The association between health literacy levels and patient-reported outcomes in Japanese type 2 diabetic patients

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Abstract

Objectives: The aim of this study is to empirically examine a full pathway model of health literacy, and health and well-being outcomes among patients with type 2 diabetes.

Methods: A three-wave longitudinal survey was administered to 148 patients with diabetes. Covariance structure analysis was conducted to create a path diagram, with health literacy and burden of medical expenses included as independent variables and with psychosocial factors, behaviors, and health and well-being outcomes included as dependent variables.

Results: The model fit indices showed a comparative fit index of 0.985 at baseline, 0.959 after 3 months, and 0.948 after 6 months, with a root mean square error of approximation of 0.040 at baseline, 0.079 after 3 months, and 0.085 after 6 months. There were 14 significant paths across the three time points between health literacy and understanding of diabetes care, self-efficacy, communication with doctors, and medication adherence.

Conclusion: The model fitness index showed an adequate result. Health literacy was significantly positively associated with understanding of diabetes care, self-efficacy, communication with doctors, and medication adherence. Health literacy had a direct positive influence on medication adherence and possibly an indirect positive influence on exercise/diet via self-efficacy. The results were generally consistent across the three time points, suggesting good reliability of the models. Improving health literacy may lead to better self-management of diabetes and favorable health outcomes.

Keywords

Type 2 diabetes, health literacy, self-management, longitudinal survey

Introduction

The number of people with diabetes worldwide is rapidly increasing, and those with type 2 diabetes account for the majority of these cases. In Japan, there are about 10 million people either diagnosed with diabetes or strongly suspected of having diabetes (HbA1c (National Glycohemoglobin Standardization Program [NGSP]) > 6.5%), and the percentage currently receiving treatment increased from 45.0% in 2007 to 76.6% in 2016.[1] Globally, US$825 billion is spent annually on medical expenses for diabetes; in Japan, these expenses amount to approximately US$37 billion, and Japan ranks seventh in the world in terms of diabetes spending.[2]

People with type 2 diabetes are greatly influenced by lifestyle and self-care behaviors such as diet and exercise, and

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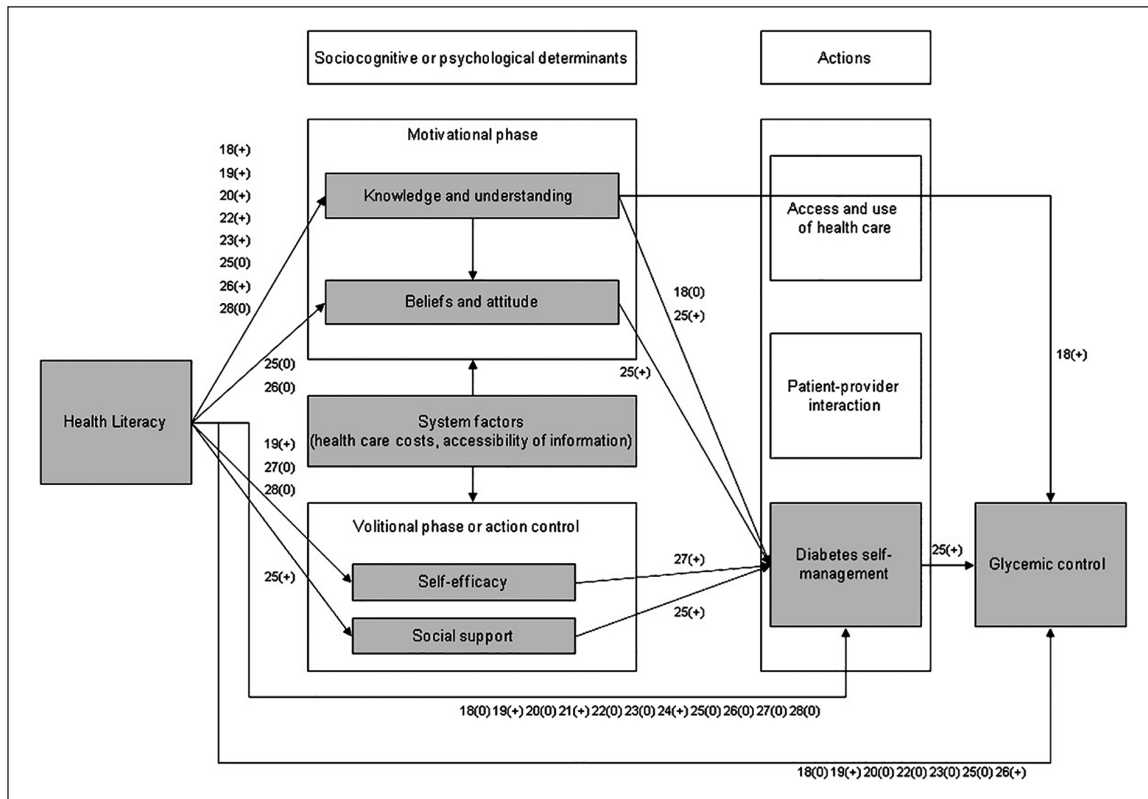Email: uenoh-tky@umin.ac.jp

Figure 1. Conceptual diagram of Fransen et al.'s[19] health literacy framework.

they are susceptible to psychological problems, including anxiety and depression.[3] Depression can affect self-care behavior and therapeutic adherence, leading to problematic glycemic control and deteriorated quality of life (QOL).[4,5] Patients' emotional burden should therefore be considered to have a strong influence on self-management behavior and glycemic control,[6,7] both globally and in Japan.

