Effectiveness of the Oral Care Program in Type 2 Diabetic Elderly Patients with Periodontitis: A Clustered Randomised Controlled Study With 6-month Follow-Up

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Abstract

Background: Diabetes mellitus and periodontal disease have a bidirectional relationship. This study aimed to assess the effectiveness of the oral care program in reducing glycaemic status and improving oral health behaviours and oral hygiene among type 2 diabetes mellitus (T2DM) older patients with periodontitis.

Methods: A clustered randomised controlled study was conducted in Nakhon Ratchasima province between July 2019 and January 2020. The two health centres were randomly assigned to control and intervention groups, which thirty-five T2DM older patients with chronic periodontitis were recruited in each group. The intervention group received the program consisted of oral health education based on Health Belief Model (HBM), individual oral hygiene instruction and scaling and root planning at one month and followed by individual oral hygiene instruction at three months. The patients in the control group received the routine program provided by the health centre. Outcomes were measured using the interviewed questionnaire, simplified oral hygiene index, and the glycaemic status (HbA1c) at baseline, 3 months and 6 months, respectively. Data were analysed using a descriptive statistic, Chi-square test, t-test, repeated measure ANOVA at p -value = 0.05.

Results: After the 3 and 6 months, the results showed that the intervention group significantly improved in the HBM scores, oral health behaviours scores, and decreased in OHI-S scores and HbA1c level ($p < 0.05$), while there was no significant difference in the control group.

Conclusion: The findings suggested that the proposed program was effective among diabetic older people with periodontitis to improve oral health perception, behaviours, oral hygiene, and decreased glycaemic status at 3- and 6-month evaluation.

Trial registration: Thai Clinical Trials Registry (TCTR), TCTR202004230005. Registered 22 April 2020 - Retrospectively registered.

Background

Diabetes is one of the fastest-growing global health problems that cause morbidity and mortality due to long-term complications¹. In 2019, the International Diabetes Federation estimated that the number of people with diabetes was 463 million and will reach 700 million by 2045². Since the diabetes prevalence increases with age, the highest estimated prevalence is in people older than 65, accounting about one-fifth of the population². The prevalence of diabetes in the old age group varies significantly between regions driven by population ageing, economic development and increasing urbanisation, which leads to more Type 2 diabetes mellitus (T2DM)³. The vast majority (87%) of diabetes-related deaths occur in low- and middle-income countries², and more than 60% of diabetes live in Asia⁴.

Periodontitis was rated to be the sixth complication of diabetes⁵. A recent systematic review confirmed that periodontitis has a significant impact on diabetes control⁶. The risk of periodontitis increases by approximately three times in diabetic patients⁷. The elevation of pro-inflammatory factors in the gingiva of patients with poorly controlled diabetes suggests a biological pathway that aggravates periodontitis⁸. Diabetes increases the risk of periodontal disease and periodontal inflammation also negatively affects glycemic control indicated its two-way relationship^{9,10}. The previous study demonstrated that patients achieved glycemic controlled through prevention and management of periodontitis¹¹. A meta-analysis showed a significant reduction of glycated haemoglobin on T2DM patients with periodontitis after non-surgical periodontal therapy using scaling and root planing (SRP) with a minimum of 3-months follow-up. A previous study in Japan found a significant improvement of bleeding on probing after 4-time, every 6–8 months dental education program for oral self-care, but did not change in glycated haemoglobin among T2DM patients with periodontitis¹². Thus, with the current evidence, professional periodontal treatment is required to improve oral health and glycemic control in diabetic patients with periodontitis, and further study needs more follow-up periods¹³.

Thailand is among the countries that have a high prevalence of diabetes¹⁴. The prevalence of diabetic patients in Thailand increased from 6.9% in 2009 to 8.8% in 2014¹⁵. The prevalence was higher in urban areas than in rural areas, higher in women than in men, and highest at aged 60–69 accounted for 17% of total diabetic patients¹⁶. The Thai National Health Examination Survey also found that only 20% of the patients could effectively control their blood sugar, and other 30% although treated could not control their blood sugar¹⁷. In Nakhon Ratchasima, the largest province in Thailand, the number of older people with T2DM has been rising rapidly according to the Health Data Centre of the Ministry of Public Health (HDC program), and the number of patients is highest in the population over aged 60¹⁸. Currently, multiple sectors attempt to educate the public about a healthy diet and physical activity to reduce the risk of T2DM. However, the relationship between periodontal diseases and diabetes are less likely to address. Thus, the aim of this study was to propose the newly develop oral health program and evaluate its effectiveness on improving the glycemic status and oral hygiene status among older uncontrolled diabetic patients with chronic periodontitis.

