Development and validation of a diabetes self-care activities questionnaire

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Article points

1. The authors developed an instrument for measuring treatment compliance among people with type 2 diabetes.

2. Their questionnaire was translated into Greek, and then back translated into English to check for discrepancies.

3. The initial version of the survey was tested on 45 people with type 2 diabetes.

4. In stage two of the study, 528 people completed the survey.

Key words

- Compliance
- Greece
- Linguistic variation
- Self-management
- Translation

Authors' details can be found at the end of the article.

The purpose of the study was to develop an instrument for measuring treatment compliance among people with type 2 diabetes and to test the validity and reliability of the Greek version of this questionnaire. The study survey was created by incorporating items from other questionnaires. The Flesch-Kincaid readability level of the instrument was 6.7. The average time required for completion was 8 minutes (standard deviation ±4.2 minutes). The instrument showed sufficient validity, discriminant ability, reliability and sensitivity to change. The new questionnaire is easy to understand but requires considerable time to complete. It can be used to reliably measure treatment compliance among Greek people with type 2 diabetes.

It is estimated by the International Diabetes Federation that diabetes now affects about 6% of the global population aged 20–79 years (Mayor, 2006). In Europe, it is estimated that there are around 55 million adults with diabetes. By 2030, this number is expected to reach 66 million. The highest increase in incidence is in those aged 30–40 years, which has, and will continue to have, a strong impact on national economies due to loss of productivity (Lindström et al, 2010). In Greece, prevalence of type 2 diabetes (T2D) is 4.11% for those aged 20–70 years (Tentolouris et al, 2009). Data also suggest that the "growing burden of diabetes will be extremely dynamic over the next years" (Panagiotakos et al, 2008).

Randomised clinical trials and prospective epidemiological studies have found improved

Table 1: Questionnaire categories.

Socio-demographic

Information was collected on age, sex, marital status, whether participants live alone or not, educational level, monthly income and insurance status.

Risk factors

Information was collected on weight, height, body mass index, smoking status, extent of smoking and duration of diabetes.

Physical and mental health

A summary score for mental and physical health. It includes coronary heart disease, hypertension, stroke, urinary incontinence, kidney health, severe renal disease, chronic infection, blindness, vision disturbances, neuropathy, lower limb problems and depression.

Physician–patient communication

Participants were asked if they see the same physician, and if so, for how many years and how often.

Self-care activities

Participants were asked about compliance and satisfaction with the plans for meals, exercise, foot care and blood glucose control.

Self-care recommendations

A series of multiple-choice questions asking what advice participants had been given about diet, exercise, checking blood glucose and medication.

Compliance with medical orders

Participants were asked to rate their compliance with diet, medication and foot care on a scale of 0–7 and were asked three questions about smoking.

lifestyles, such as healthy diet, weight reduction, smoking cessation, increased physical activity and education, can limit the burden of the illness (van Dam et al, 2002; Panagiotakos et al, 2005). Unfortunately, people with diabetes face many difficulties, particularly in complying with medical instructions for what can be a rather complex treatment regimen (Weiner et al, 1995; Hiss, 1996; Schwedes et al, 2002; Rhee et al, 2005; Parchman et al, 2006; Spann et al, 2006).

As T2D may be asymptomatic at early stages, the recommended dietary and general lifestyle modifications may seem unnecessary to patients. However, it has been suggested that healthcare professionals consider the lack of compliance with treatment as the result of lack of health education and promotion as well as of lack of motivation in changing behaviour

(Ziemer et al, 2005). Literature also suggests that apart from the effects of the condition and treatment, personal and psychological factors, economic factors, social network and family relationships may significantly influence the course of diabetes (Davis et al, 1988; Rosenthal et al, 1998; Lustman et al, 2000).

For the measurement and assessment of compliance, a variety of tools has been developed. A recent review study, for example, counted more than 150 valid tools (Skovlund, 2005). In recent years, a remarkable growth of interest in the development of tools for assessing quality of life (QoL) for people with T2D has been observed, which increases the difficulty of selecting an appropriate tool and, therefore, the risk of failure in producing valid research findings for specific populations (Polonsky, 2000; Garratt et al, 2002a; Garratt et al, 2002b).

