has content validity. The results show that both internal consistency and intra-class-correlation were good (>0.75). Cronbach's alpha and ICC were 0.84 and 0.82, respectively for all questions. To confirm structure of conceptual model, confirmatory factor analysis and Amos software was used. Goodness of Fit Index was RMSEA=0.027, GFI=0.95, AGFI=0.91, CFI=0.97; and showed that the hypothesized model is approved.

Conclusion: In general, we can say that the questionnaire is approximately comprehensive and complete. It is suggested that to assess awareness of diabetes type 2 in seven dominants (e.g. fundamentals, common symptoms, early and late complications, diet, control methods, and source of information of DMT2) this questionnaire should be used in general population.

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1. Introduction

Today, all scientists and researchers know that industrialized countries as well as life-style changes over the years can cause chronic diseases such as diabetes [1,2], obesity [1], cardiovascular disease [3], cancers [1] and even depression [4]. Until a few decades ago, type 2 diabetes was not a major problem in developing countries. But now many countries are faced with an increasing incidence of the disease and it is a major problem communities.

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shivaborzouei@umsha.ac.ir (S. Borzouei), afkhamiam@yahoo.com (M. Afkhami-Ardekan).

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Timely prevention of type 2 diabetes decrease socio-economic burden of disease in a society. Rawal has reported quoting *International Diabetes Federation* that the number of people with diabetes from 285 million in 2010 to 438 million in 2030 and more than 70% of them are in developing countries [5].

A report also show that seven of the top ten countries have the most diabetes patients, were low or medium-income countries [5]. According to statistics each year about 4 million deaths occur because of diabetes [2]. A Swedish study showed that 77% of the total cost of diabetes care related to diabetes complications [6]. It has been observed that in patients with impaired glucose tolerance (IGT), mortality and risk of heart disease greatly increases [7,8], and even seems to be that type 2 diabetes leading to disability and mortality more than type 1 diabetes [9]. Researchers have estimated that 50 to 60% of patients' pancreatic B-cell capacity

^{*} Corresponding author at: Street of Mahdieh, Research Square, Hamadan, Iran. *E-mail addresses:* soltanian@umsha.ac.ir (A.R. Soltanian),

with type 2 diabetes disappears at the time of diagnosis and the process takes more than 10 years [10]. Therefore, primary prevention would be effective strategy in reducing the burden of type 2 diabetes.

Of course everyone know that increasing the awareness and knowledge of people about type 2 diabetes, pathogenesis and its complications can be a primary preventive measures. So as a first step, accurate measurement of the knowledge of type 2 diabetes is very important.

To measure people's knowledge, the existence of valid and accurate tool such as questionnaires is very important. With an overview of published articles and documentation can be seen that a lot of questionnaires there exist to measure people's knowledge and awareness about the disease is type 2 diabetes diseases. However, either they were not comprehensive [11-16] or they have been done on patients not apparently healthy individuals [17-22].

In addition, some questionnaires in previous studies have not been validated [23–25]. For example, in Mohen's study just a question has been measured people's knowledge about complications of diabetes type 2 [26]. Such questions have taxonomy defects and cannot accurately determine people's knowledge. Al-Maskari et al. showed that a source of diabetes mellitus knowledge one-third of people is friends and family [27]. Non-physician usually had not accurate and complete information about type 2 diabetes and consult with them as a source of information will lead to confusion. So we can say that the main source of information is an index used to measure awareness.

For this reason, in the study we tried to make a comprehensive questionnaire to measure knowledge of apparently healthy individuals.

2. Methods

The cross-sectional study included people aged 18–65 years who had inhabitants in Hamadan city (west of Iran). The conceptual model of dominants of diabetes disease awareness was considered as follows (Fig. 1). The conceptual model was determined by experts' panel and literature review. The literature review was initially a lot of questions. Then, according to experts Endocrinology and Metabolism some questions were omitted and the remaining questions are divided in 7 dominants. A total of 123 participants (aged 18–65) were recruited into the study to confirm the conceptual model. After data collection from 132 participants, the conceptual model was tested by confirmatory factor analysis and goodness of fit index such as RMSEA, GFI, AGFI and CFI were determined.

Questionnaire Developing:

Primary questionnaire was used in previous study [11], and the questionnaire was developed in the study. At the stage, a list of fundamental, signs and symptoms, early and delay complications of type 2 diabetes diseases was prepared. To prepare a comprehensive set of questions related to the people's awareness

of diabetes and its complications, 10 subspecialty of endocrinology metabolism were consulted as the expert panel. Then the expert panel was reviewed, justified and approved the questions.

