

Development and validation of an educational program to enhance sense of coherence in patients with diabetes mellitus type 2

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ABSTRACT

This study aimed to develop a group education program that facilitates a sense of coherence among patients with type 2 diabetes mellitus, which was provided four times, and to validate the effect of the program among the patients. Researchers allocated 40 patients with type 2 diabetes, who had been admitted to a general hospital in Japan for diabetes education for two weeks. Twenty-one patients were allocated to the intervention group and 19 to the control group. The control group undertook a lecture-based educational program that the facility offered. The intervention group received the program, in addition to the facility's educational program. The sense of coherence scale and the Problem Areas in Diabetes Survey were used as evaluation indices. The average age of the intervention group was 59.1 years and that of the control group was 59.5 years. The intervention group showed a between-group effect of improvement in the sense of coherence score. Additionally, the intervention group showed a within-group effect of improvement in the sense of coherence score, as well as the comprehensibility and manageability scores, which are subdomains, and the Problem Areas in Diabetes Survey score. The within-group comparison showed a significant decrease in the early-morning FPG at both groups by an effect of treatment. The program suggested the possibility of improving the sense of coherence and the Problem Areas in Diabetes Survey. In order to enhance general use of the program, it is necessary to reach out to participating facilities and verify the effect of the program.

Keywords: type 2 diabetes, sense of coherence, lecture-based educational program, Problem Areas in Diabetes Survey

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INTRODUCTION

The total number of patients with diabetes in Japan is estimated to be about 9.5 million, as of 2012, which is an increase of 600,000 since 2007.¹⁾ The prevention of diabetes incidences and progression has become a national one.

Recently, the sense of coherence (SOC) has received attention, due to its relevance to the quality of life (QOL) of diabetes patients.²⁾ The sense of coherence is defined as “a global

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orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence" that the world is comprehensible, manageable, and meaningful.³⁾

In a study targeting cancer patients, a relationship between the degree of depression and SOC was reported.⁴⁾ In another study investigating patients after myocardial infarction, it was reported that the level of the SOC has an effect on aspects such as frequency of angina attacks and physical activity.⁵⁾ Particularly, previous studies have reported that the severity of diabetes patients' condition and the extent of their self-care activities are related to SOC; and that hemoglobin A1c (HbA1c), an indicator of blood glucose control, and SOC are indirectly mediated by the severity of the condition and the extent of self-care activities.⁶⁾ Other previous research has been on the relationship between the burden of diabetes and SOC⁷⁾ and between fears regarding low blood glucose and SOC.⁸⁾ The SOC of type 2 diabetes patients has also been found to be lower than that of patients with surgical diseases.⁹⁾ However, the SOC of diabetes patients is related to support by nurses.¹⁰⁾ Therefore, nurses' provision of support for improvement of diabetes patients' SOC may be positively related to improvement of patients' lifestyle habits and negatively related to the burdens associated with diabetes.

Below are some reports on intervention studies that have emphasized the importance of SOC. Haoka *et al.*¹¹⁾ reported improvement in SOC due to a rehabilitation program provided to patients with depression, aimed at facilitating their return to work. The intervention sessions entailed group therapy at a hospital 3–5 times a week and were conducted until doctors' and employers' evaluations affirmed that the patients could return to work. Langeland *et al.*¹²⁾ reported improvement in SOC as a result of a program provided to mentally challenged patients, in improving their ability to handle psychological problems, based on salutogenic treatment principles. The intervention was provided for one and a half hours, 16 times, during weekend meetings over 19 weeks, to encourage participants' self-reflection. The studies discussed below have verified the effect of nurses' intervention. Forsberg, Björkman, Sandman, and Sandlund¹³⁾ reported improvement in SOC after exposing mentally challenged patients to an intervention program aimed at improving lifestyle habits. In this program, nurses provided dietary and physical activity sessions by taking turns every week for a year. Delbar and Benor¹⁴⁾ reported improvement of SOC due to an intervention controlling for the conditions of cancer patients, who were taking either radiology or chemotherapy. The intervention was conducted twice a week (two hours per session) for three months, at the patients' homes. As stated above, some studies verified the effect of programs in enhancing SOC, but these were few. Moreover, no intervention study has been conducted on patients with diabetes.