Methods

Participants

The population for this study was the uncontrolled T2DM patients who received services at health centres, Muang district, Nakhon Ratchasima province, Thailand. Based on the previous study¹⁹, the sample size was 35 for each group calculated from Cochran's Formula²⁰. Inclusion criteria were the uncontrolled T2DM diagnosed patients aged over 60 years, who had at least 10 natural teeth, and the periodontal screening and recording (PSR) more than code 3 showing that is periodontitis²¹. The patients with serious systemic disease including stroke, severe heart disease, hyperosmolar hyperglycaemic nonketotic syndrome (HHNS), severe neuropathy, end-stage renal failure, and mental disorder were excluded. Patients who had manual dexterity problems, depended on the caretaker, deaf or blind, was unable to speak Thai, were also excluded. Cluster random sampling was used for choosing two health centres. Yangyai and Khok Kruat health centres were randomly assigned by drawing the envelope. to the intervention and control groups. Yangyai Health Centre received the intervention, and Khok Kruat Health Centre received routine program (control group). Two hundred and fifty-seven older diabetic patients in Yangyai Health Centre and 253 older diabetic patients in Khok Kruat Health Centre were eligible based on the inclusion and exclusion criteria. Then, 35 patients were randomly selected using simple random sampling technique into the intervention and the control groups (Fig. 1). All participants were blinded for their group status. The research proposal was approved and reviewed by the ethical committee of the Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, Institutional Review Board (No.MU-DT/PY-IRB 2019/042.0307; 3 July 2019).

Examiner calibration

The interviewers were two health officers who did not work in both health centres and blinded to the group assignment. The interviewers attended a one-day training program before collecting data. The examiners were two dentists who did not work in both health centres and did not know whether patients belonged to the intervention or the control groups. Intra-examiner reliability of two dentists using Cronbach's alpha coefficient was 0.99 and 0.99. The inter-examiner reliability between two dentists using the Cronbach's alpha coefficient was 0.98.

Program description

The intervention group received four weeks of the Diabetic and Oral Care program (DOC) comprised of a group oral health education, individual oral hygiene instruction and scaling and root planing (SRP). The first week, a 1-hour oral health education program was provided in a group session for T2DM patients by the interdisciplinary team. This educational program was based on the Health Belief Model (HBM)²² using slide presentations, including the relationship and complications between T2DM and oral health, oral care and the healthy diet for diabetic patients. During the second week, patients practised oral cleaning and self-oral examination conducted by a dentist and dental hygienist. During the last two

weeks, patients were scheduled for SRP (5 patients per day) performed by a dentist. Before the treatment, an individual oral hygiene instruction on tooth brushing, using an interdental brush, cleaning dentures, and how to self-check oral health was provided by a dental hygienist. At 3-month recall, an individual oral hygiene instruction was followed up and emphasised by a dentist and dental hygienist again.

The control group received a routine program that included seeing the doctor once a month, blood testing, and collecting pharmaceutical items from a nurse every 3-month and undergoing oral examination twice a year.

Measurement of outcomes

The patient's interview, oral examination and blood sample testing were obtained at baseline, 3-month and, 6-month follow up. The patients did not know to which group they belonged to, and the interviewers were blinded to the intervention assignment. The T2DM patients in both groups were interviewed about general characteristics, the oral health perception based on HBM, and oral health behaviours. The structured questionnaires were validated by 3 experts in dentistry consisted of experts in periodontology, community dentistry and, advanced dentistry. The Item-Objective Congruence Index (IOC) was 0.95. A pilot study was conducted with 30 diabetic patients receiving the service in another health centre before data collection in order to test the reliability of the questionnaires. Cronbach's alpha coefficient was 0.73–0.80, indicating good internal consistency reliability. An oral hygiene examination was performed by the two calibrated dentists using the simplified oral hygiene index (OHI-S)²³. Blood samples were tested for HbA1c by nurses every 3-months, and the results of the blood samples were retrieved from the patients' medical records.

