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Validation of behaviour measurement instrument of patients with diabetes mellitus and hypertension

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Abstract. Non-adherence to the treatment of chronic diseases such as hypertension and Diabetes Mellitus (DM) is a major obstacle in achieving patient therapy targets and quality of life of patients. A comprehensive approach involving pharmacists counselling has shown influences on changes in health behaviour and patient compliance. Behaviour changes in patients are one of the parameters to assess the effectiveness of counselling and education by pharmacists. Therefore, it is necessary to develop questionnaires of behaviour change measurement in DM-hypertension patients. This study aims to develop a measurement instrument in the form of questionnaires in assessing the behaviour change of DM-hypertension patients. Preparation of question items from the questionnaire research instrument refers to some guidelines and previous research references. Test of questionnaire instrument valid was done with expert validation, followed by pilot testing on 10 healthy respondents, and 10 DM-hypertension patients included in the inclusion criteria. Furthermore, field validation test was conducted on 37 patients who had undergone outpatient care at the PKU Muhammadiyah Yogyakarta City Hospital and The Gading Clinic in Yogyakarta. The inclusion criteria were male and female patients, aged 18-65, diagnosed with type 2 diabetes with hypertension who received oral antidiabetic drugs and antihypertensives, and who were not illiterate and co-operative. The data were collected by questionnaire interviews by a standardized pharmacist. The result of validation test using Person correlation shows the value of 0.33. The results of the questionnaire validation test on 37 patients showed 5 items of invalid questions with the value of $r < 0.33$, e: questions 2, 3, 6, 10 and 11, while the other 10 questions show the value of Pearson correlation > 0.33 . The reliability value is shown from the Cronbach's alpha value of 0.722 (> 0.6), implying that the questionnaire is reliable for DM-hypertension patients. This Behavioural change questionnaire can be used on DM-hypertension patients, and an FGD approach is required for the development of factors affecting this questionnaire.

Keywords: DM-hypertension, behaviour, compliance, validation, reliability

1. Introduction

Diabetes mellitus (DM) is a chronic condition that can cause many serious complications, such as cardiovascular, nephropathic, retinopathic, and neuropathic diseases, which raise chronic illness and mortality rates [1]. Data show that every seven minutes a person succumbs to diabetes mellitus [2]. According to WHO data, it is estimated that the world population will undergo an increase in diabetes mellitus prevalence in the period of 2000-2030 from 37% to 114% [3]. The International Diabetes



Federation also predicts that 246 million adults have DM. DM prevalence in adults in the world has reached 6.4% and will rise to 7.7% in 2030. It is projected that between 2010 and 2030 there will be a 69% increment of adult DM patients in developing countries, and 20% in developed ones [4].

High blood pressure is a significant predictor of nephropathy, retinopathy, and cardiovascular disorder in type 2 diabetes [4]. Prior studies emphasised the importance of diabetes education from professional health services on DM therapy and management, lifestyle education including diet, physical exercise, blood sugar level monitoring, foot treatment, and treatment modification that can improve the clinical outcome and quality of life of DM patients [5, 6, 7]. Educated knowledge about DM management influences changes in the behaviour and self-management of DM patients [7, 8].

Three domains that affect behaviour are cognitive, affective and psychomotor [9, 10]. Behaviour is one's response or reaction to a stimulus. Behaviour is determined by three main factors: Predisposing factors, or factors that precede behaviour, which account for the reason and motivation for certain behaviour, such as knowledge, beliefs, attitude and demography; enabling factors, such as the availability and affordability of health resources and skills related to health, which allow particular behaviour to materialise; reinforcing factors, which accompany behaviour and play a role in establishing certain behaviour, including family, peers, teachers, and health workers [11, 12, 13].

Previous research on the relationship between knowledge about DM, health beliefs, and DM management revealed that the knowledge of DM patients augments their comprehension of DM management ($\beta = 0.262$, $t = 3.328$, $p = 0.001$), and that health beliefs affect DM patients' knowledge ($\beta = 0.07865$, $t = 2.439$, $p < 0.016$). Such investigation employed the "Health Belief Model" theoretical approach to explain self-care activities, such as recommended DM management, and focus on behaviour relating to disease prevention [7, 14].