This study provided an education program seeking to instill SOC among patients with type 2 diabetes mellitus (EPSOC-2DM), aged ≥ 20 years, who had been admitted to a general hospital. The program aimed to impart diabetes education and enhance SOC, with a focus on reducing the burden caused by diabetes. This study aimed to determine the effect of the EPSOC-2DM among patients with type 2 diabetes, who had been admitted so as to receive diabetes education. The study's hypothesis was that the group receiving the EPSOC-2DM intervention would show higher SOC, as compared to the control group. The SOC scale was used as a primary evaluation index. The Problem Areas in Diabetes Survey (PAID) and early-morning FPG were used as a secondary evaluation index, to evaluate the psychological burden of the diabetes patients.

MATERIALS AND METHODS

Subjects

Subjects were 40 patients with type 2 diabetes, who had been admitted to a general hospital

in Japan for diabetes education for two weeks. The selection criteria were patients with type 2 diabetes, aged ≥ 20 years, who were admitted to the hospital for diabetes education. Exclusions applied to patients: (1) who were pregnant, (2) with dementia or low cognitive ability, (3) with severe psychiatric diseases and with learning problems, (4) who had vision loss and could not complete questionnaires, and (5) who had auditory disabilities and could not hear explanations.

Interventions

The EPSOC-2DM was developed by integrating the qualitative analysis results of previous studies' interventions that were aimed at enhancing SOC,¹⁵⁾ with those of nursing support recognized as enhancing SOC.¹⁶⁾ The EPSOC-2DM comprised four, 30-minute group sessions and was delivered by nurses who had at least three years of experience with diabetes patients. The specific types of support were as follows: The educational goal of the first session included: (1) promoting mutual understanding among participants, (2) sharing feelings during care, and (3) understanding the meaning of enhancing SOC. The educational content of the first session covered: (1) feeling burdened by the disease and treatment, (2) how patients have managed their diabetes, to date, (3) what patients learned after diabetes diagnoses, and (4) SOC. The educational method was aimed at facilitating: (1) communication, (2) discussing, and (3) listening to the explanation. The educational goal of the second session was for patients to reflect on their lives until the point when they became sick. The educational content of the second session covered such reflections, treatments, and actions. The educational method entailed: (1) patients' communication of their reflections on life up to now and (2) sharing their feelings and opinions after listening to someone talking. The educational goal of the third session was to identify problems in life and points for improvement. The educational content of the third session was for participants to become aware of the problems that they recognized while looking back on their lives, how to manage their disease, and find the solutions. The educational method included communicating what they found while looking back at their lives to date, and conveying their feelings and opinions after listening to other participants. The educational goal of the fourth session was to discover solutions to potential problems. The educational content of this session covered potential problems and concerns. The educational method entailed getting participants to: (1) communicate their ideas and (2) discuss what might happen.

Textbooks were used for each session. In the first session, materials were used to facilitate an understanding of SOC and its subdomains, namely, comprehensibility, manageability, and meaningfulness, and the scales relating to these concepts in detail. In the second and third sessions, once the process of becoming sick had been reflected upon from a viewpoint of SOC, the participants were expected to find the meaning of current treatments and recovery activities. We created materials called "life reflection sheets" for that purpose. This was intended for patients to recall the past/present "facts" and determine prospects for the future by filling in the blanks and checking off boxes regarding transformations in their lives, from the past to the present, as well as future prospects, based on this life change. Patients could prepare for each session, since they could recall the past and present life facts by filling in the sheets.

Measurement instruments

The Japanese version of the SOC scale, with 13 items on a 7-point scale,¹⁷⁾ was used as the main evaluation index. Reliability and validity have been verified for the Japanese version.¹⁸⁾ Five items pertained to comprehensibility, four were on manageability, and four others on meaningfulness. The higher the rating on the scale, the higher a given participant's SOC. The questionnaire was used with the permission of the copyright holder. The Japanese version of the PAID¹⁹⁾ was used as a secondary evaluation index. Reliability and validity have been verified

for the Japanese version.²⁰⁾ This scale consists of 20 items relating to the burdens associated with diabetes. The higher the total score, the greater the burden felt by a patient as a result of diabetes. Each item was scored on a five-point scale (range: 20–100). The higher the rating, the more the psychological burden imposed on the patient.