In Greece, a specific tool has never been developed or translated and validated to measure treatment compliance among people with T2D. There are some scales that measure compliance and QoL, but they assess the effectiveness of the treatment rather indirectly (Guyatt et al, 1993; Eiser and Tooke, 1995; Rubin and Peyrot, 1999; van Loon et al, 2000).

The purpose of this study was to develop an instrument for measuring compliance to treatment among people with T2D and to test the validity and reliability of the Greek version of this instrument.

Research design and methods

Stage 1: Development and pilot study

A team of healthcare professionals (members of Hellenic Company of Nursing Education and Research) carefully selected 38 questions and placed them in seven domains – socio-demographic, risk factors, physical and mental health, physician–patient communication, self-care activities, self-care recommendations and compliance. The questions were chosen from four existing questionnaires (found by a Medline search): Summary of Diabetes Self-Care Activities (Toobert et al, 2000), 9-item Patient Health Questionnaire (Kroenke et al, 2001), 12-item Short Form Health Survey

(Ware et al, 1996) and Diabetes Self-care Behaviors and Barriers Instrument (Daly et al, 2009) (*Table 1*).

Translation

The translation process was completed in accordance with good practice guidelines (Wild et al, 2005):

- Preparation – carried out before the translation work begins.
- Forward translation – translation of the original language into the target language.
- Reconciliation – comparing and merging multiple forward translations into a single version.
- Back translation – translation back into the original language.
- Back translation review – comparison of the back-translated versions with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised.
- Harmonisation – comparison of back translations with each other and the original to highlight discrepancies and achieve a consistent approach to translation problems.
- Cognitive debriefing – testing the instrument on a small group of relevant patients or lay people to check alternative wording, understandability, interpretation and cultural relevance of the translation.
- Review of cognitive debriefing results and finalisation – comparison of the patients' or lay persons' interpretation of the translation with the original to highlight and amend discrepancies.

- Proofreading – final review.
- Final report – documenting the development of each translation.

Initially, the questionnaire was translated into Greek separately by two translators whose native language is Greek and who have health science knowledge. The aim was for the finished translation to be easily understood by participants of at least 14 years of age. The final Greek version was obtained by comparing the two translations, focusing on the best interpretation of the original English version and respecting the specificities of the target language. Then a medical and a nursing student, who are both Greek and resident in the USA, translated the Greek version back into English to confirm that the meaning of the original questions did not change during translation. Three versions of the Greek questionnaire emerged from this process. In order to assess the clarity of interpretations and adaptations of the questionnaire in Greek and choose the most appropriate one, a pilot study was conducted with 45 people with diabetes of various cultural and socio-economic backgrounds. The pilot study was conducted with 45 subjects (21 male and 24 female) aged 20–74 years. The mean age was 42 years ±15.4 years.

The subjects were divided into three groups of 15 and asked to complete the questionnaire. A discussion followed about which questions were difficult, confusing or tricky to answer. Participants were also asked to suggest alternative formulations of the same questions. Some people pointed out terms and questions that caused them confusion.

In particular, the researchers were asked to explain the meaning of a "portion of vegetables". This is because in Greece, salads are not usually served as individual portions. Nearly half of respondents (*n*=25) wanted clarifications on whether glucose is measured by a device at home or in a laboratory.

