

博士論文

Examining the Relationship Between Self-Stigma and Self-Management

Behaviors in Patients with Type 2 Diabetes

(2 型糖尿病患者におけるセルフスティグマと自己管理行動の関係  
に関する研究)

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**Examining the Relationship Between Self-Stigma and  
Self-Management Behaviors in Patients with Type 2 Diabetes**

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## ABSTRACT

This dissertation project examines the relationship between self-stigma and self-management behaviors in patients with type 2 diabetes. Self-stigma is the issue that will impact patients' behavioral goals through decreased self-esteem, self-efficacy, and psychological well-being. As a result, patients become reluctant to seek necessary treatment and there is a reduced treatment adherence. However, there has not yet been a study on self-stigma in patients with type 2 diabetes and how self-stigma could potentially have an impact on their treatment outcomes. This dissertation project analyzes data collected both qualitatively and quantitatively to investigate three research questions aimed at revealing: 1) to explore the process of how stigma can be internalized through negative experiences; 2) to evaluate the reliability and validity of a Japanese version of the Self-Stigma Scale; and 3) to examine whether self-stigma would be an independent factor for self-care management and that a higher level of self-stigma would lower a patient's activation level for his or her self-care management. The findings reveal that self-stigma is both independently and negatively associated with patients' self-care management. Those who develop self-stigma severely limit or increase their social participation and consequently cannot devote themselves to their treatment regimen.

# CHAPTER 1

## INTRODUCTION

Type 2 diabetes is one of the most common chronic illnesses, and its prevalence has dramatically increased worldwide in the past two decades [1]. Likewise, the prevalence of type 2 diabetes in Japan has been on the rise [2]. According to the International Diabetes Federation, Japan has the tenth-highest number of people with diabetes in the world [1]. As the number of patients with type 2 diabetes increases, some preconceived ideas about their particular characteristics result in blame being placed on them, because their condition is considered to be a lifestyle-related disease. People with type 2 diabetes are often subject to stigmatizing attitudes from the general population. Recently, public stigma in relation to type 2 diabetes has been highlighted and researched [3-6]. Public stigma represents negative reactions of the general public towards a group based on stereotypical attributes that distinguish that group in society [7,8]. Public stigma is also known as social stigma. Conversely, self-stigma refers to individuals who belong to a stigmatized group and turn the negative attitudes against themselves as a result of public stigma [7,8]. Public stigma and self-stigma are two distinct constructs.

Recent studies show that public stigma has a negative impact on diabetes self-care management [3-6]. However, according to previous studies, merely perceiving public stigma does not necessarily lead to self-stigma [7,8]. Nevertheless, there has not yet been a study on

self-stigma in patients with type 2 diabetes. In the research on people with psychiatric disorders, there is evidence that self-stigma is the issue that will impact patients' behavioral goals through decreased self-esteem, self-efficacy, and psychological well-being [7,9-11]. As a result, patients become reluctant to seek necessary treatment and there is a reduced treatment adherence [9,11-12]. Therefore, it is extremely important to understand self-stigma in patients with type 2 diabetes as well, in particular how to approach those who may be experiencing public stigma and developing self-stigma. This will provide a window of opportunity for early medical interventions for self-esteem and self-efficacy to be provided in order to support optimal self-management behaviors among patients with type 2 diabetes throughout the course of their illness.

Because the phenomenon of self-stigma in type 2 diabetes is not entirely understood and needs to be theorized, we first used qualitative methods. The fundamental reason for using qualitative methods was that these are best used for extracting complicated phenomena, such as a person's feelings, emotions, and thought processes [13]. In addition, these methods are suitable for understanding the in-depth process of the phenomenon and constructing a theory based on the data. Thus, the qualitative data will help investigate the process of self-stigma in individuals with type 2 diabetes, particularly focusing on how stigma can be internalized in these individuals through negative social interactions and attributed to their own attitudes towards social life including self-management behaviors.

Furthermore, to assess the extent to which patients with type 2 diabetes develop self-stigma, there is a need for a validated tool to measure this construct. Although a number of validated tools for self-stigma have been developed, most have only focused on mental disorders [14-17]. The Self-Stigma Scale was originally developed to quantify and evaluate concealed self-stigma among various groups of minorities such as immigrants and sexual minorities, as well as mental health patients [18]. Type 2 diabetes is one of the conditions that cannot be detected by looking at patients' physical appearance. Therefore, patients with type 2 diabetes can hide their stigmatized condition from the mainstream of healthy individuals, although they do so with fear of being discovered [5,6]. For this reason, the Self-Stigma Scale is viewed as the best tool that can be easily adapted for use with the particularly concealable condition of type 2 diabetes.

In order to measure the validity of the Japanese version of the Self-Stigma Scale, the following three constructs were investigated: self-esteem, self-efficacy, and depressive symptoms. According to previous studies, these three constructs are discrete concepts but are shown to be closely related to self-stigma [7,11]. It is suggested that any patients who perceive stereotypical and negative ideas and/or actions by others to be legitimate and internalize those notions (self-stigma), may suffer diminished self-esteem and self-efficacy as a result. Additionally, not due solely to the effects of reduced self-esteem and self-efficacy, self-stigma may engender depression.

The purpose of this entire study was to examine the relationship between self-stigma and self-management behaviors in patients with type 2 diabetes both qualitatively and quantitatively. First, a qualitative study was conducted to investigate the process of self-stigma and to generate a theoretical hypothesis of it (Study 1). Second, in order to verify the hypothesis formed by Study 1, the Self-Stigma Scale needed to be translated from English to Japanese and assessed in terms of its reliability and validity. The equivalency between the original Self-Stigma Scale and the Japanese version of the scale was also tested (Study 2). Third, using the Japanese version of the Self-Stigma Scale developed in Study 2, a cross-sectional study was performed to examine the relationship between self-stigma and diabetes self-management behaviors quantitatively (Study 3).

## CHAPTER 2

### STUDY 1 (Qualitative Study)

#### **Objective**

The purpose of this study was to investigate the process of self-stigma in individuals with type 2 diabetes, particularly focusing on how stigma can be internalized in these individuals, through negative social interactions and attributed to their own attitudes towards social life including self-management behaviors.

#### **Methods**

##### **Study design and research question**

We used qualitative methods, and our research question aimed to identify how patients with type 2 diabetes interpreted negative social encounters and how they responded to them.

##### **Participants and recruitment**

Purposive sampling was used to recruit both out- and inpatients with type 2 diabetes who were referred to tertiary hospitals. Participants had to meet the following criteria to participate in the interview: (1) men and women aged 30–64 years and (2) those with a history of type 2 diabetes for >3 years. The severity of the illness in these participants in terms of their glycemic control and complications was sufficient to consult diabetologists at

tertiary hospitals. Because of this and the duration of their condition, it was expected that the patients would be able to provide sufficient diabetes-related experiences. We excluded people who underwent therapy for psychiatric disorders such as depression and those related to eating.

Participants were recruited in three different ways: through physicians, at diabetes education classes, or through poster advertisements in the hospital. Eligible individuals were invited to participate in a face-to-face interview with a female interviewer (AK). Interviews continued until reaching a level of saturation where the participants did not provide additional perspectives. Two individuals declined to participate in the interview because of other engagements after visiting the doctor, which left them with no time for the interview on that particular day. Therefore, we included a total of 26 participants in the analysis. Patient characteristics are listed in Table 1.

The study was approved by the Research Ethics Committees of the University of Tokyo Graduate School of Medicine and Faculty of Medicine (approval number #3619, Appendix 1). To avoid biasing the interviewees' responses, we explained the purpose of the interview without reference to the word 'stigma'. Terms of informed consent were verbally reviewed and included permission to audiotape the interview. Official, written informed consent was also obtained from all participants before the interview (Appendix 2).

Table 1 Demographic and clinical characteristics of participants (n=26)

Patient characteristics	N	Patient characteristics	Mean or N
<b>Sex:</b>		<b>Duration of diabetes:</b> years	11.9
Male	22	(range)	(3-26)
Female	4	<b>Primary treatment:</b>	
<b>Age:</b>		Insulin injections and	18
40s	8	oral hypoglycaemic agents	
50s	13	Insulin injections	2
60s	5	Oral hypoglycaemic agents	6
<b>Marital status:</b>		<b>HbA1c:</b> %	8.2
Married	10	(range)	(5.8-14.0)
Unmarried/Divorced/Bereaved	16	<b>Number of diabetes-related complications:</b>	
<b>Employment:</b>		0	15
Full-time work	18	1	5
Part-time work	3	≥2	6
Retired/not working	5		
<b>Highest education:</b>			
Have not graduated high school	5		
High school	9		
Technical/junior college	3		
Bachelor's degree or higher	9		

## Interview schedule and procedures

All interviews, at hospitals from June to December 2012, were conducted by an interviewer (AK) with a background in health education. Each interview lasted for approximately 90 min and was audiotaped. The interviewer had no relationship with any participants prior to the interview. Except for the interviewer and participant, no one else was present in the room during the interview. Field notes were taken throughout, with particular regards to the participant's facial expression, tone of voice, and physical posture. All participants received stationery products with a net worth of 500 Japanese Yen as a token of appreciation.

The interview guide was initially developed based on pilot interview questions. It asked for descriptions of any diabetes-related negative experiences in relationships, by a participant at



that moment or in the past, beginning from the time point when the patient was first diagnosed. Another question aimed to clarify whether people around the participant knew that he or she had the condition. This was added as a response to emerging themes within the data, after interviewing the first four participants. The interview was conducted two times in those cases, where it proved necessary to confirm what the patient had expressed.

### **Transcription and analysis**

The analysis was performed by a grounded theory approach, involving concurrent data collection and constant comparative analysis. All interviews were transcribed and coded by AK, reflecting the research question and themes raised by the participants. AK, HH, and a few graduate students reviewed and discussed the first 10 interviews, using line-by-line open coding to reach a consensus on a core theme to account for the data; this was performed in consultation with a specialist in qualitative research. Emerging themes were explored and identified by comparing and contrasting the data. Multiple diagrams and matrices were developed to compare cases. To enhance the validity of this data analysis, AK not only conducted the interviews but also conducted the analysis of the participants' observations while they freely shared their experiences with other patients at the diabetes education classes. All theoretical memos, reflecting on the field notes, were compiled and included in the data analysis. In addition, feedback on the properties of emerging concepts from participants,

diabetologists and nurses was incorporated into the analysis.

## Results

Figure 1 shows the process of how participants with type 2 diabetes cope with negative experiences related to their illness, and how some internalize those experiences as stigma.

Four themes were generated: *Encountering Negative Experiences*, *Re-Evaluating the Self with Type 2 Diabetes*, *Reconstructing a Sense of Identity*, and *Keeping a Balance between Patient and Social Roles*.

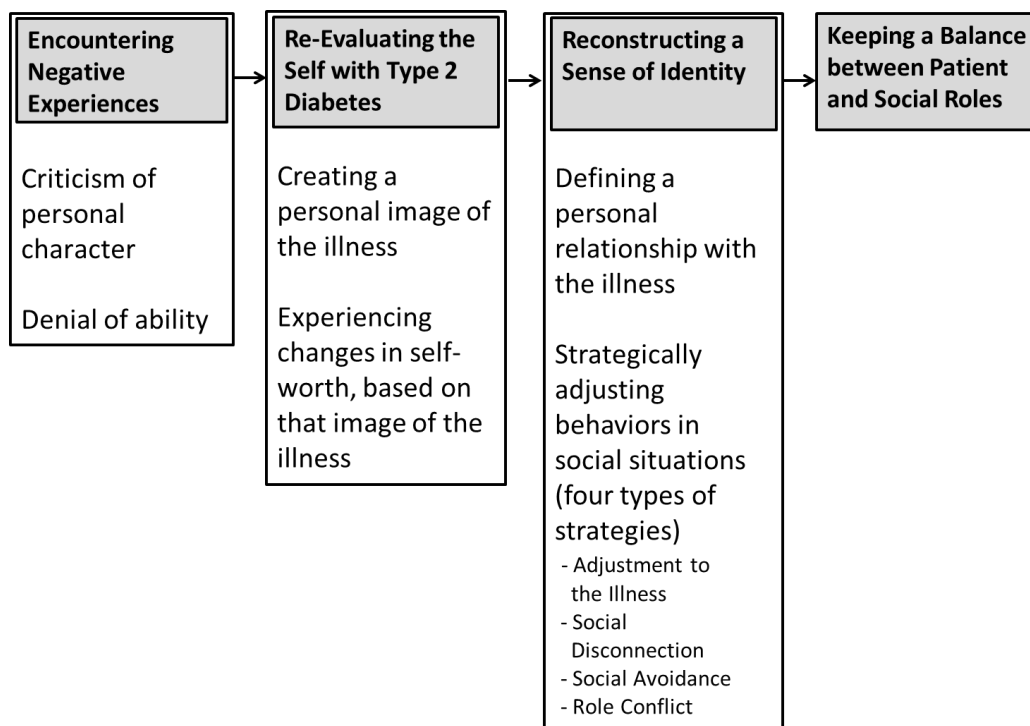


Figure 1 A process diagram of how patients with type 2 diabetes cope with negative experiences

## **Encountering Negative Experiences**

In social interactions, patients with type 2 diabetes perceive and experience criticism of their personal character and/or denial of their abilities because of the illness.

Participants with type 2 diabetes experience different types, degrees, and frequencies of negative social encounters. The negative experiences include not only personal encounters *per se* but also seeing other patients suffer from physical and social problems. There are two major types of negative experiences: (1) subtle and explicit criticism of a patient's personal character and (2) significant social disadvantages and denial of the patient's ability.