Data analysis

Statistical analysis was performed using the SPSS software (IBM SPSS statistics version 23; SPSS Inc). Data were analysed using descriptive statistics, including frequency distribution and percentages, to describe general characteristics. Mean, and the standard deviation was used to describe a patient's HbA1c, oral hygiene index, the HBM and oral health behaviour scores. Chi-square and independent sample t-tests were used to compare the difference between the two groups at baseline, 3- and 6-months. Repeated measure ANOVA and Bonferroni post-hoc analysis was used to compare the inner-group differences between baseline, 3- and, 6-months. All analyses used statistically significant at p-value = 0.05.

Results

The study was conducted during July 2019 and January 2020. All 70 patients in the intervention and control group completed the study protocol with 100% response rate and no loss of follow-up. At baseline, the results showed no statistically significant differences in general characteristics of patients between the two groups in terms of age, gender, body mass index, duration of being diabetic, systemic disease, history of smoking, occupation, education level, income, and health insurance (Table 1).

Health Belief Model scores

Perceived susceptibility

The mean scores of perceived susceptibility showed no statistically significant differences between the two groups at baseline ($p = 0.19$). There were statistically significant differences between the two groups at 3- and 6- month follow-ups, the mean differences were 0.54 ± 0.21 , $p < 0.05$ and 0.54 ± 0.22 , $p < 0.05$, respectively. A repeated measure ANOVA showed statistically significant differences of perceived susceptibility scores within the DOC group between baseline, 3- and 6-month follow-ups, ($p < 0.05$). Bonferroni post-hoc analysis revealed that the baseline (10.94 ± 1.59) was lower than that of the 3- and 6-month follow-ups with statistically significant differences (11.97 ± 0.17 , $p < 0.001$ and 11.98 ± 0.16 , $p < 0.001$) whereas there were no statistically significant differences between 3- and 6- month follow-ups ($p = 1.0$). For the patients

within the control group, there was no statistically significant differences of perceived susceptibility scores within-group between baseline, 3- and 6- month follow-ups, ($p = 0.95$).

Perceived severity

For perceived severity mean scores, there were no statistically significant differences between the two groups at baseline ($p = 0.33$). However, there was a statistically significant difference between the two groups at 3- and 6- month follow-ups, the mean differences were 0.51 ± 0.19 , $p < 0.05$ and 0.09 ± 0.08 , $p < 0.05$, respectively. A repeated measure ANOVA showed statistically significant differences of perceived severity scores within the DOC group between baseline, 3- and 6- month follow-ups, ($p < 0.05$). Bonferroni post-hoc analysis revealed that the baseline score (11.31 ± 1.13) was lower than at the 3- and 6-month follow-ups with statistically significant differences (11.93 ± 0.36 , $p < 0.001$ and 11.94 ± 0.34 , $p < 0.05$), whereas there were no statistically significant differences between 3- and 6- month follow-ups ($p = 0.97$). For the patients in the control group, it showed no statistically significant differences of perceived severity scores within-group between baseline, 3- and 6- month follow-ups, ($p = 0.11$).

Perceived benefit

For perceived benefit mean scores, there were no statistically significant differences between the two groups at baseline ($p = 0.33$). However, there was a statistically significant difference between the two groups at 3- and 6- month follow-ups. The mean differences were 0.63 ± 0.27 , $p < 0.05$ and 0.49 ± 0.21 , $p < 0.05$, respectively. A repeated measure ANOVA showed statistically significant differences of perceived benefit scores within the DOC group between baseline, 3- and 6- month follow-ups: $F(1.099, 37.354) = 55.881$, $p < 0.001$. Bonferroni post-hoc analysis revealed that the baseline score (11.20 ± 1.32) was significantly lower than 3- and 6-month follow-ups (11.94 ± 0.24 , $p < 0.001$ and 11.95 ± 0.20 , $p < 0.001$), whereas no statistically significant differences between 3- and 6- month follow-ups ($p = 1.00$). For the patients within the control group, there were no statistically significant differences of perceived benefits scores within-group between baseline, 3- and 6- month follow-ups, ($p = 0.66$).

