Original Article

Development of Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff and assessment of reliability and validity

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Abstract

Background and Purpose: To prevent interruption of diabetic care, it is necessary for patients with type 2 diabetes mellitus (T2DM) to build good relationships with medical staff. It is important that both patients with T2DM and medical staff strive for the common goal of good diabetes control. Therefore, measures capable of considering more concrete skills specific to patients with T2DM than the existing scale are required. Here, a skill scale for patients with type 2 diabetes mellitus to build relationships with medical staff was developed, and its reliability and validity were verified.

Methods: As a theoretical framework for our scale, we used the 50-item list of social skills for adolescents created by Goldstein et al. We created 76 items based on a previous study, interviews with nurses specializing in diabetes care, and our own clinical experiences. The content validity and surface validity were verified, and we carefully selected 56 items for use in the scale. All items were evaluated using a 5-point Likert scale. Valid responses to the questionnaire were obtained from 262 Japanese patients with T2DM. Exploratory factor analysis was performed to verify the construct validity. The 18-item Kikuchi Scale of Social Skills (KiSS-18) was used to investigate the criterion-related validity. The content validity index (CVI) was used to assess of content validity. The skill scale scores between the continuous diabetes care group and those with a history of diabetes care interruption were compared to determine the known-groups validity. Cronbach's alpha, item-total correlations, and good-poor analysis were used to determine the internal consistency of the scale.

Results: Our scale contained four factors and 36 items based on exploratory factor analysis: "problem-solving skills" (Factor 1), "coping skills" (Factor 2), "communication skills" (Factor 3), and "feelings-consciousness skills" (Factor 4). The four factors of this scale together had a cumulative contribution ratio of 56.12%, and construct validity was confirmed. The correlation coefficient with KiSS-18 was $r = 0.590$, and was significant ($p < 0.01$). The item-level content validity indexes (I-CVIs) of the scale were 0.80 – 1.00, the scale-level content validity index (S-CVI/Ave) was 0.95: CVI exceeded the standard. The total score of the scale was significantly lower for patients with a history of diabetes care interruption ($p < 0.01$). The Cronbach's alpha coefficient of the four factors for the 36 items was 0.960, while that of the factors was 0.791 – 0.960. Item-total correlation analysis indicated that all items were significantly correlated ($r = 0.313 – 0.798$, $p < 0.01$), and good-poor analysis indicated that all items showed a significant difference ($p < 0.001$).

Conclusions: This study confirmed the reliability and validity of a new scale for patients with T2DM in Japan. This scale could be useful to support patients with T2DM.

KEY WORDS

Type 2 diabetes mellitus, Professional–Patient Relations, Social Skills, Patient Dropouts, Scale

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Introduction

According to the International Diabetes Federation (2017)[1], treatment of type 2 diabetes mellitus (T2DM) involves regular examination at a medical institution, lifestyle management, and medication; through such treatment, patients with T2DM show good survivability and quality of life. Another study[2] further reported that the frequency of visiting medical institutions is positively associated with blood glucose control. Moreover, the relationship with the medical staff can influence whether or not patients with T2DM visit the medical institution[3]. Accordingly, it is important that patients with T2DM visit medical institutions and build good relationships with medical staff for the management of diabetes.

However, some patients with T2DM lack noticeable symptoms. Hence, they often lack sufficient motivation for self-management, which can interrupt their regular pattern of hospital visits[4]. Compared to patients who attended diabetic care at hospitals, non-attenders have higher HbA1c levels[5)-10)], poorer glycemic control than prior to diabetic care interruption[6),7),11),12)], a higher incidence of complications, and more rapid deterioration in these complications[10),13)-15)]. Therefore, to slow the progression of diabetes, it is important to prevent diabetic care interruptions.

According to our study[3], avoiding the interruption of diabetic care requires efforts of both medical staff (e.g., treating individuals as patients, exhibiting an attitude reflecting their status as a diabetes expert) and patients (e.g., maintaining relations with medical staff, honestly expressing oneself to medical staff). A particularly important element for these two parties is building a good relationship. We propose that an effective way of helping patients build good relationships with medical staff is the enhancement of social skills. Here, social skills are defined as skills useful for smoothing or improving human relationships and interactions[16),17)].

To measure social skills, Kikuchi developed Kikuchi's Scale of Social Skills: 18 items (KiSS-18)[16),17)]. In the medical setting, the KiSS-18 had been used to measure social skill among medical staff and nursing students[18)-24)], or to evaluate their education[25)-27)].

It is important that both patients with T2DM as well as medical staff strive for the common goal of good diabetes control. We thought the relationships between patient with T2DM and medical staff was different from building of general human relationships. The KiSS-18 measures the skill of general human relationships. Consequently, a measure that considers more concrete skills specific to patients with T2DM than the KiSS-18 is required. Such skills include seeking help from the medical staff for issues that the patient cannot resolve alone, or being able to speak with medical staff until one is fully satisfied.

