

# A randomised controlled trial of an educational intervention to promote Oral and dental health of Patients with Type 2 Diabetes Mellitus

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## Research article

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# Abstract

**Background:** Diabetes is the most prevalent disease resulted from metabolic disorders. This study aimed to investigate the effect of training based on health belief model (HBM) on oral hygiene-related behaviors in patients with type 2 diabetes mellitus. **Methods:** This study was conducted as an educational randomized controlled trial (single blind) on 120 patients with type 2 diabetes referring to a diabetes clinic selected through systematic sampling, who were assigned to two groups of control (N=60) and intervention (N=60). The data collection tool was a valid and reliable questionnaire based on (HBM) which was completed for both groups before the intervention. Then, the intervention group received 4 sessions of training based on health belief model in one month, and the same questionnaire was completed again after 3 months and data were analyzed using SPSS 20 applying the t-test, paired t-tests, Chi square, Mann-whitney test and Wilcoxon test analysis. The significance level was considered at 0.05. **Results:** 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 behaviors had a significant increase in the intervention group ( $p < 0.05$ ). So that before the intervention, the mean performance score of the intervention and control groups were  $2.16 \pm 0.71$  and  $2.28 \pm 0.76$ , respectively, and no significant difference was observed ( $p > 0.05$ ). However, after the intervention, the mean performance score of the intervention group ( $3.25 \pm 0.49$ ) was significantly more than that of the control group ( $2.66 \pm 0.56$ ) ( $p = 0.001$ ). **Conclusion:** Our results suggested that the training the patients with diabetes based on HBM and performing active follow-ups can enhance their skills in the field of oral and dental hygiene-related behaviors. Also, control, monitoring and training follow-up is recommended during these programs.

## Background

Diabetes is one of the metabolic diseases and is a multifactorial disorder that is characterized by a chronic rise in blood sugar or hyperglycemia and is caused by either insulin secretion disorder or insulin dysfunction or both. Diabetes is also called a silent epidemic and a major public health problem and it accounts for 9% of all deaths worldwide [1]. Patients with uncontrolled diabetes have oral complications such as increased dry mouth and burning mouth. Alterations in collagen metabolism and consequently periodontal fiber changes, cause periodontal disease, which is due to the presence of microbial plaques and poor hygiene in most diabetics [2-4].

Salivary lactate levels in diabetics are higher than in healthy individuals and in advanced cases can reach up to 5 times the normal level, which is a contributing factor to caries [5].

Moreover diabetes mellitus affects virtually all tissues and organs the body including the hard and soft tissues of the oral cavity, manifesting with several complications [6].

There are numerous studies showing that the prevalence, progression, severity, and extent of chronic oral diseases are significantly increased in diabetic patients. The main oral complications associated with

diabetes, including infection of the gums, periodontal disease, tooth decay, dry mouth, bacterial infections and fungus, halitosis, and prolonged healing of wounds from dental treatments [7]. Belazi et al. in his research showed that the growth rate of *Candida* species was significantly higher in people with diabetes than in the healthy group [8].

Knowledge of diabetics about periodontal disease, dry mouth and prevention of oral and dental problems is of great importance in these patients [5,9]. Patients with diabetes and their families need to learn and practice new lifestyle skills, including monitoring blood sugar, following medication instructions, having a proper diet, physical activity, and more. These skills are important both in controlling diabetes and in preventing or delaying its complications. Diabetic patients should be active participants in the educational process and in setting educational and behavioral goals [7,10].

The only effective and efficient strategy for solving oral health problems is prevention and compliance with oral health [7]. According to the World Health Organization (WHO), health education is the best and most effective way of providing health care to people, both in terms of human resources and heavy cost of medical care [11].

According to WHO, education is the cornerstone of diabetes treatment. In fact, education has been recommended as an essential component of promoting good control of diabetes, and studies have shown that education is effective in controlling and treating the disease, and according to studies, proper training can reduce 80% of diabetes complications [11-12]. The Health Belief Model is one of the oldest models of behavior analysis that has been used in numerous studies of health behaviors such as type 2 diabetes mellitus (T2DM) [13]. Social psychologists developed this model during the 1950s to predict the reasons for people's unwillingness to engage in preventive health behaviors [14].

In this model, diabetic patients first need to feel at risk for oral problems and to understand the seriousness of the complications. Then, in order to reduce these complications, they should understand the benefits of oral health care and reduce the barriers and move the patient toward oral health care through enhancing patients' self-efficacy and empowerment in this regard as well as the impact of cues to action as internal and external incentives (Figure 1).

Considering the lack of a theory based study regarding the oral and dental hygiene in patient with diabetes therefore the current study was conducted to design and evaluate an educational intervention to promote oral and dental hygiene-related behaviors in Patients with T2DM.

## **Methods**

### **Design, procedure and the study sample**

This study was conducted as an educational randomized controlled trial (single blind) on 120 patients with diabetes referring to the County Diabetes Clinic in the city of Kashan, Iran from 2017 to 2018. The population of the current study included all the diabetic patients admitted to Diabetes Clinic (N = 2500).

