Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessing the effect of educational intervention based on HBM in incidence of periodontitis and gingivitis among adults

Protocol summary

Study aim

Determining the effect of educational intervention based on health belief model in the incidence of periodontitis and gingivitis

Design

In this study, 196 patients with periodontitis and gingivitis who are admitted to the dentistry department are selected. The participants are randomly divided into intervention and control groups and trained in the educational program.

Settings and conduct

In this clinical trial study, the effect of educational intervention based on health belief model on incidence of periodontitis and gingivitis in adult population referred to dental clinic in Tehran is as follows. Random selection of people who have Periodontitis and inflammation of the gum are divided into two groups: intervention and control, through a randomized block of permutation, the number in each group is 98. The total sample is 196 individuals with periodontitis and gingivitis. The questionnaire is to be completed by both groups. Information is provided. In both cases, non-surgeon treatment (Scaling and root planing) is done, but dental and oral health education intervention takes place only in the intervention group. And the intervention group is not provided to the control group. A follow-up of one month and three months is done in both groups and a questionnaire is again provided to complete the information.

Participants/Inclusion and exclusion criteria

The entry criteria are for people with a pocket depth index greater than 4 mm and have gingivitis that is free of systemic disease and no smoking. The exit criteria are all those who do not have these features and have at least two sessions of absentee training sessions.

Intervention groups

In the intervention group, in addition to non-surgical treatment including rooting and leveling, oral and dental health education and only non-surgical treatment without health education were performed in the control group. Oral oral and oral practice (using replica), brushing the standard Bass and proper use of dental floss twice a day. Individual training takes place in three sessions (referral day - one month later and three months later) for fifteen minutes and a group once for 60 minutes. In the field of training based on model structures: 1. The benefits of proper oral and dental health and perceived severity are explained. 2. For expressing the perceived benefits and barriers, group discussion and lecture are used. By simply saying brushing and using dental floss, each of these behaviors is likely to be discussed. 3. In the field of self-efficacy Patients are assured that they can best observe their oral hygiene, especially in the following referrals and one and three-month follow-ups of verbal encouragement and talk about successful experiences. Patients before the intervention start a questionnaire The information is provided. Patient's referral is done after one month. Re-examination and hair indices. The rejection of the condition is re-measured. The examination is again recorded in the special form of examination of each person. Repetitive oral and dental health education is done in the intervention group; for the second time, the questionnaire is completed. Repeated reintroduction 3 months after Second visit. A re-examination and final evaluation are carried out. In the control group, health education is not provided based on the model, only the scaling and determination of plaque and periodontal indexes is done. To the control group, a three-time referral is completed.

Main outcome variables

The effect of oral and dental health education on reducing the periodontitis and gingivitis is in the subjects and reducing the plaque index to 10% and decreasing the periodontal envelope depth.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151006024381N2**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date
2017-12-28, 1396/10/07

Registrant information
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Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-06, 1396/09/15
Expected recruitment end date
2018-04-04, 1397/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of educational intervention based on HBM in incidence of periodontitis and gingivitis among adults

Public title
The effect of model-based training on periodontitis and gingivitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gums inflammation Depth of envelope greater than 4 mm No systemic disease Lack of smoking
Exclusion criteria:
Systemic disease Tobacco use Absence at least two sessions of training sessions
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **196**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals randomly divided into two groups of intervention and control group. The number of people in each group is 98
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences, Faculty of Health
Street address
Tehran University of Medical Sciences, Qods St, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-11-14, 1396/08/23
Ethics committee reference number
IR.TUMS.SPH.REC.1396.4000

Health conditions studied

1

Description of health condition studied
periodontitis
ICD-10 code
k05.3
ICD-10 code description
Chronic periodontitis

2

Description of health condition studied
gingivitis
ICD-10 code
k05.1
ICD-10 code description
Chronic gingivitis

Primary outcomes

1

Description
Perceived severity
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

2

Description
Perceived benefits
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

3

Description
Perceived barriers
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

4

Description
Self-efficacy
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

5

Description
Knowledge
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

6

Description
Performance
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

7

Description
Perceived sensitivity
Timepoint
1 and 3 months after training
Method of measurement
Self-made questionnaire

8

Description
Microbial plaque
Timepoint
1 and 3 months after training
Method of measurement
Microbial plaque detector-plaque indicator

9

Description
Depth of envelope
Timepoint
1 and 3 months after training
Method of measurement
Probe of dentistry

Secondary outcomes

empty

Intervention groups

1

Description
In this interventional study, oral and dental health education is given in the standard bass method. In addition, education based on the health belief model is also provided for periodontitis and gingivitis. In the control group, no training is given. In
Category
Prevention

2

Description
Control group: No control intervention is performed in the control group. Only the scaling and determination of the index of the plaque and the volume of the envelope takes place.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Behfar Dental Clinic
Full name of responsible person
fatemeh abbasipour
Street address
Saber Ave. Pol St. Damavand St
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1985717443

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Tehran University of Medical Sciences

Full name of responsible person

Massoud Younesian

Street address

Keshavarz Blvd.-Corner of Ghods St.- Central Organization of the University

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Garmaroudi

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In this study, because of a sample size of 196 people, no individual identifiable data is used. The name of the person with the phone number is taken entirely voluntarily and optionally.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available