Major types of negative experiences

### *Criticism of personal character*

A person's lack of self-control is generally judged by society as a weakness; people with type 2 diabetes often fail at self-management. Many people tend to believe that the patient is responsible for the onset of type 2 diabetes; therefore, many people are prone to criticize the patient's personal character. The patient is blamed for his or her sedentary lifestyles and it is felt that he or she should not be given any sympathy as a result of this. Thus, some participants are discriminated against by society because of the generalization that type 2 diabetes is caused by an individual's weakness in personal character, with regards to his or

her lifestyle habits.

‘It is said that diabetes is a “luxury disease” caused by laziness, and so this always seems to be the main focus of personal criticism’. (#10, male, age 59)

### *Denial of ability*

Society evaluates peoples’ work performance as low if their productivity is minimal because of diminished physical strength. People with type 2 diabetes often fall into this category. The illness can be associated with a lack of acceptance of the patient’s ability in the workplace or even in the household. This is because sufferers of this condition may be considered as being incapable of fulfilling their social roles, such as an employee and a family provider. Social role is defined as one in which an individual plays a part as a member of a particular social group, such as at work or in a family.

‘At a job interview, interviewers said that their company would find it rather difficult to hire someone with diabetes. They said then and there that diabetes was a disadvantage, and so that was that’. (#27, male, age 49)

Or at least, people feel uncomfortable around the patient.

‘When I was diagnosed with diabetes, my wife was really dismayed. She told me that she had cared about my health very much and put a lot of effort into the meals she prepared for me. She never cooked for me again after that. That was one of the reasons why we separated’. (#10, male, age 59)

Thus, some participants end up suffering from various social disadvantages, such as being rejected at a job interview, demotion, job displacement, divorce, or marital separation.

### **Re-Evaluating the Self with Type 2 Diabetes**

By creating their own images of the illness, patients with type 2 diabetes re-evaluate themselves while taking into account the illness, and that may affect their sense of self-worth depending on the constructed image of the illness.

Most people with this type of illness re-evaluate themselves, regardless of whether they have had unfavourable experiences because of their condition. There are two stages of self-re-evaluation for participants with type 2 diabetes.

### *Creating a personal image of the illness*

First, participants with type 2 diabetes create their own images of the illness based on their experience and understanding of their condition.

‘There is a stereotypical image of diabetics that is held by the society that we have shorter lives and cannot do our jobs well... I personally don’t have a very positive image of diabetes’. (#26, male, age 52)

However, participants differently perceive diabetes-related experiences when interacting with others. Some participants may perceive a comment about their disease as a fact or advice, while others perceive it as personal criticism or pity.

‘My boss didn’t treat me any different from the others and told me to just lose some weight. I think he means that I’ll get well if I lose weight’. (#13, male, age 51)

‘My colleague told me that I’ve spent too much money on treatment for diabetes. She also repeatedly asks me if I’m losing weight—and very harshly so. It might be her way of encouraging me, but it doesn’t sound supportive.’

(#18, female, age 55)

In addition, participants' perception of the illness is considerably affected by the words and actions of people around them, such as friends, colleagues, and healthcare professionals. Their physicians in particular, have a great impact on whether they view the illness in a good or bad way.

‘I was very embarrassed by being diagnosed with diabetes. However, when I met a medical doctor who had diabetes and who used to put an insulin pen in his chest pocket, I realized that having diabetes wasn't a shame’. (#17, female, age 45)

‘When my doctor tells me that my lab results on haemoglobin A1c are bad, I feel as if I am a bad person. I feel rejected because I've been informed by very smart physicians; I believe everything they say’. (#10, male, age 59)

It appears that if participants have had adverse experiences, they are more prone to building negative and often distorted images of the illness within themselves.

*Experiencing changes in self-worth, based on that image of the illness*

Second, depending on how they view their illness, patients' sense of self-worth may be negatively or positively affected.

Participants with type 2 diabetes evaluate their social worth according to social approval. There is an underlying social norm that one should be both physically and mentally healthy in the labor market. Those participants with a negative image of the illness feel uneasy and unworthy of being considered conscientious workers.

‘I don’t want to be seen as less hard-working by people at work’. (#5, male, age 44)

In addition, participants with type 2 diabetes assess their competence in a range of abilities and skills, based on their perception of the illness. Those participants who develop a negative view on their illness feel incapable of maintaining a job or are anxious about not being valued in the workplace.

‘I’ve often felt that if people at work find out about my condition, I might be seen as someone who can’t take on any important responsibilities. I’d feel



threatened, like I was being treated unfairly or being undervalued because of my diabetes'. (#22, male, age 53)

'I can't help thinking that I'll never be able to work as a regular full-time employee'. (#27, male, age 49)

Thus, participants who build a negative image of their illness feel unworthy or unable to maintain their current social roles. These participants worry about being judged unacceptable, misunderstood, and underestimated by others. The more they value their ability to work, the more vulnerable they are to the fear of being poorly evaluated. In addition to the negative images of the illness, encountering other patients with serious complications and gaining knowledge about their illness may further threaten the patient's self-worth. All these things may cause participants to think about the possibility of losing their current social roles.

### **Reconstructing a Sense of Identity**

Patients with type 2 diabetes reconstruct their sense of identity by defining a personal relationship with the illness and strategically adjusting their behaviors in social situations.

Participants with type 2 diabetes try to reconstruct their sense of identity after re-evaluating

themselves. They do so because they need to protect their self-worth from being threatened by their illness. Preserving certain aspects of their self-worth contributes to sustaining their sense of identity. There are two stages involved in reconstructing participants' sense of identity. First, they define a personal relationship with the illness. Second, they begin to adapt their social participation, by either limiting or increasing their social lives.

### *Defining a personal relationship with the illness*

Based on the built-up image of the illness, participants with type 2 diabetes define a personal relationship with the illness. Those who form positive images of the illness view it as something they have to live with; they accept the disease as a part of themselves.

‘Diabetes has become a part of me. We live together in harmony’. (#25,  
male, age 59)

On the other hand, those who form negative images of the illness view it as something embarrassing and misunderstood; they may try to exclude the illness from themselves or keep it hidden inside, so that it does not appear to have any major impact on their lives.

‘To me, diabetes is a real burden. I want to rid myself of this illness. I have

often been told that it's not curable, so I need to think about how I can live with it for the rest of my life. I wish it would disappear'. (#26, male, age 52)

*Strategically adjusting behaviors in social situations (four types of strategies)*

Having formed a relationship with their illness, participants with type 2 diabetes try to control their situation with regards to social participation. They behave strategically, particularly when interacting with others, to reflect their image of the illness through their social activities. This includes those areas involving self-management of diabetes and compliance with treatment. In this study, instead of the term adherence, 'compliance' is used to refer to the extent to which patients follow medical advice. In this case the term compliance indicates that some patients do not necessarily follow medical advice and/or are not proactive in terms of communicating and making decisions with their doctors.

While behaving strategically in social situations, participants with type 2 diabetes either accept, conceal, or reject their illness. This is a defensive adaptation to an individual's sense of identity in response to the illness. There are four types of strategic actions in adjusting their behaviors in social situations among participants with type 2 diabetes: *Adjustment to the Illness*, *Social Disconnection*, *Social Avoidance*, and *Role Conflict*. These actions can be explained as a graph, with Y being the participant's sense of self-worth as related to the illness, and X being the participant's attitude towards social participation (Fig. 2). The

vertical axis refers to the degree to which participants feel deserving, in that they can accept themselves as a whole, including their illness. This can be either a feeling of denial or acceptance of oneself. The horizontal axis refers to the degree to which participants are willing to participate in social life while they are ill. This is either a limitation of or an increase in their social interaction. Social participation is not associated with the actual degree of dysfunction, stemming from the severity of their condition and its complications.

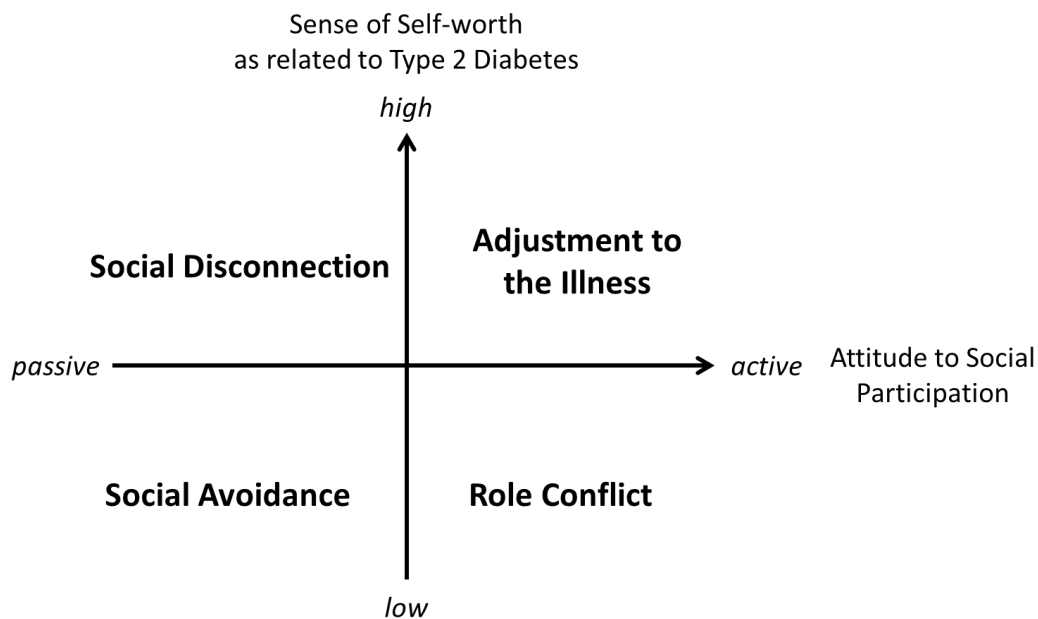


Figure 2 Strategies for adjusting behaviors in social situations in patients with type 2 diabetes

Different strategies for attitudes for social participation

*Adjustment to the Illness*

The upper right-hand quarter (Fig. 2) represents adjustment to the illness by coping with

the condition (*Adjustment to the Illness*). These participants accept the illness as a part of themselves. Through self-re-evaluation, they can find balance in their sense of identity, including what it means to be a patient. They also understand that their medical restrictions do not necessarily limit their social life; therefore, they are able to maintain social participation. They have no problem disclosing their illness to others. Rather, they try to make others better understand their illness. This makes it easier for them to ask for support from others when they need it.

‘When I had my foot amputated, I thought there was nothing I could do about it. However, I didn’t think my life was over because I was able to live a normal life with the aid of my prosthetic limb. My lifestyle hasn’t been limited’. (#20, male, age 60)

These participants know how to adopt self-care into their daily lives while under medical supervision and within the constraints of the illness. They comply with their treatment in the long term. Similar to other patients, they gradually increase their knowledge of the condition and acquire practical skills to maintain glycemic control through trial and error. However, because they do not have a negative image of the illness, they are able to learn from their mistakes and develop a positive attitude towards their illness, while at the same time maintain

their social roles in their interaction with others.

### *Social Disconnection*

The upper left-hand quarter (Fig. 2) represents a social disconnection among participants who have lost the ability to be anything other than a patient (*Social Disconnection*). These participants have a very limited number of social contacts, e.g. healthcare professionals and sales assistants. These people can treat them as important customers, give them attention, and listen to their personal stories. Under these circumstances, the participants are willing to reveal their illness to others because the only way for them to connect with others is by being a patient; thus, because of the illness, they now experience a much better treatment, in regard to social interactions, and are gradually able to develop a positive self-evaluation.

‘I’m alone all day every day. I’m beyond lonely. I feel completely isolated from society. I feel like my life is over because of my illness. However, when I’m in hospital, I have the chance to talk to many different people. It makes a pleasant change for me’. (#7, male, age 60)

These participants appear to be compliant with their medical treatment and cooperative with healthcare professionals. However, this attitude is not purely based on an aim to get

better or on any long-term perspective on their medical treatment. They regularly go to hospital, but they do so to interact with other people, such as other patients, rather than to receive medical treatment or alleviate their symptoms. They do this because the only way of socializing with others is through their illness; otherwise, they feel isolated. Thus, hospitalisation for these participants tends to recur.

### *Social Avoidance*

The bottom left-hand quarter (Fig. 2) represents participants who avoid social situations due to fear and anxiety of being rejected by society (*Social Avoidance*). Based on their own negative experiences caused by the illness, these participants have developed low self-worth. They feel less confident of their overall ability; e.g. job performance and personal relationships. They try not to disclose their illness to others, to avoid stigma. They avoid any activities involving social interaction that they previously would have participated in, including time spent in the workplace.

‘After a job interview, my application has been rejected, so I think it is better not to tell them that I have diabetes’. (#27, male, age 49)

‘Because of my diabetes, I don’t think I can get married. Wouldn’t having

diabetes be an obstacle to our marriage, especially for my partner? It's hard enough telling her that I have diabetes'. (#15, male, age 43)

These participants also only choose friends who understand their illness better. They feel detached, view their situation as unfair, and feel some resentment towards it. They eventually begin to feel that they are as useless as expected.

'There are quite a few people out there who are not that healthy and are in a situation similar to mine. Those people can probably understand what it's like to be physically distressed. They are able to share my current worries and empathize with me, even when their illness is different from mine. I can relate to them'. (#1, male, age 54)

In the eyes of healthcare professionals, these participants appear to readily comply with treatment. They tend to forcibly follow their doctors' instructions, potentially leading to excessive behavior. They may impulsively reduce their workload or resign from their respective jobs to entirely focus on treatment. However, despite their efforts, treatment outcomes in terms of glycemic control, may not appear as good as their doctors expect. Such patients are also more susceptible to loneliness because they socialize less with others.



