ORIGINAL ARTICLE

A periodontal disease care program for patients with type 2 diabetes: A randomized controlled trial

Utako Nishihara RN, PhD[1,2] | Nozomi Tanabe DH[2] | Takehiro Nakamura MD, PhD[3] | Yuko Okada MD, PhD[4] | Tetsuya Nishida DDS, PhD[5] | Shiho Akihara RN, PHN, PhD[1]

[1]Graduate School of Nursing, Osaka City University, Osaka, Japan

[2]Department of Nursing, Kobe City Hospital Organization Kobe City Medical Center West Hospital, Kobe, Japan

[3]Division of Diabetes, Kobe City Hospital Organization Kobe City Medical Center West Hospital, Kobe, Japan

[4]Division of Diabetes and Endocrinology Internal Medicine, Kobe University Graduate School of Medicine, Kobe, Japan

[5]Department of Dentistry Oral and Maxillofacial Surgery, Kobe City Hospital Organization Kobe City Medical Center West Hospital, Kobe, Japan

Correspondence
Utako Nishihara, School of Nursing, Osaka City University, Osaka, Japan.
Email: uta.sakura.pinkuiro@gmail.com

Abstract

Background: Diabetes and periodontitis are interrelated, and patient education and guidance are important. Therefore, we conducted a periodontitis care program for patients with type 2 diabetes to provide education about diabetes and periodontitis and to promote self-care skills, and we evaluated the effectiveness of this program.

Methods: This was a randomized controlled trial. Thirty-eight and 39 adult patients diagnosed with type 2 diabetes were allocated to the intervention and control groups, respectively. The program comprised content that promoted optimal behavior for the improvement of diabetes and periodontitis. Periodontitis status, diabetes status, tumor necrosis factor-α levels, self-efficacy in relation to periodontitis, and teeth-brushing behaviors were evaluated before and after the intervention program.

Results: After the intervention program, the intervention group demonstrated significant improvements in bleeding on probing, which was used to evaluate periodontitis status (F=7.919; P<.01), and in clinic visit (F=11.765; P<.01), brushing teeth (F=21.606; P<.01), and meal (F=10.884; P<.01) scores on the Self-Efficacy Scale for Self-care among Periodontal Disease Patients; patients in the intervention group also exhibited improvements in dental health-related behaviors (F=7.141; P<.01).

Conclusions: These results suggest that the intervention program was effective at improving periodontitis, self-efficacy in relation to periodontitis, and dental health-related behaviors in patients with type 2 diabetes.

KEYWORDS
care guideline program, periodontal disease, type 2 diabetes

1 | INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by chronic hyperglycemia caused by insulin deficiency.[1] Periodontal disease is a chronic inflammation caused by plaque.[2] While the pathologies underlying these diseases differ, periodontal disease can be triggered by a bacterial infection caused by diabetes compromising the immune system, and the ways in which periodontal disease

and glycemic control interact have been clarified.[3] Bacterial infection secondary to diabetes leads to periodontal disease, and chronic inflammation caused by periodontal disease worsens glycemic control. Hence, diabetes is considered a risk factor for periodontal disease,[4,5] and periodontal disease is a risk factor for diabetes progression.[6]

In a previous report, the treatment of periodontal disease in patients with type 2 diabetes resulted in a statistically significant change in glycated hemoglobin (HbA1c) levels, with a weighted mean

difference of −0.4% compared with pre-treatment levels.[7] Other reports have described the effects of the treatment of periodontal disease; treatment results in reductions in the concentrations of tumor necrosis factor (TNF)-α, which causes insulin resistance, within the bloodstream and within periodontal tissue.[8,9] Furthermore, noticeable improvements in glycemic control following the topical application of antibiotics to patients with both type 2 diabetes and periodontal disease have been described.[8,10] These findings suggest that the treatment of periodontal disease improves both periodontal disease and glycemic control in patients with type 2 diabetes.