Therefore, developing a new scale of skills for patients with diabetes to build good relationships with medical staff is important. To aid future efforts for improving social skills of patients with diabetes, this study aimed to develop a Skill Scale for Patients with T2DM to Build Relationships with Medical Staff, and evaluated its reliability and validity.

Definition of terms

Medical staff were defined as any medical professional involved in the treatment of diabetes.

Methods

1．Participants

Participants were patients with T2DM aged 30–75 years attending a medical institution for diabetes treatment in Japan. We excluded patients who expressed difficulty answering the questionnaire because of visual impairments or neuropathy.

The medical institutions surveyed were four general hospitals—that provided diabetes treatment— in I prefecture extracted at random. A medical examination is a reservation system, and the same doctor conducts the examinations. These institutions surveyed had Certified Diabetes Educator of Japan or Certified Nurses in Diabetes Nursing.

2．Conceptual Framework

As the theoretical framework for our scale, we used the 50-item list of social skills for adolescents created by Goldstein et al[28]. This list classifies social skills required by adolescents into six types: I. beginning social skills, II. advanced social skills, III. skills for dealing with feelings, IV. skill alternatives to aggression, V. skills for dealing with stress, and VI. planning skills. Although the target population for our scale was patients with T2DM, not adolescents in general, we thought that Goldstein et al.'s[28] list contained a

number of skills for helping patients with T2DM build relationships with medical staff; therefore, it seemed useful as a theoretical framework.

3. Instrument Development

The question items were created to measure the skills that patients with T2DM require to build a good relationship with medical staff. We created 76 items based on a previous study (Fujita et al., 2013)[3], interviews with nurses specializing in diabetes nursing, and researchers' own clinical experiences. These items were also based on the 50 items of the list of social skills for adolescents created by Goldstein et al[28]. To verify the content validity of the items, three specialists with considerable experience in diabetes nursing evaluated the items, focusing on their wording, the accuracy of the intention of the question, and the response method. Next, three patients with T2DM, differing in terms of gender and age, were pretested in the hospital. They completed all 76 items. We then asked them to freely give their opinions on the response time, numbers of questions, the degree of comprehension of contents, and ease of answering. Based on these analyses, 56 items were chosen for the scale. Subsequently, we pretested another three patients with T2DM to confirm the surface validity, leading to our preparation of the draft scale (56 items).

4. Instrument Scoring

All items were evaluated using a 5-point Likert scale. For items 1–13 and 22–56, the scale was as follows: 1 = *impossible*, 2 = *somewhat impossible*, 3 = *neither*, 4 = *somewhat possible*, and 5 = *possible*. For items 14–21, the scale was as follows 1 = *not at all*, 2 = *not very often*, 3 = *neither*, 4 = *sometimes*, 5 = *often* (note that some items are reverse scored). The total score is calculated by summing the item scores; higher scores indicate that the respondent has higher skills in building relationships with medical staff.

5. Data collection

1) Survey items

（1）Draft scale(56items)

（2）Kikuchi's Scale of Social Skills: 18 items (KiSS-18)

To assess the criterion-related validity, the KISS-18 developed by Kikuchi was used[16),17)]. The KiSS-18 items are based on the six types of social skills created by Goldstein et al[28]. The KiSS-18 items are rated on a five-

point Likert scale (1 = *strongly disagree*, 2 = *disagree a little*, 3 = *neither*, 4 = *agree a little*, 5 = *strongly agree*). The total score is calculated by summing the item scores; higher scores indicate better social skills.

（3）Basic information

This included gender, age, diabetes history, period of being with their current primary care doctor, HbA1c, complications, state of diabetic examination, and a history of diabetes care interruption.

2) Procedures

We requested the cooperation of medical institutions involved in the treatment of diabetes with this study, and ultimately carried out the study at those that agreed to cooperate. Researcher distributed the questionnaire to target patients, and completed questionnaire were collected by researcher or placed in a collection box. The answer to the questionnaire was bearer. Data were collected from January to September 2016.

6. Data Analysis

Data were analyzed using the IBM SPSS Statistics 22 (IBM Corp., Armonk, NY).

1) Construct validity

We verified the scale's construct validity using exploratory factor analysis, particularly the maximum likelihood method with a Promax rotation.

2) Criterion-related validity

Our scale was created to measure the skills of patients with T2DM in building a good relationship with medical staff. The KiSS-18 is a widely-used general measure of social skills (i.e., whether an individual can carry a relationship smoothly). Given the similarity of the scales, we performed a Spearman's rank-correlation analysis of both scales to assess our scale's criterion-related validity.