### *Role Conflict*

The bottom right-hand quarter (Fig. 2) represents participants who struggle between two conflicting roles, that of being a patient and that of playing some kind of social role (*Role Conflict*). These participants suffer from fear and anxiety regarding possible deterioration in their job performance because of the illness. As a result of their own negative experiences and perceptions of the illness, they tend to have low self-worth and try to conceal their illness by maintaining social participation and acting like healthy individuals. They try to avoid the stigma attached to their condition by physically exerting themselves. They increase their workload and activities across a wide range of social interactions, solely to make themselves appear healthy.

‘I increase my workload little by little and I even manage to complete my tasks during working hours. I try to do this, especially before I am admitted to hospital. That way, I can impress them with how good I am, like “Hey, I did it!”’. (#5, male, age 44)

Healthcare professionals view these participants as less compliant with their treatment. Their attitude towards their illness is very short-sighted. They find it hard to fit self-care into

their daily lives, although they are well aware and knowledgeable of their condition. This is because, to them, social relationships, particularly how they appear to others, are far more important than complying with their doctors' orders. They tend to strongly protest against starting any new treatment regimen or having further medication added to their treatment curriculum. While in the company of others, they may show negligence towards their medication and insulin injections or eat the wrong types of food. All of this is intentionally done.

‘I don’t want anyone to see the medication. I don’t like taking it in front of anyone. For me, the biggest problem is when I go to a business dinner. Then, I find it really difficult to find the time to take my medication. In that situation, I don’t take it. It’s really important to me that no one sees me taking my medication, so skipping it doesn’t bother me’. (#22, male, age 53)

### **Keeping a Balance between Patient and Social Roles**

Patients with type 2 diabetes learn to perform the role of being a patient in order to participate in their own treatment, while still performing a regular social role in their workplaces and households.

As mentioned above, participants with type 2 diabetes apply various strategies by manipulating their self-image and interacting with healthy members of society, to balance their sense of identity between two roles: patient and social being. This can give them a fundamental sense of purpose and security in their lives. The patient role is defined as one in which a patient follows medical advice and takes charge of day-to-day self-care. While being a patient, there is still a need to continue serving a social role. People with type 2 diabetes are not entirely excluded from society; thus, they have to live with the stigma. Acquiring both roles, patient and social individual, is a learning process because they have to respond to the stigma associated with the illness within society. This is the core theme of this study.

‘My aim is to continue working. I feel it gives me a sense of identity. I think it’s important to get out into the real world, interact with people and perform my social role’. (#20, male, age 60)

## **Summary**

In Study 1, a core theme, *Keeping a Balance between Patient and Social Roles*, emerged to explain the overall process of experiencing the stigma of type 2 diabetes. Participants with type 2 diabetes had diverse perceptions of their negative experiences related to the illness. It is only when patients form a negative image of and relationship to the illness that stigma

affects the patient's psychology and behavior in these three processes: *Encountering Negative Experiences*, *Re-Evaluating the Self with Type 2 Diabetes*, and *Reconstructing a Sense of Identity*. While behaving strategically in social situations, participants with type 2 diabetes either accept, conceal, or reject their illness. There are four types of strategic actions in adjusting their behaviors in social situations among participants with type 2 diabetes: *Adjustment to the Illness*, *Social Disconnection*, *Social Avoidance*, and *Role Conflict*. These actions can be explained using the following two dimensions: a patient's sense of self-worth when taking into account their illness, and a patient's attitude towards social participation. When a patient develops a feeling of low self-worth and is either severely limited or highly active in terms of social participation, then he or she is in a state of self-stigma (*Social Avoidance* or *Role Conflict*). Self-stigma can also be assessed by observing a patient's self-management of diabetes. Patients in the "*Social Avoidance*" group show a seemingly high degree of 'compliance' with treatment, while patients in the "*Role Conflict*" group show a lesser degree of 'compliance'.

## **STUDY 2 (Scale Development)**

### **Objective**

Based on an analysis of the qualitative data in Study 1, we found that many patients with type 2 diabetes who were in a state of self-stigma tended to conceal their illness. Among a number of validated existing tools for measuring self-stigma, the Self-Stigma Scale was originally developed to quantify and evaluate self-stigma for various groups of minorities that cannot be detected by looking at patients' physical appearance [18]. Patients with type 2 diabetes can also hide their stigmatized condition from the mainstream of healthy individuals. For this reason, we viewed the Self-Stigma Scale as the best tool that can be easily adapted for use with type 2 diabetes.

The aim of this study was to translate the Self-Stigma Scale from English to Japanese and examine its reliability and validity in patients with type 2 diabetes. Furthermore, we tested the equivalency between the Self-Stigma Scale (hereafter defined as “the original scale”) and the Japanese version (SSS-J) when assessing patients with type 2 diabetes.

### **Methods**

#### **Development of the SSS-J**

Translation procedures were based on the Consensus-based Standards for the Selection of Health Measurement Instruments checklist [19]. Four steps were followed (Figure 3).

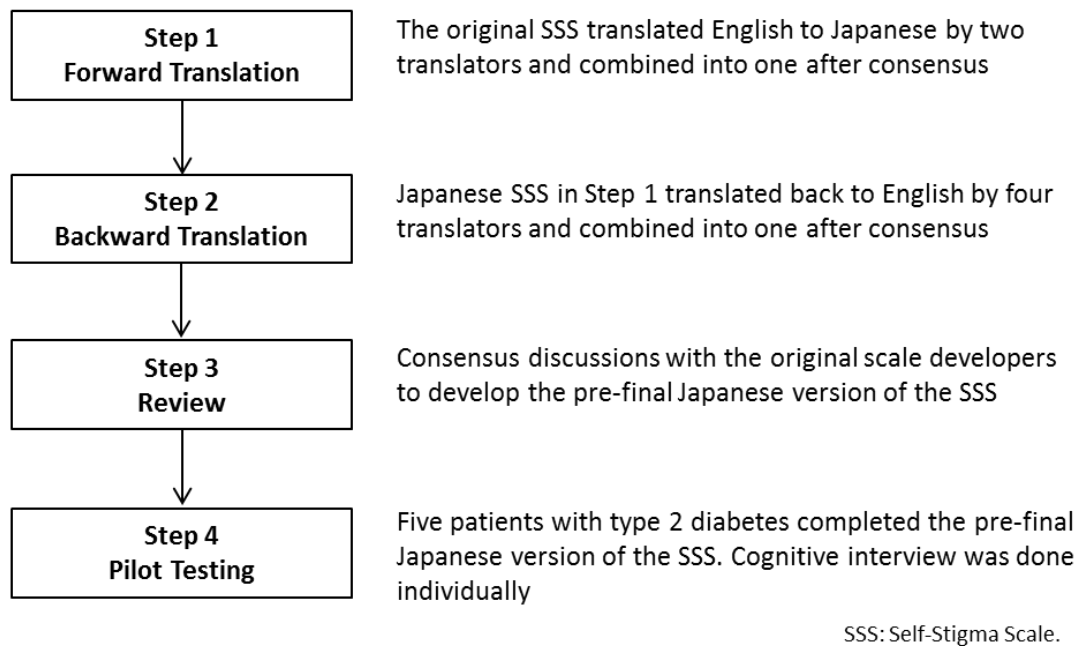
Multiple forward and backward translations were performed by six translators. They were selected according to the following criteria:

- 1 There were two forward translators who were both native Japanese speakers. One translator had expertise on stigma, and the other was a language expert but lacked knowledge about stigma.
- 2 There were four backward translators. Two were native English speakers, and the other two were native Japanese speakers. They were all language experts with no knowledge of stigma or the original scale.

In Step 1, two native Japanese speakers worked independently and translated the original scale into Japanese. They were fully informed about the objectives of the whole translation procedure, and forward translated all the questionnaire items, not word-for-word but with emphasis on the meaning of each item. We then combined these two Japanese translations into one. To amalgamate these Japanese translations, the two translators and three authors had discussions to reach a consensus in terms of the following four criteria: content, semantics, conceptualization, and technical equivalence with the original scale, as well as cultural adaptations. In Step 2, another two native Japanese speakers worked independently and were asked to back translate the Japanese translation in Step 1 into English. We then combined

these two English translations into one by reaching a consensus with the two translators in the same way as in Step 1. Afterwards, two bilingual individuals, whose native language was English, checked for any semantic discrepancies between the Japanese translation in Step 1 and the backward translation in Step 2. All these back translators were blinded to the original scale. In Step 3, the English translation produced in Step 2 was reviewed by the original scale developers. Based on suggestions from them, some questionnaire items were revised through repeated forward and backward translation procedures (Steps 1 and 2) to reflect the original meaning after translation.

In Step 4, the translation was pretested in cognitive interviews by five outpatients with type 2 diabetes to ensure accessibility and comprehension. They were men and women aged 30–74 years with different educational backgrounds ranging from those without a high school education to those with a bachelor’s degree. According to their comprehension level of the Japanese translation, some words were altered to even plainer language. Additionally, Japanese patients with type 2 diabetes did not understand the direct translation of the term “identity”. Therefore, with permission of the original scale developers, we replaced the term with a Japanese phrase, “oneself with the illness, diabetes”, while maintaining the conceptual equivalence in the original scale. Thereafter, we processed Steps 2 and 3 in the same way. Finally, we obtained permission from the original scale developers to field test the revised translation.



**Figure 3 Flow chart describing the development of the Japanese version of the Self-Stigma Scale.**

### **Testing the SSS-J in type 2 diabetes patients**

The SSS-J was tested between November 2013 and March 2014. Consecutive sampling was used to recruit all outpatients with type 2 diabetes, who visited a diabetologist on a specific date at four locations, comprising two university hospitals (The University of Tokyo Hospital and Teikyo University Hospital), one non-university affiliated hospital (Mitsui Memorial Hospital), and one non-university affiliated clinic (The Institute for Adult Diseases Asahi Life Foundation) in Japan. The following patients were excluded: non-native Japanese speakers; those aged 75 years or older; and those with a serious mental disorder, such as dementia, that affected their cognition. Additionally, patients who required urgent medical procedures or examinations were excluded.



During enrollment, the purpose of the study was explained by study staff, and informed consent was obtained from those who agreed to the terms of the study (Appendix 3). The SSS-J was self-administered in the majority of the participants (Appendix 4). For those who had either visual loss or poor literacy skills, an audiotape was provided to read out each question. To determine the test-retest reliability, all participants took home another SSS-J questionnaire to complete after 2 weeks and this was mailed back to our office. Reminder phone calls were made up to two times as necessary.

The sample size was calculated based on the number required to perform the factor analysis for the psychometric assessment of the scale. Because it had 39 items, the minimal sample size was 195 based on a participant-to-item ratio of 5:1 [20].

This study was approved in advance by the Research Ethics Committee of The University of Tokyo Graduate School of Medicine and Faculty of Medicine (approval number #3629, Appendix 5).

## **Measures**

A self-administered questionnaire was used to assess diabetes-related complications and hemoglobin A1c. The number of complications was calculated with reference to the Diabetes Complications Index (DCI) [21]. The score ranged from 0 to 6. Participants were asked to fill out their hemoglobin A1c levels based on a copy of laboratory results received that day.

### **SSS-J scale**

The SSS-J comprises 39 items that allow four responses in a Likert scale: strongly disagree, disagree, agree, and strongly agree. The responses are afforded a score of 0, 1, 2, and 3, respectively. The total possible scores have a range of 0–117. A higher score represents a higher level of self-stigma.

We predicted that the SSS-J would be negatively associated with several self-identity measures, such as self-esteem and self-efficacy, and that it would also be related to greater levels of depressive symptoms. Our predictions in a Japanese sample of patients with type 2 diabetes were informed by the results of a previous study [18]. For comparison, participants completed the following measures in addition to the SSS-J.

### **Self-esteem**

The Rosenberg Self-Esteem Scale was used to assess the level of self-esteem [22,23]. It is a widely accepted scale because of its high reliability and validity. It contains 10 items scored on a 4-point Likert scale from 1 (strongly disagree) to 4 (strongly agree). Five negative items were reverse-scored to compute the total scores of individual participants. In this study, it had an internal consistency of 0.79.

### **Self-efficacy**

The General Self-Efficacy Scale was applied to assess individual strength in general self-efficacy across a variety of settings in everyday life [24]. It is reliable and valid, and is commonly used to measure self-efficacy in Japan. It is a 16-item scale using dichotomous (yes/no) questions. In this study, it had an internal consistency of 0.84.

### **Depressive symptoms**

The nine-item depression module of the Patient Health Questionnaire (PHQ-9) was used to assess depressive symptoms during the previous 2 weeks [25,26]. It is a reliable and valid measure of depression severity for clinical use. Each item is scored on DSM-IV (*Diagnostic and Statistical Manual of Mental Disorders-IV*) criteria from 0 (not at all) to 3 (nearly every day). In this study, it had an internal consistency of 0.86.