According to the study Baghiani Moghadam et al. [15] with considering  $\alpha$  equal to 5% and  $\beta$  to 0.1 using the following formula, the sample size was calculated as 58 participants in each group of control and intervention, which this number increased to 60 considering sample loss. So, the total sample size was 120. (see Formula 1 in the Supplementary Files)

In this study having means of 10.8 and 12.42 and standard deviations of 2.79 and 2.57 for the intervention group before and after the intervention for perceived susceptibility construct respectively in Baghiani Moghadam et al. [15] an effect rate of 0.6 was obtained indicating a large effect size and the same effect rate was considered for this study.

Out of the patients having medical records in the clinic, 120 patients were selected through systematic sampling and were randomly (every other person) assigned to two 60-member groups: control and intervention.

Random allocation was achieved using sealed numbered envelopes developed so that randomization is computer-generated. A research assistant who was not involved in the recruitment of participants prepared the envelopes. Participants allocated to the control group (n= 60) received standard care. Participants assigned to the intervention group (n= 60) also received standard care plus the educational intervention based on HBM.

Three months after the intervention, the posttest was conducted for both intervention and control groups to examine the effects of education on the primary and secondary outcomes.

The primary outcomes of the current research include the construct of HBM (Perceived Susceptibility, severity, benefit, barrier, cues to action and self-efficacy). The secondary outcome was oral and dental health behavior's.

According to the panel of experts, three months of follow-up was considered sufficient time to establish consistency, stability, and sustainability in oral health care behaviors.

Based on the nature of the intervention in the current study, the instructor was not blinded to group assignment, but participants and statistical investigator were blinded to group assignment.

Inclusion criteria were having medical records in the Diabetes Clinic, being at the age range of 40-60 years, being literate, living in the city of Kashan, having no oral symptoms, having no history of radiotherapy and hemodialysis, not having another chronic systemic illnesses, not consuming medicines with complications such as dry mouth, not wearing dentures and signing informed consent form to participate in the study. Exclusion criteria were not being willing to participate in the study, moving from Kashan, not being continuously present in training sessions and being afflicted with any condition.

The conceptual framework of conducting this study was that according to the study criteria, the samples were selected by referring to the diabetes clinic and divided into control and intervention groups. Then pretest was administered to both groups based on the questionnaire and the intervention group received

training based on the Health Belief Model. By utilizing the perceived susceptibility construct, patients are firstly exposed to oral and dental problem and understand the complications and at the same time they are taught the benefits and barrier of preventive behaviors. Then by utilizing the internal and external cues to action and increasing patients' self-efficacy, they were taught behaviors related to oral care. The control group also received routine diabetes clinic training. Then the patients were followed for three months and then posttest was administrated and the effect of education on their preventive behaviors was re-evaluated.

Figure 2 shows the framework and flow diagram of the participants during the study period.

## Measures

The data collection tool in this study was a valid and reliable researcher-made questionnaire consisting of questions on demographic information, awareness, constructs of the health belief model and performance in oral hygiene-related behaviors in patients with T2DM. The validity and reliability of this questionnaire was approved and it was completed before the training intervention and three month after the intervention by both control and intervention groups. In this tool, those questions with Content Validity Ratio (CVR) score higher than 0.62 and Content Validity Index (CVI) score higher than 0.79 were considered as appropriate and included in the study [16].

To verify its reliability, the questionnaire was given to 30 diabetes patients and its reliability was calculated as 0.866 using Cronbach's alpha. The validity of the questionnaire was also approved by three hygiene training experts, three internal diseases specialists, one endocrinologist, one dentist, and one expert having a PhD in epidemiology and one executive focal point in the National Program for Prevention and Control of Diabetes (NPPCD) of Iran after removing or modifying some of its statements.

The diabetes patients' awareness of oral care questionnaire consisted of 9 questions. The health belief model constructs questionnaire on oral hygiene-related behaviors consisted of perceived susceptibility (7 questions), perceived severity (10 questions), perceived barriers (7 questions), perceived benefits (8 questions), self-efficacy (11 questions), internal cues to action (triggers) (4 questions) and external cues to action (5 questions). The performance questionnaire on oral hygiene-related behaviors also consisted of 10 questions.

## Scoring

For the awareness the correct answer scored 1 and the wrong one scored 0 and the total score of awareness was calculated out of 9.

The questions of the health belief model constructs were scored on a 5-point scale from strongly agree, agree, no idea, disagree and strongly disagree scoring 1 to 5.

Therefore the scores range of each model construct was finally calculated and reported between one and five.

The questions of performance questionnaire were scored on a 5-point scale of behavior evaluation from never, rarely, sometimes, often and always scoring from 0 to 4 and the scores in this part were reported out of 4.

In this study higher score indicate higher level of awareness, perceived (susceptibility, severity, benefit, barrier, cues to action, self-efficacy) and performance of oral hygiene in patient of diabetics.

## **Intervention**

Before performing the training intervention and in pretest stage, the questionnaires were completed by both groups and entered the computer to be used for determining the training needs and the constructs to be presented in training sessions. Then, according to the health belief model and based on the results of the needs analysis, the training program was prepared for four 120-minute sessions in one month targeted at the intervention group. The materials were presented in the sessions through lectures, question and answer, slide presentation, pamphlets and booklets to benefit all the time in class and make the training available for further study by the patients.