It is imperative to improve disease management for patients with type 2 diabetes and to increase efforts to prevent disease progression. To this end, self-management—including a healthy diet, exercise, and a medication regimen—is required on a daily basis. For self-management of chronic diseases, patients need to understand their illness and the necessity of treatment, and they need to implement self-management in daily life. The empowerment approach, aimed at effective decision making, patient participation in treatment, and clarifying the patient's goals, values, and motivations, has become a focus of attention.[8,9]

Schulz and Nakamoto[10] noted that, for patients to be empowered, in addition to receiving knowledge, they need to be able to appropriately use their knowledge and information (i.e. health literacy). Health literacy has been defined as "the cognitive and social skills which determine the motivation and ability of individuals to gain access, understand and use information in ways which promote and maintain good health."[11] The empowerment approach focuses mainly on

enabling psychological aspects, such as motivation—the power to independently make decisions and cause actions. However, health literacy goes beyond this, encompassing both the knowledge necessary to maintain and improve health outcomes and the ability and skills to use this knowledge. Psychological empowerment and improved health literacy need to be encouraged to facilitate patients' effective self-management.

The active involvement of patients and diverse types of support from health care providers are also required in the self-management of diabetes, and collaborative relationships between these groups are needed.[12–15] For this purpose, good communication between the patients and health care providers is essential. Patients who can communicate well with their primary doctors have confidence in their own ability to acquire the information necessary for their treatment and for self-management, and to understand and use this information effectively.[16]

Previous studies[17,18] have proposed causal pathways between health literacy and health outcomes. These have covered topics, including access to and use of health care, provider–patient interaction, and self-care. Based on a review of previous studies on health literacy and diabetes self-management, Fransen et al.[19] developed a framework for health literacy and health outcomes. This framework, which is shown in Figure 1, suggests that health literacy is

related to psychosocial factors (e.g. knowledge, understanding, and self-efficacy), behavior (e.g. quality of patient–provider communication and diabetes self-management, including diet, exercise, and medication), and health outcomes (e.g. glycemic control measured with HbA1c and diabetic complications).

Regarding psychosocial factors, self-efficacy has been shown to be strongly related to diabetes-related knowledge and self-management.[20,21] Health literacy increases patients' self-efficacy[20] and knowledge about diabetes[22] and thereby improves self-management of diabetes.[23]

Effective self-management of diabetes also requires considering the patient's psychological burden. Previous studies have examined the associations of both degree of emotional burden[6,7] and depression[24] with the self-management of diabetes. In terms of the influence of health literacy on psychological burden, no link has been found between health literacy and the prevention of depressive symptoms,[25] but interventions to improve health literacy have been found to improve suffering from diabetes.[26] However, this association remains unclear. Medical expenses such as those for external factors and psychological effects have also been noted,[19] although their association is also somewhat unclear.

Regarding the relationship of health literacy with health outcomes, patients with diabetes with low health literacy may have poor control of their blood glucose level,[27] a high prevalence of diabetic retinopathy,[28] and other complications.[29] Many studies have treated HbA1c as a direct outcome, but one study has reported an association between health literacy and HbA1c.[28,30] Other studies testing the association between health literacy and HbA1c have reported that these variables are unrelated,[22,23,25,31–33] and there is still no consensus among scholars regarding this potential association.[19] In Japan, one study found no association between HbA1c and health literacy,[34] and another study found that HbA1c levels were low when communicative health literacy was high.[35]

Factors such as satisfaction and QOL with regard to patient treatment and self-management may also be important for patients with diabetes and for outcomes such as HbA1c. Research has been conducted on aspects of QOL such as self-efficacy and satisfaction with treatment.[36,37] However, no work has yet clarified how diabetes treatment, self-management, QOL, and health literacy relate to satisfaction.

The previous findings summarized above indicate that improving health literacy may increase individual patients' adherence to required treatments. Health literacy thus may be a pertinent factor for changing behavior and decision making regarding the implementation of self-management and sound daily health habits. However, no studies have yet verified Fransen et al.'s[19] entire model. The present study aimed to empirically examine a full pathway model of health literacy, and health and well-being outcomes among patients with type 2 diabetes. The examined model was based on Fransen et al.'s[19] framework and focused on psychosocial factors, diabetes knowledge, self-efficacy, communication with doctors, and self-management behavior.

Methods

Participants in this study were patients with type 2 diabetes who visited the outpatient internal medicine department for diabetes metabolism at a university-affiliated hospital in Tokyo. The inclusion criteria were having type 2 diabetes, being aged ⩾20 years, and requiring periodic medication. Exclusion criteria were not using diabetes medication, having dementia, or being judged unsuitable by the attending doctor. Patients who were eligible for recruitment were randomly selected from the appointment logs of the study physicians. From October to November 2013, 193 potential participants were identified. These patients were approached in the waiting room after they had attended a consultation, and they were given an explanation of the study purpose and procedures. A total of 153 patients provided written consent to participate in the study and to complete the questionnaire.

A longitudinal study was carried out at three time points: baseline (T1), 3 months after baseline (T2), and 6 months after baseline (T3). The questionnaire responses were kept confidential. Patients were asked to give their name, address, and contact telephone number on the consent form at the time of the first survey. The consent form was linked to the questionnaire by an ID number. The baseline sample of 148 patients introduced by the attending doctor, excluding five patients who were found to be ineligible because of the exclusion criteria, provided consent before the T1 survey. They were asked to complete a self-administered multiple-choice questionnaire at each time point at the hospital or to return the questionnaire by mail from January to March 2014 (T2) and from April to July 2014 (T3). The most common reasons for refusal to participate were a lack of time and poor physical condition on the day of the survey. The study was conducted with the approval of the Ethical Review Committee of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo.

Measures

Health literacy. Health literacy was measured using the health literacy scale developed by Ishikawa et al.[35] The reliability and validity of this scale have been confirmed.[35] The scale includes 14 items: 5 assessing functional health literacy, 5 gauging communicative health literacy, and 4 measuring critical health literacy. All items are rated on a four-point scale, with higher scores indicating higher health literacy levels.