### **Statistical analysis**

The mean and standard deviation of each item of the SSS-J were determined. Cronbach's coefficient alpha was calculated to assess the internal reliability of each subscale defined by the original scale. Confirmatory factor analysis was conducted on the SSS-J to confirm that the three-factor model theorized in the original scale would achieve the best fit for the data in

Japanese patients with type 2 diabetes. Model fitness was assessed based on the maximum likelihood method by using the following fit indices: goodness-of-fit index (GFI), adjusted goodness-of-fit index (AGFI), comparative fit index (CFI), and root mean square error of approximation (RMSEA). The model was built using three self-stigma subscales, which consisted of 19 cognitive, 14 affective, and six behavioral items as observed variables. The construct validity was examined with Pearson's correlations in the Self-Esteem, General Self-Efficacy, and PHQ-9 scales.

All analyses were conducted with SPSS version 18.0 (SPSS Japan Inc., Tokyo, Japan), except for the confirmatory factor analysis, which was performed using AMOS version 18.0 (SPSS Japan Inc., Tokyo, Japan).

## **Results**

Physicians recruited 259 patients with type 2 diabetes and written informed consent was obtained from 218, giving a response rate of 84.2%. Of these patients, 217 completed the questionnaire (one patient declined). The percentage of missing data was zero for all questionnaire items. In the analysis, we excluded five participants who answered all 39 items of the SSS-J with a “strongly disagree” response, because they responded strongly to stigma, and we did not know whether the scale could measure what it was originally intended to assess. We also excluded two participants who had vision loss and completed the

questionnaire with the aid of an audiotape, because they used different cognitive tasks from those who were able to answer all of the questionnaire items on their own. Therefore, 210 participants were included in our final analysis. Of these remaining participants, 187 answered and returned the second questionnaire containing the SSS-J items 2 weeks later, producing a response rate of 89.0%.

### **Descriptive statistics for the SSS-J**

The sociodemographic and clinical characteristics of the participants are shown in Table 2. There were 169 male participants (80.5%) and 41 female participants (19.5%), and the mean age was  $60.1 \pm 10.0$  years. The mean duration of type 2 diabetes was  $13.3 \pm 9.6$  years and the mean hemoglobin A1c level was  $7.3 \pm 1.2\%$ . The number of complications was calculated as the simple sum of the six complications from the Diabetes Complications Index (DCI) [21]. The score range was 0–6, and 62.4% of participants had no complications.

Table 3 indicates the means and standard deviations for each item of the SSS-J questionnaire. In the SSS-J, the mean scores were lower and the standard deviations were smaller in our patients for all items compared with the scores for mental health patients using the original scale. The score distributions were not found to be highly skewed.

**Table 2 Sociodemographic and clinical characteristics of participants (n = 210)**

Patient characteristics	N (%) or Mean ( $\pm$ SD)
<b>Sex:</b>	
Men	169 (80.5)
Women	41 (19.5)
<b>Age (years):</b>	60.1 ( $\pm$ 10.0)
<b>Marital status:</b>	
Married	152 (72.4)
Unmarried/Divorced/Bereaved	58 (27.6)
<b>Employment:</b>	
Full-time work	121 (57.7)
Part-time work	50 (23.8)
Retired/not working	36 (17.1)
Others	3 (1.4)
<b>Highest education:</b>	
Haven not graduated high school	16 (7.6)
High school	66 (31.4)
Technical/junior college	34 (16.2)
Bachelor's degree or higher	94 (44.8)
<b>Duration of diabetes (years):</b>	13.3 ( $\pm$ 9.6)
<b>Primary treatment:</b>	
Oral hypoglycemic agents	123 (58.6)
Insulin injections	15 (7.1)
Insulin injections and oral hypoglycemic agents	45 (21.4)
Other injectable medications (other than insulin)	14 (6.7)
Lifestyle	13 (6.2)
<b>HbA1c (%):</b>	7.3 ( $\pm$ 1.2)
<b>Numbers of diabetes-related complications:</b>	
0	131 (62.4)
1	53 (25.2)
2	16 (7.6)
3	9 (4.3)
4	1 (0.5)

SD: standard deviation; HbA1c: glycated hemoglobin.

**Table 3 Scores of items in the Japanese version of the Self-Stigma Scale in patients with type 2 diabetes**

		M	SD
<b>COGNITIVE</b>	Being a ___ takes away many opportunities from me. (29)	1.85	0.67
	I think that I am less competent than ordinary people because I am a ___. (26)	1.59	0.57
	I feel that my life is unenjoyable because of myself with the illness, ___. (31)	1.81	0.69
	No matter how hard I work, I cannot match others because of myself with the illness, ___. (30)	1.64	0.55
	Who I am: having the illness, ___, is a heavy burden to me. (38)	2.17	0.78
	I have low expectations in life because I am a ___. (18)	1.80	0.64
	I am not qualified to compete with others because I am a ___. (27)	1.54	0.54
	Who I am: having the illness, ___, is a stigma in my life. (13)	1.92	0.73
	Who I am: having the illness, ___, has a negative impact on my financial situation. (35)	2.15	0.83
	I am inferior to others because I am a ___. (21)	1.66	0.58
	Who I am: having the illness, ___, causes inconvenience on my daily life. (34)	2.13	0.76
	I cannot measure up to ordinary people because I am a ___. (10)	1.68	0.65
	I cannot change myself with the illness, ___. (11)	1.90	0.67
	I lower my standards of living because I am a ___. (6)	1.90	0.65
	My life is meaningless because I am a ___. (4)	1.63	0.51
	I need assistance from others because I am a ___. (12)	1.77	0.67
	My social interactions are limited because I am a ___. (2)	2.04	0.66
	It is quite normal for me to be alienated by others because I am a ___. (5)	1.55	0.51
	I feel much stressed because I am a ___. (1)	2.49	0.73
<b>AFFECTIVE</b>	I cannot feel confident about who I am because of myself with the illness, ___. (33)	1.74	0.61
	I am worried about who I am: having the illness, ___, would create obstacles to me. (25)	1.90	0.74
	I have negative feelings about myself with the illness, ___. (23)	1.79	0.68
	I am unhappy because I am a ___. (32)	1.80	0.69
	I feel helpless because I am a ___. (37)	1.59	0.57
	I am discouraged because I am a ___. (28)	1.84	0.71
	I hate myself because I am a ___. (24)	1.89	0.71
	I get embarrassed because of myself with the illness, ___. (39)	1.68	0.68
	I feel angry because I am a ___. (22)	1.96	0.75
	I feel uncomfortable being a ___. (17)	2.22	0.80
	I feel sorry that I am a ___. (8)	1.98	0.73
	I feel there is nothing I can do about being a ___. (16)	1.92	0.74
	I fear that people around me would find out that I am a ___. (15)	1.75	0.78
	I am ashamed of being a ___. (3)	1.99	0.72
<b>BEHAVIORAL</b>	I avoid interacting with others because I am a ___. (36)	1.55	0.56
	I keep my distance from others because I am a ___. (19)	1.57	0.62
	I give up on myself because I am a ___. (14)	1.69	0.63
	I hide myself with the illness, ___. (20)	1.66	0.77
	I make friends only with people who are in the same condition as mine. (9)	1.48	0.56
	I dare not to make new friends because they might find out that I am a ___. (7)	1.53	0.58

\_\_\_ in each question item was replaced by either "diabetes" or "patient with diabetes". The numerical values in parentheses after each question item reflect the order in which the items appeared as the patients completed the SSS-J. Questionnaire items within each subscale are listed in descending order of factor loading. M: mean; SD: standard deviation; SSS-J: Self-Stigma Scale, Japanese version.

### **Confirmatory factor analysis**

The results of the confirmatory factor analysis are demonstrated in Figure 4. All path coefficients were significant. The model fit indices were as follows: GFI = 0.78, AGFI = 0.70, CFI = 0.88, and RMSEA = 0.07. The goodness-of-fit indices for the confirmatory factor analysis were acceptable. There was a relatively good fit between the three-factor model and the observed data. The GFI in this sample was below 0.9. However, the GFI depends on the total number of observed variables [27]. As the SSS-J was tested using 39 items, the GFI in this sample would be less than 0.9. However, all factor loadings based on the three-factor model of the 39 items were higher than the general standard (0.4) in this sample. Additionally, the CFI value of 0.88 is close to 0.90, indicating a relatively good fit [28]. The RMSEA value of 0.07 is in the reasonable fit range of 0.05–0.08 [29].



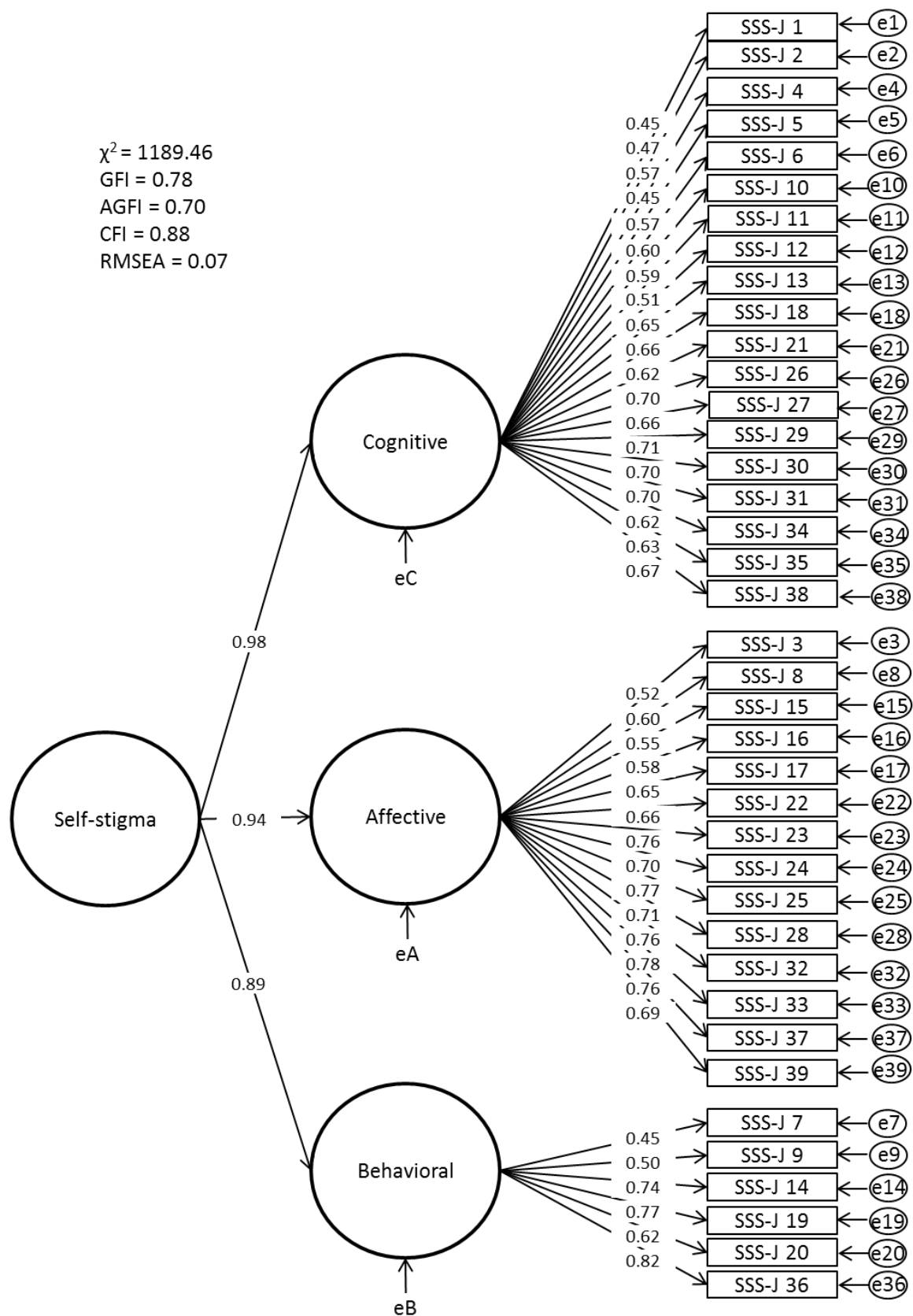


Figure 4 Result of the confirmatory factor analysis of the Japanese version of the Self-Stigma Scale in patients with type 2 diabetes.

### **Internal consistency**

The internal consistency of the SSS-J was excellent: Cronbach's  $\alpha = 0.96$ . The internal consistency of each conceptual dimension of the SSS-J ranged from acceptable to excellent: cognitive (Cronbach's  $\alpha = 0.92$ ), affective (Cronbach's  $\alpha = 0.93$ ), and behavioral (Cronbach's  $\alpha = 0.83$ ). This demonstrated excellent internal consistency reliability, indicating adequate interrelations between the items of the scale.

### **Test-retest reliability**

Test-retest reliability was determined by comparing responses to the SSS-J among 187 participants (89.0%) who completed the questionnaire at home after a 2-week interval. The correlation coefficient for test-retest reliability was 0.76 ( $p < 0.01$ ). This demonstrated acceptable reproducibility. A correlation coefficient range of 0.7–0.8 is acceptable [30].

### **Construct validity**

Significant Pearson's correlations were observed when analyzing the scores in the SSS-J and the other comparable scales. The Rosenberg Self-Esteem ( $r = -0.43$ ,  $p < 0.01$ ) and the General Self-Efficacy ( $r = -0.38$ ,  $p < 0.01$ ) scales were negatively correlated with the SSS-J, whereas the PHQ-9 demonstrated a positive correlation ( $r = 0.39$ ,  $p < 0.01$ ). This was consistent with predictions based on the results of the original scale.

In the samples of participants in this study, the median self-stigma score was 75 and it ranged from 40 to 109, and the median depressive symptoms score was 3 and it ranged from 0 to 25.