3) Content validity

The content validity of each item and the whole scale was verified using the content validity index (CVI). For this, we conducted a questionnaire survey with 10 specialists in diabetes nursing. The specialists of diabetes nursing had been involved in diabetes nursing for over three years or had the certification of Certified Diabetes Educator of Japan. They were asked to rate the relevance of the items and the scale on a 4-point rating scale of Lynn[29], ranging from 1 (*not relevant*) to 4 (*highly relevant*). We then calculated the item-level CVI (I-CVI) by tallying the number of experts who

gave a rating of either 3 or 4 (thus dichotomizing the ordinal scale into *relevant* and *not relevant*) to each item and dividing this by the total number of experts. The scale-level CVI (S-CVI/Ave) was calculated by averaging the I-CVIs for all items on the scale. Scales with excellent content validity for 6–10 experts would have I-CVIs of at least 0.78 and S-CVI/Ave of at least 0.90[30].

４）Known-groups validity

The average of the total score of the scale and each factor for the continuation diabetes care group and those with a history of diabetes care interruption. We set the significance level as $p < 0.05$.

５）Reliability

The Cronbach's alpha coefficient was used to determine the internal consistency of the scale, with values of over 0.70 indicating good internal consistency. To further confirm the internal consistency, we performed an item-total (I-T) correlation analysis and good-poor (G-P) analysis after the exploratory factor analysis. I-T correlation analysis confirmed the correlation between the total score of this scale and each item. In the G-P analysis, the total score of the scale was divided into upper group and subordinate group, and the average value of each item was obtained for each group, and the score were compared. For the I-T correlation analysis, items with $|r| < 0.2$ were excluded. In the G-P analysis, we set the significance level as $p < 0.001$.

７．Ethical Considerations

This study was approved by the Kanazawa University Medical Ethics Review Committee (Approval number: $601-1$). A researcher explained the purpose of the study and our obligation to protect patients' confidentiality to the medical institution. We conducted the research after obtaining consent from the medical institution and individual patients. In publishing the survey results, we have avoided identifying any individuals. All patients' personal information was kept in a locked desk and managed strictly to prevent leaks, theft, or loss. All participants took part in the study of their own free will, and we ensured that their participation did not affect their treatment or nursing care in any way. We avoided pressuring patients to participate in our study. Handing in the questionnaire was considered indicative of consent to participate in the study.

Results

１．Participant Characteristics

The questionnaire was distributed to 293 patients with T2DM at four general hospitals that involved in the treatment of diabetes in I prefecture. The

Table 1. Draft of Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff

Item	I-T Correlation coefficient (56items)	I-T Correlation coefficient (36items)
I-1. Are you able to talk about yourself in such a way that a doctor treating you for the first time could understand?	0.632	0.632
I-2. Are you able to initiate conversations when speaking with your doctor?	0.678	0.705
I-3. Are you able to talk about matters that concern you with your doctor?	0.641	0.651
I-4. Are you able to ask your doctor the questions you want to?	0.715	
I-5. Are you able to verbally express your gratitude to your doctor?	0.538	
I-6. Are you able to share information about the people involved in your diabetes care in such a way that your doctor can understand?	0.497	0.512
I-7. Are you able to thank your doctor for his/her help?	0.542	
II-8. Are you able to seek help from your doctor when your diabetes care isn't going well?	0.686	0.709
II-9. Are you able to force yourself to visit the hospital and see a doctor, even when you don't want to?	0.523	
II-10. Are you able to communicate to your doctor what you want him/her to do?	0.759	0.768
II-11. Are you able to follow your doctor's advice in a straightforward way?	0.594	
II-12. Are you able to promptly apologize to your doctor when you are in the wrong?	0.540	
II-13. Are you able to share your opinions with your doctor in such a way that he/she can understand?	0.736	0.746
III-R14. Do you ever doubt whether you really have diabetes?	0.116	
III-R15. Do you ever have the dishonest feeling that you tell yourself you're probably fine since you lack obvious symptoms, when you want to turn a blind eye to your diabetes status?	0.254	
III-R16. Do you ever get scared when your diabetes worsens without you realizing it?	0.090	
III-R17. Do you ever feel like you want to live your life as you please, free of restrictions?	0.197	