Perceived barriers

For perceived barriers mean scores, there were no statistically significant differences between the two groups at the baseline ($p = 0.50$). However, there was a statistically significant difference between the two groups at 3- and 6- month follow-ups. The mean differences were 8.06 ± 0.38 , $p < 0.001$ and 8.74 ± 0.34 , $p < 0.001$, respectively. A repeated measure ANOVA showed statistically significant differences of perceived barriers scores within the DOC group between baseline, 3- and 6- month follow-ups, ($p < 0.001$). Bonferroni post-hoc analysis revealed that the baseline score (10.46 ± 0.18) was significantly higher than 3- and 6-month follow-ups (2.40 ± 0.35 , $p < 0.001$ and 1.69 ± 0.25 , $p < 0.001$). No statistically significant differences were recorded between 3- and 6- month follow-ups ($p = 0.29$). While, the patients within the control group, there were no statistically significant differences of perceived barriers scores within-group between baseline, 3- and 6- month follow-ups, ($p = 0.06$).

Perceived self-efficacy

In the case of the mean scores for the last component, perceived self-efficacy, there were no significant differences between the two groups at baseline ($p = 0.06$). There were statistically significant differences between the two groups at 3- and 6- month follow-ups. The mean differences were 0.89 ± 0.31 , $p < 0.05$ and 0.49 ± 0.21 , $p < 0.05$, respectively. A repeated measure ANOVA showed a statistically significant difference of perceived self-efficacy scores within the DOC group between baseline, 3- and 6- month follow-ups. Bonferroni post-hoc analysis revealed that the baseline score (10.74 ± 1.42) was significantly lower than 3- and 6-month follow-ups (11.80 ± 0.47 , $p < 0.001$ and 11.89 ± 0.40 , $p < 0.001$). There were no statistically significant differences between 3- and 6- month follow up scores ($p = 1.00$). For the patients within the control group, there were no statistically significant differences of perceived self-efficacy within the group between baseline, 3- and 6- month follow-ups, ($p = 0.26$).

Oral health behaviour scores

At baseline, the result showed no statistically significant differences in oral health behaviour scores between the two groups ($p = 0.07$). The oral health behaviour scores between the two groups demonstrated statistically significant differences at 3- and 6- month follow-ups ($p < 0.001$, and $p < 0.001$). The mean difference was highest (3.94 ± 0.45) at 6-month follow-ups.

A repeated measure ANOVA showed statistically significant differences in oral health behaviour scores within the DOC group between baseline, 3- and 6- month follow-ups. Bonferroni post-hoc analysis revealed that the baseline score (18.43 ± 3.37) was the lowest ($p < 0.001$). For the patients within the control group, there were no statistically significant differences in oral health behaviour scores within the group between baseline, 3- and 6- month follow-ups, ($p = 0.08$).

Oral hygiene status

Comparing the oral hygiene status between the two groups was no statistically significant difference in the mean for OHI-S at baseline ($p = 0.56$). The mean difference of OHI-S was significantly highest (2.53 ± 0.14) at 3- and 6- month follow-ups ($p < 0.001$, and $p < 0.001$). Moreover, a repeated measure ANOVA showed statistically significant differences of OHI-S scores within the DOC group between baseline, 3- and 6- month follow-ups. Bonferroni post-hoc analysis revealed that the baseline score (3.31 ± 1.04) was significantly higher than that at the 3- and 6-month follow-ups (0.88 ± 0.46 , $p < 0.001$ and 0.68 ± 0.53 , $p < 0.001$). There were no statistically significant differences between 3- and 6- month follow-ups ($p = 0.09$). No statistically significant differences of OHI-S scores were found within the control group between baseline, 3- and 6- month follow-ups, ($p = 0.18$).