## **Summary**

In Study 2, we examined the reliability and validity of the Japanese version of the Self-Stigma Scale (SSS-J) to assess the extent of self-stigma among individuals with type 2 diabetes. The SSS-J was developed based on several forward and backward translations with cross-cultural validation. All the questionnaire items were comprehensible by both elderly people and individuals with lower educational levels. The SSS-J also offered reliable and valid determination of psychometric properties as well as the relevant structure of self-stigma consisting of cognitive, affective, and behavioral subscales in the same manner as the original scale [18]. The results indicated that the SSS-J consistently constructed the three-factor model as in the original scale while using a different focus group and language. Furthermore, they indicated that each subscale had adequate internal consistency, that the 2-week test-retest reliability had satisfactory stability, and that the SSS-J was negatively correlated with self-esteem, self-efficacy, and depressive symptoms. This demonstrates that the SSS-J can be used to assess self-stigma among Japanese people with type 2 diabetes.

### STUDY 3 (Quantitative Study)

#### Objective

Based on previous studies, in clinical practice, educational interventions for patients with type 2 diabetes to increase treatment adherence have been predominantly focused on enhancing self-efficacy and screening for depression [38-41]. Nevertheless, with all current educational interventions, there are some patients who show less improvement in treatment adherence [42-44]. Therefore, patient self-management behaviors cannot be fully understood only in terms of enhancing self-efficacy and screening for depression. Furthermore, based on an analysis of the qualitative data in Study 1, we found that a state of self-stigma in patients resulted in decreased self-esteem and impacted the self-management of their diabetes, including suboptimal treatment outcomes. Thus, in Study 3, we added self-stigma as well as self-esteem into the current patient educational model which included enhancing self-efficacy and screening for depression, in order to examine the relationship between self-stigma and self-care management in patients with type 2 diabetes (Figure 5).

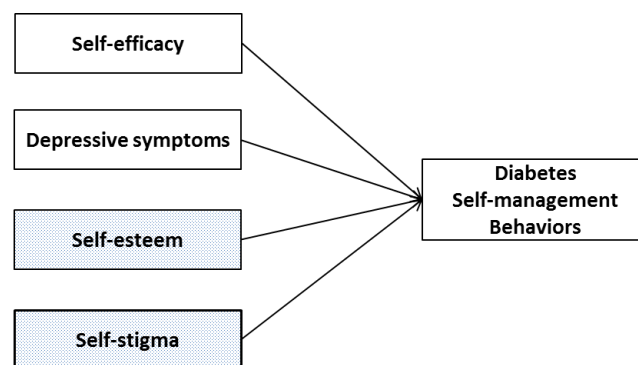


Figure 5 A hypothesis for the relationships between diabetes self-management behaviors and other variables: self-efficacy, depressive symptoms, self-esteem, and self-stigma.

The purpose of this study was to examine the relationship between self-stigma and self-care management in patients with type 2 diabetes. First, we hypothesized that self-stigma would be independently associated with patient activation in relation to self-care management. Second, we hypothesized that a higher level of self-stigma in terms of the illness would lower patient activation levels with regard to self-care management in patients with type 2 diabetes.

## **Methods**

### **Study participants**

A questionnaire-based, cross-sectional study was conducted between November 2013 and March 2014. Consecutive sampling was used to recruit all outpatients with type 2 diabetes, who visited the diabetologist on a specific date, at the following four specified locations, including two university hospitals, one non-university affiliated hospital, and one non-university affiliated clinic in Japan. Participants were recruited by their physicians. After permission from the physician was obtained, participants received an explanation of the purpose of the study by study staff, after which written informed consents were collected (Appendix 3). Inclusion criteria were as follows: presence of type 2 diabetes, aged 20–74 years, ability to read and speak Japanese, no diagnosis of dementia and psychosis, and no urgent medical procedures or examinations needed. Participants filled out a questionnaire taking approximately 15–20 minutes (Appendix 4). This study was approved in advance by

the Research Ethics Committee of the University of Tokyo Graduate School of Medicine and Faculty of Medicine (approval number #3629, Appendix 5).

## **Measures**

Participants' sociodemographics included: sex, age, education (in years), marital status, and size of households. A patient's level of education was collected as categorical data (have not graduated high school, high school, technical/junior college, or bachelor's degree or higher) and then converted into years of schooling. Marital status was collected as categorical data (married, unmarried, divorced, or bereaved) and then summarized into two categories (married or unmarried/divorced/bereaved).

Participants' clinical information such as body mass index (BMI), time (in months) since diagnosis, injection therapy, diabetes-related complications, and hemoglobin A1c was also collected. Injection therapy was collected as categorical data (oral hypoglycaemic agents, insulin injections, insulin injections and oral hypoglycaemic agents, other injectable medications (other than insulin), or lifestyle). This is then summarized into two categories (injection use or non-use). The number of diabetes-related complications was calculated as the simple sum of the 6 complications with reference to the Diabetes Complications Index (DCI) [21]. The score ranged from 0 to 6. Hemoglobin A1c level was filled out, based on a copy of laboratory results received that day.

## **Patient activation**

To assess patient's self-care management, the Patient Activation Measure (PAM-13) was used as a suitable approximation since self-care management behaviors are clearly associated with patient activation levels [31-33]. Patient activation is a concept that includes a comprehensive approach to a number of elements related to activation, including the knowledge, skills, beliefs, and behaviors that patients need to manage their illness. The PAM-13 is a clinically used, highly reliable and valid scale containing 13 questions, scored using a Likert scale (strongly disagree, disagree, agree and strongly agree, as well as not applicable). A score of 1, 2, 3 or 4 was given. This gave a total possible score of 13–52. These scores were then converted into an interval scale (0–100). A high score corresponds with a positive attitude toward the necessary behavioral changes during the course of treatment. The Japanese version of the PAM-13 for mental health (PAM13-MH) was used without the “mental health” wording as stipulated by the developer of the scale.

## **Self-stigma**

The Japanese version of the Self-Stigma Scale (SSS-J) was used to assess the level of self-stigma; its reliability and validity were reported in Study 2. It comprises 39 items to assess that allow four responses in a Likert scale: strongly disagree, disagree, agree, and

strongly agree. The responses are afforded a score of 0, 1, 2, and 3, respectively. The total possible scores have a range of 0–117 and the score was treated as continuous. A higher score represents a higher level of self-stigma.

### **Self-efficacy**

The General Self-Efficacy Scale was applied to assess individual strength in general self-efficacy across a variety of settings in everyday life [24]. It is reliable and valid, and is commonly used to measure self-efficacy in Japan. It is a 16-item scale using dichotomous (yes/no) questions. The total possible scores have a range of 0–16 and the score was treated as continuous. A higher score represents a higher level of self-efficacy.

### **Depressive symptoms**

The nine-item depression module of the Patient Health Questionnaire (PHQ-9) was used to assess depressive symptoms during the previous 2 weeks [25,26]. It is a reliable and valid measure of depression severity for clinical use. Each item is scored on DSM-IV (*Diagnostic and Statistical Manual of Mental Disorders-IV*) criteria from 0 (not at all) to 3 (nearly every day). The total possible scores have a range of 0–36 and the score was treated as continuous.

### **Self-esteem**



The Rosenberg Self-Esteem Scale was used to assess the level of self-esteem [22,23]. It is a widely accepted scale because of its high reliability and validity. It contains 10 items scored on a 4-point Likert scale from 1 (strongly disagree) to 4 (strongly agree). Five negative items were reverse-scored to compute the total scores of individual participants.

### **Statistical analysis**

Descriptive statistics were calculated using means and standard deviations or numbers and percentages based on the nature of the variables. Data were evaluated for normality before analysis. Dummy variables were created for categorical variables (i.e., sex, marital status, injection therapy). The relationship of each independent variable to the dependent variable (patient activation) was calculated using Pearson's correlation coefficient. Furthermore, Variance Inflation Factor (VIF) values were calculated to detect multicollinearity.

Multiple linear regression models were analyzed to assess the independent effects of self-stigma on patient activation scores for their self-care management. Patient activation scores were considered a dependent variable, while self-stigma, self-esteem, self-efficacy, and depressive symptoms were considered independent variables. Two models were constructed. The possible influence of sociodemographic and clinical variables were adjusted for as priori covariates and were included in each model. A direct method was used for the multiple linear regression analyses. To examine the predictive capacity of the models,

analysis of variance was used to test the significance of the overall regression equation by calculating the F value. The coefficients of determination were calculated to evaluate the explanatory capacity of patient activation scores. The standardized partial regression coefficients were also calculated to quantify the degree of association between the dependent and independent variables. All analyses were performed using SPSS version 18.0 (SPSS Japan Inc., Tokyo, Japan).

## **Results**

Physicians recruited 259 patients with type 2 diabetes and written informed consent was obtained from 218, giving a response rate of 84.2%. Of these patients, 217 completed the questionnaire (one patient declined). The percentage of missing data was zero for all questionnaire items. In the analysis, we excluded three participants who answered all 13 items of the PAM-13 with a “strongly agree” response: the original scale developer recommended this as these respondents were likely to provided untruthful or inaccurate answers. We also excluded another five participants who answered all 39 items of the self-stigma scale with a “strongly disagree” response, because they responded strongly to stigma, and we did not know whether the scale could measure what it was originally intended to assess. Therefore, 209 participants were included in our final analysis.

The sociodemographic and clinical characteristics of the participants are shown in Table 4.

There were 168 male participants (80.4%) and 41 female participants (19.6%), and the mean age was  $60.2 \pm 10.1$  years. The mean number of years of education was  $13.9 \pm 2.3$ . The majority of patients were married (72.2%), and the mean number of people living in a patient's dwelling was  $2.5 \pm 1.2$  (including the patient). The mean BMI was  $26.3 \pm 5.2$ , the mean duration of type 2 diabetes was  $159.1 \pm 113.8$  months, and 34.9% of participants received therapy for injections (insulin or other injectable medications). The mean number of diabetes-related complications was  $0.57 \pm 0.86$ , and the mean hemoglobin A1c level was  $7.3 \pm 1.2\%$ .

Participants were grouped into two categories based on the median of hemoglobin A1c: lower than 7.0%, and higher than or equal to 7.0%. According to the results of the Self-Stigma Scale derived from this study, the mean score of self-stigma in the lower group was  $68.7 \pm 17.6$  and in the higher group was  $73.4 \pm 15.3$ . We found the difference in the two groups' mean scores to be statistically significant ( $t(207) = 2.04$ ,  $p = 0.04$ ). Participants were also grouped into three categories based on the number of diabetes-related complications: 0, 1, and 2 or more complications. According to the results of the Self-Stigma Scale derived from this study, the mean score of each group was as follows: the 0 complication group ( $69.1 \pm 16.8$ ), the 1 complication group ( $73.4 \pm 15.8$ ), and the 2 or more complications group ( $76.0 \pm 15.9$ ). The differences between the three groups' mean scores were not statistically significant, but patients with severe conditions showed a tendency toward increased self-stigma (F

(2,206) = 2.78,  $p = 0.06$ ).

**Table 4 Sociodemographic and clinical characteristics of participants (n = 209)**

<b>Patient characteristics</b>	<b>N (%) or Mean (<math>\pm</math> SD)</b>
<b>Sex:</b>	
Male	168 (80.4)
Female	41 (19.6)
<b>Age (years):</b>	60.2 ( $\pm$ 10.1)
<b>BMI (kg/m<sup>2</sup>):</b>	26.3 ( $\pm$ 5.2)
<b>Diabetes duration (months):</b>	159.1 ( $\pm$ 113.8)
<b>Injection therapy:</b>	
Yes	73 (34.9)
No	136 (65.1)
<b>Number of diabetes-related complications (0-6):</b>	0.57 ( $\pm$ 0.86)
<b>HbA1c (%):</b>	7.3 ( $\pm$ 1.2)
<b>Education (years):</b>	13.9 ( $\pm$ 2.3)
<b>Marital status:</b>	
Married	151 (72.2)
Unmarried/Divorced/Bereaved	58 (27.8)
<b>Size of households (including the patient):</b>	2.5 ( $\pm$ 1.2)
<b>Self-stigma:</b>	
HbA1c < 7.0%	68.7 ( $\pm$ 17.6)
HbA1c $\geq$ 7.0%	73.4 ( $\pm$ 15.3)
<b>Self-stigma:</b>	
Number of diabetes-related complications	
0	69.1 ( $\pm$ 16.8)
1	73.4 ( $\pm$ 15.8)
$\geq 2$	76.0 ( $\pm$ 15.9)

SD: standard deviation. BMI: body mass index. HbA1c: glycated hemoglobin.

Appendix 6 shows Pearson's correlation coefficients between each independent variable and the dependent variable (patient activation). All the correlation coefficients were found to be either moderate or weak. Additionally, all the VIF for each variable was smaller than 1.82; therefore, there were no multicollinearity problems.

Using multiple linear regression models, the associations between self-stigma and patient activation scores were systematically examined. Covariates including sex, age, BMI, diabetes duration, injection therapy, education, marital status, and size of household were adjusted for. Table 5 shows the results of multiple linear regression analysis of patient activation scores as a dependent variable. In Model 1, the coefficient of determination was 0.29 ( $F(11,197) = 7.35, p < 0.001$ ). Self-esteem was significantly positively associated with patient activation scores ( $b = 0.28, p = 0.001$ ), while neither self-efficacy nor depressive symptoms were significantly associated with patient activation scores ( $b = 0.13, p = 0.101, b = -0.13, p = 0.076$ , respectively). When self-stigma was added to the model (Model 2), the coefficient of determination was increased to 0.32 ( $F(12,196) = 7.62, p < 0.001$ ), and the self-stigma was found to be significantly negatively associated with patient activation scores ( $b = -0.19, p = 0.006$ ). In Model 2, self-esteem still had a statistically significant association with patient activation scores; however, the standardized partial regression coefficient of self-esteem was slightly decreased from 0.28 to 0.24. We also conducted a multiple linear regression with self-stigma as the independent variable and patient activation scores as the dependent variable, without including the independent variables of self-esteem, self-efficacy, and depressive symptoms (Appendix 7).