III-R18. Do you ever feel fed up about continuing your diabetes treatment?	0.362	0.313
III-R19. Are you ever afraid of angering your doctor?	0.369	0.367
III-R20. Are you ever hesitant to visit your doctor because you are reluctant to go to the hospital?	0.352	0.314
III-R21. Do you ever feel so awkward that it's difficult for you to meet your doctor face to face?	0.449	0.438
III-22. Are you able to communicate feelings of aversion and disgust to your doctor, such as being fed up with medical visits or feeling exhausted by continuing treatment?	0.660	
III-23. Are you able to talk openly with your doctor, even when you feel bad or guilty about your behavior?	0.687	
III-24. When your diabetes care doesn't feel like treatment to you, are you able to communicate that sentiment to your doctor?	0.726	
III-25. Are you able to discern your doctor's emotions based on his/her facial expressions, tone of voice, gestures, etc.?	0.458	
III-26. When your doctor gets upset around you, are you able to stay calm by telling yourself that the diabetes, not you personally, is the cause of his/her anger?	0.455	0.460
III-27. When criticized by your doctor, are you able to allow some time for your anger to abate, without causing a dispute?	0.480	0.458
III-28. Are you able to interact with your doctor in a favorable and positive way?	0.635	
III-29. Even when you feel afraid or think your doctor will get angry with you, are you able to reassure yourself and go to the hospital anyway?	0.665	
III-30. Even when fear makes you reluctant to go to the hospital, are you able to force yourself to go by drawing strength from a referral letter, your family, or other sources?	0.479	
III-31. When you feel that your treatment isn't going well, are you able to honestly reflect on your lifestyle and consider that you may be partially to blame?	0.565	
IV-32. Are you able to consult with your doctor about what is permissible in different aspects of your lifestyle, such as how much of certain foods you can eat and how much you should exercise?	0.713	0.703
IV-33. When you feel that your doctor's ideas are at odds with your own, are you able to infer his/her thoughts, and figure out and tell the intentions behind them?	0.633	0.659
IV-34. When you get angry, are you able to get over it by talking about it with family, friends, and other medical staff, without venting to your doctor directly?	0.557	0.563
IV-35. When your doctor tells you to try to stop snacking, are you able to proactively assert that while you could reduce the amount, you would find it difficult to completely stop?	0.603	0.613
IV-36. When you feel an oncoming dispute with your doctor, are you able to avoid it by saying you understand what he/she wants to say, but you need some time to think about it?	0.628	0.653
IV-37. When you want to make nasty remarks or complaints to your doctor, are you able to get back into the constructive mood of wanting to give it your best again by sharing your feelings with your friends, family, or medical staff?	0.634	0.644
V-38. When you feel dissatisfied or discontent with your doctor, are you able to communicate that without giving offense?	0.707	0.727
V-39. Are you able to take your doctor's advice when he/she cautions you?	0.716	0.714
V-40. Are you able to join your doctor in commending yourself on your efforts, regardless of whether the outcome is good or bad?	0.751	0.769
V-41. Are you able to consult with your doctor when you're indecisive about something?	0.780	0.798
V-42. Are you able to demand that your doctor treat you as a patient with diabetes, such as requesting certain treatments or tests, when you feel he/she is not doing so?	0.704	0.730
V-43. When your doctor has tried to persuade you to do something, such as be hospitalized or go on insulin, have you been able to speak with him/her until you were fully satisfied?	0.732	0.748
V-44. When your relationship with your doctor deteriorates, are you able to think of potential reasons for it?	0.637	0.656
V-45. When your doctor gives you various opinions and suggestions, are you able to selectively decide and implement what is possible for you personally?	0.713	0.716
V-46. Are you able to seek help from your doctor about issues you can't resolve alone?	0.750	0.782
V-47. When your doctor explains something using a lot of specialist terminology in a way you can't understand, are you able to ask him/her to explain things in a way that's easier for you to understand?	0.730	0.753
V-48. When medical staff involved in your care (e.g., doctors, nurses, nutritionists) join together to make demands of you, are you able to forthrightly state the limits of your capabilities?	0.718	0.744
VI-49. Are you able to decide on an ultimate goal as you go through treatment by comparing your ideal to your doctor's?	0.744	0.760
VI-50. Are you able to work together with your doctor to reflect on your life so far and determine the challenges facing you?	0.711	0.740
VI-51. Are you able to work together with your doctor to decide on your treatment goals?	0.768	0.784
VI-52. Are you able to check with your doctor about whether you are capable of achieving your goals at present?	0.734	0.762
VI-53. Are you able to ask your doctor for the information you need?	0.730	0.758
VI-54. When you have several problems, are you able to consult with your doctor about which you should resolve first?	0.772	0.792
VI-55. Are you able to decide for yourself to follow the treatment plan you established together with your doctor?	0.605	
VI-56. Are you able to follow through with the decisions you make to the very end?	0.518	

Note. All items are based on a classification of social skills for adolescents: I. beginning social skills, II. advanced social skills, III. skills for dealing with feelings, IV. skill alternatives to aggression, V. skills for dealing with stress, VI. planning skills. R = Reverse-scored item.

questionnaire was collected from 284 patients (recovery rate 96.9%), and the number of valid responses was 262 (effective response rate 92.3%). The sample contained 184 men (70.2%) and 78 women (29.8%), and participants' mean age was 59.67 (SD = 9.79) years. Their mean diabetes history was 10.61 (SD = 9.12) years, and their mean period of being with their current primary care doctor was 3.32 (SD = 4.60) years. Participants' mean HbA1c level was 7.46% (SD = 1.44). Fifty-nine patients (22.5%) exhibited complications, while nearly all (n = 249, 95.0%) patients attended the hospital regularly. A total of 36 patients had a history of diabetes care interruption (13.7%).