Psychosocial factors

Understanding of diabetes care. Inoue et al.[34] created a Japanese version of the measurement tool for understanding diabetes care, which was developed by Heisler et al.[38] Items on this scale are rated on a five-point scale, with higher scores indicating higher understanding of diabetes care.

Self-efficacy. Fitzgerald et al.[39] developed a measurement tool for self-efficacy in diabetes management. Items on this scale are rated on a five-point scale, with higher scores indicating higher self-efficacy in diabetes management.

Emotional burden (Problem Areas in Diabetes scale). To measure the emotional burden associated with diabetes, Ishii et al.[6] created a Japanese version of the Problem Areas in Diabetes (PAID) scale, which was developed by Polonsky et al.[7] The reliability and validity of the Japanese version of the PAID scale have been verified previously.[6] From among the scale's 20 items, the present study used five reliable and valid items from the PAID-5 shortened version.[40] Each of these items is rated on a five-point scale, with higher scores indicating a higher degree of emotional burden.

Burden of medical expenses for diabetes. The burden of medical expenses related to the treatment of diabetes was scored on a five-step range from "none" to "high," with higher scores indicating a higher burden.

Behavior

Communication with doctors. We used a scale developed by Clayman et al.[41] to assess communication with doctors and in a clinical setting: The Ask, Understand, Remember Assessment (AURA) comprises four items measuring self-efficacy in collecting, understanding, remembering, and evaluating medical information. We created a Japanese version of the scale after receiving the original authors' approval, and we performed a reverse translation of the content for verification. All items on the AURA are rated on a four-point scale ranging from agree or disagree with a statement "a little" or "a lot." Higher scores reflect a higher sense of self-efficacy regarding communication in a clinical setting.

Self-management

Medication adherence. Medication adherence was measured using a 12-item version of the Medication Adherence Scale developed by Ueno et al.[42] for patients with chronic diseases. This scale comprises four subscales. The first contains three items on medication compliance, the second has three items on collaboration with health care providers, the third has three items on willingness to access and use information about medication, and the fourth has three items on acceptance to take medication and how taking medication fits patient's lifestyle. These items are rated on a five-point scale ranging from 1 ("never") to 5 ("always"). Higher scores indicate higher medication adherence.

Exercise/diet. Regarding exercise and dietary habits related to diabetes treatment, patients were asked to what extent they followed the instructions of their health care providers, with response options of 1 = "I have received no instructions," 2 = "I have received some instructions but am not sure what to do," 3 = "I know what I should do but rarely follow the instructions," 4 = "I usually follow the instructions," and 5 = "I almost always follow the instructions." Higher scores indicate greater adherence to these instructions.

Health and well-being outcomes

Diabetes Therapy-Related QOL: satisfaction with treatment subscale. The Diabetes Therapy-Related QOL (DTR-QOL) questionnaire, developed by Ishii,[43] addresses four areas of diabetes treatment: burden on social activities and daily activities (13 items), anxiety and dissatisfaction with treatment (8 items), hypoglycemia (4 items), and satisfaction with treatment (4 items). The present study included the four items from the "satisfaction with treatment" subscale. These items are rated on a seven-point Likert-type scale (1 = "strongly agree" to 7 = "strongly disagree"). For each item, a score of 1 represents the highest level of satisfaction with the treatment.

Glycemic control (HbA1c). HbA1c level at the time of each survey was extracted from the patient's medical chart. The test results of HbA1c were measured on the same day as the questionnaire was administered at T1. For T2 and T3, the test results of the dates around 3 and 6 months after baseline (T1) were extracted from the patient's chart, respectively.

Basic characteristics. Sex and age were identified from the patients' medical records. Data on highest level of education, marital status, living with someone else, and working for income were collected from the questionnaires.

Characteristics related to treatment of diabetes and current physical condition. Number of years since being diagnosed with type 2 diabetes, presence of diabetes-related complications, and type of medicine taken for diabetes were determined from medical records, and body mass index was indicated on the questionnaires.

Statistical analysis. All data analyses were performed using SPSS, Version 21.0 (IBM SPSS Japan, Inc., Tokyo, Japan), except for the covariance structure analysis, which was performed using AMOS, Version 21.0 (IBM SPSS Japan, Inc.). Covariance structure analysis is a statistical technique in which a theoretical model, or a covariance structure, is constructed, and the covariance values predicted by the theoretical model are compared with those of the observed data. The adequacy of the model in reproducing the sample covariance values is reflected by estimates of the parameters of the model and measures indicating the goodness of fit.[44]

Results

Sample characteristics

Table 1 shows the characteristics of the 148 participants at T1. The average age was 67.9 (range: 32–87) years, and roughly 67% were men and 33% were women. More than 70% were married, 83.1% were living with someone else (i.e. immediate family, relatives, partners, or roommates, irrespective of marital status), 48% had a high level of education (technical college, junior college, or university graduates), and 43.9% were engaged in income-generating work.

The mean disease duration of diabetes was 12.0 (range: <1–45) years, mean HbA1c was 7.0% (range: 5.1%–12.6%), and 30.4% of the participants were using insulin injections. Complications were seen in retinopathy (28.4%), nephropathy (51.4%), and neuropathy (32.4%). Some participants had multiple complications. The average body mass index was 24.4 (range: 16.0–51.4) kg/m^2.

The final sample at baseline comprised 148 patients. Six of these patients dropped out at T2 ($n = 142$), and another two dropped out at T3 ($n = 140$). The drop-out rate was very low (5.4%).