Table 5 Multiple linear regression models including self-stigma, self-esteem, self-efficacy, and depressive symptoms as independent variables, with patient activation scores as dependent variable (n=209)

	Model 1		Model 2	
	R <sup>2</sup> = 0.29*		R <sup>2</sup> = 0.32*	
	b	P values	b	P values
Self-stigma	-	-	-0.19	0.006
Self-esteem	0.28	0.001	0.24	0.003
Self-efficacy	0.13	0.101	0.09	0.227
PHQ-9	-0.13	0.076	-0.09	0.205

Abbreviations: R<sup>2</sup>: coefficient of determination; b: standardized partial regression coefficient; PHQ-9: Patient Health Questionnaire.

\*  $p < 0.001$ .

† Sex (male), age (years), body mass index (kg/m<sup>2</sup>), diabetes duration (months), injectable therapy (yes), education (years), marital status (married), and size of households were adjusted as covariates.

## Summary

In Study 3, a cross-sectional quantitative study was performed in order to examine the association between self-stigma and self-care management (patient activation) in patients with type 2 diabetes. Self-stigma was found to be both significantly and negatively associated with patient activation scores for their self-care management after adjusting for covariates. This study showed that self-stigma was an important predictor of self-care management in patients with type 2 diabetes, and that it had a similar impact to that of self-esteem on diabetes self-care management. The results of this study suggested that in order to optimize treatment outcomes, patients' self-stigma should be reduced while also enhancing their self-esteem.

## CHAPTER 3

### DISCUSSIONS AND CONCLUSIONS

The findings of the qualitative study (Study 1) are comparable to previous studies of the process of identity reconstruction and adjustment experienced by many patients with chronic illnesses [34-36]. These models are profoundly conceptualized as to how patients struggle to find a new self while balancing between their physical status and current social duties. The findings also support part of Parsons' model. Parsons theorized the concept of the 'sick role', i.e. that the sick could temporarily enter a role of 'sanctioned deviance' in society and were wholly obliged to restore their health by collaborating with healthcare professionals [37]. However, Study 1 found that patients with type 2 diabetes were not completely exempt from the obligation of serving their current social roles. They had to continue to perform their social roles and found that they were always held personally accountable either for the onset of illness, or poor response to treatment, even after diagnosis. Thus, self-stigma could be developed through negative social interactions in patients with type 2 diabetes.

Other important results found in Study 1 were supported by the quantitative studies (Study 3). For some patients with type 2 diabetes, their sense of self-worth was lowered by a built-up negative image of and relationship to their illness. This affected their attitude towards social participation, including areas involving the self-management of diabetes. This whole process is called self-stigma. Study 3 showed that, separate from self-esteem, self-efficacy, and

depressive symptoms, self-stigma was independently associated with self-care management in patients with type 2 diabetes. Simply enhancing self-esteem as well as self-efficacy and preventing depressive symptoms are insufficient. Rather, patients need help in developing a positive attitude towards type 2 diabetes and reducing any self-stigma in order to support their self-care management throughout the course of their illness.

### **Strengths**

The strength of this entire study was that recruited participants underwent treatment by diabetologists. Their symptoms were severe enough in terms of glycemic control to visit specialists. The findings in Study 3 showed that patients with poor glycemic control were more likely to experience a significant number of instances of stigma and consequently develop self-stigma. Additionally, numerous previous studies show that poor glycemic control is a risk factor for depression [45-48]. Thus, interviewing those vulnerable patients with severe symptoms and assessing their attitudes towards stigma using a validated tool were the best ways to examine the stressful process of self-care management, including the ways they incorporated it into their social lives.

More importantly, the strength of this entire study was that we used mixed method research, including both qualitative study through interviews and quantitative study through a survey instrument, to explore complex phenomena, self-stigma, in ways that cannot be fully



understood through a single study approach. Our findings supported the results found by two different study methods and were convergent with them.

## **Limitations**

There are some limitations to this entire study. First, there was a sex imbalance in our entire sample. In Study 1, in order to focus attention on a patient's regular psychological response to the stigma against type 2 diabetes, we excluded people who underwent therapy for psychiatric disorders such as depression and eating disorders. Many women who were recruited in Study 1 turned out to suffer from these conditions. Therefore, all these women were excluded from the analysis. Additionally, in Study 2 and 3, the percentage of men was 80% and the percentage of women was 20%. Although the prevalence of type 2 diabetes is higher among men (15.3%) than women (7.3%) in Japan [2], it is not known exactly why we had such a large number of male respondents, compared with female respondents. Second, the English version of the PAM-13 was originally tested for its reliability and validity among patients with chronic conditions, such as diabetes and hypertension. However, the reliability and validity of the Japanese version of the PAM-13 were evaluated only in patients with mental illnesses, not in those with diabetes. Third, all the participants in Study 1 recruited underwent treatment by diabetologists at tertiary hospitals. Therefore, the findings do not capture the entire picture of patients with type 2 diabetes with differing levels of severity. In

Study 2-3, there are the same types of limitations as those found in Study 1. The participating patients with type 2 diabetes were recruited from specialist hospitals/clinics. Any patients who were seen regularly by a primary care doctor were not included, nor were those who were not treated after diagnosis. Further research with a more representative population will be needed, not only in this specialized field but also in primary care settings. Finally, another limitation in Study 2 in terms of reliability and validity of the Japanese version of the Self-Stigma Scale (SSS-J) is that a sample with similar disease characteristics as used in the original scale, i.e., patients with mental disorders, was not tested. Further research using this sample will be needed to assess the cross-cultural validity of the SSS-J more precisely.

### **Implications for Practice**

To optimize the effectiveness of the treatment of type 2 diabetes, healthcare professionals should assess whether patients are suffering from self-stigma, and then provide guidance on medication and diet. Self-stigma can be observed by healthcare professionals during their daily practice. Those who develop self-stigma severely limit or increase their social activities against medical advice and consequently cannot devote themselves to their treatment regimen. However, it would be more practical for healthcare professionals to use the validated Japanese version of the Self-Stigma Scale (SSS-J) to assess the levels of self-stigma in individual patients with type 2 diabetes in clinical practice. This is because this

self-administered scale is a valuable and handy assessment tool to help healthcare professional identify high-risk self-stigma patients with type 2 diabetes. For clinical use of the SSS-J, given its length, a shorter version should be developed as this will avoid some redundant items while incorporating more relevant ones. Additionally, further studies are needed to discover the optimum time during the treatment process to respond to self-stigma in individual patients with type 2 diabetes, as well as the most effective places to assess the extent of self-stigma.

Nevertheless, patient self-care is a must in type 2 diabetes, and any possible barriers, such as self-stigma, should be eliminated to achieve optimal treatment. As a result of using this assessment tool for self-stigma, it would be possible to provide patients with different treatment strategies in addition to early intervention in order to help reduce self-stigma. This could then lead to optimal treatment outcomes. In psychiatric patients, there is evidence that self-stigma reduction programs are effective in improving their self-esteem, promoting their readiness to change their problematic behavior, and facilitating their treatment adherence [49-51]. Similar effects may be expected in patients with type 2 diabetes, with improved treatment adherence by lowering levels of self-stigma through patient education programs.

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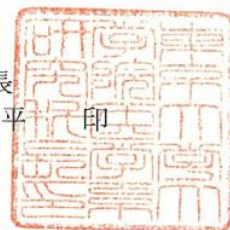
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審査番号 3619

研究課題 糖尿病患者の社会生活における心理的ストレスに関する研究

上記研究計画を平成23年11月21日の委員会で審査し下記のとおり判定しました。  
ここに通知します。

判定	<input type="radio"/> 承認する。 条件付きで承認する。 変更を勧告する。	承認しない。 該当しない。
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## 研究参加者の皆様へ

### 研究課題

## 糖尿病患者の社会生活における心理的ストレスに関する研究

### へのご協力をお願い

#### 1. この研究の概要

##### 【研究課題】

糖尿病患者の社会生活における心理的ストレスに関する研究

##### 【研究機関名及び研究責任者氏名】

この研究が行われる研究機関と研究責任者は次に示す通りです。

研究機関	東京大学大学院医学系研究科 臨床疫学経済学分野
研究責任者	橋本英樹（データ収集・匿名化・データ解析）

##### 【共同研究機関】

東京大学医学部附属病院（東京都文京区）

##### 【研究目的】

糖尿病を持つ方々を取り巻く社会環境については十分に明らかにされていません。本研究は、糖尿病を持つ方々が社会生活を送る中で、どのような心理的ストレスを経験し、また緩和しながら過ごされているのかを明らかにすることを目的としています。

##### 【研究方法】

個別面接（インタビュー）を実施します。質問内容は、糖尿病診断後から現在までを振り返り、社会生活の中で経験された（現在もされている）心理的ストレスについて伺いたく思います。面接時間は30～40分程度です。なお、お話いただいた内容はすべて分析のため、ICレコーダーに録音させていただきたく思います。どうぞご理解をお願いいたします。

万が一、回答されたくない質問があった場合には、無理をして想起いただかなくて構いません。また途中で研究への参加を中止したくなった場合にも、いつでも自由に研究参加の中止をして構いません。

分析過程で、個別面接（インタビュー）でお話いただいた内容に誤りがないかどうか確認させていただくことがあります。そのため、後日、担当者から連絡をさせていただくことがあるかもしれません。どうぞご理解をいただけますようお願いいたします。

#### 2. 研究協力の任意性と撤回の自由

この研究にご協力いただくかどうかは、研究参加者の皆様の自由意思に委ねられています。もし同意を撤回される場合は、同意撤回書に署名し、東京大学大学院医学系研究科 臨床疫学経済学分野にご提出ください。なお、研究にご協力いただけない場合にも、皆様の不利益につながることはありません。研究期間中にご本人の申し出があれば、いつでもいただいた資料等及び調べた結果を廃棄します。

### 3. 個人情報の保護

この研究に関わる成果は、他の関係する方々に漏えいすることのないよう、慎重に取り扱う必要があります。録音させていただいた音声データの中に個人情報に関わる部分があった場合には、分析過程で削除するなど個人が同定されることがないように配慮し、当研究室において厳重に保管します。

### 4. 研究結果の公表

研究の成果は、あなたの氏名など個人情報が明らかにならないようにした上で、学会発表や学術雑誌及びデータベース上で公表します。ご希望があれば、下記の連絡先にお問い合わせをいただければ、個別および全体の分析結果についてご説明いたします。

### 5. 研究参加者にもたらされる利益及び不利益

この研究が、あなたに直ちに有益な情報をもたらす可能性は高いとはいえません。しかし、この研究の成果は、糖尿病を持つ方々の心理的ストレスが軽減されるような社会づくりに向けて、今後の政策の発展に寄与することが期待されます。したがって、将来、あなたに生活面で利益をもたらす可能性があると考えられます。

### 6. 研究終了後の資料（試料）等の取扱方針

あなたからいただいた資料等は、この研究のためにのみ使用します。研究終了後、あなたからいただいた資料等は適切な方法で破棄します。

### 7. あなたの費用負担

今回の研究に必要な費用について、あなたに負担を求めることはありません。なお、あなたへの謝品は約 500 円の文房具となります。

### 8. その他

この研究は、東京大学倫理委員会の承認を受けて実施するものです。なお、この研究に関する費用は、東京大学大学院医学系研究科臨床疫学経済学分野橋本研究室の運営費から支出されています。この研究に関するご意見ご質問などがございましたら、お気軽に当研究室までご連絡ください。

20 年 月 日

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# 同 意 書

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研究課題「糖尿病患者の社会生活における心理的ストレスに関する研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、  
担当者名 \_\_\_\_\_ から説明を受け、これを十分理解しましたので本研究の研究参加者となることに同意いたします。

以下の項目について、説明を受け理解しました。

- ☐ この研究の概要について
- ☐ 研究協力の任意性と撤回の自由について
- ☐ 個人情報の保護について
- ☐ 研究結果の公表について
- ☐ 研究参加者にもたらされる利益及び不利益について
- ☐ 研究終了後の資料（試料）等の取扱方針について
- ☐ あなたの費用負担について
- ☐ 録音することについて
- ☐ その他について

平成     年     月     日

氏名（研究参加者本人）（自署） \_\_\_\_\_

連絡先（電話番号） \_\_\_\_\_

# 同 意 撤 回 書

東京大学医学系研究科長・医学部長 殿

研究課題「糖尿病患者の社会生活における心理的ストレスに関する研究」

私は、上記研究への参加にあたり、説明文書の記載事項について説明を受け同意しましたが、同意の是非について再度検討した結果、同意を撤回いたします。

平成 年 月 日

氏名（研究参加者本人）（自署） \_\_\_\_\_

## 研究参加者の皆様へ

### 研究課題

# 糖尿病患者の健康状態に影響を及ぼす心理的ストレスに関する研究 へのご協力をお願い

## 1. この研究の概要

### 【研究課題】

糖尿病患者の健康状態に影響を及ぼす心理的ストレスに関する研究

### 【研究機関名及び研究責任者氏名】

この研究が行われる研究機関と研究責任者は次に示す通りです。

研究機関	東京大学大学院医学系研究科 保健社会行動学分野
研究責任者	橋本英樹（データ収集・データ解析）

### 【共同研究機関】

東京大学医学部附属病院（東京都文京区）

### 【研究目的】

糖尿病を持つ方々を取り巻く社会環境については十分に明らかにされていません。本研究は、糖尿病を持つ方々がどのようにご自身の病気をとらえて、日常および社会生活の中の様々な状況を解釈されているのかを明らかにすることを目的としています。

