

TITLE OF RESEARCH:
Effect of pre-treatment
photographs on oral
hygiene maintenance in
orthodontic patients
DESCRIPTION: Study
protocol and statistical
analysis plan

NCT number: NCT06010797

DATE: 20-08-2023

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

MATERIAL AND METHODS

1) Setting

The study was carried out in Orthodontics department, Rehmat Memorial Dental Teaching Hospital, Abbottabad

2) Duration of Study

The study lasted from month of August 2020 to month of July 2021.

3) Sample Size

The sample size was calculated to be 60 patients (30 in each group) using the WHO software for sample size calculation in health studies using the formula for hypothesis tests for two population mean (one sided) with the following assumptions: Statistical significance=5%, Statistical Power=80%, Anticipated mean \pm SD PI score of Study group after 3 months=1.68(0.40) and Anticipated mean \pm SD PI score of Control group after 3 months=1.72(0.33).

4) Sampling Technique

The sampling technique used was non-probability consecutive sampling. Patients visiting Orthodontic Department of Rehmat Memorial Postgraduate Dental Teaching Hospital to start their Orthodontic treatment were selected.

5) Sample Selection

Inclusion Criteria

- Patients of both genders
- Between age 13-25 years

Exclusion criteria

- Patients with previous orthodontic treatment
- Handicapped patients
- Patients with any systemic disease
- Generalized periodontal disease
- Congenital malformations

6) Study Design

The study design was a double blinded randomized controlled trial.

7) Data Collection Procedure

After taking approval (Annexure A) from ethical approval committee of Rehmat Memorial Dental Teaching Hospital an informed written consent (Annexure B) was taken from the patient. The oral hygiene maintenance of the patients were examined with the University of Michigan 'O' probe with Williams markings for the Plaque Index (PI) on the first visit (T_0) and then 3 months after starting treatment (T_1). Patients were divided into two groups using block randomization to remove confounding factor.

- **Measuring PI:**

For PI (Silness-Löe Index)^{1,2} plaque was assessed on buccal, lingual, mesial and distal surface of teeth number 16, 12, 24, 32, 36 and 44. Each surface was given a score from 0-3. The score from the four surfaces of the tooth were added and divided by four to get plaque index for individual tooth. The index for the patient was obtained by summing the indices for all six teeth and dividing by six. Scoring was recorded on form (Annexure C).

- **Camera settings for photographs:**

Patients' pre-treatment photographs were taken with Nikon D3500 SLR camera with 18 – 55mm kit lens. Settings for extra-oral photographs were aperture size of f/8, shutter speed of 1/200, ISO 100 and magnification of 1:10.³ Extra-oral photographs were taken with white clear background. Camera settings for intra-oral photographs were aperture size of f/20, shutter speed of 1/125, ISO 200 and magnification of 1:2.³ To eliminate shadows Meike MK-14 EXT macro ring flash with twin tubes was attached to the camera.

- **Randomized Controlled Trial Design:**

- (a) **Participants:**

- Orthodontic patients.

- (b) **Intervention:**

- Patients' own pre-treatment dental photographs.

- (c) **Study group:**

- Orthodontic patients who are shown dental photographs.

- (d) **Comparison group:**

- Orthodontic patients who are not shown dental photographs.

- (e) **Outcome:**

- Good oral hygiene measured by plaque index.

- (f) **Block randomization:**

To decrease selection or accidental bias, patients were assigned group A or B using block randomization technique. Blocks were created, size of each block was 4 with 2 'A's and 2 'B's. For 2 groups there were 6 possible blocks. From random number table a random sequence of blocks was generated. Patients were then assigned groups according to blocks.

(g) Subjects:

I. Group 1:

Included 30 patients and these patients were shown full extra-oral and intra-oral photographs.

II. Group 2:

Included 30 patients and these patients were not shown any photographs.

All subjects received similar oral hygiene instructions. Those in group A were shown their photographs while those in B were not shown any photographs.

8) Data Analysis Plan

Statistical analysis was done on SPSS (version 26.0) software. Categorical variables like occupation, address and gender were described as frequencies or percentages. Quantitative variables like age and PI were described as mean \pm SD. The two groups were compared regarding gender, occupation and address distribution with chi-square test at 5% level of significance at p value < 0.05. The two groups were compared with independent t test in the case of plaque index which showed a normal distribution and with Mann Whitney U Test in the case of age which showed a non-normal distribution. For intra-group comparison paired t-

test was performed. All these were taken at 5 % level of significance at $p \text{ value} < 0.05$. Relative risk was also calculated at 95 % confidence interval.

Annexure – A

ETHICAL APPROVAL LETTER



WOMEN MEDICAL & DENTAL COLLEGE, ABBOTTABAD.

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Ref. No. WMC/RM/DH/EO/621

Date. 03/05/2019

**THE ETHICAL COMMITTEE AT REHMAT MEMORIAL DENTAL HOSPITAL,
ABBOTTABAD AFFILIATED WITH WM&DC ABBOTTABAD APPROVAL LETTER**

This is to certify that the protocol of the study "Effect of pre-treatment photographs on oral hygiene maintenance in Orthodontic patients" has been reviewed. The ethical committee of Rehmat Memorial dental hospital has found no objections in the study.

Dr. Eizza Niaz, the investigator of this study, has agreed on maintaining the confidentiality of any personal information acquired from the subjects included in this study. All information will be acquired and subjects included after their informed consent. All subjects will be thoroughly apprised of the study design its advantages and disadvantages. No remuneration will be provided.

Dr. Zahur Quyyum

BDS, MCPS, FCPS

Professor,

Oral & Maxillofacial Surgery.

Annexure-B

CONSENT FORM FOR RESEARCH

I _____ D/S/O _____

assure the following that:

- I have been informed and understand the procedure and protocol of this study.
- I have been given the opportunity to ask questions.
- I agree to take part in this study.
- I understand that participation involves examination of my oral cavity.
- I have been informed of the possible recall visits.
- I understand that my participation is voluntary and that I can withdraw from research any time.
- I understand that all information I provide for this study will be treated confidentially.
- I agree to digital images during research.

Signature of the participant: _____

Date of interview: _____

Signature of investigator taking consent: _____

Annexure-C

QUESTIONNAIRE

EFFECT OF PRE-TREATMENT PHOTOGRAPHS ON ORAL HYGIENE MAINTENANCE IN ORTHODONTIC PATIENTS SURVEY INFORMATION

Date of Interview: _____

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DEMOGRAPHIC DETAILS:

First Name:			
Father's Name:			
Age:			
Gender:	Male:	Female:	
Occupation:			
Address:			
Group:			

SCORING CHART:

Maxilla												
Tooth	16				12				24			
PI score	B	L	M	D	B	L	M	D	B	L	M	D
Mandible												
Tooth	36				32				44			
PI score	B	L	M	D	B	L	M	D	B	L	M	D

Average PI score: _____

(B=Buccal,L=Lingual,M=Mesial,D=Distal,PI=Plaque index)

REFERENCES:

1. Hiremath S. Textbook of Public Health Dentistry. 3rd ed. India: Elsevier India; 2016;chapter 17;pg 162-168
2. Oral health database. Silness-Loe Index. [cited on 23rd April,2019]. Available from:<http://www.mah.se/CAPP/Methods-and-Indices/Oral-Hygiene-Indices/Silness-Loe-Index/>.
3. Guide to Dental photography. Decisions in Dentistry. [cited on 5th August,2021]. Available from: <http://www.decisionsindentistry.com/article/guide-to-dental-photography/>.