2．Item Analysis Results

Of the 56 items of the draft scale, five exhibited a ceiling effect (mean + 1 SD), and thus were excluded. None of the items had a floor effect. The results of the I-T correlation analysis revealed two items that had a weak correlation with the total score ($|r|$ < 0.2, Table 1). However, as these two items were created from the results of previous studies, they were not excluded at this stage.

3．Construct Validity

A factor analysis of the 51 items remaining after the item analysis was performed. Prior to this, we calculated the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy; as it was higher than 0.5, it was judged to be valid (KMO = 0.944). Bartlett's test of sphericity was significant (p < 0.01). Based on these results, the sample was suitable for a factor analysis. We used the Kaiser–Guttman rule and scree plots to determine the appropriate number of factors. The factor analysis was repeated, excluding all items with commonalities close to 0 and factor loadings of less than 0.35, until no items could be excluded.

Four factors with 37 items meeting the above criteria were extracted. The Cronbach's alpha coefficients of the factors ranged from 0.783 to 0.960. The whole scale had a Cronbach's alpha coefficient of 0.958. Next, I-T correlation analysis and G-P analysis were performed, which indicated that item 17 had a weak correlation with the total score and did not significantly differ between the higher rank group and the lower rank group in the total score of the 37 items. Therefore, we conducted another factor analysis with the 36 remaining items. This yielded similar results as the previous factor analysis. However, the factor loading of item 42 was 0.348, making it slightly below the criterion for inclusion. Therefore, it was excluded and another factor analysis (this one with 35 items) was performed. The pattern matrix for the 35-item analysis was similar to that for the 36-item and 37-item analyses. When comparing the Cronbach's alpha coefficients of the 36-item and 35-item scales, we found that the former scale had higher coefficients than did the latter. Item 42 was based on a previous study[3], which found that interruption of diabetic care was affected by patients with T2DM feeling that they were not treated as patients with T2DM by their doctor (e.g., they feel that their doctor did not perform the correct treatment and examination for diabetes). Consequently, we decided not to exclude it. Ultimately, then, the scale was judged to have four factors and 36 items. The cumulative contribution ratio (proportion of variance explained) of these four factors was 56.12% (Table 2).

Factor 1 comprised 18 items. The items in this factor

Table 2. Factor Analysis Results of the Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff (36 items)

Item No.	Question	Factor			
		1	2	3	4
Factor 1: Problem-solving skills (18 items)					
VI-1	When you have several problems, are you able to consult with your doctor about which you should resolve first?	**0.919**	-0.101	-0.008	0.019
VI-2	Are you able to work together with your doctor to reflect on your life so far and determine the challenges facing you?	**0.928**	-0.050	-0.072	-0.080
VI-3	Are you able to check with your doctor about whether you are capable of achieving your goals at present?	**0.925**	-0.044	-0.057	-0.069
VI-4	Are you able to work together with your doctor to decide on your treatment goals?	**0.902**	-0.032	-0.029	-0.041