Data collection

Patients who were admitted to the target facility were requested to participate in the study. First, upon outpatient doctors' determination that patients should be admitted to the hospital for education, they also distributed flyers stating that the EPSOC-2DM was being conducted, following patients' admission. Next, admitted patients with type 2 diabetes, who met the inclusion criteria, were introduced by the chief ward nurse and were informed of the study overview and ethical considerations, according to the study instructions. Patients who agreed to participate on the consent form became the study subjects. Data were collected through self-administered questionnaires after participants' admission and before discharge. Questionnaires were distributed and collected directly by the researcher. The allocation of subjects was determined by the admission period. Patients who were admitted prior to the commencement of the EPSOC-2DM were allocated to the control group. Once data collection for the control group was complete, admitted patients were allocated to the intervention group. The intervention group received the EPSOC-2DM, in addition to the lecture-based educational program that the facility provided. The EPSOC-2DM was provided in the first week, and two to four times in the second week. The control group received only the educational programs offered by the facility. The program offered by the facility was mainly lectures concerning diabetes by doctors, nurses, and nutritionists. The effect of the short-term intervention provided by the EPSOC-2DM was measured before and after the two-week educational admission.

Sample size

The sample size was set at about 20 for both the intervention and control groups. The calculation of the sample size was as follows. It required standardization for significance level, detection ability, differences between the groups, standard deviation, and the ratio of the number of people in the intervention group and the control group.²¹⁾ In this study, the standard significance level was set at 5%, and the detection ability at 80%. The difference in SOC between the groups was set at 9 points, in reference to previous studies.¹³⁾ The average value of the control group was 57.2.¹³⁾ The standard deviation was set at 10, as per previous studies.^{9,22)} The ratio of the intervention group size to the control group size was set at 1:1.

Statistical analysis

In order to evaluate the effect of the EPSOC-2DM, intention to treat analysis was used. As a comparison between the groups, two-way analysis of covariance, which adjusted the baseline value, was conducted. A paired t-test was used for within-group comparisons. Within-group comparisons represent the differences in scores before and after education by EPSOC-2DM in each group. Basic characteristics, SOC scores, and PAID scores of the intervention group and the control group in the baseline were confirmed through the unpaired t-test and the chi-square test. The significance level was set at $p < .05$. Statistical analysis was carried out using the Japanese version of IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA).

Ethical considerations

Participants received an explanation of the study objectives and methods verbally and in writing. Upon agreeing to participate, participants signed the consent form and kept one copy

thereof for their reference. The study complied with the Declaration of Helsinki, with regard to confidentiality and data management.²³⁾ Participants were also informed that they could withdraw from the study at any time, and that they could withdraw participation or cooperation without penalty. The clinical research review committee of the author's institution approved of the study.

RESULTS

Study subjects & baseline characteristics

Fig. 1 shows the results of allocation of the participants. Forty-eight patients who were admitted to the education program were requested to participate in the study. Six people declined, and 42 agreed to participate. Twenty-one patients who were admitted from April 24, 2015 to August 4, 2015 and consented to participate in the study were allocated to the control group. Another 21 patients, who were admitted from August 5, 2015 to January 19, 2016 and consented to participate in the study, were allocated to the intervention group. The analysis was conducted among 21 patients in the intervention group and 19 patients in the control group, excluding two who could not follow up. The intervention group received the EPSOC-2DM four times, in total.