We performed a sample size calculation with a 5% significance level for the test of close fit, with 0.05 as the null value of the root mean square error of approximation (RMSEA) and 0.08 as the alternative value of RMSEA. For the test of not-close fit, 0.05 was the null value of RMSEA and 0.01 was the alternative value of RMSEA.[45] This yielded a minimum target sample size of 95 to 152 participants and a power estimate 0.50 to 0.75. A total of 148 patients with diabetes participated in this study.

Relationships of health literacy at T1 with psychosocial factors, behavior (communication with doctors and self-management), and health and well-being outcomes at T1, T2, and T3

Figures 2–4 show the results of the covariance structure analysis, presented as path diagrams for T1 ($n = 148$), T2 ($n = 142$), and T3 ($n = 140$), respectively. Health literacy and the burden of medical expenses were included as independent variables, and psychosocial factors (understanding of diabetes care, self-efficacy, and emotional burden), behaviors related to communication with doctors and self-management (medication adherence, exercise/diet), and health and well-being outcomes (satisfaction with treatment and HbA1c) were included as dependent variables. When adjusting for educational background, age, and sex, the model fit index decreased. We therefore refer to the results of the models where these attributes were not adjusted. The model fitness indices showed χ^2 to degrees of freedom ratios of 1.237 (T1), 1.876 (T2), and 2.011 (T3); comparative fit index values of 0.985 (T1), 0.959 (T2), and 0.948 (T3); and RMSEA values of 0.040 (T1), 0.079 (T2), and 0.085 (T3).

Table 1. Demographic and clinical characteristics of participants ($N = 148$).

Age (years)	67.9 ± 11.0 (32–87)
Sex	
Male	99 (66.9)
Female	49 (33.1)
HbA1c (%)	7.0 ± 1.1 (5.1–12.6)
Body mass index (kg/m^2)	24.4 ± 5.2 (16.0–51.4)
Diabetes duration (years)	12.0 ± 9.4 (0.2–45)
Education level	
High school or lower	75 (50.6)
College or higher	71 (48.0)
Unknown	2 (1.4)
Marital status	
Married	109 (73.6)
Unmarried	38 (25.7)
Unknown	1 (0.7)
Living with someone else	
Yes	123 (83.1)
No (living alone)	24 (16.2)
Unknown	1 (0.7)
Work with income	
Yes	65 (43.9)
No	83 (56.1)
Burden of medical expenses for diabetes	
None	29 (19.6)
Rarely	58 (39.2)
Sometimes	45 (30.4)
Often	12 (8.1)
High	4 (2.7)
Oral hypoglycemic agents	
No	19 (12.8)
Yes	129 (87.2)
Insulin injections	
No	103 (69.6)
Yes	45 (30.4)
Complications	
None	48 (32.4)
Retinopathy	42 (28.4)
Nephropathy	76 (51.4)
Neuropathy	48 (32.4)

Data are presented as mean ± standard deviation (range), or as *n* (%).

Fourteen paths were significant at the 5% level (red arrows) at T1, T2, and T3: from health literacy to understanding of diabetes care, self-efficacy, communication with doctors, and medication adherence; from burden of medical expenses to emotional burden and HbA1c; from self-efficacy to emotional burden, exercise/diet, HbA1c, and satisfaction with treatment; from emotional burden to communication with doctors and satisfaction with treatment; from communication with doctors to medication adherence; and from HbA1c to satisfaction with treatment.

Regarding the relationships between health literacy and psychosocial factors, a positive path that was significant at
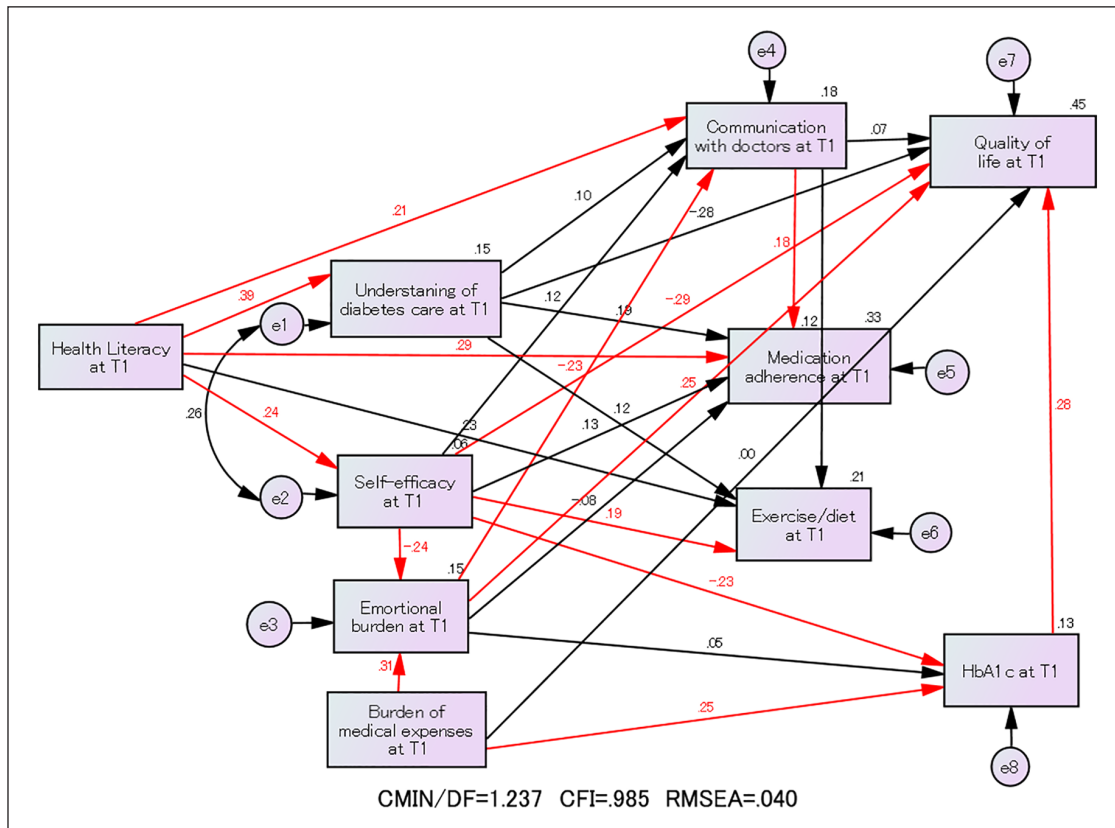
Figure 2. Relationships of health literacy at baseline (T1) with psychosocial factors, behavior (communication with doctors and self-management), and health and well-being outcomes at T1.
Red arrow: Significance level of 5%; Black arrow: Does not reach significance level of 5%.