### 【研究方法】

無記名にて、質問紙（アンケート）を実施します。質問内容は、日常および社会生活の中で直面する様々な状況に対しての感じ方や考え方について伺いたく思います。回答時間は10～15分程度です。回答に正解や不正解はありません。

## 2. 研究協力の任意性と撤回の自由

この研究にご協力いただくかどうかは、研究参加者の皆様の自由意思に委ねられています。研究にご協力いただけない場合にも、皆様の不利益につながることはありません。なお、無記名による調査ですので、一度研究協力に同意いただきましたら、後に同意撤回はできません。

## 3. 個人情報の保護

この研究に関わる成果は、他の関係する方々に漏えいすることのないよう、慎重に取り扱う必要があります。質問紙（アンケート）では、住所などの個人情報を伺うことはありません。ご回答いただいた質問紙は、研究終了まで当研究室において厳重に保管します。

## 4. 研究結果の公表

研究の成果は、あなたの氏名など個人情報が明らかにならないようにした上で、学会発表や学術雑誌及びデータベース上で公表します。ご希望があれば、下記の連絡先にお問い合わせをいただければ、全体の分析結果についてご説明いたします。なお、無記名の調査となりますので、個別の分析結果についてはお答えできません。



5. 研究参加者にもたらされる利益及び不利益

この研究が、あなたに直ちに有益な情報をもたらす可能性は高いとはいえません。しかし、この研究の成果は、糖尿病を持つ方々の心理的ストレスが軽減されるような社会づくりに向けて、今後の政策の発展に寄与することが期待されます。したがって、将来、あなたに生活面で利益をもたらす可能性があると考えられます。

6. 研究終了後の資料（試料）等の取扱方針

あなたからいただいた資料等は、この研究のためにのみ使用します。研究終了後、同意書および質問紙（アンケート）は適切な方法で破棄します。

7. あなたの費用負担

今回の研究に必要な費用について、あなたに負担を求めることはありません。

8. その他

この研究は、東京大学倫理委員会の承認を受けて実施するものです。なお、この研究に関する費用は、東京大学大学院医学系研究科保健社会行動学分野橋本研究室の運営費から支出されています。この研究に関するご意見ご質問などがございましたら、お気軽に当研究室までご連絡ください。

20 年 月 日

【連絡先】

研究責任者：橋本 英樹

連絡担当者：加藤 明日香

〒113-0033 東京都文京区本郷 7-3-1

東京大学大学院医学系研究科 保健社会行動学分野

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# 同 意 書

東京大学医学系研究科長・医学部長 殿

研究課題「糖尿病患者の健康状態に影響を及ぼす心理的ストレスに関する研究」

私は、上記研究への参加にあたり、説明文書の記載事項について、  
担当者名 \_\_\_\_\_ から説明を受け、これを十分理解しましたので本研究の研究参加者となることに同意いたします。

以下の項目について、説明を受け理解しました。

- ☐ この研究の概要について
- ☐ 研究協力の任意性と撤回の自由について
- ☐ 個人情報の保護について
- ☐ 研究結果の公表について
- ☐ 研究参加者にもたらされる利益及び不利益について
- ☐ 研究終了後の資料（試料）等の取扱方針について
- ☐ あなたの費用負担について
- ☐ その他について

平成     年     月     日

氏名（研究参加者本人）（自署） \_\_\_\_\_

## ご記入にあたって

- ◆ 質問番号順にお答えください。
- ◆ お答えは、あてはまる数字に○を囲んでいただくか、☒印をつけていただきます。「その他」にあてはまる場合は、あわせて（ ）内に具体的な内容を記入してください。
- ◆ 正しい答えというものはありませんので、あまり深く考えずにお答えください。
- ◆ 回答はすべて統計的に処理をいたしますので、個人名が出たり、回答内容から個人が特定されたりすることは一切ありません。どうかご安心いただき、ありのままをお答えください。
- ◆ ご記入が終わりましたら、もう一度、記入漏れがないかお確かめください。

2013年11月～2014年2月

研究機関：東京大学大学院医学系研究科

保健社会行動学分野

研究責任者：橋本 英樹

研究従事者：加藤明日香

記入日：平成 年 月 日

**問 1** あなたの健康状態についてうかがいます

お生まれの年・月	昭和・平成 年 月	性別	<input type="checkbox"/> 男性 <input type="checkbox"/> 女性
身長	cm	体重	kg
糖尿病の 診断を受けた年・月	昭和・平成 年 月	この病院に 通院しはじめた年・月	昭和・平成 年 月から
ヘモグロビン A 1 c （変更後の新しい値：NGSP）		今日の血液検査結果 . %	
糖尿病の 治療方法	<input type="checkbox"/> 食事療法のみ <input type="checkbox"/> 経口薬のみ <input type="checkbox"/> インスリンのみ <input type="checkbox"/> 経口薬とインスリン <input type="checkbox"/> インスリン以外の注射薬 *「経口薬」：血糖値を下げる飲み薬		
糖尿病の 合併症  <input type="checkbox"/> なし	網膜症	<input type="checkbox"/> レーザー治療 <input type="checkbox"/> 硝子体手術 <input type="checkbox"/> 眼底出血 <input type="checkbox"/> 網膜剥離 <input type="checkbox"/> 視覚障害 <input type="checkbox"/> 緑内障 <input type="checkbox"/> 失明	
	腎症	<input type="checkbox"/> 尿たんぱく <input type="checkbox"/> 腎機能の低下 <input type="checkbox"/> 腎不全 <input type="checkbox"/> 透析療法中	
	神経障害	<input type="checkbox"/> 手足のしびれ・痛み <input type="checkbox"/> 便秘・下痢 <input type="checkbox"/> 排尿障害 <input type="checkbox"/> 勃起障害 <input type="checkbox"/> その他（ ）	
	動脈硬化	<input type="checkbox"/> 心筋梗塞 <input type="checkbox"/> 狭心症 <input type="checkbox"/> 脳梗塞 <input type="checkbox"/> 脳出血 <input type="checkbox"/> 歩行困難 末梢動脈閉塞症（ <input type="checkbox"/> 感染 <input type="checkbox"/> 足壊疽 <input type="checkbox"/> 下肢の切断）	
	その他	（ ）	
既往症 （これまでにかかっ たことのある病気）	<input type="checkbox"/> なし <input type="checkbox"/> 喘息 <input type="checkbox"/> 血液 <input type="checkbox"/> 甲状腺 <input type="checkbox"/> 肝臓 <input type="checkbox"/> 膵臓 <input type="checkbox"/> 悪性新生物（がん） <input type="checkbox"/> うつ病など <input type="checkbox"/> こころの病気 <input type="checkbox"/> その他（ ）		
ご家族の中に 糖尿病の方はいますか		<input type="checkbox"/> いいえ・はい（ <input type="checkbox"/> 祖父 <input type="checkbox"/> 祖母 <input type="checkbox"/> 父 <input type="checkbox"/> 母 <input type="checkbox"/> 兄弟姉妹）	

## 問 2

下の表には、自分自身を全般的にどのように感じているか、という文が並んでいます。  
あなたにあてはまる番号に○をつけてください。

	強く 思う	そう 思う	そう 思わない	強く 思わない
わたしは、自分自身にだいたい満足している	1	2	3	4
時々、自分はまったくダメだと思うことがある	1	2	3	4
私にはけっこう長所があると感じている	1	2	3	4
私は、他の大半の人と同じくらいに物事がこなせる	1	2	3	4
私には誇れるものが大してないと感じる	1	2	3	4
時々、自分は役に立たないと強く感じる	1	2	3	4
自分は少なくとも他の人と同じくらい価値のある人間だ、と感じている	1	2	3	4
自分のことをもう少し尊敬できたらいいと思う	1	2	3	4
よく、私は落ちこぼれたと思ってしまう	1	2	3	4
私は、自分のことを前向きに考えている	1	2	3	4

## 問 3

過去1ヵ月間に、家族、友人、近所の人、その他の仲間とのふだんのつきあいが、身体的  
あるいは心理的な理由で、どのくらい妨げられましたか。

ぜんぜん、 さまた 妨げられなかった	わずかに、 さまた 妨げられた	少し、 さまた 妨げられた	かなり、 さまた 妨げられた	非常に、 さまた 妨げられた
1	2	3	4	5

#### 問 4

下記項目は、糖尿病であることを<sup>たい</sup>に対するあなたの<sup>かんが</sup>考えについて質問しています。  
各項目を丁寧に読み、現在のあなたの考えを最も表している番号に○をつけてください。

\*質問内容があなたにあてはまらない場合は、「4. 全くそう思わない」に○をつけてください。

	強く 思う つよ おも	そう 思う おも	そう 思わ ない おも	全く そう 思わ ない まった おも
糖尿病患者であることを、私はとてもストレスに感じる <sup>とうりょうびょうかんじや わたし かん</sup>	1	2	3	4
糖尿病患者であるために、私の社会的交流には制限がある <sup>とうりょうびょうかんじや わたし しゃかいできこうりゅう せいげん</sup>	1	2	3	4
私は、糖尿病患者であることが恥ずかしい <sup>わたし とうりょうびょうかんじや は</sup>	1	2	3	4
糖尿病患者であるので、私の人生は無意味である <sup>とうりょうびょうかんじや わたし じんせい む い み</sup>	1	2	3	4
糖尿病患者であるので、私が他人から疎外されるのはまったく当然のことだ <sup>とうりょうびょうかんじや わたし たにん そ が い とうぜん</sup>	1	2	3	4
糖尿病患者であるので、私は生活水準を下げている <sup>とうりょうびょうかんじや わたし せいかつすいじゅん さ</sup>	1	2	3	4
糖尿病患者であることが知られてしまうので、私はあえて自ら進んで <sup>とうりょうびょうかんじや し わたし みづかすす</sup>	1	2	3	4
新しい友人をつくらない <sup>あたら ゆうじん</sup>				
私は、自分が糖尿病患者であることを、かわいそうだと思う <sup>わたし じぶん とうりょうびょうかんじや おも</sup>	1	2	3	4
私は、自分と同じ状態の人とだけ友達になる <sup>わたし じぶん おな じょうたい ひと ともだち</sup>	1	2	3	4
糖尿病患者であるので、私は一般の人々にかなわない <sup>とうりょうびょうかんじや わたし いっぱん ひとびと</sup>	1	2	3	4
私は、糖尿病という「病気」を持った自分を変えることができない <sup>わたし とうりょうびょう びょうき も じぶん か</sup>	1	2	3	4
糖尿病患者であるので、私は他人の援助が必要である <sup>とうりょうびょうかんじや わたし たにん えんじょ ひつよう</sup>	1	2	3	4

	強く思う つよ おも	そう思う おも	そう思わない おも	全くそう思わない まった おも
とうにょうびょう 糖 尿 病 という「病氣」を持った自分は、 わたし じんせい おてん 私の人生の汚点である	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるために、 わたし じぶん 私は自分をあきらめている	1	2	3	4
わたし じゅうい ひと とうにょうびょうかんじや 私は、周囲の人に糖 尿 病患者であることを知られるのを恐れる	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であることについて、 わたし どうする こともできないと感じる	1	2	3	4
わたし とうにょうびょうかんじや 私は、糖 尿 病患者であることが不快だ	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるので、 わたし じんせい たい 私は人生に対してあまり期待しないようにしている	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるため、 わたし たにん あいだ きより お 私は他人との間に距離を置いている	1	2	3	4
とうにょうびょう 糖 尿 病 という「病氣」を持った自分を、 わたし たにん かく 私は他人に隠している	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるので、 わたし たにん おと 私は他人より劣っている	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるので、 わたし はらだ かん 私は腹立たしく感じる	1	2	3	4
とうにょうびょう 糖 尿 病 という「病氣」を持った自分に、 わたし ひていてき かんじょう 私は否定的な感情をもっている	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるために、 わたし じぶん じぶん じしん いや 私は自分で自分自身が嫌になる	1	2	3	4
とうにょうびょう 糖 尿 病 という「病氣」を持った自分が、 わたし さまた 私の 妨げとなるのではないかと しんぱい 心配している	1	2	3	4
とうにょうびょうかんじや 糖 尿 病患者であるので、 わたし いっぱん ひとびと のうりよく おも 私は一般の人々より能力がないと思う	1	2	3	4