The American Association of Diabetes Educators has developed standards for measuring the outcomes of DM self-management education. One of the recommended standards of diabetes self-care behaviour in DM management is assessing seven self-care behaviours, comprising physical activities, diets, the use of medicinal therapy and management, blood sugar level monitoring, overcoming hypoglycaemia occurrences, declines in DM complications, and psychosocial adaptation in living life [7,8].

A preceding study found that education and counselling by Brief Counselling 5A on hypertension patients can influence changes in their behaviour [9]. Modified Brief Counselling 5A is developed through five stages: Assess, the stage of current behaviour, the importance of changing it, the level of readiness for change, and social support; Advise, where individual behaviour clearly and specifically changes, including information about personal health gains and losses; Agree, which is the stage of collaboration towards the targeted behaviour; Assist, where help is given to solve various problems in order to achieve the expected behavioural change; Arrange, in which further actions are taken to evaluate progress and hurdles, and to adjust planning [15].

The behavioural change of a patient into greater compliance can be used as parameter in assessing the effectiveness of education and counselling by a pharmacist [2]. Instruments measuring therapeutic compliance have been widely developed, but instruments gauging patients' behaviour by assessing their change and readiness have yet to receive the same attention, raising the need to develop a DM-hypertension patient behaviour measurement instrument.

2. Materials and Methods

2.1. Methods

This study was reviewed and approved by the Research Ethics Committee of Universitas Ahmad Dahlan, numbered EC 011610143. The arrangement of question items in the research questionnaire instrument referred to guidelines and prior studies. The development of the DM-hypertension patient behaviour measurement instrument utilised a research and development design by a pharmacist and a researcher. The questionnaire draft was then reviewed by a psychology expert and an expert researcher of endocrines. The validity test for the questionnaire instrument was done by expert validation, with pilot testing on 10 healthy respondents and 10 DM-hypertension patients within the inclusion criteria

[2]. Next, a field validation test was conducted on 37 patients under outpatient care at the PKU Muhammadiyah Hospital and the Gading Clinic, both in the city of Yogyakarta [11, 12]. The inclusion criteria were male and female patients aged 18-65 diagnosed with type 2 diabetes with hypertension who received oral antidiabetic drugs and antihypertensives, and who were not illiterate and co-operative. Data were collected by means of questionnaire interviews given by standardised pharmacists. Statistical analysis of validity used Pearson correlation, and factor analysis. Reliability test used Cronbach's alpha value.

2.2. *Materials*

The DM-hypertension patient behaviour measurement instrument consists of 15 question items in cognitive, affective and psychomotor domains, given in Indonesian. The cognitive domain contains questions on knowledge about DM-hypertension disorders, complications, and the therapeutic management of oral antidiabetic and antihypertensive drugs. The affective domain comprises questions related to the feelings and preconceptions of patients regarding regular oral antidiabetic and antihypertension medications to control their blood sugar and blood pressure levels. The psychomotor domain enquires patients' behaviour towards compliance in taking medications, diet including the consumption of carbohydrate, sugar and salt, and ceasing medication without consulting the doctor.

The questionnaire employs yes-no questions, for which a "yes" answer is scored 1 and a "no" is given 0, except for items number 9, 14, and 15 where a "no" is scored 1, and a "yes" response 0. Patient behavioural levels measured by the questionnaire are categorised into pre-contemplation (if there is no affirmative answer in the cognitive, affective, and psychomotor domains), contemplation (if the answers are affirmative only in the cognitive domain), preparation (if the answers are affirmative only in the cognitive and affective domains), and action (if the answers are affirmative in all three domains).