In the first training intervention sessions, awareness of diabetes patients was emphasized aiming at gaining an appropriate knowledge of diabetes and factors affecting deterioration and acceleration of oral complications, the second session's focus on; perceived susceptibility and severity was touched by presenting the statistics on prevalence of oral problems resulted from diabetes and vulnerability of patients and severity of oral complications resulted from inappropriate blood sugar control and not performing oral hygiene-related behaviors. The third session's focus on perceived benefit, barrier and cues to action; the materials of these sessions emphasized on the benefits resulted from performing oral hygiene-related behaviors (reduced oral complications, reduced need to dentistry services and lower medical expenses, feeling of calmness and internal joy), identifying and removing perceived barriers on the way of performing oral hygiene-related behaviors (unawareness, bodily weakness, fatigue, feeling bored, etc.) external cues to action affecting performing oral hygiene-related behaviors (including physicians, diabetes clinic nurses, family members, television, books and magazines in health centers, other diabetes patients) and the role of internal cues to action or triggers (motivation and internal calmness resulted from performing hygiene-related behaviors) were emphasized. The fourth session's focus on perceived self-efficacy and performance of oral and dental health hygiene behaviors; Self-efficacy construct was emphasized by empowering the patients by the aim of facilitating performance of hygiene-related behaviors through presenting educational images on slides, practical training and

distributing packages consisting of a toothbrush, a toothpaste and a floss threader among the patients and providing them with booklets and pamphlets. The performance dimension was approached through operationalizing oral hygiene-related behaviors by patients (brushing the teeth, using a floss threader, washing the tongue, massaging the gum, performing preventive behaviors and caring for probable oral complications of diabetes).

In this study control group received only standard (routine) care with County Diabetes Clinic. It is noteworthy that standard care in Iran includes monthly visits at a healthcare clinic from a doctor, a dietitian, and a nurse and lasts for less than 20 min. These visits were held individually or in groups.

Three months after the training intervention, the questionnaire was given again to the both groups and the all 120 patients completed them.

### **Statistical analysis**

The data were analyzed using SPSS 20 through descriptive and inferential statistics (including independent t-test, paired t-test, Chi-square). The significance level was considered at 0.05. To investigate the normality of the data, Kolmogorov-Smirnov test was used and normal distribution of the data was obtained.

Concerning the gender difference between diabetic men and women with regard to oral hygiene behaviors(which the reviewer considered), due to the small size of the groups (men and women), the distribution of data was non normal and nonparametric tests (Wilcoxon and Mann-Whitney) were used.

This study will be conducted and reported on the basis of Consolidated Standards of Reporting Trials (CONSORT) 2010 statement. A flow diagram of randomized controlled protocol is shown in Fig 2.

### *Design and sample study*

This study was a quasi-experimental research on 120 patients with diabetes referring to the Diabetes Clinic in the city of Kashan, Iran from 2017 to 2018. The population of the current study included all the diabetic patients admitted to Diabetes Clinic (N = 2500).

Considering equal to 5% and  $\beta$  to 0.1 using the following formula, the sample size was calculated as 58 participants in each group of control and intervention, which this number increased to 60 considering sample loss. So, the total sample size was 120.



Out of the patients having medical records in the clinic, 120 patients were selected through systematic sampling and were randomly (every other person) assigned to two 60-member groups: control and intervention.

Randomization was achieved using sealed numbered envelopes developed from a random number generator. A research assistant who was not involved in the recruitment of participants prepared the envelopes. Participants allocated to the control group (n = 60) received standard care. Participants assigned to the intervention group (n = 60) also received standard care plus the educational intervention based on HBM.

Three months after the intervention, the posttest was conducted for both intervention and control groups to examine the effects of education on the primary and secondary outcomes. Based on the nature of the intervention in the current study, the instructor was not blinded to group assignment, but participants and statistical investigator were blinded to group assignment.

Inclusion criteria were having medical records in the Diabetes Clinic, being at the age range of 40–60 years, being illiterate, living in the city of Kashan, having no oral symptoms, having no history of radiotherapy and hemodialysis, not consuming medicines with complications such as dry mouth, not wearing dentures and signing informed consent form to participate in the study. Exclusion criteria were not being willing to participate in the study, moving from Kashan, not being continuously present in training sessions and being afflicted with any condition. Figure 2 shows a flow diagram of the participants during the study period.

### *Research tools*

The primary outcomes of the current research include the construct of HBM (Perceived Susceptibility, severity, benefit, barrier, cues to action and self-efficacy). The secondary outcome was oral and dental health behavior's.

The data collection tool in this study was a valid and reliable researcher-made questionnaire consisting of questions on demographic information, awareness, constructs of the health belief model and performance in oral hygiene-related behaviors in patients with T2DM. The validity and reliability of this questionnaire was approved and it was completed before the training intervention and three month after the intervention by both control and intervention groups. In this tool, those questions with CVR score higher than 0.62 and CVI score higher than 0.79 were considered as appropriate and included in the study [15].