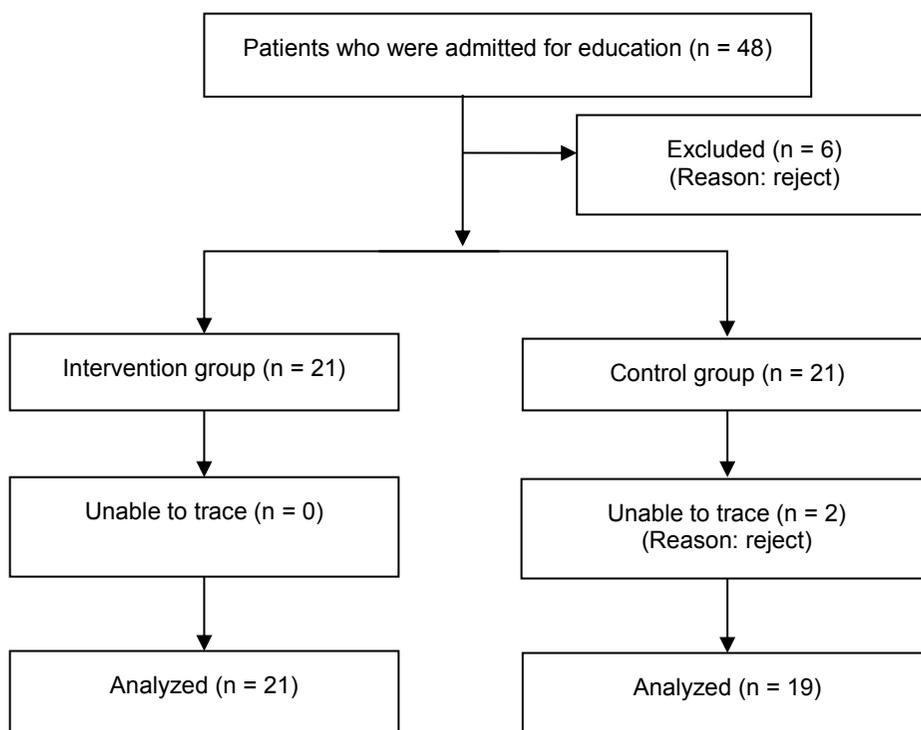


Fig. 1 Allocation of the Participants

Forty-eight patients who were admitted to the education program were requested to participate in the study. Six people declined, and 42 agreed to participate. Twenty-one patients who were admitted and consented to participate in the study were allocated to the control group. Another 21 patients were allocated to the intervention group. The analysis was conducted among 21 patients in the intervention group and 19 patients in the control group, excluding two who could not follow up.

Sixteen patients (76.2%) participated in all four sessions, 4 patients (19.0%) in three sessions, and one patient (4.8%) in two sessions.

Table 1 shows a comparison of the characteristics of the intervention group and the control group. The mean age of the male participants in the intervention group was 59.1 ± 14.2 years,

Table 1 A comparison of the intervention and control groups' characteristics

		Intervention group (n = 21)	Control group (n = 19)	p-value
Age		59.1±14.2	59.5±12.4	.429
Gender	Male	9 (42.9)	9 (47.4)	.775
	Female	12 (57.1)	10 (52.6)	
Profession	Yes	19 (85.7)	12 (63.2)	.148
	No	3 (14.3)	7 (36.8)	
BMI ^a		28.8±8.1	25.7±4.3	.147
Duration of disease (in years)		4.7±8.0	10.4±10.6	.061
Early-morning FPG ^a		165.1±48.3	194.9±83.7	.185
HbA1c (NGSP-value) ^a		9.51±3.00	9.94±2.34	.621
Anti-diabetes drug	Yes	13 (61.9)	19 (100.0)	.004
	No	8 (38.1)	0 (0.0)	
Type of drug (Multiple answer)	Oral	12 (92.3)	17 (89.5)	
	Insulin	4 (30.8)	6 (31.6)	
	Other	0 (0.0)	1 (5.0)	
Complications	Yes	4 (19.0)	6 (31.6)	.473
	No	17 (81.0)	13 (68.4)	
Types of complications (Multiple answer)	Retinopathy	2 (50.0)	6 (100.0)	
	Nephropathy	2 (50.0)	3 (50.0)	
	Nerve disorder	1 (25.0)	4 (66.7)	
Disease besides diabetes	Yes	11 (52.4)	9 (47.4)	.752
	No	10 (47.6)	10 (52.6)	
Number of past admissions for education ^a		0.4±1.1	1.2±2.7	.223
Sense of coherence (SOC) score ^a		59.5±13.8	64.4±8.6	.177
Comprehensibility score ^a		22.9±5.4	23.7±3.4	.561
Manageability score ^a		18.4±4.8	18.8±3.6	.761
Meaningfulness score ^a		18.1±5.1	21.8±3.5	.012
PAID score ^a		49.0±12.3	47.9±11.0	.778

Note. Number appearing in the table shows n (%) or average value = standard deviation.