3. **Results and Discussion**

This research aims to develop a DM-hypertension patient behaviour measurement instrument. The arrangement of the question items referred to previous studies and DM-hypertension management guidelines. The questionnaire validation test was carried out at the PKU Muhammadiyah Yogyakarta City Hospital and the Gading Clinic in Yogyakarta from June to August 2016. As subjects of this preliminary study, 45 DM type 2 patients with hypertension meeting the inclusion criteria were obtained, but 8 patients were excluded because they could not follow the research to the end, leaving 37 patients for this validation test. Description of the demographical characteristics of patients in this study is presented in Table 1.

The patients were predominantly women (70.3%), married (91.9%), and aged 60 or over (59.5%), and their last education was mostly at senior high school (48.6%). Most of them were merchants, pensioners and housewives (62.2%), and were covered by the government (BPJS) (78.4%). The majority of patients did not have diabetes mellitus history (51.4%), practiced a diet controlling the consumption of salt, sugar and coffee (89.2%), and did not smoking (94.6%).

Table 1. Demographical characteristics of patients for questionnaire validation

Demographical characteristic	n	No (%) / Mean \pm SD
Sex		
Female	26	70.3%
Male	11	29.7%
Marital status		
Married	34	91.9%
Not married	3	8.1%
Age		
<60	15	40.5%
\geq 60	22	59.5%
Body weight (kg)		64.62 \pm 11.82
Body height (m)		1.57 \pm 0.07
Body mass index		25.97 \pm 4.10
Education		
Primary school	9	24.3%
Junior high school	6	16.2%
Senior high school	18	48.6%
D1/D2/D3/S1	3	8.1%
No school education	1	2.7%
Occupation		
Civil servant	1	2.7%
Entrepreneur	4	10.8%
Private employee	3	8.1%
Unemployed	5	13.5%
Other	23	62.2%
Payment		
Self-funded	2	5.4%
BPJS	29	78.4%
Other insurance	6	16.2%
Diabetes mellitus history		
Yes	18	48.6%
No	19	51.4%
Diet		
Salt and sugar	3	8.1%
Coffee	1	2.7%
Salt, sugar and coffee	33	89.2%
Habit		
Smoking	2	5.4%
Not smoking	35	94.6%

3.1. Behavioural Level Questionnaire Validation

Results of the behavioural level questionnaire validity and reliability tests are provided in Table 2. The validity test by Pearson correlation resulted in a value greater ($>$) than critical r , namely > 0.33 . Validation of the questionnaire on 37 patients disclosed five invalid question items with $r < 0.33$, which were questions number 2, 3, 6, 10 and 11, while the other ten questions had a Pearson correlation coefficient of $r > 0.33$. Reliability was affirmed by a Cronbach's alpha value of 0.722 (>0.6), indicating that this behaviour measurement questionnaire is reliable for DM-hypertension patients.

The re-validity test was done by removing the invalid item, and a number of 10 question items showed the value of $r > 0.3$, with the Cronbach's alpha value being 0.722 (> 0.6) (Table 3). Several questions 2, 3, 6, 10 and 11 showed invalid, this can be seen from the answers of patients who are mostly uniform. This indicates that the questionnaire's differentiation is quite low, in addition to the question asked too easily so it can not distinguish the answers between patients. Question number 2 and 3 are designed in the cognitive domain, the whole patient answers "yes" and the uniform answer makes the validation value low. Become input for the researcher related to sentence question in item 2 and 3. While question number 6 is arranged in the affective domain, it also showed uniform answer so that validation value was low. In the psychomotor domain the behavioral adherence behavior is shown from items 10 and 11.

Table 2. Results of validation and reliability test of the DM-hypertension patient behavioural level questionnaire