VI-5	Are you able to ask your doctor for the information you need?	**0.869**	-0.180	0.117	-0.032
VI-6	Are you able to decide on an ultimate goal as you go through treatment by comparing your ideal to your doctor's?	**0.861**	0.108	-0.163	-0.017
V-7	When your doctor gives you various opinions and suggestions, are you able to selectively decide and implement what is possible for you personally?	**0.711**	0.084	-0.080	0.059
V-8	When medical staff involved in your care (e.g., doctors, nurses, nutritionists) join together to make demands of you, are you able to forthrightly state the limits of your capabilities?	**0.672**	0.020	0.062	0.061
V-9	Are you able to seek help from your doctor about issues you can't resolve alone?	**0.649**	0.050	0.135	0.017
V-10	Are you able to consult with your doctor when you're indecisive about something?	**0.623**	0.004	0.190	0.082
V-11	When your doctor explains something using a lot of specialist terminology in a way you can't understand, are you able to ask him/her to explain things in a way that's easier for you to understand?	**0.603**	-0.038	0.240	0.012
IV-12	Are you able to consult with your doctor about what is permissible in different aspects of your lifestyle, such as how much of certain foods you can eat, and how much you should exercise?	**0.579**	0.012	0.089	0.113
IV-13	When your doctor tells you to try to stop snacking, are you able to proactively assert that while you could reduce the amount, you would find it difficult to completely stop?	**0.525**	0.109	0.042	-0.057
V-14	Are you able to take your doctor's advice when he/she cautions you?	**0.492**	0.313	-0.100	0.131
V-15	When your relationship with your doctor deteriorates, are you able to think of potential reasons for it?	**0.496**	0.306	-0.009	-0.147
V-16	Are you able to join your doctor in commending yourself on your efforts, regardless of whether the outcome is good or bad?	**0.456**	0.428	-0.051	0.043
V-17	When your doctor has tried to persuade you to do something, such as be hospitalized or go on insulin, have you been able to speak with him/her until you were fully satisfied?	**0.417**	0.139	0.202	0.120
V-18	Are you able to demand that your doctor treat you as a patient with diabetes, such as requesting certain treatments or tests, when you feel he/she is not doing so?	**0.348**	0.208	0.294	-0.061
Factor 2: Coping skills (7 items)					
IV-19	When you feel an oncoming dispute with your doctor, are you able to avoid it by saying you understand what he/she wants to say, but you need some time to think about it?	-0.061	**0.729**	0.108	0.004
IV-20	When you want to make nasty remarks or complaints to your doctor, are you able to get back into the constructive mood of wanting to give it your best again by sharing your feelings with your friends, family, or medical staff?	0.086	**0.709**	-0.067	0.038
III-21	When criticized by your doctor, are you able to allow some time for your anger to abate, without causing a dispute?	0.037	**0.652**	-0.127	-0.054
IV-22	When you get angry, are you able to get over it by talking about it with family, friends, and other medical staff, without venting to your doctor directly?	0.142	**0.635**	-0.080	-0.086
III-23	When your doctor gets upset around you, are you able to stay calm by telling yourself that the diabetes, not you personally, is the cause of his/her anger?	-0.232	**0.589**	0.143	0.095
V-24	When you feel dissatisfied or discontent with your doctor, are you able to communicate that without giving offense?	0.128	**0.574**	0.129	0.027
IV-25	When you feel that your doctor's ideas are at odds with your own, are you able to infer his/her thoughts, and figure out and tell his/her intentions behind them?	0.161	**0.414**	0.215	-0.073
Factor 3: Communication skills (7 items)					
I-26	Are you able to talk about yourself in such a way that a doctor treating you for the first time could understand?	-0.008	-0.097	**0.876**	-0.039
I-27	Are you able to initiate conversations when speaking with your doctor?	0.000	-0.017	**0.867**	-0.017
I-28	Are you able to talk about matters that concern you with your doctor?	0.041	0.057	**0.695**	-0.060

II-29	Are you able to share your opinions with your doctor in such a way that he/she can understand?	0.277	0.001	**0.558**	0.017
II-30	Are you able to communicate to your doctor what you want him/her to do?	0.391	-0.006	**0.430**	0.079
I-31	Are you able to share information about the people involved in your diabetes care in such a way that your doctor can understand?	-0.102	0.313	**0.423**	-0.064
II-32	Are you able to seek help from your doctor when your diabetes care isn't going well?	0.334	0.054	**0.376**	0.045
Factor 4: Feelings-consciousness skills (4 items)					
III-R33	Are you ever hesitant to visit your doctor because you are reluctant to go to the hospital?	-0.071	0.093	-0.170	**0.842**
III-R34	Do you ever feel so awkward that it's difficult for you to meet your doctor face to face?	0.001	0.089	-0.023	**0.720**
III-R35	Are you ever afraid of angering your doctor?	-0.068	-0.151	0.205	**0.719**
III-R36	Do you ever feel fed up about continuing your diabetes treatment?	0.120	-0.076	-0.085	**0.589**
Factor correlation matrix		1	2	3	4
1		1.000	0.725	0.728	0.356
2		0.725	1.000	0.573	0.315
3		0.728	0.573	1.000	0.390
4		0.356	0.315	0.390	1.000
The cumulative contribution (proportion of variance explained) of the four factors extracted by factor analysis = 56.12%					

Note. Pattern matrix with maximum likelihood estimation and promax rotation. All items are based on a classification of social skills for adolescents: I. beginning social skills, II. advanced social skills, III. skills for dealing with feelings, IV. skill alternatives to aggression, V. skills for dealing with stress, VI. planning skills. R = Reverse-scored item. All factor loadings had to be over 0.35.