BMI body mass index, HbA1c

χ^2 -test. ^aunpaired t-test.

and that of those in the control group was 59.5 ± 12.4 years. There were 9 men (42.9%) in the intervention group, and 9 men (47.4%) in the control group. The average HbA1c was $9.51 \pm 3.00\%$ in the intervention group and $9.94 \pm 2.34\%$ in the control group. Nineteen (85.7%) of the participants in the intervention group were employed, and 12 (63.2%) of those in the control group were employed. The mean BMI of participants in the intervention group was 28.8 ± 8.1 , and that of participants in the control group was 25.7 ± 4.3 . The mean disease duration was 4.7 ± 8.0 years in the intervention group and 10.4 ± 10.6 years in the control group. Thirteen (61.9%) in the intervention group used anti-diabetes drugs, whereas 19 (100.0%) in the control group did. Four participants (19.0%) in the intervention group had complications, whereas 6 (31.6%) in the control group did. The duration of past admissions for education was 0.4 ± 1.1 years for the intervention group, and 1.2 ± 2.7 years for the control group.

There were no significant differences in terms of age, gender, profession, early-morning FPG (fasting plasma glucose), HbA1c, and the existence or absence of complications. There was, however, significant differences with regard to use of anti-diabetes drugs ($p < .01$) and the meaningfulness score ($p < .05$).

Outcome in intervention

Table 2 shows a comparison between the groups at two points, at admission and before discharge. Between-group comparisons showed significant change in SOC scores ($p < .05$), but no significant changes in SOC subdomain scale scores, or PAID scores, or early-morning FPG, based on the two-way analysis of covariance results, with the baseline value adjusted. With regard to within-group comparisons (Table 3), t-test results showed significant improvement in

Table 2 Evaluation index and change before and after intervention (between-group comparisons)

Evaluation index	Intervention group (n = 21)	Control group (n = 19)	F-value	p-value
SOC				
Admission	59.5±13.8	64.4±8.6	4.26	.047
Discharge	63.0±12.9	64.0±10.0		
Comprehensibility score				
Admission	22.9±5.4	23.7±3.4	2.34	.136
Discharge	24.3±4.9	23.6±5.0		
Manageability score				
Admission	18.4±4.8	18.8±3.6	3.29	.079
Discharge	19.9±4.1	19.4±4.0		
Meaningfulness score				
Admission	18.1±5.1	21.8±3.5	3.74	.062
Discharge	18.8±5.2	21.0±3.4		
PAID-scale score				
Admission	49.0±12.3	47.9±11.0	.096	.758
Discharge	43.5±13.9	43.9±15.0		
Early-morning FPG				
Admission	165.1±48.3	194.9±83.7	.028	.867
Discharge	125.8±21.7	113.2±20.6		

Note. Number appearing in the table shows the average value = standard deviation.

Table 3 Evaluation index and change before and after intervention (within-group comparisons)

Evaluation index	Intervention group (n = 21)		Paired t-test	Effect level	Control group (n = 19)		Paired t-test	Effect level
	Admission	Discharge	p-value	Cohen's <i>d</i>	Admission	Discharge	p-value	Cohen's <i>d</i>
SOC	59.5± 13.8	63.0± 12.9	.002	.262	64.4± 8.6	64.0± 10.0	.829	.043
Comprehensibility score	22.9± 5.4	24.3± 4.9	.005	.271	23.7± 3.4	23.6± 5.0	.923	.023
Manageability score	18.4± 4.8	19.9± 4.1	.001	.336	18.8± 3.6	19.4± 4.0	.505	.158
Meaningfulness score	18.1± 5.1	18.8± 5.2	.239	.136	21.8± 3.5	21.0± 3.4	.119	.232
PAID-scale score	49.0± 12.3	43.5± 13.9	.036	.419	47.9± 11.0	43.9± 15.0	.173	.304
Early-morning FPG	165.1± 48.3	125.8± 21.7	.002	1.05	194.9± 83.7	113.2± 20.6	<.001	1.34

Note. Number appearing in the table shows the average value = standard deviation.