To improve periodontal disease, it is important to treat and manage the disease. In terms of periodontal care, it has been proven that self-care by patients, which includes brushing the teeth and being aware of the mouth's condition, is effective.[11-13] Hence, we think that it is necessary to educate and guide patients with diabetes about self-care in relation to periodontal disease. In recent years, patients with type 2 diabetes who were provided with interventional education about caring for periodontal disease, including information on "how to brush teeth carefully," "how to perform oral care," and "how to eat well," demonstrated improvements in their brushing habits,[14-16] periodontal disease,[14-18] and diabetes.[14-16] However, as far as we are aware, no valid studies have been conducted in Japan to investigate the effectiveness of educational intervention for type 2 diabetics and periodontal care. Therefore, it is necessary to consider how such an educational intervention could be delivered to prevent periodontal disease and to improve diabetes control.

This study aimed to provide a periodontal disease care program to patients with type 2 diabetes and to evaluate its effectiveness.

2 | MATERIALS AND METHODS

2.1 | Trial design

This nonblinded randomized controlled trial study was conducted at a general hospital. We inserted 40 cards into envelopes for each of the intervention and control groups and drew a card every time we chose a participant. The researcher randomly allocated the participants to the intervention and control groups in a nonmasking process.

2.2 | Interventions

We created a 120-minutes program to be conducted by a nurse or the intervention group that spanned 6 months and was presented in four sessions, with 6-8 week intervals between each session. In addition to the information and guidance about treatment that patients routinely receive from the diabetes clinic, the Oral and Maxillofacial Surgery (OMS) Department, and the standard dental health instructions from the dental hygienists, the intervention group received information about the relationship between diabetes and periodontal disease, and was taught how to administer self-care for their periodontal disease. The program was conducted from May 2013 to July 2014.

We assessed the patients' self-care habits and routines at the first education, including how and how often they brushed their teeth, and what, when, and how often they ate. Then, we presented brochures to the subjects, including those titled "About Diabetes and Periodontal Disease," "What is Periodontal Disease?", "The Need for Oral Care," "Timing of Oral Care and Meals," "The Need for Regular Checkups at the Dentist," and "The How to Guide on Oral Care", and we explained the content of each brochure to them. After explaining the content of the brochure called "The How to Guide on Oral Care," we used model teeth and a toothbrush to demonstrate how teeth should be brushed. Subsequently, we worked with subjects to develop goals to achieve before the next self-care session (Table 1, Program 1).

At the second, third, and fourth education sessions, we again assessed the participants' self-care habits and routines. We counseled the participants about self-care and discussed how to overcome the challenges posed by self-care and the areas that required improvement. During the third session, we showed the participants the results and performed a 3-month dental check-up (Table 1, Program 2).

The participants in the control group underwent diabetes checks at the clinic and received guidance about treatment, which they would receive routinely. The control participants also underwent examinations at the OMS Department, along with routine dental health instruction.

2.3 | Participants

The participants were selected from adult outpatients who were receiving care for type 2 diabetes, who were diagnosed with periodontal disease, but not dementia, at the OMS Department, and who were deemed capable of administering self-care. The inclusion criteria were as follows: HbA1c levels of 6.5-10% with fluctuations of ≤ ±1.0% along with stable diabetes status, regardless of medication changes, 9-15 weeks before registration for study participation; nonedentulous status; and presence of mild-to-moderate periodontal disease that did not require treatment with antibiotics. The exclusion criteria were concurrent conditions that could influence the diabetic condition (eg, cancer), steroid use, and diseases that required surgery that would create external wounds. The exclusion criteria also included changes in medications as well as administration of antibiotics after registration.

2.4 | End-points and assessments

The primary end-points were improvements in the participants' brushing habits and periodontal disease 6 months after the program was completed. To evaluate the participants' periodontal disease, the dental hygienist tested for bleeding on probing (BOP) $\left(\frac{\text{the number of pockets of 4 mm and more}}{\text{the number of teeth} \times 6} \times 100 \right)$ and probing pocket depth (PPD) $\left(\frac{\text{the number of bled points}}{\text{the number of teeth} \times 6} \times 100 \right)$ using a six-point measurement method. The tests baseline and at 6 months were conducted by the same dental hygienist blinded to the patient data.