To verify its reliability, the questionnaire was given to 30 diabetes patients and its reliability was calculated as 0.866 using Cronbach's alpha. The validity of the questionnaire was also approved by three hygiene training experts, three internal diseases specialists, one endocrinologist, one dentist, and one expert having a PhD in epidemiology and one executive focal point in the National

Program for Prevention and Control of Diabetes (NPPCD) of Iran after removing or modifying some of its statements.

The diabetes patients' awareness of oral care questionnaire consisted of 9 questions. The correct answer scored 1 and the wrong one scored 0 and the total score of awareness was calculated out of 9.

The health belief model constructs questionnaire on oral hygiene-related behaviors consisted of perceived susceptibility (7 questions), perceived severity (10 questions), perceived barriers (7 questions), perceived benefits (8 questions), self-efficacy (11 questions), internal cues to action (triggers) (4 questions) and external cues to action (5 questions).

The questions of the model constructs were scored on a 5-point scale from strongly agree, agree, no idea, disagree and strongly disagree scoring 1 to 5. The lowest and highest scores in each part of questions of health belief model constructs was different due to the different number of the questions of each construct. So, the score of each dimension was calculated out of 5.

The performance questionnaire on oral hygiene-related behaviors also consisted of 10 questions. This questions of this questionnaire were scored on a 5-point scale of behavior evaluation from never, rarely, sometimes, often and always scoring from 0 to 4 and the scores in this part were reported out of 4.

### *Intervention*

Before performing the training intervention and in pretest stage, the questionnaires were completed by both groups and entered the computer to be used for determining the training needs and the constructs to be presented in training sessions. Then, according to the health belief model and based on the results of the needs analysis, the training program was prepared for four 120-minute sessions in one month targeted at the intervention group. The materials were presented in the sessions through lectures, question and answer, slide presentation, pamphlets and booklets to benefit all the time in class and make the training available for further study by the patients.

In the training intervention sessions, awareness of diabetes patients was emphasized aiming at gaining an appropriate knowledge of diabetes and factors affecting deterioration and acceleration of oral complications; perceived susceptibility and severity was touched by presenting the statistics on prevalence of oral problems resulted from diabetes and vulnerability of patients and severity of oral complications resulted from inappropriate blood sugar control and not performing oral hygiene-related behaviors. Also, the materials of these sessions emphasized on the benefits resulted from performing oral hygiene-related behaviors (reduced oral complications, reduced need to dentistry services and lower medical expenses, feeling of calmness and internal joy), identifying and removing perceived barriers on the way of performing oral hygiene-related behaviors (unawareness, bodily weakness, fatigue, feeling bored, etc.) external triggers affecting performing oral hygiene-related behaviors (including physicians, diabetes clinic nurses, family members, television, books and magazines in health centers, other diabetes patients) and the role of internal cues to action or triggers (motivation and internal calmness resulted

from performing hygiene-related behaviors) were emphasized. Self-efficacy construct was emphasized by empowering the patients by the aim of facilitating performance of hygiene-related behaviors through presenting educational images on slides, practical training and distributing packages consisting of a toothbrush, a toothpaste and a floss threader among the patients and providing them with booklets and pamphlets. The performance dimension was approached through operationalizing oral hygiene-related behaviors by patients (brushing the teeth, using a floss threader, washing the tongue, massaging the gum, performing preventive behaviors and caring for probable oral complications of diabetes).

Three months after the training intervention, the questionnaire was given again to the both groups and the all 120 patients completed them.

### *Data Analysis*

The data were analyzed using SPSS 20 through descriptive and inferential statistics (including independent t-test, paired t-test, Chi-square). The significance level was considered at 0.05. To investigate the normality of the data, Kolmogorov-Smirnov test was used and normal distribution of the data was obtained.

### *Ethical Considerations*

Informed consent was obtained from all the participants (consent was written and no verbal).

All the procedures performed in the study involving human participants, were in accordance with the ethical standards.

The present study was approved by the Research Council of Arak University of Medical Sciences (Grant Number: 1711). Ethics committee approval code number is (IR.ARAKMU.REC.1395.444). This study has been registered in Clinical Trial Registry with the code of IRCT2017050733847N1. After granting the consent of the patients, the aim of the study, the methodology, and the advantages and disadvantages of the study were explained to them. The participants were assured that they are not obliged to participate in the research and that they can leave it whenever they wish. They were also assured of the confidentiality of their information.

## **Results**

In total, 120 patient with T2DM (control group=60 and intervention=60) were enrolled (from 2017 to 2018). Figure 2 shows a flow diagram of the participants during the study period.

The average age of the diabetes patients in the control and intervention groups was  $53.26 \pm 4.46$  and  $53.48 \pm 4.38$  years, respectively, which showed no significant difference based on the results of the independent t-test ( $p=0.675$ ). Table 1 shows the other demographic characteristics of the patients (Table 1).

There was no statistically significant difference between the two groups in terms of age, gender, income level, marital status, health insurance and educational qualifications.

The results showed that there was no significant difference between the intervention and the control groups in terms of health belief model constructs before the intervention.