	強く 思う つよ おも	そう 思う おも	そう 思わない おも	全く 思う おも まった
とうにょうびょうかんじゃ 糖 尿 病患者であるので、 わたし た に ん き そ し か く 私 は他人と競う資格がない	1	2	3	4
とうにょうびょうかんじゃ 糖 尿 病患者であるので、 わたし き お 私 は気落ちしている	1	2	3	4
とうにょうびょうかんじゃ 糖 尿 病患者であることは、 わたし おお き か い う ば 私 から多くの機会を奪う	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分により、 どん な に けんめい はたら どんなに懸命に働いたとしても	1	2	3	4
わたし た に ん およ 私 は他人に及ばない				
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分により、 わたし じんせい たの かん 私の人生は楽しくないと感じる	1	2	3	4
とうにょうびょうかんじゃ 糖 尿 病患者であるので、 わたし ふ こう 私 は不幸だ	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分のため、 わたし じ ぶ ん じ し ん 私は自分に自信がもてない	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分は、 わたし にちじょうせいかつ ふ つ ご う 私の日常生活に不都合をもたらす	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分は、 わたし けいざいじょうたい あくえいきょう あた 私の経済状態に悪影響を与える	1	2	3	4
とうにょうびょうかんじゃ 糖 尿 病患者であるために、 わたし た に ん さ 私は他人とのかかわりを避けている	1	2	3	4
とうにょうびょうかんじゃ 糖 尿 病患者であるので、 わたし むりよく かん 私は無力に感じる	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分は、 わたし ふ た ん おお 私 にとって負担が大きい	1	2	3	4
とうにょうびょう 糖 尿 病 という「病気」をも じ ぶ ん を持った自分のために、 わたし は おも 私は恥ずかしい思いをする	1	2	3	4



つぎ もん しんたいてき りゆう しんりてき りゆう わ しつもん  
次の2問は、「身体的な理由」と「心理的な理由」を分けて、質問しています

**問5** か こ げつかん しごと かつどう か じ しんたいてき りゆう つぎ  
過去1ヵ月間に、仕事やふだんの活動(家事など)をするにあたって、身体的な理由で次の  
ような問題がありましたか。

	いつも	ほとんどいつも	ときどき	まれに	ぜんぜんない
しごと かつどう じかん 仕事やふだんの活動をする時間をへらした	1	2	3	4	5
しごと かつどう おも 仕事やふだんの活動が思ったほど、 <u>できなかった</u>	1	2	3	4	5
しごと かつどう ないよう 仕事やふだんの活動の <u>内容</u> によっては、できないものがあった	1	2	3	4	5
しごと かつどう 仕事やふだんの活動をすることが <u>むずかしかった</u>	1	2	3	4	5
たと どりよく ひつよう (例えば、いつもより努力を必要としたなど)	1	2	3	4	5

**問6** か こ げつかん しごと かつどう か じ しんりてき りゆう  
過去1ヵ月間に、仕事やふだんの活動(家事など)をするにあたって、心理的な理由で  
(例えば、気分がおちこんだり不安を感じたりしたために)、次のような問題がありましたか。

	いつも	ほとんどいつも	ときどき	まれに	ぜんぜんない
しごと かつどう じかん 仕事やふだんの活動をする時間をへらした	1	2	3	4	5
しごと かつどう おも 仕事やふだんの活動が思ったほど、 <u>できなかった</u>	1	2	3	4	5
しごと かつどう しゅうちゅう 仕事やふだんの活動がいつもほど、 <u>集中して</u> できなかった	1	2	3	4	5

## 問 7

健康について、以下のような発言がきかれることがあります。あなたの場合、どの程度、同意するあるいは同意しないか、あてはまる番号に○をつけてください。該当しない項目には、「あてはまらない」を選択してください。

\*主治医が望んでいるだろうと思う回答ではなく、あなたにとって本当のことをお答えください。

	非常に そう思う おも	そう 思う おも	そう 思わない おも	全く そう 思わない おも	あて はまら ない
結局のところ、自分の健康を管理する責任は自分にある	1	2	3	4	5
健康管理に自分から積極的に取りくむことは、健康と活動する	1	2	3	4	5
力を左右する最も重要な要因である					
症状や不調を予防したり、やわらげたりするために行動できる	1	2	3	4	5
自信がある					
処方されている薬にそれぞれどんな効果があるか知っている	1	2	3	4	5
健康問題について、自分で解決できることか、あるいは専門家に	1	2	3	4	5
相談すべきことかを判断できる自信がある					
気がかりなことについて、促されなくても医療スタッフに話せ	1	2	3	4	5
る自信がある					
自宅ですべき治療を指示通りに行うことができる自信がある	1	2	3	4	5

	非常に そう思う ひじょう おも	そう 思う おも	そう 思わない おも	全く そう 思わない まった おも	あては まらない
自分の問題の特徴と要因を理解している じぶん もんだい とくちょう よういん りかい	1	2	3	4	5
自分の健康問題に対して、いろいろな治療方法があることを知っている じぶん けんこうもんだい たい ちりょうほうほう し	1	2	3	4	5
自分の健康のために、生活習慣を変えていくことができる じぶん けんこう せいかつしゅうかん か	1	2	3	4	5
健康不調がさらに悪くなることをどのようにしたら予防できるかわかっている けんこうふちょう わる よぼう	1	2	3	4	5
健康に影響する新たな状況や問題が生じた場合に、解決策を けんこう えいきょう あら じょうきょう もんだい しょう ばあい かいけつさく	1	2	3	4	5
見つけ出すことができる自信がある み だ					
ストレスがかかっているときでも、 しょくじ うんどう かいぜん せいかつしゅうかん たも じしん	1	2	3	4	5
食事や運動など、改善した生活習慣を保てる自信がある					

## 問 8

過去1 ヲ月間に、友人や親せきを訪ねるなど、人とのつきあいが、身体的あるいは  
心理的な理由で、時間的にどのくらい妨げられましたか。

いつも	ほとんど いつも	ときどき	まれに	ぜんぜん ない
1	2	3	4	5

# 問 9

この2週間、次のような問題にどのくらい頻繁に悩まされていますか。

	全 く な い	数 日	半 分 以 上	ほ と ん ど 毎 日
ものごと たい 物事に対してほとんど興味が ない、または楽しめない	1	2	3	4
きぶん お こ 気分が落ち込む、 憂うつになる、または絶望的な 気持ちになる	1	2	3	4
ね っ つ ね っ つ 寝付きが悪い、 途中で目がさめる、または逆 に眠り過ぎる	1	2	3	4
つか かん 疲れた感じがする、 または気力がない	1	2	3	4
あまり しょくよく 食欲がない、 または食べ過ぎる	1	2	3	4
じぶん にんげん じんせい はいぼくしゃ き や 自分はダメな人間だ、 人生の敗北者だと気に病む、 または自分自身あるい	1	2	3	4
かぞく もう わけ かん は家族に申し訳がないと 感じる				
しんぶん よ み しゅうちゅう むずか 新聞を読む、 またはテレビを見ることなどに 集中することが難しい	1	2	3	4
たにん き うご はな かた おそ 他人が気づくぐらいに動きや 話し方が遅くなる、あるいはこれ と反対に、	1	2	3	4
そわそわしたり、お 落ちつかず、 ふだんよりも動き回ることが ある				
し ほう じぶん なん ほうほう きず おも 死んだ方が ましだ、あるいは自分を何らかの 方法で傷つけようと思ったこ とがある	1	2	3	4

問 10

各項目を読んで、今のあなたにあてはまるかどうかを判断してください。あてはまる場合には「1. はい」、あてはまらない場合には「2. いいえ」に○を囲んでください。どちらにもあてはまらないと思われる場合でも、より自分に近いと思う方に必ず○をつけてください。

	はい	いいえ
何か仕事をするとき、自信を持ってやるほうである	1	2
過去に犯した失敗や嫌な経験を思いだして、暗い気持ちになることがよくある	1	2
友人より優れた能力がある	1	2
仕事を終えた後、失敗したと感じることのほうが多い	1	2
人と比べて心配性なほうである	1	2
何かを決めるとき、迷わずに決定するほうである	1	2
何かを決めるとき、うまくいかないのではないかと不安になることが多い	1	2
引っ込み思案なほうだと思う	1	2
人より記憶力がよいほうである	1	2
結果の見通しがつかない仕事でも、積極的に取り組んでいくほうだと思う	1	2
どうやったらよいか決心がつかずに仕事にとりかかれないことがよくある	1	2
友人よりも特に優れた知識を持っている分野がある	1	2
どんなことでも積極的にこなすほうである	1	2
小さな失敗でも人よりずっと気にするほうである	1	2
積極的に活動するのは、苦手なほうである	1	2
世の中に貢献できる力があると思う	1	2

## 問 11 ご自身のことについておうかがいします

婚姻状況	<input type="checkbox"/> 未婚 <input type="checkbox"/> 既婚 <input type="checkbox"/> 離別 <input type="checkbox"/> 死別	
同居（いま一緒に暮らしている）されている方は、あなたを含めて何人ですか。		何人
同居されている方	<input type="checkbox"/> なし <input type="checkbox"/> 配偶者（夫または妻） <input type="checkbox"/> 恋人 <input type="checkbox"/> 配偶者の親 <input type="checkbox"/> あなたの親 <input type="checkbox"/> 子 <input type="checkbox"/> 子の配偶者 <input type="checkbox"/> 孫 <input type="checkbox"/> あなたの兄弟姉妹 <input type="checkbox"/> その他（ ）	
最終学歴	<input type="checkbox"/> 中学 <input type="checkbox"/> 高校 <input type="checkbox"/> 専門学校 <input type="checkbox"/> 高専 <input type="checkbox"/> 短大 <input type="checkbox"/> 大学 <input type="checkbox"/> 大学院	
現在の働き方 (主なものを1つ)	<input type="checkbox"/> 無職 <input type="checkbox"/> 専業主婦・主夫 <input type="checkbox"/> 経営者／役員 <input type="checkbox"/> 正社員／正職員 <input type="checkbox"/> 自営業主／自由業者 <input type="checkbox"/> 派遣社員 <input type="checkbox"/> パート／アルバイト／契約 <input type="checkbox"/> 家族従業者 <input type="checkbox"/> 内職 <input type="checkbox"/> 学生 <input type="checkbox"/> その他（ ）	
仕事の内容 (1つのみ)	<input type="checkbox"/> 専門職／技術職 <input type="checkbox"/> 管理職 <input type="checkbox"/> 事務職 <input type="checkbox"/> 販売職 <input type="checkbox"/> サービス職 <input type="checkbox"/> 生産現場職／技能職 <input type="checkbox"/> 運輸／保安職 <input type="checkbox"/> その他（ ）	
過去一年間のあなた個人の収入はどれくらいですか。 (臨時収入，副収入も含めて)		差支えない範囲でお答えください 万円／年
あてはまるものがあれば <input checked="" type="checkbox"/>	<input type="checkbox"/> 年金・恩給 <input type="checkbox"/> 障害年金 <input type="checkbox"/> 生活保護 <input type="checkbox"/> 雇用保険（失業給付）	

## 問 12

あなたが糖尿病であることを話している方はいますか	<input type="checkbox"/> いない <input type="checkbox"/> いる（ <input type="checkbox"/> 家族 <input type="checkbox"/> 親せき <input type="checkbox"/> 友人 <input type="checkbox"/> 知り合い <input type="checkbox"/> 上司 <input type="checkbox"/> 同僚 <input type="checkbox"/> その他（ ）
--------------------------	--

質問は以上です。

長い時間ご協力いただき、ありがとうございました。

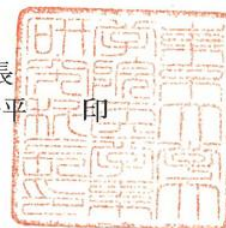
様式第2号

倫理委員会  
審査結果報告書

平成23年11月24日

申請者  
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審査番号 3629

研究課題 糖尿病患者の健康状態に影響を及ぼす心理的ストレスに関する研究

上記研究計画を平成23年11月21日の委員会で審査し下記のとおり判定しました。  
ここに通知します。

判定	<input type="radio"/> 承認する。 条件付きで承認する。 変更を勧告する。	<input type="radio"/> 承認しない。 該当しない。
条件あるいは変更勧告の理由（細則第3条第2項）		

## Appendix 6

**Pearson's correlation coefficients for the association between patient activation, self-stigma, and sociodemographic/ clinical variables (n=209)**

	Age	BMI	Diabetes Duration	Number of complications	HbA1c	Education	Size of households	PHQ-9	Self-efficacy	Self-stigma	Patient activation
Age	1.000	-	-	-	-	-	-	-	-	-	-
BMI	-.480**	1.000	-	-	-	-	-	-	-	-	-
Diabetes Duration	.420**	-.301**	1.000	-	-	-	-	-	-	-	-
Number of Complications	.213**	-.098	.320**	1.000	-	-	-	-	-	-	-
HbA1c	-.314**	.233**	-.073	.003	1.000	-	-	-	-	-	-
Education	-.090	.123*	-.207**	-.079	-.031	1.000	-	-	-	-	-
Size of households	-.019	.078	-.059	-.074	-.158*	.082	1.000	-	-	-	-
PHQ-9	-.078	.119	.071	.099	.207**	-.130	-.057	1.000	-	-	-
Self-efficacy	.164**	-.067	.049	-.026	-.100	.101	.013	-.418**	1.000	-	-
Self-stigma	-.094	.056	.125*	.160**	.168**	-.098	-.112	.388**	-.373**	1.000	-
Patient activation	.168**	-.240**	-.040	-.087	-.208**	.096	.036	-.301**	.343**	-.351**	1.000

\*  $P < .005$ . \*\*  $p < .001$ . BMI: body mass index. HbA1c: glycated hemoglobin. PHQ-9: Patient Health Questionnaire.



## Appendix 7

A multiple linear regression for self-stigma as the independent variable with patient activation scores as the dependent (n=209)

	Model	
	$R^2 = 0.23^*$	
	b	P values
Self-stigma	-0.35	< 0.001

Abbreviations:  $R^2$ : coefficient of determination; b: standardized partial regression coefficient.

\*  $p < 0.001$ .

† Sex (male), age (years), body mass index (kg/m<sup>2</sup>), diabetes duration (months), injectable therapy (yes), education (years), marital status (married), and size of households were adjusted as covariates.