SOC scores ($p < .01$) and PAID scores ($p < .05$) among patients in the intervention group, compared to the baseline point. Early-morning FPG was significantly improved in both group. The SOC subdomain scores indicated improvement in comprehensibility and manageability ($p < .01$). There were no significant improvements among patients in the control group, compared to the baseline point.

DISCUSSION

Patient characteristics

The mean age for both the intervention and control group was approximately 60 years. There were more women than men and approximately 20–30% of the participants had diabetes complications. Moreover, 85.7% of the intervention group and 63.2% of the control group were employed. Based on the age range, it was presumed that many of the patients were in the late middle-age group, and had professional responsibilities.

The participants in the intervention group had had diabetes for approximately five years, whereas those in the control group had had it for approximately 10 years. The control group participants tended to have longer diabetes histories, but there was no significant difference between the groups, in this regard. With regard to FPG, patients in the control group tended to have unfavorable glucose control, but there was no significant difference between the groups. The treatment mode for 61.9% of patients in the intervention group was anti-diabetes drugs, and this was so for all patients in the control group. Many patients in the control group were taking anti-diabetes drugs. Of patients using anti-diabetes drugs, approximately 90% used oral medicine, and approximately 30% used insulin. Both groups predominantly used oral medicine. Moreover, both groups had more or less one previous experience of being admitted to the hospital for education, on average. Many of them were being admitted for the first time. The BMI was the average value that warranted assessment for obesity. Therefore, it can be said that

the group in this study had unfavorable glucose control, required glucose control during drug therapy, was inclined to be obese, but did not have abundant experience of being admitted for diabetes education.

The ratio of the presence of complications was half or less for both groups. In addition, retinopathy and nephropathy caused more than half of the complications. Therefore, it could be concluded that the group in this study did not have many complications, although some showed noticeable complications.

The intervention group had similar SOC scores to those of average Japanese people.²⁴⁾ In the current study, the SOC scores of the control group were likely to be higher. The meaningfulness scores, SOC subdomain scores, were significantly low in the intervention group, compared to the control group. However, we could not propose a justification for the high score on meaningfulness, obtained by the control group.

The PAID scores were higher than those reported in previous studies (41.2 ± 15.4).²⁰⁾ Accordingly, it was presumed that the overall sample in this study was inclined to experience a higher burden as a result of diabetes.

As shown above, the group in this study showed significant differences only in terms of educational background, use or non-use of medication, and meaningfulness between the intervention group and the control group at the baseline point. Therefore, the allocation can be considered equivalent, overall.

Primary outcome in the intervention group

Significant difference was observed for SOC in the between-group comparison. In a previous study, it was shown that SOC and cancer-associated symptoms improved after interventions to control cancer patient symptoms receiving radiotherapy or chemotherapy, with the intervention conducted twice a week for 2 hours each session for 3 months.¹⁴⁾ EPSOC-2DM consisted of 4 sessions in total, 30 minutes each and we were able to confirm its effect on improving SOC using fewer intervention sessions with less time compared to previous studies. In addition, with regard to the within-group comparisons before and after the intervention, the intervention group showed improved SOC scores. Further, the subdomain scales showed no significant change in meaningfulness, but the comprehensibility and manageability scores improved significantly. On the other hand, the control group showed no significant change in either SOC or subdomain scale scores. Therefore, we were able to confirm a certain level of effect due to the intervention. This warrants an examination of the program content and intervention effect, based on the within-group comparison of scores on the subdomain scales of the SOC.