Based on the results, before the intervention, the mean performance of the intervention and control groups were  $2.16 \pm 0.71$  and  $2.28 \pm 0.76$ , respectively, with no statistically significant difference observed ( $p=0.97$ ). However, after the intervention, the mean performance score of the intervention group ( $3.25 \pm 0.49$ ) was significantly more than that of the control group ( $2.66 \pm 0.56$ ) ( $p = 0.001$ ).

After the training interventions, independent t-test showed a significant difference in terms of awareness, susceptibility, severity, perceived benefits and barriers, self-efficacy and internal cues to action between the intervention and control groups. However, there was no significant difference between the two groups in terms of external cues to action (Table 2).

Concerning the gender difference between diabetic men and women with regard to oral hygiene behaviors, the results showed that in the intervention group before and after the training, the behavior score of the diabetic women significantly increased from  $2.22 \pm 0.52$  to  $3.19 \pm 0.58$  ( $p= 0.025$ ), while it was not significant in the male group ( $p \geq 0.5$ ). The results are presented in Table 3.

## Discussion

Based on the results of this study, the training intervention caused a significant enhancement in oral hygiene-related behaviors in the intervention group compared to the control group. In fact, this enhanced behavior can be attributed to the training method based on the health belief model. The method of performing the training is itself a mechanism which can bring about a positive attitude toward the oral hygiene in diabetes patients.

The significant change in awareness after the intervention in the intervention group showed the effect of the training intervention on enhancing the oral hygiene information related to oral hygiene in diabetes patients. These results were compatible with the results of many interventional studies such as those by Shabibi et al [17] and Tawfik [18] on the awareness of diabetes care. Also, the results of other studies are compatible with those of the present study [14, 19-23]. Therefore, preparing training and educational text and messages appropriate to the characteristics of the audience is one of the necessary principles of any training program as this study tried to present the training materials in a simplified way considering the age and literacy level of the learners.

In this study, perceived susceptibility of diabetes patients increased after the training intervention, while the average score of perceived susceptibility did not change in the control group. This increase can be attributed to the training classes and question and answer and group discussions aiming at making the participants sensitive. This finding is compatible with those of Farahani et al. [24] on compliance with

medicine regime in diabetes patients and other studies on nutritional and care taking behaviors of diabetes patients [25-26].

The results of this study indicate an increased perceived severity among patients compared to that perceived before the intervention, which is due to the effect of training classes, mentioning complications of the disease and presenting images on slides, distributing pamphlets and more interaction of patients as a result of group discussions. However, this increase was not observed among the patients in the control group. This finding is compatible with the results of the studies related to increased perceived severity among diabetes patients and care aspects in nutrition and medicine regime and other care behavior in diabetes control [24-28].

In this study, the perceived barriers of the diabetes patients were lower compared to those before the intervention. Factors such as insufficient awareness of different kinds of oral healthcare and the way to do them, bodily weakness and physical diseases due to diabetes, high expenses of dentistry services and being afraid of dental treatments were identified as barriers and decreased through the training intervention, providing standard and programmed solutions and strategies aiming at enhancing the oral hygiene, provision of tools required for oral hygiene and teaching required skills to the patients. The obtained results were compatible with those of other similar studies on the barriers perceived by diabetes patients regarding the diabetes healthcare [18, 24, 25, 28, 29].

The perceived benefits of patients increased after the training intervention as they understood how observing oral hygiene can decrease the risk of tooth decay, cardiac and digestive diseases and halitosis, keep the gums healthy and reduce the dentistry expenses. This finding was compatible with the similar interventional studies such as those by Sohrabivafa et al. [19], Sharifirad et al. [25] and other studies [18, 24, 28, 29].

In this study an external cues to action in the intervention group after training slightly increased (from 3.5 to 3.77), which may be due to the fact that both groups have been receiving their information from social media and health centers and clinics before the intervention, and the educational intervention has not had much impact.

After the training intervention, self-efficacy construct increased by empowering the patients by the aim of facilitating performance of hygiene-related behaviors through presenting educational images on slides, practical training, dividing the behaviors into smaller parts and distributing packages consisting of a toothbrush, a toothpaste and a floss threader among the patients and providing them with booklets and pamphlets. Self-efficacy increased the capability of diabetes patients for controlling and managing their oral hygiene and this behavior was kept and performed continuously after the training intervention. This finding was compatible with those of Farahani et al. [24] and other studies on enhancing perceived self-efficacy of diabetes patients in diabetes care [18, 25, 27-30].

The performance of oral hygiene-related behaviors by the patients increased in this study. This increase was due to operationalizing the oral hygiene-related behaviors (teaching the correct way of brushing the

teeth, using a floss threader, washing the tongue, massaging the gum, performing preventive behaviors and caring for probable oral complications of diabetes).

In the present study, health behaviors were reported more in women than in men, so it seems that women are more sensitive to their health and the rate of their participation in health programs and their acceptance and practice of health behaviors are more than men. Therefore, designing educational programs to increase the participation of diabetic men in accepting oral health behaviors should be considered in future studies.