The questionnaire in addition demographic variables consisted of 51 questions in seven parts (Appendix A). First, fundamentals diabetes disease with eight questions; Second, common symptoms of Diabetes disease with 11 questions; Third, early complications of diabetes disease with seven questions; Fourth, delay complications of diabetes disease with six questions; Fifth, diet with 12 questions; Sixth, methods to control blood sugar and prevention of diabetes disease with three questions; Seventh, source of information with four questions.

The questionnaire was framed in a close ended with three options (i.e. "Yes/No/I do not know") for each question. The correct answer was given score 1, and incorrect or "I do not know" answers was given score zero. Based on these scores, the minimum and maximum points related to the questionnaire are 0 and 51, respectively. Score less than 13.5, 13.5 to 38.5, and \geq 38.5 was considered poor, moderate and good awareness, respectively.

Validity of Questionnaire:

After ensuring face validity of questions to evaluate content validity ratio (CVR) 10 matter expert panelists in endocrinology metabolism were consulted, and they were asked to give their opinion about relationship between each question with awareness of diabetes disease on a Likert scale of three options present. To determine contend validity ratio the expert's panel should be judged for each item by the question: "Is diabetes' awareness measured by this item?" They were choose one of three answers i)'essential', ii) 'useful but not essential', or iii) 'neither necessary nor useful' to the performance of the construct.

After collecting and compiling questions, content validity was calculated using content validity ratio (CVR) by following equation.

$$CVR = \frac{\left(n_e - \frac{N}{2}\right)}{\frac{N}{2}}$$

where, n_e is number of subject matter expert panelists indicating 'essential' and N is total number of subject matter expert panelists. All content validity ratios were more than 0.8. So in accordance with Lawshe's table [28], we can say that all valid questions are complete.

Reliability of Questionnaire:

To determine reliability of the questionnaire 123 people aged 18–65 years were recruited in Hamadan city (Iran) in 2015. Reliability of the questionnaire was determined by internal consistency (Cronbach's alpha) and intra-class-correlation (ICC; Spearman's' coefficient) methods. Cronbach's alpha coefficient was used to measure internal consistency by following:

$$\alpha = \frac{k(\overline{r})}{1 + (k-1)\overline{r}}$$

where, *k* is the number of questions (sum of components) and \overline{r} is the mean of the $\frac{k(k-1)}{2}$ non-redundant correlation coefficient.



Fig. 1. Conceptual model for awareness of DMT2 and its' dominants.

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SPSS statistical software (version 16, SPSS Inc., Chicago, IL, USA) was used to data analysis.

3. Results

Of the 123 participants, 108 (88%) were completed questionnaires in this study. We studied 74 (68.52%) female and 34 (31.48%) male with mean \pm sd age of 37.11 ± 8.54 and 42.05 ± 7.64 years, respectively. There were more employees 65 (52.85%) than students 28 (22.76%) and housewives or unemployed 30 (24.39%).

Initially 67 questions designed and according to the experts' panel, 16 questions were removed and 11 questions were edited. Finally, content validity of 51 questions has been approved by the experts' panel (Table 1). According to Lawshe's score if CVRs were

Table 1

Measures of content validity ratio (CVR), internal consistency (Cronbachs' Alpha) and test-re-test (Spearman's correlation coefficient) from 108 participants.