Glycaemic status

At baseline, the result showed no statistically significant differences for HbA1c values between the two groups ($p = 0.99$). A significant difference in glycaemic status between the two groups was found at 3- and 6- month follow-ups ($p = 0.04$, and $p = 0.02$, respectively). The mean difference of HbA1c value was significantly highest (0.97 ± 0.39) at 6-month. A repeated measure ANOVA showed statistically significant differences of HbA1c values within the intervention group between baseline, 3- and 6- month follow-ups, ($p < 0.05$). Bonferroni post-hoc analysis revealed that the baseline score ($8.94 \pm 1.95\%$) was significantly higher than the 3- and 6-month follow-ups ($8.08 \pm 1.66\%$, $p < 0.001$ and $7.83 \pm 1.81\%$, $p < 0.05$). There were no statistically significant differences between 3- and 6- month ($p = 1.00$). For the patients within the control group, there were no statistically significant differences of HbA1c value within-group between baseline, 3- and 6- month follow-ups, ($p = 0.10$).

Discussion

The outcomes in this study demonstrate that the proposed intervention program improved the glycaemic and oral hygiene status in T2DM older patients with chronic periodontitis. On completion of the program, the patients' glycaemic values significantly decreased when comparing the DOC group and the control group at 3- and 6-months follow-ups. The results showed an improvement in HbA1c value in the intervention group from $8.94-8.08\%$ in 3-month, and $8.08-7.83\%$ in 6-month. Therefore, the program could reduce HbA1c 0.86% in 3-month, and 0.25% in 6-month. However, the reduction of HbA1c level did not meet the target of American Diabetes Association treatment goal that the HbA1c level must be reduced to less than 7.5 in healthy older people¹². In other previous studies²⁴⁻²⁷, periodontal therapy in diabetic patients could significantly reduce HbA1c levels from $0.29-0.64\%$ in 3-month and 0.2% in 6-month after completion of the therapy²⁸. As the combination of lifestyle changes and dental care program also decreased HbA1c (0.29%) after 3-months follow-ups, whereas the HbA1c increased 0.09% in the control group¹⁹. Simpson et al.¹³ found periodontal therapy could reduce the HbA1c values of 0.29% at 3-month and 0.02% at the 6-month period. However, the effect of periodontal treatment alone on uncontrolled type 2 diabetes mellitus in Thai older subjects was not significant although HbA1C values for the treatment group dropped by -0.2% three months after completion of the treatment²⁹. Similar to full-mouth non-surgical scaling and root planing, it could improve periodontal health, but it had no significant effects on glycaemic control based on HbA1c values of -0.04% ³⁰.

The oral hygiene status of participants, including OHI-S in the intervention group, also decreased after the DOC program was finished, and it showed the improvement of the OHI-S score when compared with the control group. Previous research showed a similar result that non-surgical periodontal therapy and oral hygiene instruction of T2DM subjects with chronic periodontitis could reduce the plaque index by more than 80% after three months³¹. Intensive oral hygiene care for periodontitis in T2DM patients could significantly reduce the plaque index after six months³². The oral health instruction of periodontitis patients with T2DM also reduced plaque index significantly, and HbA1c was reduced by 0.2% within 6-months period, although the difference was not statistically significant³³.

In this study, the component of the Health Belief Model, perceived susceptibility, perceived severity, perceived benefit of diabetic older patients increased in the DOC group. This increase can be attributed to the effect of education, presenting the image on a slide presentation, distributing leaflets, interactions of patients in the group training and individual oral hygiene consulting also could increase their understanding. The perceived barrier of these patients decreased due to the education intervention, oral care practising, available of dental treatment services, distributing a package of oral care tools. Moreover, perceived self-efficacy also increased by empowering the patient's practical training to increase the capability of controlling and managing their oral health care behaviours continuously. Similar to the previous study found that knowledge, behaviour and attitude toward T2DM and oral health were increased after the intervention¹⁹ whereas the education package in T2DM patients did not affect knowledge scores between the two groups after one month³⁴ due to lack of motivation periods. Moreover, a similar study based on the Health Belief Model to promote the oral and dental health of patients with type 2 diabetes mellitus, three months after the intervention, awareness of the patients and perceived susceptibility, benefits, self-efficacy, internal cue to action, and performance in oral and dental hygiene-related behaviours had increased in the intervention group³⁵.