reflected skills related to discussing goals and plans for diabetes care with medical staff (i.e., primary doctor) and resolving factors that impede the achievement of goals. It was thought that this factor reflected problem-solving skills for handling issues with diabetes care together with medical staff. Therefore, it was named "problem-solving skills". Factor 2 contained 7 items, which related to skills for dealing with emotions and stress, and not attacking medical staff (i.e., the primary doctor) for anticipated problems. Thus, these appeared to be coping skills for calming down and dealing with anticipated trouble. Accordingly, it was named "coping skills". Factor 3 also contained 7 items. It related to basic communication skills, such as introducing oneself to the primary doctor, as well as advanced communication skills for deepening that relationship. In other words, it was considered to reflect communication skills to tell others about yourself. Consequently, it was named "communication skills". Finally, Factor 4 contained 4 items; its items related to

expressing negative feelings related to hospital care and the primary doctor and understanding one's aversion to diabetes care. This factor therefore seemed to reflect conscious skills in dealing with negative feelings associated with medical visits. Thus, it was named "feelings-consciousness skills".

4．Criterion-Related Validity

We calculated the Spearman's rank-correlation between the total score of our scale and the total score of the KiSS-18. The correlation coefficient was $r = 0.590$, and was significant ($p < 0.01$).

5．Content Validity

To verify the content validity of the 36-item scale, a questionnaire survey was conducted on the relevance of the items with 10 specialists in diabetes nursing. The specialists were nine women (90.0%), and their mean age was 42.60 years ($SD = 10.33$, range=28-58). Participants had a mean years of diabetes nursing experience was 14.60 years ($SD = 6.50$, range=7-25). Four participants (40.0%) were Certified Diabetes

Table3. The difference in score of the Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff by a history of diabetes care interruption (n=261)

Factor	Mean(*SD*)		p
	Had not a history of diabetes care interruption (n=225)	Had a history of diabetes care interruption (n=36)	
Factor 1: Problem-solving skills (18 items)	70.38(11.646)	63.83(16.507)	0.027*
Factor 2: Coping skills (7 items)	24.87(4.699)	22.81(6.773)	0.085
Factor 3: Communication skills (7 items)	26.28(5.268)	23.89(6.902)	0.054
Factor 4: Feelings-consciousness skills(4 items)	14.94(3.363)	11.67(3.719)	0.000**
The Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff (36 items)	136.47(20.737)	122.19(29.777)	0.008**

Table 4. Cronbach's Alpha Coefficients of Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff (n = 262)

Factor	Cronbach's alpha
Factor 1: Problem-solving skills (18 items)	0.960
Factor 2: Coping skills (7 items)	0.852
Factor 3: Communication skills (7 items)	0.888
Factor 4: Feeling-consciousness skills (4 items)	0.791
Total of 36 items	0.960

Educator of Japan.

The I-CVIs of this scale were 0.80–1.00, all items had at least 0.78. Furthermore, the S-CVI/Ave was 0.95, meaning that it was above the 0.90 criterion.

6．Known-groups validity

A t-test was performed with the total scores on the scale and each factor between the continuation diabetes care group and those who with a history of diabetes care interruption (Table3). The total score of the scale was significantly lower for patients with a history of diabetes care interruption ($p < 0.01$).

7．Reliability

The Cronbach's alpha coefficient of the 36-item version was 0.960, while those of the factors were 0.791–0.960 (Table 4). The I-T correlation analysis indicated that all items were significantly correlated with the total score ($r = 0.313–0.798$, $p < 0.01$). The G-P analysis indicated that all items showed a significant difference ($p < 0.001$).

Discussion

1．Reliability and validity of the scale

The scale's construct validity was verified via exploratory factor analysis. The four factors of this scale together had a cumulative contribution ratio of 56.12%, indicating that the scale adequately reflects the skills required by patients with T2DM to build relationships with medical staff. Further, the criterion-related validity, content validity and known-groups validity were confirmed.

The Cronbach's alpha coefficient was more than 0.7 for the lower scale and overall scale. I-T correlation analysis showed a significant correlation between all items. The G-P analysis also showed a significant difference in all items. Accordingly, the internal consistency of this scale was confirmed to be high.

Therefore, this study confirmed the reliability and validity of the scale developed.

Our scale was based on Goldstein et al.'s list of "social skills for the adolescent" [28]. The exploratory factor analysis yielded four factors for our scale, in contrast to Goldstein et al.'s [28] list of social skills for adolescents, comprising six factors. Although the four factors included some aspects of Goldstein et al.'s list, it was possible to explain these factors because similar items were aggregated into each factors.

Our scale was also positive correlated with the KiSS-18. Therefore, the higher total score of our scale indicates that patients with T2DM in our study had not only adequate skills in building good relationships with medical staff but also had good social skills.

Given that the total score of the scale was lower for

patients with a history of diabetes care interruption, it is suggested that the scale score is affected by the interruption of diabetes care.