Sub-scale	Questions	CVR	Internal consistency	ICC
Fundamentals of diabetes disease	 Do you know normal level of blood sugar in human? Is the rise in blood sugar symptoms of diabetes disease? Diabetes is both hereditary and non-hereditary disease Is diabetes disease being prevented? Is diabetes disease curable? Did you know type I diabetes and its properties? Did you know type II diabetes and its properties? Did you know gestational diabetes and its properties? 	0.8 1 1 1 0.8 1 0.8	0.94	0.92
Common symptoms of Diabetes disease	 Polydipsia is one of symptom of type 2 diabetes disease. Urinating more often than normal, particular needing to do so during the night is one of symptom of type 2 diabetes disease. Enuresis is one of symptom of type 2 diabetes disease. Feeling tired during the day; particularly after meals is one of symptom of type 2 diabetes disease. Sudden loss of weight is one of symptom of type 2 diabetes disease. Birth weight more than 4 kg is one of symptom of type 2 diabetes disease Often feeling hungry, particularly if you feel hungry shortly after eating is one of symptom of type 2 diabetes disease Itching of the skin, particularly itchiness around the genitals is one of symptom of type 2 diabetes disease Slow Healing is one of symptom of type 2 diabetes disease 	1 1 1 1 0.8 1 1 1	0.85	0.82
Early complications of diabetes disease	 Coma is early complication of diabetes. Failing blood pressure is early complication of diabetes. Breathe deep and hard is early complication of diabetes. Recurrent infections are early complication of diabetes. Dizziness is early complication of diabetes. Wannes is early complication of diabetes Burring vision is early complication of diabetes 	0.8 1 1 0.8 1 1 1	0.81	0.80
Late complications of diabetes disease	 Ocular disorders is late complication of diabetes. Kidney disease and kidney disorders are late complication of diabetes. Ulcers in the legs is late complication of diabetes. Heart failure is late complication of diabetes. Stroke is late complication of diabetes. Inpotence is late complication of diabetes. 	1 1 1 1 1	0.79	0.79
Diet	 Excessive consumption of Rice and Grains increase blood sugar. Excessive consumption of Bean increase blood sugar. Excessive consumption of Green Vegetables increase blood sugar. Excessive consumption of Sweet Fruits (such apple, orange, banana, grapes and etc.) increase blood sugar. Excessive consumption of Fruit Tart (such lemon, Sour and etc.) increase blood sugar. Excessive consumption of Meat increase blood sugar. Excessive consumption of Poultry increase blood sugar. Excessive consumption of Milk, Yogurt and Buttermilk increase blood sugar. Excessive consumption of Butter, Cream, and Curd increase blood sugar. Excessive consumption of Honey and Ice-Cream increase blood sugar. Excessive consumption of Mayonnaise increase blood sugar. Excessive consumption of Sausage increase blood sugar. 	1 1 0.8 1 1 1 1 1 1 1 0.8	0.76	0.75
Methods for blood sugar control	 Low calorie diet is a ways to prevention of diabetes Periodic visit to physician and blood sugar test is a ways to prevention of diabetes Regular sport and physical activity is a ways to prevention of diabetes Get more fiber is a ways to prevention of diabetes Weight loss is a ways to prevention of diabetes 	1 1 1. 0.8 1	0.91	0.92
Source of information about type 2 diabetes	 I get diabetes information from Physician. I get diabetes information from Newspaper and magazines. I get diabetes information from Internet and Social Network such Facebook, Twitter and etc. I get diabetes information from Radio or TV programs. I get diabetes information from Friends, Acquaintances and Colleagues. I get diabetes information from Friends, Acquaintances and Colleagues. 	1 1 1 1 1 1	0.89	0.87

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at least 0.8, items will be has content validity. The results show that both internal consistency and intra-class-correlation were good (>0.75, Table 1). Cronbach's alpha and ICC were 0.84 and 0.82, respectively for all questions.

After confirming the content validity of the questionnaire by experts' panel, as well as construct validity was evaluated by confirm factor analysis.

To confirm structure of conceptual model (Fig. 1), confirmatory factor analysis and Amos software was used. Goodness of Fit Index were RMSEA = 0.027, GFI = 0.95, AGFI = 0.91, CFI = 0.97; and showed that the hypothesized model is approved. The minimum and maximum of questionnaire score was zero and 51, respectively. So score less than 13.5 (first quartile) was considered as the low awareness, score between 13.5–38.5 (first to third quartile) as moderate awareness, and 38.5 and more as high awareness.

4. Discussion

This questionnaire was developed to assess awareness of DMT2 in general population. The most important feature of this questionnaire, its application in education programs and intervention studies to increase the awareness level in type 2 diabetes. This questionnaire can be determine what dominant of peoples' awareness about DMT2 has weaknesses, and thereby curriculum be developed.

The results showed that the designed questionnaire with 51 questions to assess the awareness of type 2 diabetes has good validity and reliability. The questionnaire was more complete and comprehensive than other questionnaire [11-16]. A unique feature of this questionnaire is to assess awareness of diabetes type 2 and its complications in general population. While most previous questionnaire often designed to assess awareness of diabetic type 2 about diabetes type 2 complications [17-22]. Another strong point to be noted is that all questions of the questionnaire have been examined in terms of taxonomy design questions, while previous studies have been ignored it [26,27].