The strengths of this study are 100% response rate, the use of biomarkers to examine outcomes, and a double-blinded technique due to our study has gathered data in one place that dentists and interviewers did not know that patients come from interventions or control groups. Moreover, patients did not know which group they belong to, and there is less contamination between the two groups because they lived in a remote village, and we made an appointment at different times. The limitation of this study is to reduce the oral hygiene index from the DOC program, which cannot ensure that the decline came from changes in oral health behaviour or scaling and root planing treatment since our program included of both activities. We suggest that future research should have a longer follow-up period or repeat DOC program at six months per year. For immediate action, with the potential benefit to all diabetic patients, the DOC program could be used routinely in other health centres or hospitals at least every six months. For further action, we recommend that the policy should make fast-track dental services for diabetic patients to receive scaling and root planning every 6 months for preventing periodontal disease and control glycaemic status. Finally, the program needs to be repeated in other contexts such as in different provinces and cross cultures to confirm the positive effects and broad application in various settings.

Conclusion

The diabetic and oral care program in type 2 diabetic elderly patients with periodontitis was effective in reducing glycaemic status and improving oral hygiene and oral health behaviours. Through the oral health education based on Health Belief Model, scaling and root planing and continuous active follow-ups can improve oral health perception, oral health behaviours, oral hygiene, and glycaemic status within six months among diabetic older patients with chronic periodontitis.

Abbreviations

DM: Diabetes Mellitus; T2DM: Type 2 Diabetes Mellitus; DOC: The Diabetic and Oral Care Program; FPG: Fasting Plasma Glucose; HbA1c: Glycated Haemoglobin; OHI-S: Simplified Oral Hygiene Index; PSR: Periodontal Screening Record; HBM: Health Belief Model

Declarations

Authors' contributions

NP, TV and CA contributed to research design; NP collected the data; NP and TV contributed to acquisition, analysis or interpretation of data and drafted the manuscript; TV and CA critically revised manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

All the data and intervention materials during the study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

This research followed the Declaration of Helsinki. The research was approved and reviewed by the ethical committee of the Faculty of Dentistry/Faculty of Pharmacy, Mahidol University, Institutional Review Board (No.MU-DT/PY-IRB 2019/042.0307; 3 July 2019). Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors have no competing interests.

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Tables

Table 1. General Characteristic (n=70)				
Variable	DOC group (n = 35) (%)	Control group (n = 35) (%)	p-value	
Age				
Mean ± SD	65.6 ± 3.9	67.4 ± 4.4	0.08	
Min-Max	60 – 74	61 – 75		
Gender				
Male	7 (20.0)	10 (28.6)	0.11	
Female	28 (80.0)	25 (71.4)		
Body mass index				
Mean ± SD	24.9 ± 4.1	24.9 ± 3.4	0.97	
Min-Max	18.4 – 35.5	19 – 34.4		
Duration of being diabetic				
Mean ± SD	12.6 ± 9.0	12.31 ± 8.8	0.90	
Min-Max	1 – 35	1 – 33		
Teeth				
Mean ± SD	18.49 ± 6.41	21.26 ± 8.50	0.13	
Min-Max	10 - 32	10 – 32		
Other Systemic diseases				
None	3 (8.6)	12 (34.3)	0.58	
Hypertension (HTN)	12 (34.3)	10 (28.6)		
Dyslipidaemia (DLP)	4 (11.4)	2 (5.7)		
HTN + DLP	12 (34.3)	8 (22.9)		
Chronic kidney disease	3 (8.6)	2 (5.7)		
Heart disease	1 (2.9)	1 (2.9)		
Smoking				
Never	30 (85.7)	26 (74.3)	0.24	
Ever	5 (14.3)	9 (25.7)		
Current smoker	0 (0)	0 (0)		
Occupational				
Work	8 (22.9)	10 (28.6)	0.25	
Non-working	27 (77.1)	25 (71.4)		
Educational level				
Primary school	33 (94.3)	29 (82.9)	0.14	

Secondary school	2 (5.7)	6 (17.1)	
Income			
< 5,000 baht	24 (68.6)	18 (51.4)	0.29
- 5,000 – 10,000 baht	5 (14.3)	10 (28.6)	
- > 10,000 baht	6 (17.1)	7 (20)	
Health insurance			
Universal coverage	32 (91.4)	31 (88.6)	0.70
Government	3 (8.6)	4 (11.4)	
<i>p</i> -value comparing the two groups using chi-square or independent t-test (<i>p</i> = 0.05)			