the 5% level was found from health literacy results at T1 to understanding of diabetes care and self-efficacy at all three time points.

Regarding the relationship between health literacy and behavior, there was a significant positive path from health literacy at T1 to communication with doctors at all three time points. In terms of the relationship between health literacy and self-management, there was a significant positive path between health literacy at T1 and medication adherence at all three time points.

Discussion

The present study aimed to examine a pathway model based on the framework proposed by Fransen et al.,[19] linking health literacy to health and well-being outcomes among patients with type 2 diabetes. This study was the first to empirically examine a conceptual framework linking health literacy, psychosocial factors, communication with doctors, self-management behavior, and health and well-being outcomes among patients with type 2 diabetes.

The model fit index was highest at T1. Although it slightly declined at T2 and T3 with a decrease in sample size, the relationships among the variables in the model were generally comparable across the three time points.

In terms of the relationship between health literacy and psychosocial factors, there were significant positive paths from health literacy at T1 to understanding of diabetes care and self-efficacy at all three time points. A similar positive association between health literacy and understanding of diabetes care has been shown in previous studies,[20] suggesting that higher levels of health literacy correspond to higher degrees of understanding.[22]

Regarding the relationship between health literacy and behavior, there was a significant positive path from health literacy at T1 to communication with doctors at all three time points. Similar results have been reported in previous studies,[21] suggesting that health literacy is an important factor in successful communication in doctors' examinations. This suggests that the ability to properly collect and exchange information such as health literacy leads to a high level of communication ability such as the exchange of information with doctors.[21] In addition, it is thought that good relationships with doctors will lead to further improvement in communication, as it will also lead to patients participating proactively in treatment and decision making.[46] However, the effect of health literacy for a particular patient depends on the complexity of the health information provided to him or her.[47] In addition to their efforts to improve patients' health literacy, medical personnel should also communicate
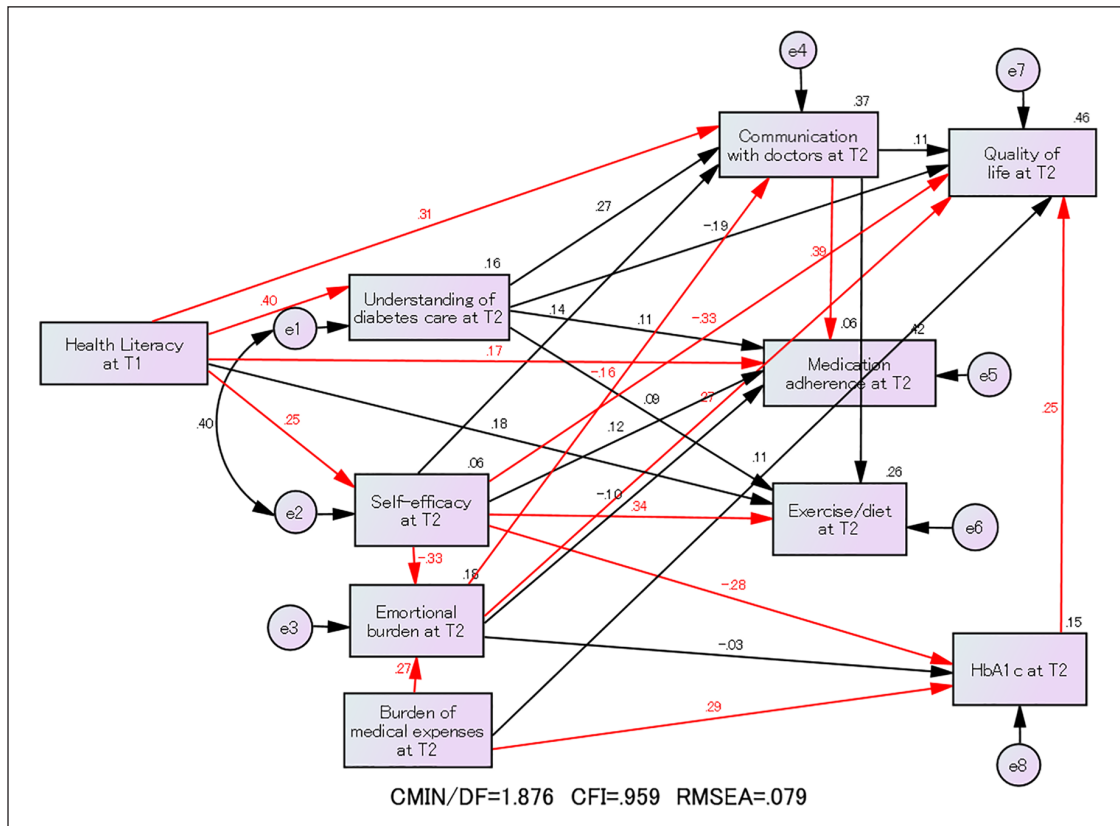
Figure 3. Relationships of health literacy at baseline (T1) with psychosocial factors, behavior (communication with doctors and self-management), and health and well-being outcomes after 3 months (T2).
Red arrow: Significance level of 5%; Black arrow: Does not reach significance level of 5%.

health information in a way that is easy for their patients to understand.