Successful control of oral health of diabetes patients mainly depends on performing hygiene-related behaviors by the patients [31]. In this study, the patients who stopped following the recommended oral hygiene-related behaviors mentioned lack of motivation, fatigue, laziness and high dentistry expenses as the reasons. Therefore, motivation and dentistry services with appropriate expenses are required for diabetes patients to perform the recommended oral hygiene-related behaviors correctly and continuously. The results of this study were compatible with those of the studies by Khani Jeihouni et al. investigating the health belief model constructs and tooth decay index in pregnant women [32], by Friel et al. evaluating the effect of oral hygiene intervention among teenagers in Ireland [33] and by Shabibi et al. investigating the application of health belief model to diabetes patients self-care [17].

With considering in the process of creating health behaviors in order to change people's attitudes and create stability and sustainability in health behaviors, group discussions with adequate time in educational sessions are needed. However, it is suggested for the general population, some educational content can be delivered indirectly by means of educational booklets, pamphlets, or via social media to reduce the number of training sessions.

One of the strengths of this study is that the training intervention on oral hygiene care for diabetes patients was designed based on the needs analysis (pre-test) and programmed according to the health belief model constructs and the patients' behaviors were followed up three months after the training intervention.

Several limitations of this study could be the current research was performed in one geographical area in Iran, the generalizability of our results is decreased. Other limitations of this study include the small sample and use of self-report questionnaires. Also, we followed up the patients for 3 months as the longer follow up may lead to more accurate outcomes. In addition, other factors that can affect the results such as the amount of stress and its effect on oral and dental health and especially gums were not measured in this study, and thus could be addressed in future studies.

It is suggested that in future studies the study design is based on double-blind randomization and it is also suggested that more studies be conducted with a larger sample size and in addition to the questionnaire, dental tests and examinations for diabetic patients are also used to assess health behaviors.

## Conclusion

The training intervention based on the health belief model lead to enhanced oral hygiene-related behaviors in patients with T2DM. It was found that diabetes patients' skills regarding the oral hygiene-related behaviors can be enhanced through training these patients and performing active follow-ups. This can finally lead to a reduction in incidence of oral complications in diabetes patients. Control, monitoring and training follow-ups are also recommended to be included in these training programs.

## List Of Abbreviations

HBM: Health Belief Model; CVR: Content Validity Ratio; CVI: Content Validity Index; T2DM: Type 2 Diabetes Mellitus.

## Declarations

### Acknowledgment

We would like to thank all patients who participated in this study. This study was financially sponsored by Arak University of Medical Sciences with grant number 1711.

### Ethics approval and consent to participate

All participants were informed about the study and confidentiality protocols informed consent was obtained from all the participants (Consent was written and no verbal).

The present study was approved by the Research Council of Arak University of Medical Sciences (Grant Number: 1711).

The Ethics Committee of Arak University of Medical Sciences confirmed the morality and ethics of that study; (IR.ARAKMU.REC.1395.444) ). This study has been registered in Clinical Trial Registry with the code of IRCT2017050733847N1 .

All the procedures performed in the study involving human participants, were in accordance with the ethical standards. After granting the consent of the patients, the aim of the study, the methodology, and the advantages and disadvantages of the study were explained to them. The participants were assured that they are not obliged to participate in the research and that they can leave it whenever they wish. They were also assured of the confidentiality of their information

### Consent for publication

Not applicable.

### Availability of data and materials

Upon request, we can offer onsite access to external researchers to the data analyzed at Arak University of Medical Sciences, Arak, Iran.

### **Competing interests**

The authors declare that they have no competing interests.

### **Funding**

This study is financially supported by Arak University of Medical Sciences (Grant Number: 1711), Arak, Iran.

### **Authors' contributions**

The authors' responsibilities were as follows: Study design: MS, NR and MM; data collection: MM; analysis and interpretation of the data: RM; drafting of the manuscript: MM, MS and NR; critical revision of the manuscript: MS, NR, and RM; study supervision: MS. All authors read and approved the final manuscript.

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## Tables

**Table 1.** Comparison of the intervention and control groups, concerning the demographic variables

Variable	Group	Control		Intervention		P-Value
		Frequency (N)	Percent (%)	Frequency (N)	Percent (%)	
Sex	Female	36	60	40	66.6	<b>0.44</b>
	Male	24	40	20	33.4	
Health insurance	Yes	59	98.2	60	100	<b>0.315</b>
	No	1	1.8	0	0	
marital status	Married	58	96.6	59	98.3	<b>0.390</b>
	Single	2	3.4	1	1.7	
Educational qualification	Elementary	35	58.4	43	71.6	<b>0.019</b>
	Diploma	18	30	16	26.6	
	University	7	11.6	1	1.8	
Income level	Weak	11	18.3	6	10	<b>0.264</b>
	medium	42	70	51	85	
	Good	7	11.7	3	5	