Table 2. Comparison of the Health Belief Model scores at baseline, 3 months and 6 months between the DOC and the control group

Variable	DOC Group (n=35) Mean ± S.D.	Control Group (n=35) Mean ± S.D.	t	Mean difference	*p-value
Perceived susceptibility					
Baseline	10.94 ± 1.59	11.37 ± 1.11	1.306	0.43±0.33	0.19
3 months	11.97 ± 0.17	11.43 ± 1.22	2.608	0.54±0.21	0.01*
6 months	11.98 ± 0.16	11.43 ± 1.31	2.427	0.54±0.22	0.02*
p_1 value	<0.001*	1.00			
p_2 value	<0.001*	1.00			
p_3 value	1.00	1.00			
Perceived severity					
Baseline	11.31 ± 1.13	11.57 ± 0.49	2.193	0.26±0.21	0.33
3 months	11.93 ± 0.36	11.49 ± 1.12	2.714	0.51±0.19	0.01*
6 months	11.94 ± 0.34	11.46 ± 0.36	1.034	0.09±0.08	0.01*
p_1 value	<0.001*	0.48			
p_2 value	0.01*	1.00			
p_3 value	0.97	0.26			
Perceived benefits					
Baseline	11.20 ± 1.32	11.37 ± 0.88	5.096	0.17±0.27	0.33
3 months	11.94 ± 0.24	11.31 ± 1.59	2.913	0.63±0.27	0.03*
6 months	11.95 ± 0.20	11.46 ± 1.25	2.268	0.49±0.21	0.03*
p_1 value	<0.001*	1.00			
p_2 value	<0.001*	1.00			
p_3 value	1.00	1.00			
Perceived barriers					
Baseline	10.46 ± 0.18	10.63 ± 0.17	3.442	2.20±0.64	0.06
3 months	2.40 ± 0.35	10.46 ± 0.35	2.508	0.97±0.38	<0.001*
6 months	1.69 ± 0.25	10.43 ± 0.25	2.183	0.74±0.34	<0.001*
p_1 value	<0.001*	0.06			
p_2 value	<0.001*	0.12			
p_3 value	0.29	0.13			
Perceived self-efficacy					

Baseline	10.74 ± 1.42	11.11 ± 3.16	3.544	0.37±0.39	0.06
3 months	11.80 ± 0.47	10.91 ± 1.74	2.909	0.89±0.31	0.01*
6 months	11.89 ± 0.40	11.40 ± 1.94	2.371	0.49±0.21	0.02*
p_1 value	<0.001*	1.00			
p_2 value	<0.001*	0.73			
p_3 value	1.00	0.27			
<p><i>*p value</i> – comparing intergroup scores using independent t-test</p> <p>p_1 value – comparing between baseline and 3 months using Bonferroni post-hoc analysis</p> <p>p_2 value – comparing between baseline and 6 months using Bonferroni post-hoc analysis</p> <p>p_3 value – comparing between 3 months and 6 months using Bonferroni post-hoc analysis</p> <p>$p \leq 0.05$ – statistically significant</p>					

Table 3. Repeated measure ANOVA within group					
Source of variation	S.S.	df	M.S.	F	p-value
Health Belief Model total scores					
DOC group (within Subjects)					
Time	1570.362	1.194	1315.098	99.804	<0.001*
Within subject error	534.971	40.599	13.177		
Control group (within Subjects)					
Time	375.562	1.772	211.948	18.282	0.064
Within subject error	698.438	60.246	11.593		
Perceived susceptibility					
DOC group (within Subjects)					
Time	24.686	1.037	23.800	14.150	0.001*
Within subject error	59.314	35.266	1.682		
Control group (within Subjects)					
Time	0.076	1.748	0.044	0.036	0.949
Within subject error	71.257	59.428	1.199		
Perceived severity					
DOC group (within Subjects)					
Time	10.133	1.129	8.976	10.590	0.002*
Within subject error	32.533	38.385	0.848		
Control group (within Subjects)					
Time	2.648	1.361	1.945	2.454	0.114
Within subject error	36.686	46.277	0.793		
Perceived benefits					
DOC group (within Subjects)					
Time	70.876	1.099	64.512	55.881	<0.001*
Within subject error	43.124	37.354	1.154		
Control group (within Subjects)					
Time	1.162	1.704	0.682	0.374	0.656
Within subject error	105.505	57.933	1.821		
Perceived barriers					
DOC group (within Subjects)					
Time	164.133	1.293	126.899	50.185	<0.001*
Within subject error	111.200	43.976	2.529		
Control group (within Subjects)					