In the question which asked "On how many of the last 7 days did you check the inside of your shoes?", 14 people wondered what they should look for inside their shoe. Finally, the majority of the sample (*n*=37) did

Table 2. Problems in completing the questionnaire by category.		
Category	**Number reporting problem (*n*=45)**	**Rate (%)**
Socio-demographic	0	0
Risk factors	0	0
Physical and mental health	0	0
Physician–patient communication	0	0
Self-care activities	8	17.8
Self-care recommendations	10	22.2
Compliance with medical orders	2	4.5

Table 3. Construct validity.				
	Authors' questionnaire		Habits, attitudes and knowledge	
	Spearman coefficient	*P* value	Spearman coefficient	*P* value
Socio-demographic	0.837	0.000	0.814	0.000
Risk factors	0.817	0.000	0.798	0.000
Physical and mental health	0.876	0.000	0.812	0.000
Physician–patient communication	0.816	0.000	0.679	0.001
Self-care activities	0.768	0.000	0.784	0.000
Self-care recommendations	0.796	0.000	0.752	0.000
Compliance with medical orders	0.871	0.000	0.834	0.001

not know exactly what kind of food contains carbohydrates. Problems in completing the seven domains of the questionnaire are presented in *Table 2*.

Results

Using the Flesch-Kincaid readability scale, the final questionnaire scored 6.7, indicating it is in the easy reading range and should be understood by most people. The average time for completing the questionnaire was 8 minutes (standard deviation ± 4.2 minutes).

The translation of the questionnaire was found to be appropriate for Greek participants. It is in accordance with the characteristics of the Greek language and culture. All members of the sample (*n*=45) commented on how easy it was to read and understand. They mentioned that the questions did not include complex words. Particular emphasis was given on whether it was readily apparent in participants with lower educational or economic backgrounds.

Stage 2: Validity and reliability

In total, 528 people with T2D participated in this study. Most were treated as outpatients and several others were hospitalised during the study. They were asked to complete the questionnaire twice, 2–3 weeks apart. However, 43 people refused to complete the questionnaire the second time (within 2–3 weeks) and five people were subsequently excluded because the second time they gave opposite answers to the questions that did not relate to compliance.

Data from 480 people (192 male and 288 female) were analysed. The sample's mean age was 40.3 ± 17.6 years.

The statistical analysis was completed using the t-test, the Wilcoxon test and the Mann–Whitney test.

Statistical analysis
Construct validity
Construct validity is a quantitative assessment of a questionnaire's ability to measure specific parameters, for example, compliance in the treatment of T2D (Hyland, 1992; Spilker, 1996). To compare the values of the designed questionnaire, the habits, attitudes and knowledge (HAK) questionnaire in Greek was distributed (Gafarian et al, 1999). These results were compared with the results of the researchers' own questionnaire.

Discriminant ability
Discriminant ability refers to the ability of a questionnaire to distinguish the difference between two or more groups. For this study, people were divided into two categories: those who showed compliance and those who did not, as determined by self-reporting. The aim was to examine whether the questionnaire showed a significant difference between the two groups.

Reliability
Reliability is a measure indicating whether questionnaire results are restated in other, subsequent measurements (Naughton et al,

Table 4. Discriminant ability, compliant versus non-compliant patients.	
Category	
Socio-demographic	*P*=0.000
Risk factors	*P*=0.000
Physical and mental health	*P*=0.006
Physician–patient communication	*P*=0.004
Self-care activities	*P*=0.014
Self-care recommendations	*P*=0.003
Compliance with medical orders	*P*=0.007

1996). The rates of patients who completed the questionnaire twice (*n*=480) and reported no change in compliance between the first and the second time would normally have no significant statistical difference between them.

Sensitivity to change

Sensitivity to change is a parameter indicating whether a questionnaire responds to clinically significant changes that occur in patients. For example, people who reported changes in compliance between the two visits should normally show significant statistical difference in their responses.

Results

Construct validity

To assess the validity of the questionnaire, its seven subcategories were correlated to the HAK questionnaire (Pearson correlation coefficients and Spearman coefficient). The results show that there is a high correlation

between the two questionnaires in the seven subcategories (*Table 3*).

Discriminant ability

Of the 480 people, 184 were compliant and 296 were not. Statistically significant differences were found between these two groups in all seven subcategories of the questionnaire (*P*<0.001). Multivariate analysis comparing the two groups followed the method of discriminant analysis and used the backward stepwise fashion. Reclassification of observations based on the discriminant function was the impartial estimation method, removing each time point for the classification (leaving-one-out method). The reclassification rate was high, 86.7% for the non-compliance group, 94.3% for the compliance group.