The present questionnaire (Appendix A) has been developed Soltanians' questionnaire in 2007 [11]. To determine the validity of the questionnaire a number of ways, such as face validity and content validity ratio was used. In addition, confirmatory factor analysis was used to confirming dividing questions in 7 dominant. Such analysis and standard procedures were not observed in previous studies.

To determine reliability of the questionnaire two ways, ICC and internal consistency were used, which minimum value obtained was 0.76 (p < 0.001) and 0.75 (p < 0.001), respectively. Therefore, the questionnaire has acceptable reliability.

In general, we can say that the questionnaire is approximately comprehensive and complete. It is suggested that to assess awareness of diabetes type 2 in seven dominants (e.g. fundamentals, common symptoms, early and late complications, diet, control methods, and source of information of DMT2) this questionnaire should be used in general population.

A limitation of this study was determination of cut-off-points. Because there was no accurate tool (gold standard), and also this questionnaire (Appendix A) is more complete and comprehensive than other questionnaires, so cut-off-points were determined based on quartiles.

Conflict of interest

None.

Acknowledgments

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Appendix A

Subscale	Question	Agree	Disagree	I do not know
undamentals of diabetes disease	 Do you know normal level of blood sugar in human? Is the rise in blood sugar symptoms of diabetes disease? Diabetes is both hereditary and non-hereditary disease Is diabetes disease being prevented? Is diabetes disease curable? Did you know type I diabetes and its properties? Did you know type II diabetes and its properties? Did you know gestational diabetes and its properties? 			
Common symptoms of Diabetes disease	 Polydipsia is one of symptom of type 2 diabetes disease. Urinating more often than normal, particular needing to do so during the night is one of symptom of type 2 diabetes disease. Enuresis is one of symptom of type 2 diabetes disease. Feeling tired during the day; particularly after meals is one of symptom of type 2 diabetes disease. Sudden loss of weight is one of symptom of type 2 diabetes disease. Budden loss of weight is one of symptom of type 2 diabetes disease. Birth weight more than 4 kg is one of symptom of type 2 diabetes disease Feeling abnormally thirsty is one of symptom of type 2 diabetes disease Often feeling hungry, particularly if you feel hungry shortly after eating is one of symptom of type 2 diabetes disease Itching of the skin, particularly itchiness around the genitals is one of symptom of type 2 diabetes disease Slow Healing is one of symptom of type 2 diabetes 			
Early complications of diabetes disease	 Coma is early complication of diabetes. Failing blood pressure is early complication of diabetes. Breathe deep and hard is early complication of diabetes. Recurrent infections is early complication of diabetes. Dizziness is early complication of diabetes. 			

6. Blurring vision is early complication of diabetes.

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(Continued)								
Subscale	Question	Agree	Disagree	I do not know				
Late complications of diabetes disease	 Ocular disorders is late complication of diabetes. Kidney disease and kidney disorders are late complication of diabetes. Ulcers in the legs is late complication of diabetes. Heart failure is late complication of diabetes. Stroke is late complication of diabetes. Impotence is late complication of diabetes. 							
Diet	 Excessive consumption of Rice and Grains increase blood sugar. Excessive consumption of Bean increase blood sugar. Excessive consumption of Green Vegetables increase blood sugar. Excessive consumption of Sweet Fruits (such apple, orange, banana, grapes and etc.) increase blood sugar. Excessive consumption of Fruit Tart (such lemon, Sour and etc.) increase blood sugar. Excessive consumption of Meat increase blood sugar. Excessive consumption of Poultry increase blood sugar. Excessive consumption of Milk, Yogurt and Buttermilk increase blood sugar. Excessive consumption of Butter, Cream, and Curd increase blood sugar. Excessive consumption of Honey and Ice-Cream increase blood sugar. Excessive consumption of Mayonnaise increase blood sugar. Excessive consumption of Mayonnaise increase blood sugar. Excessive consumption of Sausage increase blood sugar. 							
Methods for blood sugar control	 Low calorie diet is a ways to prevention of diabetes Periodic visit to physician and blood sugar test is a ways to prevention of diabetes Regular sport and physical activity is a ways to prevention of diabetes Get more fiber is a ways to prevention of diabetes Weight loss is a ways to prevention of diabetes 							
Source of information about type 2 diabetes	 I get diabetes information from Physician. I get diabetes information from Newspaper and magazines. I get diabetes information from Internet and Social Network such Facebook, Twitter and etc. I get diabetes information from Radio or TV programs. I get diabetes information from Friends, Acquaintances and Colleagues. I get diabetes information from Friends, Acquaintances and Colleagues. 							

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