2．Relevance to Nursing Practice, and Education

The American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) both advocated for the management of T2DM using a patient-centered approach in 2012[31),32)]. The ADA reported that a patient-centered communication style can optimize patient health outcomes and health-related quality of life, while a patient-centered approach to care can build a close working relationship between patients and clinicians involved in treatment planning[33)]. However, the DAWN2, a study focusing on the psychological and social aspects of patients with diabetes, reported that the communication between patients and medical staff in Japan is insufficient compared to global data[34)]. Therefore, to build good relationships between patients and medical staff, it is important that they have sufficient time for communication and openly communicate their thoughts and feelings.

We believe that our scale will be effective for improving the communication skills of patients with T2DM. When our scale is used for patients with T2DM, medical staff might be able to grasp which skills individual patients have weaknesses in. Through support and patient education, medical staff might be able to resolve these weaknesses. The 36 items in our scale are also concrete skills, making them well-suited to support skill improvement. Particularly, the scale results can be used to help patients reflect back on themselves, thereby making patients more conscious of their weak skills. Potentially, it can help patients think about ways to build relationships with medical staff, and the skills they might need to so. Therefore, in the future, patients might be able to build and maintain better relationships with medical staff.

Further, by looking at the 36 items of our scale, medical staff might able to understand how to relate to patients with T2DM (e.g., how to explain, converse, and guide patients). Therefore, our scale might also be useful as a tool for improving the communication skills of medical staff as well.

Limitations

This study was carried out in Japan, and the scale was developed in Japanese. Therefore, the English version of the scale has not been assessed. Furthermore, the sample selection was biased as only four facilities from a limited area were included. Therefore, the findings might not be applicable to all patients with T2DM.

Conclusions

The Skill Scale for Patients with Type 2 Diabetes Mellitus to Build Relationships with Medical Staff contains four factors and 36 items: "problem-solving skills" (Factor 1), "coping skills" (Factor 2), "communication skills" (Factor 3), and "feelings-consciousness skills" (Factor 4). The total score of this scale was positively correlated with the KiSS-18. The content validity of each item and the overall scale was also confirmed. The total score of the scale was significantly lower for patients with a history of diabetes care interruption. The Cronbach's alpha coefficient of four factor for the 36 items is 0.960. The I-T correlation analysis indicated that all items were significantly correlated with the total score. The G-P analysis indicated that all items showed a significant difference. This study confirmed the reliability and validity of the scale for patients with T2DM in Japan. The scale could be useful to measure skills of patients with T2DM in building relationships with medical staff.

Acknowledgements

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2 型糖尿病患者における医療者との関係構築スキル尺度の開発および 信頼性と妥当性の評価

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要　旨

　背景・目的：糖尿病の通院中断予防には、患者と医療者が良好な関係を築けるようなスキルを高めることが必要である。2 型糖尿病患者と医療者は良好な糖尿病コントロールの維持を共通目標とし、両者の努力が重要である。これより、2 型糖尿病患者には既存尺度よりも特有で具体的なスキルを考慮した尺度が必要と考えた。本研究は 2 型糖尿病患者における医療者との関係構築スキル尺度を開発し、信頼性と妥当性を検証することを目的とした。

　方法：本尺度の理論的枠組みには、ゴールドステインらの作成した若者のための社会的スキルを用いた。先行研究、糖尿病看護に携わる看護師への面接、研究者の臨床経験を基に 76 項目を作成した。その後、内容妥当性と表面妥当性を検証し、原案 56 項目を作成した。全項目は 5 段階のリッカート尺度で評価した。日本の 2 型糖尿病患者 262 名の有効回答を得た。データは探索的因子分析を行った。妥当性の検討として、基準関連妥当性はKiSS-18、内容妥当性は内容妥当性指標 (CVI) を用い、既知集団妥当性は通院中断経験の有無と尺度得点の比較を行った。信頼性の検討はクロンバックα、I-T 相関分析、G-P 分析を行った。

　結果：探索的因子分析により 4 因子 36 項目を抽出した。4 因子は、「問題解決スキル」、「対処スキル」、「コミュニケーションスキル」、「感情自覚スキル」と命名した。本尺度の累積寄与率は56.12%であった。KiSS-18 との相関係数は0.590 と有意な相関であった ($p < 0.01$)。CVI は各項目 0.80 ～ 1.00、尺度全体 0.95 と基準を上回っていた。通院中断経験者は尺度総得点が有意に低かった ($p < 0.01$)。尺度全体のクロンバックα係数は 0.960 であった。全項目において、I-T 相関分析は有意な相関であり ($r = 0.313 \sim 0.798,\ p < 0.01$)、G-P 分析では有意差が得られた ($p < 0.001$)。

　結論：本研究は日本の 2 型糖尿病を持つ患者において信頼性と妥当性のある尺度と確認できた。