**Table 2.** Comparison of the intervention and control groups, concerning the HBM, before and after the intervention

Variable	Group	Control		Intervention		P-value <sup>a</sup>
		Mean	SD	Mean	SD	
Knowledge	Before	5.26	2.03	5.45	2.2	0.99
	After	5.85	1.5	8.16	0.95	0.012
	P-value <sup>b</sup>	0.63		0.001		
Perceived susceptibility	Before	3.23	0.76	3.33	0.66	0.168
	After	3.64	1.01	4.09	0.49	0.156
	P-value <sup>b</sup>	0.074		0.001		
Perceived of severity	Before	4.22	0.61	4.33	0.68	0.71
	After	4.52	0.6	4.95	0.6	0.001
	P-value <sup>b</sup>	0.17		0.001		
Perceived barrier	Before	3.38	0.75	3.54	0.74	0.68
	After	3.35	0.51	2.69	1.05	0.001
	P-value <sup>b</sup>	0.77		0.001		
Perceived of benefit	Before	4.29	1.13	4.18	0.66	0.94
	After	4.14	0.68	4.84	0.29	0.001
	P-value <sup>b</sup>	0.72		0.001		
Self-efficacy	Before	3.37	0.71	3.42	0.62	0.65
	After	3.65	0.66	4.08	0.56	0.001
	P-value <sup>b</sup>	0.04		0.001		
Internal of cues to action	Before	3.92	0.85	4	0.74	0.60
	After	4	0.65	4.25	0.72	0.17
	P-value <sup>b</sup>	0.27		0.033		
External of cues to action	Before	3.67	0.70	3.50	0.83	0.67
	After	3.53	0.46	3.77	0.68	0.005
	P-value <sup>b</sup>	0.71		0.33		
Performance	Before	2.28	0.76	2.16	0.71	0.97
	After	2.66	0.56	3.25	0.49	0.001
	P-value <sup>b</sup>	0.714		0.001		

<sup>a</sup> Independent t test

<sup>b</sup> Paired t test

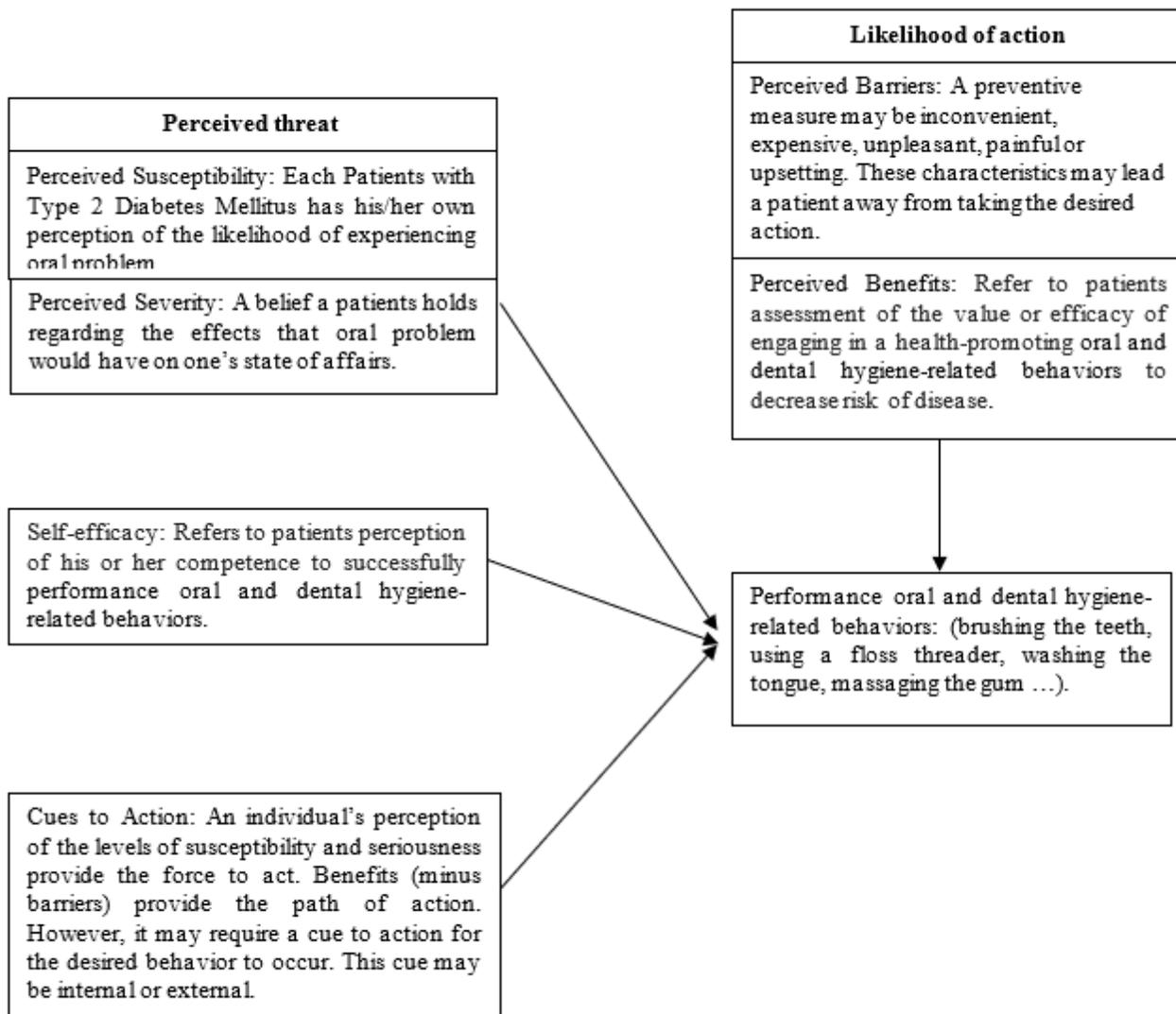
**Table 3.** Comparison of the intervention and control groups, concerning the performance of oral hygiene based on sex, before and after the intervention