To enhance comprehensibility, during the first two sessions, patients' preparation statuses were checked and they were encouraged to understand the concept of SOC and the scales before reflecting on their lives, as per the reflection sheet. With this support, since patients were encouraged to commit themselves to the EPSOC-2DM itself, the significance of reflection on their lives, which led to the disease, was reinforced. With regard to enhancing manageability, in the third and fourth sessions, participants tried to identify their current problems and discussed how to overcome future ones. These approaches were considered effective, since they helped patients recognize problems in their own lives. Previous studies reported that external interventions such as family members and friends or reflection on internal resources such as a sense of value and assertions helped enhance comprehensibility, manageability, and meaningfulness.²⁵⁾ The EPSOC-2DM provides an opportunity to patients who can reconfirm or discover internal and external resources that can be useful for reflections on their own lives leading to the disease, recognizing their current problems, and discussing ways of overcoming potential problems. It is presumed that these processes could help improve comprehensibility and manageability. As a means of

enhancing meaningfulness, in the first session, patients were encouraged to disclose and share their feelings and burdens relating to the disease and treatment with other patients. In the second session through to the fourth session, the meaningfulness of self-control and recovery actions was induced through patients' appreciation of their commitment more than that of others. This was done through communication of their positive efforts to other patients, enhancement of their treatment incentives, and sharing their feelings and opinions after listening to other participants' stories. However, no significant improvement in meaningfulness scores was confirmed as a result of this program. This may be because, although the support content aimed at enhancing meaningfulness is reported "to induce the meaningfulness of self-control" and "to involve so that the patients can find the meaning of the recovery actions,"¹⁶⁾ these were not fully incorporated into the educational content in this study. Moreover, previous studies include one in which a psychiatrist used cognitive therapy to enhance SOC.¹¹⁾ The current intervention entails support, to enhance meaningfulness. Therefore, the possibility of enhancing meaningfulness through the incorporation of cognitive therapy, provided by a specialist, is considered. Furthermore, there were a few participants per group in the EPSOC-2DM, with two to three per group. Therefore, there is a possibility that the group dynamics did not function fully. Therefore, we have to examine how to operate, including increasing the number per group, in order to improve meaningfulness in future.

Secondary outcome in intervention

There was no significant difference in the PAID scores in the between-group comparison, but the within-group comparison showed a significant decrease in the PAID scores. The EPSOC-2DM is a program aiming to directly improve SOC. At the same time, the intervention content espoused specific commitment to the educational goals of reflecting on one's life, leading up to the disease, recognizing the problems and points to be improved in one's life, and finding solutions to potential problems, while facilitating mutual understanding with other participants. We presume that these were connected to the alleviation of participants' psychological burden.

There was significant difference in the early-morning FPG in the between-group comparison, and the within-group comparison showed a significant decrease in the early-morning FPG at both groups. It was considered to be a large effect of treatment.

Implications

In this study, the effect of the educational program delivered to the SOC was validated. As a result, it was concluded that the EPSOC-2DM improves SOC and the subdomains, comprehensibility, and manageability, as well as the psychological burden caused by diabetes. However, in order to achieve improvement in one of the SOC's subdomains, namely, meaningfulness, it may be necessary to set the educational content required to improve meaningfulness (e.g., the meaningfulness of self-control) and to increase the number of participants, to maximize chances of the group achieving the effect of the EPSOC-2DM.

There were several limitations of the study. First, the intervention effect was demonstrated among patients at one facility and in one ward only. Second, the study method did not entail complete randomization. Although allocation was equivalent, overall, with no significant differences between the intervention group and the control group, it can still not be said that biases due to differences between the characteristics were fully controlled for. Based on the study results, there is a limit to the general applicability of the content for all patients with type 2 diabetes. Therefore, it is necessary to expand the target facilities, in order to verify the effect of the EPSOC-2DM. For long-term effects of EPSOC-2DM, it is necessary to investigate the changes in SOC and PAID together with whether there has been a decrease in the number of

educational hospitalizations.

CONCLUSION

In this study, the EPSOC-2DM, comprising four sessions, was developed and its enhancement of the SOC of patients with type 2 diabetes was validated. As a result, the EPSOC-2DM showed the possibility of improvement in SOC and the subdomains, comprehensibility and manageability, in addition to the within-group effects of psychological burden caused by diabetes. Accordingly, the content of the EPSOC-2DM was reasonable, overall. On the other hand, since no improvement was observed for meaningfulness, it was assumed that it would be necessary to modify the educational content, to improve meaningfulness. This could include the incorporation of the meaningfulness of self-control and of operational arrangements, such as increasing the number of participants in the group.

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AUTHOR DISCLOSURE STATEMENT

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