Time	374.800	1.248	300.295	41.845	0.061
Within subject error	304.533	42.436	7.176		
Perceived self-efficacy					
DOC group (within Subjects)					
Time	103.029	1.285	80.208	61.486	<0.001*
Within subject error	56.971	43.673	1.304		
Control group (within Subjects)					
Time	4.171	1.751	300.295	1.384	0.258
Within subject error	102.495	59.532	7.176		
Oral health behaviour score					
DOC group (within Subjects)					
Time	525.733	1.254	419.086	59.398	<0.001*
Within subject error	300.933	42.652	7.056		
Control group (within Subjects)					
Time	28.248	1.957	14.436	3.277	0.079
Within subject error	293.086	66.529	4.405		
Oral hygiene index score (OHI-S)					
DOC group (within Subjects)					
Time	1.048	2.000	0.524	1.763	<0.001*
Within subject error	20.223	68.000	0.297		
Control group (within Subjects)					
Time	149.647	1.349	14.436	167.395	0.179
Within subject error	30.395	45.867	4.405		
HbA1C					
DOC group (within Subjects)					
Time	28.853	1.107	21.548	8.856	0.004*
Within subject error	91.576	37.636	2.433		
Control group (within Subjects)					
Time	5.136	1.493	3.441	10.385	0.100
Within subject error	16.812	50.753	0.331		
SS = sum of squares; df = degrees of freedom; MS = mean squares; F = F-test					
$p \leq 0.05$ – statistically significant					

Table 4. Comparison of Oral Health Behaviour score, OHI-S, HbA1c value at baseline, 3 months and 6 months between the DOC and the control group

Variable	DOC Group	Control Group	t	Mean difference	p* value
	(n=35)	(n=35)			
	Mean ± S.D.	Mean ± S.D.			
Oral Health Behaviour score					
Baseline	18.43 ± 3.37	19.77 ± 2.58	1.871	1.34±0.72	0.07
3 months	22.44 ± 1.12	18.66 ± 2.61	7.796	3.74±0.48	<0.001*
6 months	23.69 ± 0.63	19.74 ± 2.59	8.739	3.94±0.45	<0.001*
p ₁ value	<0.001*	0.15			
p ₂ value	<0.001*	1.00			
p ₃ value	<0.001*	0.06			
Oral hygiene index score (OHI-S)					
Baseline	3.31 ± 1.04	3.18 ± 0.73	0.591	0.13±0.21	0.56
3 months	0.88 ± 0.46	2.99 ± 0.97	11.61	2.10±0.18	<0.001*
6 months	0.68 ± 0.53	3.21 ± 0.62	18.368	2.53±0.14	<0.001*
p ₁ value	<0.001*	0.33			
p ₂ value	<0.001*	1.00			
p ₃ value	0.09	0.38			
HbA1c					
Baseline	8.94 ± 1.95	8.95 ± 1.65	0.018	0.01±0.43	0.99
3 months	8.08 ± 1.66	8.86 ± 1.58	2.020	0.78±0.39	0.04*
6 months	7.83 ± 1.81	8.80 ± 1.42	2.485	0.97±0.39	0.02*
p ₁ value	<0.001*	0.33			
p ₂ value	0.01*	0.56			
p ₃ value	1.00	1.00			
*p-value – comparing intergroup scores using independent t-test					
p ₁ value – comparing between baseline and 3 months using Bonferroni post-hoc analysis					
p ₂ value – comparing between baseline and 6 months using Bonferroni post-hoc analysis					
p ₃ value – comparing between 3 months and 6 months using Bonferroni post-hoc analysis					
p ≤ 0.05 – statistically significant					

Figures

Figure 1

Consort flow diagram of the study design.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORT2010Checklist.doc](#)