Concerning the relationship between health literacy at T1 and self-management, there was a significant positive link between health literacy and medication adherence at all three time points. This finding is consistent with previous studies that have examined the association between patient health literacy and medication adherence.[48,49] Health literacy is important in improving education and communication, which can increase patients' understanding of medication adherence.[48] Our findings suggest that improving health literacy may increase medication adherence among patients with diabetes. However, health literacy at T1 was not a statistically significant predictor of exercise/diet at any of the three time points. Previous studies have also indicated that there is no direct relationship between health literacy and adherence to diet and/or exercise therapy,[20,22,23,25,31] but that there is a direct relationship between health literacy and drug therapy.[48,49]

We found a significant strong positive association between burden of medical expenses and degree of emotional burden at all three time points. This suggests that a high economic burden of medical expenses for treating diabetes increases the degree of emotional burden among

patients with diabetes—a conclusion that can also be found in previous studies.[19]

Regarding the relation between burden of medical expenses and the examined health outcomes, there was no strong relation between burden of medical expenses and medical satisfaction; however, there was a significant positive association between burden of medical expenses and HbA1c at all three time points. Our findings suggest that, if the burden of medical expenses is high, HbA1c also tends to be high. However, careful attention should be paid to the interpretation here because high HbA1c can lead to morbidity and complications and therefore to a high burden of medical expenses (e.g. for treatment and medicine).

An increased level of health literacy may directly improve medication adherence, and health literacy may indirectly influence exercise and diet behaviors by improving self-efficacy. Self-efficacy has a positive effect on self-management for many chronic health conditions.[50,51] Self-efficacy theory states that perceived self-efficacy refers to the belief in one's capabilities to organize and execute the courses of actions required to produce given attainments.[50]

It is argued that motivation for behavior change can be attained by enhancing self-efficacy, so that actions such as exercising and eating a healthy diet can be achieved.
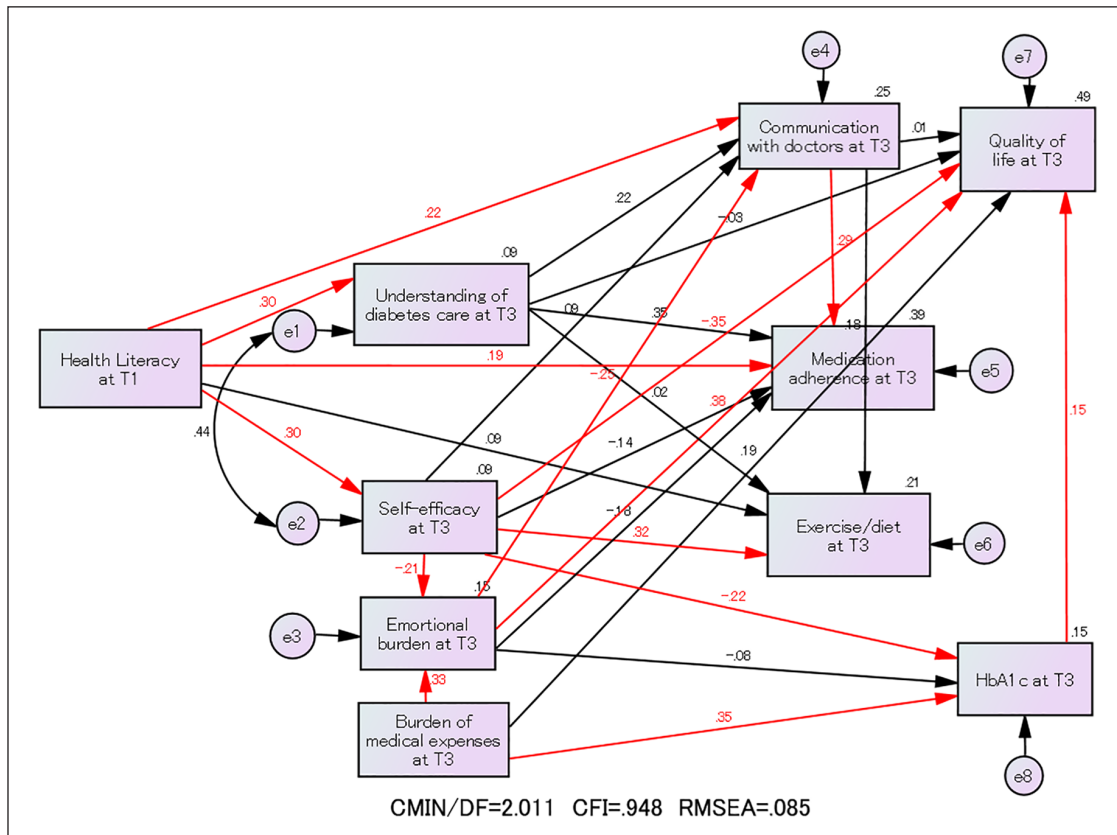
Figure 4. Relationships of health literacy at baseline (T1) with psychosocial factors, behavior (communication with doctors and self-management), and health and well-being outcomes after 6 months (T3).
Red arrow: Significance level of 5%; Black arrow: Does not reach significance level of 5%.

Furthermore, actions can be maintained by successful experiences of these actions.[50,51] A previous study found high self-efficacy to be associated with high levels of self-care behavior, such as exercise and diet, among diabetic patients.[20] The rationale for this association is that the improvement of the sense of self-efficacy is thought to lead to the implementation of actual exercise/dietary behavior changes. We observed a significant positive effect of health literacy on understanding of diabetes care, self-efficacy, communication with doctors, and medication adherence at all three time points. Health literacy might also have had a positive influence on exercise/diet through self-efficacy at the three time points.