TABLE 1 Program protocol

Occasion	Contents	Method
Program 1 The first session (30 min	Self-care activities (including how and how often they brushed their teeth, and what, when, and how often they ate)	Interview
	"About diabetes and periodontal disease" "What is periodontal disease?" "The need for oral care" "The Need for Regular Checkups at the Dentist"	Lecture with brochure
	"How to perform oral care"	We use model teeth and a toothbrush
	Make "self-care goal plans"	Make plans together with participants (patients make plans by the next session)
Program 2 Total of 3 education sessions every 6-8 week 30 min each, after the first session	Self-care activities (including how and how often they brushed their teeth, and what, when, and how often they ate)	Interview
	"Review self-care goal" "What they succeed" "What problems they had" "How they improved" "The result of dental checkup"	Counseling
	"Make "self-care goal plans"	Make plans together with participants (patients make plans by the next session)

To evaluate the treatment activities related to periodontal disease, including brushing habits, we asked the patients to complete self-administered questionnaires, namely, the Self-Efficacy Scale for Self-care (SESS) among Periodontal Disease Patients [19] and the Hiroshima University Dental Behavioral Inventory (HU-DBI).[20]

The SESS among Periodontal Disease Patients has been validated for use in Japan. It is recognized as having a significant correlation and concurrent validity with the general self-efficacy scale. The questionnaire comprises three items categorized under the "Clinic Visit Score," "Brushing Teeth Score," and "Meal Score," and it uses a five-level Likert scale that ranges from "I can definitely do it" to "I definitely cannot do it." Each category has a maximum score of 25 points, and higher scores are indicative of self-efficacy. The HU-DBI is used domestically and internationally and has 20 items that mainly focus on tooth-brushing habits. The questions require "Yes" or "No" dichotomous responses, 12 is the highest score that can be obtained, and higher scores indicate better attention and care given to dental health.

The secondary end-points were improvements in the participants' chronic inflammation levels and type 2 diabetes. To evaluate the level of chronic inflammation, TNF-α levels were measured in blood samples taken at the time of diabetes evaluations. TNF-α levels were measured by SRL Inc. (Tokyo, Japan).

To evaluate the participants' diabetes, HbA1c levels were measured when the patients visited the diabetes clinic.

2.5 | Statistical analysis

The sample size was determined using G*Power 3.1.9.2, the F test ANOVA option with repeated measures, and the within-between interaction test (effect size: 0.25; α error probability: 0.05; power [1-B error probability]: 0.80; number of groups: 2; number of measurements: 2; correlation between the levels of the repeated measures: 0; and nonsphericity correction: 1);66 samples were required, comprising 33 samples for the intervention group and 33 samples for the control group.

To compare the characteristics of the subjects in each group at baseline, we used the chi-square test or Fisher's exact test for the nominal scale, and we used either the unpaired t test or the Mann-Whitney U test for the ordinal scale and interval scale, after testing the validity of the data using the Shapiro-Wilk test.

To evaluate the effectiveness of the 6-month intervention program, periodontal disease status, active engagement in the treatment of periodontal disease, diabetes status, and chronic inflammation status were examined, and we compared parameters between the intervention group and the control group. This was achieved by scrutinizing the independent variables within the parallel groups (ie, those who were receiving or not receiving the intervention, baseline versus 6 months), by examining the dependent variables (periodontal disease status, active engagement in the treatment of periodontal disease, diabetes status, and chronic inflammation status), and by undertaking a mixed design two-way analysis of variance. When differences were observed between the parallel groups at baseline, we took into consideration the effects of the initial values on the results, and to test the effectiveness of the intervention program after 6 months, we conducted an analysis of covariance. The independent variables were receiving or not receiving the intervention, and the dependent variables were the levels of change in the evaluation index values after 6 months compared with the baseline index values; for the covariates,

we used the baseline evaluation index values. Statistical analyses were performed using IBM®SPSS® software version 22 (IBM Corporation, Armonk, NY, USA), and we set the significance level at 5%.

2.6 | Ethical considerations

This study was approved by the ethics committee at each researcher's university (No.24-8-2) and from the facilities providing research assistance. Participants were fully informed regarding the purposes, duration, methods, confidentiality, benefits, risks of the study, and the option of voluntary participation, and written informed consent was obtained from all participants. For participants who were assigned to the control group, we offered the periodontal disease care program after the 6-month study period, if they wished.

3 | RESULTS

3.1 | Participant flow

Seventy-seven subjects participated in the study. Six months after the study began, two of 38 people in the intervention group and 10 of 39 people in the control group dropped out. The remaining 36 individuals in the intervention group and 29 individuals in the control group were included in the analysis, and they were continuously evaluated for 6 months (Figure 1).