No.	Question	Mean	SD	Pearson correlation ($r > 0.33$) N=37	Cronbach's alpha (when item deleted)
COGNITIVE					
1	Do you know that diabetes mellitus with hypertension complication is a dangerous disease?	0.9189	0.27672	0.489	0.708
2	<i>Do you know that antidiabetic drugs must be used continuously to control blood sugar level?</i>			(invalid)	
3	<i>Do you know that antihypertension drugs must be used continuously to control blood pressure?</i>			(invalid)	
4	Do you know that untreated high blood pressure will cause blood vessel damage and trigger heart disorder and stroke?	0.9189	0.27672	0.651	0.697
5	Do you know that high blood sugar level and blood pressure will cause functional disorder of other organs, such as the kidneys and incurable wounds?	0.8919	0.31480	0.573	0.700
AFFECTIVE					
6	<i>Do you believe that using antidiabetic drugs can control blood sugar level?</i>			(invalid)	
7	Do you believe that using antihypertension drugs can control blood pressure?	0.9459	0.22924	0.459	0.712
8	Do you have the willingness to use antidiabetic and antihypertension drugs regularly to control blood sugar level and blood pressure?	0.9730	0.16440	0.456	0.717
9	Do you presume that using antihypertension drugs continuously can damage the kidneys?	0.4324	0.50225	0.373	0.719
PSYCHOMOTOR					
10	<i>Do you always bring antidiabetic drugs when travelling or working?</i>			0.058 (invalid)	
11	<i>Do you always bring antihypertension drugs when travelling or working?</i>			0.134 (invalid)	
12	Have you reduced sugar consumption to control blood sugar level?	0.9459	0.22924	0.329	0.719
13	Have you reduced salt consumption to control blood pressure?	0.8108	0.39706	0.345	0.716
14	Will you stop using antidiabetic drugs if the clinical symptoms of diabetes mellitus do not occur?	0.6486	0.48398	0.750	0.666
15	Will you stop using antihypertension drugs if the clinical symptoms of hypertension do not occur?	0.6757	0.47458	0.796	0.660

Table 3. Result of re-validity test of the DM-hypertension patient behavioural level questionnaire

No	Item of Question	r (Pearson correlation)	Validity
Cognitive			
1	Item 1	0.489	Valid
2	Item 4	0.651	Valid
3	Item 5	0.573	Valid
Affective			
4	Item 7	0.459	Valid
5	Item 8	0.456	Valid
6	Item 9	0.373	Valid
Psychomotor			
7	Item 12	0.329	Valid
8	Item 13	0.345	Valid
9	Item 14	0.750	Valid
10	Item 15	0.796	Valid

Table 4. Percentage distribution of the respondents' answers to each question item of the DM-hypertension patient behavioural level questionnaire

No	Question	Yes	No
COGNITIVE		N (%)	N (%)
1	DM-hypertension is a dangerous disease.	34 (91.9)	3 (8.1)
2	DM drugs are used regularly to control blood sugar level.	37 (100)	0 (0)
3	Antihypertension drugs are used regularly to control blood pressure.	37 (100)	0 (0)
4	Untreated high blood pressure will trigger heart disorder and stroke.	34 (91.9)	3 (8.1)
5	High blood sugar level and blood pressure will cause functional disorder of other organs, such as the kidneys and incurable wounds.	33 (89.2)	4 (10.8)
AFFECTIVE			
6	Belief in the regular use of DM drugs to control blood sugar level	37 (100)	0 (0)
7	Belief in the regular use of antihypertension drugs to control blood pressure	35 (94.6)	2 (5.4)
8	Willingness to use antidiabetic and antihypertension drugs regularly to control blood sugar level and blood pressure	36 (97.3)	1 (2.7)
9	Presumption that long-term drug use damages the kidneys	16 (43.2)	21 (56.8)
PSYCHOMOTOR			
10	Always carrying DM drugs when travelling	34 (91.9)	3 (8.1)
11	Always carrying antihypertension drugs when travelling	35 (94.6)	2 (5.4)
12	Sugar diet to control blood sugar level	35 (94.6)	2 (5.4)
13	Salt diet to control hypertension	30 (81.1)	7 (18.9)
14	Ceasing DM medication when clinical symptoms abate	24 (64.9)	13 (35.1)
15	Ceasing antihypertension medication when clinical symptoms abate	25 (67.6)	12 (32.4)

The results of the validation test items 10 and 11 are very low, this is because the repetition of almost identical questions turns the answer "yes" to the respondents. Most of the answers are uniform (yes = 91-94%), so the power difference is quite low. The invalidity of questions number 2, 3, 6, 10 and 11 can be observed from the virtually uniform responses given by patients. This implies that the differentiating power of the questionnaire was rather low, coupled with overly easy questions that could not distinguish responses among patients. Further research is needed to develop this instrument

through focus group discussions (FGD) to explore the understanding levels of patients. The percentage distribution of the respondents' answers to each question item are given in Table 4.