The significant effects of health literacy found in this study suggest that efforts to increase proactive behavior on the part of patients will lead to positive self-management behavior,[21,30] including medication adherence[48,49] and effective exercise and dietary practices, by improving self-efficacy.[20] In addition, improving communication with doctors can increase patients' ability to collect and exchange high-quality information, which can, in turn, lead to patients' greater involvement in decision making regarding their treatment.[10,12,15,16,38,49]

A limitation of this research is that the survey was conducted at only one university hospital in Tokyo. Compared with patients with diabetes who visit general hospitals and clinics in outlying areas, there is a possibility of bias because the participants in the present study represent more serious cases and have higher levels of education. It would be desirable for future studies to consider including larger numbers of facilities and patients. In addition, all indicators used in the survey in this study were based on self-report, which may have resulted in measurement error because of bias in the response tendencies of participants. It would therefore be desirable to conduct future studies using more objective indicators. Finally, although we observed relationships between health literacy and self-efficacy and between self-efficacy and exercise/diet, this does not mean that health literacy has a positive effect on exercise/diet through self-efficacy, because there are other variables that we have not measured that may independently affect both self-efficacy and exercise/diet.

Conclusion

The present research empirically examined the pathway model linking health literacy to health and well-being outcomes among patients with diabetes, based on a theoretical model proposed in a previous study. Our results suggest that

health literacy may be indirectly related to patient health and well-being outcomes through psychosocial factors, communication with doctors, and self-management behaviors. The relationships among the variables in the model were generally comparable across the three time points. Further research is needed to investigate whether the results and models of this study can be applied to patients with other chronic diseases that require self-management.

We found significant positive effects of health literacy on understanding of diabetes care, self-efficacy, communication with doctors, and medication adherence. In addition, health literacy might have a positive influence on exercise/diet through self-efficacy. Improving health literacy may lead to better self-management and improved health and well-being outcomes, although the impact of improvements in health literacy may be determined by the relationship between a patient's health literacy level and the understandability of the information provided.[47] Educational programs focusing on health literacy[52,53] should be considered in the future as a means of improving health and well-being outcomes.

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Declaration of conflicting interests

Ethical approval

The study was conducted with the approval of the Ethical Review Committee of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo (No. 10240-(3)).

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Informed consent

Written informed consent was obtained from all subjects before the study.

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References

1. Ministry of Health, Labour and Welfare. Results of the "National Health and Nutrition Survey" in 2016 (in Japanese), https://www.mhlw.go.jp/file/04-Houdouhappyou-10904750-Kenkoukyoku-Gantaisakukenkouzoushinka/kek-kagaiyou_7.pdf (2017, accessed 23 October 2018).

2. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. *Lancet* 2016; 387(10027): 1513–1530.

3. Anderson RJ, Freedland KE, Clouse RE, et al. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. *Diabetes Care* 2001; 24(6): 1069–1078.

4. Penckofer S, Doyle T, Byrn M, et al. State of the science: depression and type 2 diabetes. *West J Nurs Res* 2014; 36(9): 1158–1182.

5. Golden SH, Lazo M, Carnethon M, et al. Examining a bidirectional association between depressive symptoms and diabetes. *JAMA* 2008; 299(23): 2751–2759.

6. Ishii H, Welch G, Jacobson A, et al. The Japanese version of Problem Area in Diabetes scale: a clinical and research tool for the assessment of emotional functioning among diabetes patients. *Diabetes* 1999; 48(Suppl. 1): A319.

7. Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. *Diabetes Care* 1995; 18: 754–760.

8. Anderson R and Funnell M. *The art of empowerment: stories and strategies for diabetes educators*. Alexandria, VA: American Diabetes Association, 2000.

9. Funnell M and Anderson R. Empowerment and self-management of diabetes. *Clin Diabetes* 2004; 22: 123–127.

10. Schulz PJ and Nakamoto K. Health literacy and patient empowerment in health communication: the importance of separating conjoined twins. *Patient Educ Couns* 2013; 90(1): 4–11.

11. Nutbeam D. Health promotion glossary. *Health Promot Int* 1998; 13(4): 349–364.

12. Van Dam HA, Van der Horst F, Van den Borne B, et al. Provider–patient interaction in diabetes care: effects on patient self-care and outcomes. *Patient Educ Couns* 2003; 51(1): 17–28.

13. Ciechanowski P and Katon WJ. The interpersonal experience of health care through the eyes of patients with diabetes. *Soc Sci Med* 2006; 63(12): 3067–3079.

14. Bissell P, May CR and Noyce PR. From compliance to concordance: barriers to accomplishing a re-framed model of health care interactions. *Soc Sci Med* 2004; 58(4): 851–862.

15. Fuertes JN, Mislowack A, Bennett J, et al. The physician–patient working alliance. *Patient Educ Couns* 2007; 66: 29–36.

16. Kaplan SH, Greenfield S and Ware JE Jr. Assessing the effects of physician–patient interactions on the outcomes of chronic disease. *Med Care* 1989; 27(3 Suppl.): S110–S127.

17. Paasche-Orlow MK and Wolf MS. The causal pathways linking health literacy to health outcomes. *Am J Health Behav* 2007; 31(Suppl. 1): S19–S26.

18. VonWagner C, Steptoe A, Wolf MS, et al. Health literacy and health actions: a review and a framework from health psychology. *Health Educ Behav* 2009; 36(5): 860–877.

19. Fransen MP, VonWagner C and Essink-Bot ML. Diabetes self-management in patients with low health literacy: ordering findings from literature in a health literacy framework. *Patient Educ Couns* 2012; 88(1): 44–53.