3.2 | Participants' characteristics

Table 2 presents a comparison of the participants' characteristics. The mean (standard deviation [SD]) age of the intervention group was 65.3 (10.1) years, and the mean (SD) age of the control group was 66.1 (8.9) years. The proportions of subjects aged 65 years or older were 60% or more in the intervention group and 55% or more in the control group. The mean (SD) HbA1c values were 7.3% (0.6%) in the intervention group and 7.3% (0.7%) in the control group. In both groups, about half of the subjects had HbA1c levels at around 7%. The BOP testing used to determine the periodontal disease state showed that 26.2% (22.8%) of the participants in the intervention group and 16.2% (16.3%) of the participants in the control group had BOP. The mean (SD) PPDs were 56.4% (37.8%) in the intervention group and 37.8% (30.9%) in the control group. Regarding scores from the SESS among Periodontal Disease Patients questionnaire, the mean (SD) clinic visit scores were 20.1 (4.2) points for the intervention group and 21.0 (3.3) points for the control group. The mean (SD) brushing teeth scores were 18.2 (3.4) points for the intervention group and 18.5 (4.3) points for the control group. The mean (SD) meal scores were 19.1 (3.8) points for the intervention group and 18.5 (4.5) points for the control group. Both groups showed the highest self-efficacy in relation to the clinic visit score. The mean (SD) HU-DBI scores were 3.5 (1.7) points for the intervention group and 4.8 (2.0) points for the control group.

No significant differences between the groups were noted with respect to age, gender, number of years since diagnosed with diabetes, complications, treatment method, diabetes status, periodontal disease status, chronic inflammation status, or self-efficacy toward periodontal disease. The HU-DBI score was significantly higher in the control group compared with the intervention group.

3.3 | Analysis of the effect indicators

3.3.1 | Periodontal condition

Following the intervention program, the mean values for BOP declined from 26.2% to 13.7% in the intervention group and from 16.2%
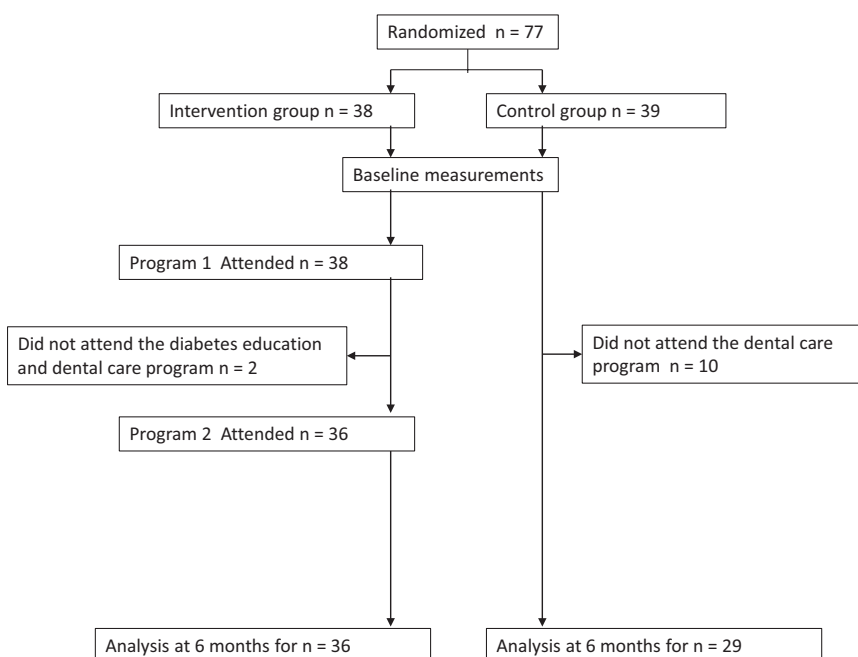

