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The effect of viewing digital images of the severe consequences of poor oral hygiene on patients' adherence to good oral hygiene practice

Submission date
08/01/2024

Recruitment status
No longer recruiting

Registration date
09/01/2024

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims.
Adhering to good oral hygiene is vital for people's oral health and dental treatment success. However, it is difficult to achieve good oral hygiene adherence in dental patients. Several studies have explored different methods to increase patients' oral hygiene adherence. For instance, studies have used verbal oral hygiene instructions, while others employed written leaflets or digital oral hygiene instructions. This pilot trial aims to study the effect of oral hygiene instructions given via video while supplemented with images showing the severe consequences of poor oral hygiene on patients' oral hygiene adherence.

Who can participate?
Healthy female adults aged 18-30 years

What does the study involve?
The participants will be divided into three oral hygiene instruction groups:
Group 1: They will receive verbal oral hygiene instructions
Group 2: They will receive video-based oral hygiene instructions
Group 3: They will receive video-based oral hygiene instructions similar to group 2 but will also be shown images of the severe consequences of poor oral hygiene
The oral hygiene instructions (video or verbal) will be given to each participant at the initial visit. The researchers will also measure participants' oral hygiene status at the initial visit using three methods:
1. Plaque accumulation on teeth surfaces after rinsing with a discoloring solution.
2. The percentage of teeth that exhibit gum bleeding
3. Gum bleeding index based on the total percentages calculated from method number 2.

What are the possible benefits and risks of participating?
This study involves no expected risks to participants. This study's obtained results will be of great importance for dental practitioners and especially for orthodontic specialists in the control of optimum oral hygiene in pre-orthodontic patients.

Where is the study run from?
Qassim University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
May 2022 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nabeel Almotairy, n.s.almotairy@qu.edu.sa

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical efficacy of verbal versus video oral hygiene instructions in reducing plaque accumulation and gingival bleeding in healthy female adults

Study objectives
The null hypothesis is that showing patients' digital images displaying the consequences of poor oral hygiene (OH) will not influence their oral hygiene adherence.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2022, Committee of Research Ethics at Qassim University (AlQassim, Buraidah, 51452, Saudi Arabia; +966 (0)163010355; bioethics@qu.edu.sa), ref: 21-19-05

Study design
Prospective single-blinded randomized clinical three-arm parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
University/medical school/dental school

Study type(s)
Prevention

Participant information sheet
Not availabe in web format, please use contact detials to request a participant information sheet.

Health condition(s) or problem(s) studied
Oral hygiene adherence in healthy female adults

Interventions
The experiment will be conducted by a dentist with a minimum of 2 years' experience.

Using the randomization.com website, a computer-generated random selection list with a 1:1:1 allocation ratio for the three intervention groups will be prepared. Sealed opaque envelopes will be prepared following the generated list to reduce the risk of concealing the group allocation to the examining dentists before recruiting the study participants. Trained and calibrated dentists who are not involved in generating the random list or creating the sealed envelope will be responsible for recruiting the participants and collecting the oral health parameters. After ensuring the participation eligibility, each participant will be allowed to draw an envelope to be assigned to one of the three groups.

The participants will be randomly divided into three groups of patients:
1. The group will be given verbal oral hygiene instructions
2. The group will be shown a one-to-one 5-minute video-based presentation containing recommended brushing and flossing techniques WITH images displaying the consequences of poor oral hygiene will be presented
3. The group will be shown a one-to-one 5-minute video-based presentation containing recommended brushing and flossing techniques WITHOUT images displaying the consequences of poor oral hygiene will be presented.

The verbal or video-based oral hygiene instructions will be given at the baseline visit only. Each participant will be asked if she understood the verbal or video-based instructions, and she will be given the chance for any clarifications. Then, their oral hygiene status will be assessed using the below outcome measures.

The participants will come back after 4 weeks to assess their oral hygiene status.

Intervention Type
Behavioural

Primary outcome measure
Plaque score: a modified O'Leary Index is used to define the number of surfaces free of plaque as a percentage of surfaces in the mouth following a rinse with a discoloring solution — six surfaces will be assessed per tooth at baseline and 4 weeks post-intervention.

Secondary outcome measures
1. Gingival bleeding index as follows: 0: no bleeding on probing, 1: a single bleeding point, 2: several bleeding points or thin line, 3: interdental space filled with blood
2. Bleeding on probing: the percentage of teeth surface numbers that are free from gingival bleeding — four surfaces per tooth.
Each will be measured at baseline and 4 weeks post-intervention.

Overall study start date
15/05/2022

Completion date
20/11/2023

Eligibility

Key inclusion criteria
1. Have at least 20 natural teeth
2. Be willing to participate in this study and sign the consent form

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Upper age limit
30 Years

Sex
Female

Target number of participants
21

Total final enrolment
21

Key exclusion criteria
1. Students in medical or dental fields
2. Under current dental or orthodontic treatment
3. Active smoker
4. Has acute or chronic immune disturbances
5. Currently pregnant
6. Have any systemic diseases that could directly or indirectly inhibit optimum oral health maintenance, such as diabetes, known antibiotic treatments, and oral-related diseases such as periodontitis
7. Has insufficient Arabic language skills than can inhibit understanding of the study goals and oral health instructions

Date of first enrolment
15/08/2023

Date of final enrolment
20/10/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Qassim University
College of Dentistry
AlQassim
Buraidah
Saudi Arabia
51452

Sponsor information

Organisation
Qassim University

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Sponsor type
University/education

Website
http://www.qu.edu.sa/Pages/Home.aspx

ROR
https://ror.org/01wsfe280

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
10/04/2024

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be available upon request from Dr Nabeel Almotairy (n.s.almotairy@qu.edu.sa). The type of data that will be shared is currently not known. The timing for availability is upon a reasonable request. Informed consent was obtained.

IPD sharing plan summary
Available on request