Ten valid items were then tested for validity by factor analysis to see the correlation among fellow indicators simultaneously [18]. The Determinant of Correlation Matrix value is 0.001, this value approaches 0 thus the correlation matrix between the variables is interrelated. The results showed that the value of Kaiser Meyer Olkin (KMO) Measure of Sampling of 0.521. The KMO complied requirement because the value above 0.5. The calculation results with SPSS resulted in a Barlett Test of Sphericity of 210,643 with a significance of 0.000. Indicated that Bartlett Test of Sphericity fulfilled the requirements because of significance below 0.05 (<5%). While the matrix component of this questionnaire were 4 factor components, with each component matrix value or factor loading > 0.5. This indicated that ten question items were valid for use in patients with DM-hypertension [18].

Based on the Trans-Theoretical Model (TTM) theory developed by DiClemente, patient behaviours are classified into pre-contemplation, contemplation, preparation, action and maintenance [9, 14]. The distribution of the patients' behavioural levels is displayed by Table 5. TTM was designed to acquire direct impact (expected/deliberate behavioural change) on individuals or groups. This model is the most widely used concept of behavioural change in health behaviour studies [16, 17].

Table 5. Distribution of DM-hypertension patient behavioural level

Behaviour category	N (%)
Pre-contemplation	6 (16.2)
Contemplation	17 (45.9)
Preparation	7 (18.9)
Action	7 (18.9)

At the pre-contemplation stage, the individual does not consider or intend to alter problematic behaviour (start healthy behaviour) soon (within six months), because the patient usually does not understand facts concerning risks posed by unhealthy behaviour. Such patients need encouragement to become more aware of their decisions and the benefits of adopting healthy behaviour. The contemplation stage is where the patient becomes aware and willing to change problematic behaviour, and is able to consider the advantages and disadvantages of changes that one will face. The preparation stage sees the individual ready to take action in the near future (in 30 days ahead). At this level, the gains (pros) which support change towards healthy behaviour are greater than the hurdles (cons), and patients take small steps that they believe can help make healthy behaviour part of their lives. The action stage is where patients have altered their behaviour in the last six months and work hard to keep going forward. In TTM, an individual attaining this phase has undergone half the changing process, and thus is most likely to undergo relapses to unhealthy behaviour. If one is not sufficiently prepared for change and committed to planning actions of their choice, reversions to problematic behaviour would be largely possible. At the maintenance stage, the patient has successfully achieved and maintained behavioural change for at least six months. Risks of setbacks are still present but not too considerable, and the individual tries to keep practicing healthy behaviour [9, 14, 15, 17].

This inquiry found that most of the patients were at the contemplation behavioural level (45.9%). This suggests that the majority of patients had the awareness and will to change their behaviour to action or maintenance level. However, re-monitoring is required at least in second visits as follow-up to this research. Nonetheless, 16.2% patients were at pre-contemplation level, indicating that they were not yet prepared for and had not cognitively comprehend knowledge about DM-hypertension disease, and had not had the disposition to take medications regularly. This calls for intervention in the shape of education regarding DM-hypertension management and the motivation to improve patient compliance.

Limitations in this study are still needed FGD in digging factors that affect the understanding of patients, and compilation of sentences in the questionnaire items questionnaire. Interventions are needed in the form of education related to DM-Hypertension management and motivation in improving patient compliance.

4. Conclusions

This research showed that the DM-hypertension patient behaviour measurement questionnaire was valid and reliable. Further research in the form of FGDs is required to divulge factors which affect patients' understanding and responses, and to evaluate the impact of intervention on their behavioural changes.

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