FIGURE 1 Flow diagram

TABLE 2 Comparison of the subjects' characteristics

Characteristic	Intervention group, n=36	Individuals assessed, n	Control group, n=29	Individuals assessed, n	P
Age, years, mean (SD)	65.3 (10.1)	36	66.1(8.9)	29	.749[a]
Sex					
Man, n	23	36	12	29	.085[b]
Woman, n	13		17		
Number of years since a diabetes diagnosis, mean (SD)	11.9 (8.2)		11.5 (10.0)		.499[c]
Type of treatment					
Insulin, n	28	36	25	29	.433[b]
Oral medication, n	8		4		
Complications					
None, n	26	36	15	29	.066[b]
Retinopathy, n	7		9		
Nephropathy, n	1		5		
Retinopathy and nephropathy, n	2		0		
Diabetes condition					
HbA1c level, mean (SD)	7.3 (0.6)	36	7.3 (0.7)	28	.961[c]
History of periodontal disease treatment					
Yes, n	9	36	3	29	.200[b]
No, n	27		26		
Smoker					
Yes, n	5	36	4	29	.532[b]
No, n	31		25		
Periodontal condition					
Bleeding on probing, mean (SD), %	26.2 (22.8)	36	16.2 (16.3)	29	.164[a]
Probing pocket depth, mean (SD), %	56.4 (37.8)		37.8 (30.9)		.053[c]
Chronic inflammation condition					
TNF-α level, ng/mL, mean (SD)	1.4 (0.7)	20	1.4 (0.8)	13	.703[c]
Treatment activities related to periodontal disease					
SESS					
Clinic visit score, mean (SD)	20.1 (4.2)	36	21.0 (3.3)	29	.655[c]
Brushing teeth score, mean (SD)	18.2 (3.4)		18.5 (4.3)		.832[a]
Meal score, mean (SD)	19.1 (3.8)		18.5 (4.5)		.546[a]
HU-DBI, mean (SD)	3.5 (1.7)		4.8 (2.0)		.008[a]

Self-Efficacy Scale for Self-care against Periodontal Disease=clinic visits/brushing teeth/meals, 25 points each.

Dental Health Behavioral Inventory Test Score=12 points maximum.

SESS, the Self-Efficacy Scale for Self-care among Periodontal Disease; HU-DBI, the Hiroshima University Dental Behavioral Inventory; SD, standard deviation; TNF, tumor necrosis factor; HbA1c, glycated hemoglobin.

[a]t test.

[b]chi-squared test or Fisher's exact test.

[c]Mann-Whitney U test.

TABLE 3 Changes in the outcome indices for the intervention and control groups.

	n	Baseline mean (SD)	6 mo mean (SD)	Effect (a) Group F statistic	P	Time F statistic	P	Group×Time F statistic	P	Effect (b) Parallelism F statistic	P	Significance of regression P	F statistic	P
Periodontal condition														
Bleeding on probing (%)														
Intervention group	36	26.2 (22.8)	13.7 (12.7)	0.966	.329	8.872	.004[c]	7.919	.007[c]					
Control group	29	16.2 (16.3)	15.8 (19.4)											
Probing pocket depth (%)														
Intervention group	36	56.4 (37.8)	33.9 (34.8)	2.664	.108	19.857	<.001[c]	3.209	.078[c]					
Control group	29	37.8 (30.9)	28.2 (25.9)											
Diabetes condition														
Glycated hemoglobin, %														
Intervention group	35	7.3 (0.6)	7.1 (0.7)	0.233	.631	0.151	.699[c]	2.196	.143[c]					
Control group	28	7.3 (0.7)	7.3 (0.9)											
Chronic inflammation condition														
Tumor necrosis factor-α														
Intervention group	20	1.4 (0.7)	1.2 (0.5)	0.024	.878	5.103	.031[d]	0.055	.817[d]					
Control group	13	1.4 (0.8)	1.2 (0.5)											
Treatment activities related to periodontal disease														
SESS														
Clinic visit score														
Intervention group	36	20.1 (4.2)	22.9 (4.0)	2.203	.143	1.167	.284[d]	10.884	.002[d]					
Control group	29	21.0 (3.3)	19.5 (5.6)											
Brushing teeth score														
Intervention group	36	18.2 (3.4)	21.3 (3.1)	4.156	.046	4.267	.043[d]	11.765	.001[d]					
Control group	29	18.5 (4.3)	17.7 (5.2)											
Meal score														
Intervention group	36	19.1 (3.8)	21.1 (2.8)	6.741	.012	0.729	.396[d]	21.606	<.001[d]					
Control group	29	18.5 (4.5)	17.1 (4.4)											

(Continues)

TABLE 3 (Continued)

	n	Baseline mean (SD)	6 mo mean (SD)	Effect (a)						Effect (b)				
				Group		Time		Group×Time		Parallelism		Significance of regression		
				F statistic	P	F statistic	P	F statistic	P	F statistic	P	P	F statistic	P
HU-DBI														
Intervention group	36	3.5 (1.7)	6.3 (2.0)							1.363	.248	0.008	7.414	<.001
Control group	29	4.8 (2.0)	5.1 (2.5)											

Effect "a" determined using a two-way analysis of variance, effect "b" determined using an analysis of covariance based on the dental health behavior score as the baseline of the covariance.