20. Sarkar U, Fisher L and Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy. *Diabetes Care* 2006; 29(4): 823–829.

21. Sarkar U, Piette JD, Gonzales R, et al. Preferences for self-management support: findings from a survey of diabetes

patients in safety-net health systems. *Patient Educ Couns* 2008; 70(1): 102–110.

22. Bains SS and Egede LE. Associations between health literacy, diabetes knowledge, self-care behaviors, and glycemic control in a low income population with type 2 diabetes. *Diabetes Technol Ther* 2011; 13(3): 335–341.

23. Bohanny W, Wu SF, Liu CY, et al. Health literacy, self-efficacy, and self-care behaviors in patients with type 2 diabetes mellitus. *J Am Assoc Nurse Pract* 2013; 25: 495–502.

24. De Groot M, Anderson R, Freedland KE, et al. Association of depression and diabetes complications: a meta-analysis. *Psychosom Med* 2001; 63(4): 619–630.

25. Mancuso JM. Impact of health literacy and patient trust on glycemic control in an urban USA population. *Nurs Health Sci* 2010; 12(1): 94–104.

26. Wallace AS, Seligman HK, Davis TC, et al. Literacy-appropriate educational materials and brief counseling improve diabetes self-management. *Patient Educ Couns* 2009; 75(3): 328–333.

27. Al Sayah F, Majumdar SR, Williams B, et al. Health literacy and health outcomes in diabetes: a systematic review. *J Gen Intern Med* 2013; 28(3): 444–452.

28. Schillinger D, Grumbach K, Piette J, et al. Association of health literacy with diabetes outcomes. *JAMA* 2002; 288: 475–482.

29. Guerra C and Shea J. Functional health literacy, comorbidity and health status; abstract. *J General Intern Med* 2003; 18(Suppl. 1): 174.

30. Powell CK, Hill EG and Clancy DE. The relationship between health literacy and diabetes knowledge and readiness to take health actions. *Diabetes Educ* 2007; 33(1): 144–151.

31. Kim S, Love F, Quistberg DA, et al. Association of health literacy with self-management behavior in patients with diabetes. *Diabetes Care* 2004; 27(12): 2980–2982.

32. Morris NS, MacLean CD and Littenberg B. Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes. *BMC Fam Pract* 2006; 7: 49.

33. Hawthorne K and Tomlinson S. Pakistani Moslems with type 2 diabetes mellitus: effect of sex, literacy skills, known diabetic complications and place of care on diabetic knowledge, reported self-monitoring management and glycaemic control. *Diabet Med* 1999; 16(7): 591–597.

34. Inoue M, Takahashi M and Kai I. Impact of communicative and critical health literacy on understanding of diabetes care and self-efficacy in diabetes management: a cross-sectional study of primary care in Japan. *BMC Fam Pract* 2013; 14: 40.

35. Ishikawa H, Takeuchi T and Yano E. Measuring functional, communicative, and critical health literacy among diabetic patients. *Diabetes Care* 2008; 31(5): 874–879.

36. Jahanlou AS and Alishan Karami N. The effect of literacy level on health related-quality of life, self-efficacy and self-management behaviors in diabetic patients. *Acta Med Iran* 2011; 49(3): 153–158.

37. DeWalt DA, Boone RS and Pignone MP. Literacy and its relationship with self-efficacy, trust, and participation in medical

decision making. *Am J Health Behav* 2007; 31(Suppl. 1): S27–S35.

38. Heisler M, Bouknight RR, Hayward RA, et al. The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management. *J Gen Intern Med* 2002; 17(4): 243–252.

39. Fitzgerald JT, Davis WK, Connell CM, et al. Development and validation of the diabetes care profile. *Eval Health Prof* 1996; 19(2): 208–230.

40. McGuire BE, Morrison TG, Hermanns N, et al. Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes scale (PAID)-5 and PAID-1. *Diabetologia* 2010; 53(1): 66–69.

41. Clayman ML, Pandit AU, Bergeron AR, et al. Ask, understand, remember: a brief measure of patient communication self-efficacy within clinical encounters. *J Health Commun* 2010; 15(Suppl. 2): 72–79.

42. Ueno H, Yamazaki Y, Yonekura Y, et al. Reliability and validity of a 12-item medication adherence scale for patients with chronic disease in Japan. *BMC Health Serv Res* 2018; 18(1): 592.

43. Ishii H. Development and psychometric validation of the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire. *J Med Econ* 2012; 15(3): 556–563.

44. Van Hell JG, Oosterveld P and De Groot AMB. Covariance structure analysis in experimental research: comparing two word translation models. *Behav Res Methods Instrum Comput* 1996; 28: 491–503.

45. MacCallum RC, Browne MW and Sugawara HM. Power analysis and determination of sample size for covariance structure modeling. *Psychol Methods* 1996; 1: 130–149.

46. Greenfield S, Kaplan SH, Ware JE Jr, et al. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med* 1988; 3(5): 448–457.

47. Baker DW. The meaning and the measure of health literacy. *J Gen Intern Med* 2006; 21(8): 878–883.

48. Maniaci MJ, Heckman MG and Dawson NL. Functional health literacy and understanding of medications at discharge. *Mayo Clin Proc* 2008; 83(5): 554–558.

49. Karter AJ, Subramanian U, Saha C, et al. Barriers to insulin initiation: the translating research into action for diabetes insulin starts project. *Diabetes Care* 2010; 33(4): 733–735.

50. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977; 84(2): 191–215.

51. Lorig KR and Holman HR. Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med* 2003; 26(1): 1–7.

52. Morris NS, Maclean CD and Littenberg B. Change in health literacy over 2 years in older adults with diabetes. *Diabetes Educ* 2013; 39(5): 638–646.

53. Soto Mas F, Cordova C, Murrietta A, et al. A multisite community-based health literacy intervention for Spanish speakers. *J Community Health* 2015; 40(3): 431–438.