Group		Intervention N=60 (Female=40, Male=20)		P- value <sup>a</sup>	Control N=60 (Female=36, Male=24)		P- value <sup>a</sup>
		Before intervention	After intervention		Before intervention	After intervention	
sex	Female	2.22±0.52	3.19±0.58	0.025	2.35±0.50	2.39±0.58	0.18
	Male	2.40±0.54	2.88±0.65	0.42	2.17±0.55	2.30±0.61	0.36
	P- value <sup>b</sup>	0.78	0.89		0.99	0.88	

<sup>a</sup> Wilcoxon test

<sup>b</sup> Mann-Whitney test

## Figures



**Figure 1**

Health Belief Model (HBM)

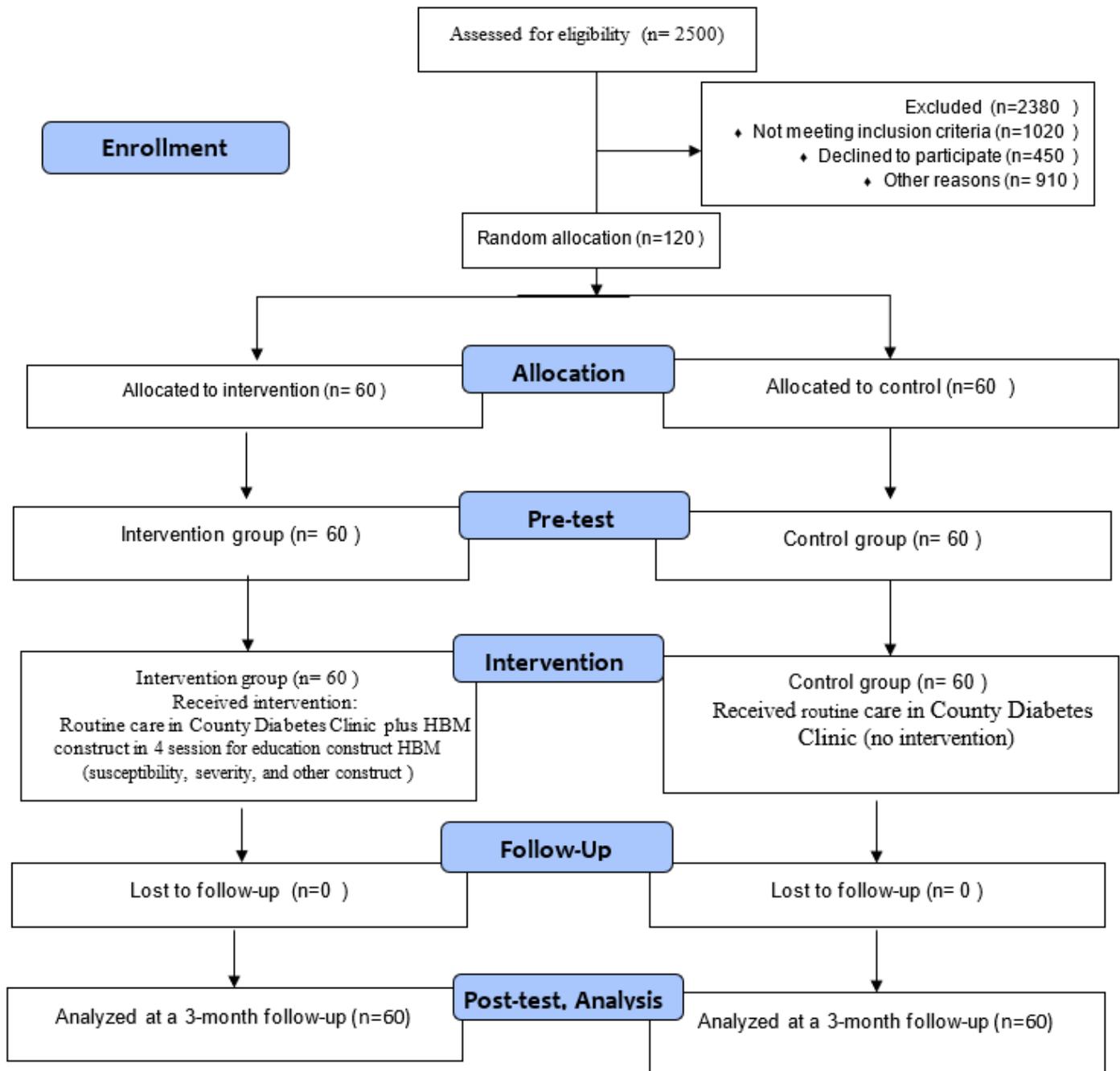


Figure 2

Flow diagram of the participants

## Supplementary Files

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- [Formula1.jpg](#)