The groups in the two-way analysis of variance were the intervention group and the control group. Time was at baseline and 6 months after the program. Group × time shows the results regarding interactions in both groups.

SESS, the Self-Efficacy Scale for Self-care among Periodontal Disease; HU-DBI, the Hiroshima University Dental Behavioral Inventory; SD, standard deviation.

[c]Mauchly's sphericity test.

[d]test based on the Greenhouse-Geisser correction.

to 15.8% in the control group. The intervention group had a significant reduction in the mean BOP value, and there was a group × time interaction (F=7.919; P<.01) (Table 3). Following the intervention program, the mean PPD values declined from 56.4% to 33.9% in the intervention group and from 37.8% to 28.2% in the control group; while both groups showed reductions, a group×time interaction (F=3.209; P=.078) could not be determined (Table 3). Hence, a significant improvement occurred in relation to BOP in the intervention group following the intervention program.

3.3.2 | Diabetes condition

The mean HbA1c level declined from 7.3% before intervention to 7.1% after the intervention program in the intervention group and the mean HbA1c level in the control group remained at 7.3%; a group×time interaction could not be determined (F=2.196; P=.143) (Table 3). This finding suggests that the intervention program did not significantly improve the diabetic condition.

3.3.3 | Chronic inflammation condition

The mean TNF-α levels declined from 1.4 ng/mL before intervention to 1.2 ng/mL after intervention in both groups; a group × time interaction could not be determined (F=0.055; P=. 817) (Table 3). This suggests that the intervention program did not significantly improve chronic inflammation.

3.3.4 | Treatment activities related to periodontal disease

Following the intervention program, the mean clinic visit score rose from 20.1 points at baseline to 22.9 points in the intervention group, and it declined from 21 points at baseline to 19.5 points in the control group; a group × time interaction was determined (F=10.884; P<.01) (Table 3). The mean brushing teeth score increased from 18.2 points at baseline to 21.3 points after the program in the intervention group, and it declined from 18.5 points at baseline to 17.7 points in the control group; a group×time interaction was determined (F=11.765; P<.01) (Table 3). Following the intervention program, the mean meal score rose from 19.1 points at baseline to 21.2 points in the intervention group, and it declined from 18.5 points at baseline to 17.1 points in the control group; a group×time interaction was determined (F=21.606; P<.01) (Table 3). Hence, all of the scores on the SESS among Periodontal Disease Patients questionnaire increased in the intervention group and decreased in the control group.

Following the intervention program, the mean HU-DBI score rose from 3.5 points at baseline to 6.3 points in the intervention group, and it rose from 4.8 points at baseline to 5.1 points in the control group. The change in the mean HU-DBI score in the intervention group was statistically significant (F=7.414; P<.01) (Table 3). These results enabled us to verify significant increases in self-efficacy and in the HU-DBI score in the intervention group in relation to self-care against periodontal disease.

4 | DISCUSSION

This study focused on providing patients with type 2 diabetes and periodontal disease with a periodontal disease care program and evaluating the effectiveness of the program. The program was designed to provide participants with knowledge about diabetes and periodontal disease, and actively guided and encouraged them toward self-care to improve their periodontal disease. Following the intervention program, patients with type 2 diabetes and periodontal disease showed improvements in the disease condition and their active engagement in periodontal disease treatment.