During the completion of the second questionnaire, patients were asked to make a self-assessment on whether their compliance with medical instructions was getting better, worse or remained the same. Better compliance was reported by 192 patients. Having the same level of compliance as before was reported by 204 patients, while 84 patients reported worse compliance. The results of the comparison between the two groups are presented in *Table 4* (Mann–Whitney U test).

Reliability

According to our estimates, 204 people remained compliant during the period between the completion of the two questionnaires. The results are presented in *Table 5*. All

Table 5. Reliability of the questionnaire. Correlation between two measurements within the first 6–8 weeks (*n*=204).						
Category	**Initial mean**	**Mean follow-up**	**Difference in averages**	***P* (t-test)**	**Intraclass coefficient**	***P* (F-test)**
Socio-demographic	27.30	27.84	−0.54	0.121	0.979	<0.001
Risk factors	8.14	8.21	−0.07	0.094	0.992	<0.001
Physical and mental health	24.84	24.97	−0.13	0.088	0.997	<0.001
Physician–patient communication	1.20	1.42	−0.22	0.347	0.985	<0.001
Self-care activities	7.45	7.64	−0.19	0.488	0.988	<0.001
Self-care recommendations	8.13	8.21	−0.08	0.675	0.984	<0.001
Compliance with medical orders	3.12	3.20	−0.08	0.904	0.938	<0.001

Table 6. Sensitivity to change. Values for those who reported a difference in compliance between the first and second interview (improved compliance: n=192; reduced compliance: n=84).

Category	Mean	Standard deviation	t	P
Socio-demographic	–8.31/–8.25	7.74/7.45	–4.324/–4.521	0.000
Risk factors	–1.45/–1.54	1.12/1.14	–7.854/–6.548	0.000
Physical and mental health	–9.32/–9.16	7.65/7.45	–7.254/–6.473	0.000
Physician–patient communication	–0.20/–0.14	0.12/0.08	–12.456/–11.476	0.000
Self-care activities	–1.32/–1.48	0.74/0.78	–5.213/–6.212	0.000
Self-care recommendations	–2.14/–2.71	1.12/1.45	–8.255/–7.565	0.000
Compliance with medical orders	–1.47/–1.18	0.87/0.49	–4.568/–4.558	0.000

subcategories showed no statistically significant difference between the first and second time of completion. Cronbach alpha was 0.83.

Sensitivity to change

According to people's assessment of their compliance, 192 respondents reported improvement and 84 reported reduction of compliance. To study the questionnaire's sensitivity to change, values were compared between the two measurements (*Table 6*).

Discussion

During the first stage of development, the questionnaire was translated based on best practice guidelines. Participants' age and sex distributions were representative of the population of people with T2D examined in the outpatient department of the hospital. To assess the cultural adaptation of the new questionnaire, it was necessary to assess its validity, discriminant ability, reliability and sensitivity to change (Streiner and Norman, 1995).

The validity of the questionnaire was based on the correlation with the total value of the HAK questionnaire. The correlation was higher in patients who increased their compliance. The questionnaire was able to distinguish differences between those who had shown compliance and those who did not or who had reduced their compliance. People who showed no difference in compliance also showed no significant statistical differences in their values when completing the questionnaire (Wilcoxon test).

The questionnaire's sensitivity to change was measured according to the value comparison patients reported in accordance with their personal assessment of their change in compliance, between the first and second interview. In contrast, patients who reported no change in compliance did not show significant difference in the values of the questionnaire between the first and second interview.

Conclusion

The instrument presented here proved to have sufficient validity, discriminant ability, reliability and sensitivity to change. It is easy to understand although it requires considerable time to complete it. We suggest that it is a reliable and valid instrument to be used effectively in therapy compliance measurements among Greek populations. ∎

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