The intervention program was effective at improving BOP, which improved the patients' periodontal disease. This program involved providing the participants with detailed instructions on how and how often to brush their teeth using model teeth and a tooth brush. During this process, we instructed the participants to be mindful of and focus on the areas of the mouth that bled. The SESS and HU-DBI scores increased after the intervention; therefore, we could conclude that the patients followed the rules regarding teeth brushing after every meal and regarding sweets avoidance. We believe that BOP improved because the patients learnt to brush their teeth more effectively, they got into the habit of brushing after each meal, and they were able to prevent plaque buildup. As one goal for periodontal treatment BOP elimination, the decline in the BOP values for the intervention group from 26.2% to 13.7% can be considered clinically significant. In other studies that informed patients with type 2 diabetes about how to brush their teeth more effectively and provided instruction about oral hygiene,[15,16] the intervention groups showed significant improvements in BOP, which concurs with the current study's results. However, there was no significant change in the intervention group in relation to PPD, which is associated with plaque accumulation. BOP causes changes over a relatively short period of time because of the accumulation of plaque in the gum tissue. However, increased PPD is a chronic that worsens over time through bacterial infection, and hence, it takes time to improve[21]; it is possible that the current study's intervention period was too short to enable any significant improvement in PPD. Therefore, extending the intervention period might have improved PPD.

During this study, the intervention program improved the sense of self-efficacy in treating periodontal disease and it increased the HU-DBI score. According to Bandura's theory,[22] rather than being instinctive, self-efficacy develops through "successful experiences," "social persuasion," "modeling," and "physiological and emotional factors." During the program, we provided counseling every 6-8 weeks, we assessed the participants' situations in relation to self-care and their periodontal status, and we advised the patients about where the improvements were occurring and where improvements were required. When we compared our actions with the four established elements of self-efficacy, we could identify "successful experiences in administering self-care," "education through a nurse," and "feeling the periodontal disease improve," we consider that these factors might improve the participants' self-efficacies. However, according to the theory, nothing

aligned with the definition of "modeling," and we consider that including time with others who had successfully addressed their periodontal disease who could share their experiences as part of the program would have improved the patients' sense of self-efficacy more effectively. Indeed, the effectiveness of self-care in managing periodontal disease has been reported.[11-13] We established the program to enable patients to manage their periodontal disease at home with support provided through counseling and by developing specific goals with the patients. When these goals were developed, we clearly conveyed to each patient the best tooth-brushing times and methods based on their circumstances, and this was reflected in their self-care goals. We hypothesize that this motivated the patients to improve their brushing habits and to increase their HU-DBI scores.

This program did not lead to improvements in TNF-α and HbA1c levels. As described previously, the effectiveness of the program was demonstrated in relation to improvements in BOP. However, improvements were not observed in relation to increased PPD, which is a chronic, long-term condition that worsens with an infection, or chronic inflammation, which was assessed by examining TNF-α levels. Moreover, reports from studies that investigated the treatment of periodontal disease in diabetic patients have described improvements in HbA1c levels and periodontal disease[8,10]; similar improvements were seen in studies that educated patients about how to care for periodontal disease and diabetes simultaneously.[14-16] On the other hand, studies like the current study, which only provided education related to caring for periodontal disease,[17,18] have demonstrated improvements in periodontal disease, but no significant improvements in HbA1c levels. Similarly, our study did not show any significant improvements in HbA1c levels. The results suggest that to improve both diabetes and periodontal disease, it would be valuable to incorporate education about caring for diabetes into a program that provides information about periodontal disease management.

This study had certain limitations. First, the intervention program was implemented at a single center, and consequently, the findings cannot be generalized. Furthermore, it is worth noting that although the SESS among Periodontal Disease Patients questionnaire is recognized for its validity and high level of reliability, not many studies have been published that have used this scale, and this limits the interpretation of the results. Finally, the intervention program was implemented by just one researcher, and this could have affected the results. Therefore, future studies should include an investigation of the methods used for evaluation, nurse training on the implementation of the program, and a greater number of participants and organizations to assess the effectiveness of the intervention program in a randomized controlled study.

Despite these limitations and future considerations, this was the first randomized controlled trial conducted in Japan to assess the effectiveness of a periodontal disease care program administered to patients with type 2 diabetes. Moreover, as this experimental program improved periodontal disease and its associated treatment activities in the intervention group, it has the potential to be beneficial in the field.

5 | CONCLUSIONS

In conclusion, the findings from this study have demonstrated the effectiveness of a periodontal disease care program, emphasizing on improvement of periodontal disease condition and related self-care treatment activities, for patients with type 2 diabetes. In the future, hospital-based and community-based multidisciplinary diabetes teams should be assembled, which would facilitate access to periodontal disease care programs.

CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

REFERENCES

1. Defronzo RA. Banting Lecture. From the triumvirate to the ominous octet: a new paradigm for the treatment of type 2 diabetes mellitus. Diabetes. 2009;58:773–95.
2. Hiromasa Y, Itoh K, Murakami S, et al.: The study of clinical periodontal disease (Rinsho Shishubyo Gaku) (JA) Ishiyakushuppan Inc 2. 2007.
3. Faria-Almeida R, Navarro A, Bascones A. Clinical and metabolic changes after conventional treatment of type 2 diabetic patients with chronic periodontitis. J Periodontol. 2006;77:591–8.
4. Chávarry NG, Vettore MV, Sansone C, Sheiham A. The relationship between diabetes mellitus and destructive periodontal disease: a meta-analysis. Oral Health Prev Dent. 2009;7:107–27.
5. Salvi GE, Carollo-Bittel B, Lang NP. Effects of diabetes mellitus on periodontal and peri-implant conditions: update on association and risks. J Clin Periodontol. 2008;35:398–409.
6. Mealey BL, Oates TW. American Academy of Periodontology. Diabetes mellitus and periodontal diseases. J Periodontol. 2006;77:1289–303.
7. Teeuw WJ, Gerdes VE, Loos BG. Effect of periodontal treatment on glycemic control of diabetic patients: a systematic review and meta-analysis. Diabetes Care. 2010;33:421–7.
8. Iwamoto Y, Nishimura F, Nakagawa M, et al. The effect of antimicrobial periodontal treatment on circulating tumor necrosis factor-alpha and glycated hemoglobin level in patients with type 2 diabetes. J Periodontal. 2001;72:774–8.
9. Navarro-Sanchez AB, Faria-Almeida R, Bascones-Martinez A. Effect of non-surgical periodontal therapy on clinical and immunological response and glycaemic control in type 2 diabetic patients with moderate periodontitis. J Clin Periodontol. 2007;34:835–43.
10. Katagiri S, Nitta H, Nagasawa T, et al. Multi-center intervention study on glycohemoglobin (HbA1c) and serum, high-sensitivity CRP (hs-CRP) after local anti-infectious periodontal treatment in type 2 diabetic patients with periodontal disease. Diabetes Res Clin Pract. 2009;83:308–15.
11. Douglass CW. Risk assessment and management of periodontal disease. J Am Dent Assoc. 2006;137(Suppl):27S–32S.
12. Kressin NR, Boehmer U, Nunn ME, Spiro A. Increased preventive practices lead to greater tooth retention. J Dent Res. 2003;82:223–7.
13. Axelsson P, Nyström B, Lindhe J. The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults. Results after 30 years of maintenance. J Clin Periodontol. 2004;31:749–57.
14. Basak Cinar A, Schou L. Health promotion for patients with diabetes: health coaching or formal health education? Int Dent J. 2014;64:20–8.
15. Cinar AB, Schou L. The role of self-efficacy in health coaching and health education for patients with type 2 diabetes. Int Dent J. 2014;64:155–63.
16. Saengtipbovorn S, Taneepanichskul S. Effectiveness of lifestyle change plus dental care (LCDC) program on improving glycemic and periodontal status in the elderly with type 2 diabetes. BMC Oral Health. 2014;14:72.
17. Almas K, Al-Lazzam S, Al-Quadairi A. The effect of oral hygiene instructions on diabetic type 2 male patients with periodontal diseases. J Contemp Dent Pract. 2003;4:40–51.
18. López NJ, Quintero A, Casanova PA, Martínez B. Routine prophylaxes every 3 months improves chronic periodontitis status in type 2 diabetes. J Periodontol. 2014;85:e232–e240.
19. Kakudate N, Morita M, Fujisawa M, Nagayama M, Kawanami M. Development of a self-efficacy scale for self-care (SESS) among periodontal disease patients-reliability and validity examination. Nihon Shishubyo Gakkai Kaishi. 2007;49:285–95.
20. Kawabata K, Kawamura M, Miyagi M, Aoyama H, Iwamoto Y. The dental health behavior of university students and test-retest reliability of the HU-DBI. J Dent Health. 1990;40:474–5.
21. Lang NP, Adler R, Joss A, Nyman S. Absence of bleeding on probing an indicator of periodontal stability. J Clin Periodontol. 1990;17:714–21.
22. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev. 1977;84:191–215.