

RESEARCH TITLED :

Comparison of Traditional Instructions Vs AI based Instructions with
Customized ChatGPT as Remote Support System on Education of Orthodontic
Patients: A Randomized Control Trial

Date of ERB approval: 31/7/25

MATERIALS AND METHODS:

Study Design: A two arm randomized controlled trial (RCT) will be conducted

SETTING: Department of Orthodontics, School of Dentistry Islamabad

Participants

DURATION OF STUDY: One year after the approval of synopsis

SAMPLE SIZE: By using open EPI calculator sample size is 60 (30 each group) with level of significance 5%, power of test 80%. Mean of 1.03 and 1.27 with standard deviation of 0.06 and 0.08 in intervention group and control group respectively.(3)

SAMPLE SELECTION:

• Inclusion Criteria:

- Patients aged 18–30 years undergoing bracket placement
- No prior experience of orthodontic treatment
- In good state of physical and mental health
- Understand the medium of instructions properly which will be Urdu language in this study

- Internally motivated patients with fairly good oral hygiene at the start of treatment

- Access to smart phone or internet at home

Exclusion Criteria;

- Systemic conditions affecting oral hygiene
- Cognitive impairments that may hinder comprehension
- Patients with language barriers that might affect their understanding of instructions

SAMPLING TECHNIQUE: Simple random probability sampling will be employed

DATA COLLECTION PROCEDURE

Interventions:

- Group A(Intervention Group): Verbal instruction will be given by Advance Voice Feature of ChatGPT plus in chair side sitting.Moreover an AI assistant **Brace AI**, a custom GPT tailored by researcher will be shared with patients via QR code or URL link which will be available to patients for remote support
- Group B(Control Group): Verbal instructions will be given to patients after placement of brackets in a traditional chair-side manner by an experienced orthodontist. All the instructions and information given will be in accordance with the guidelines given by leading orthodontic societies (American Board of Orthodontics). Moreover a written pamphlet including all post braces care will be given to patients

Outcome Measurement:

- Oral hygiene outcome will be measured by using oral hygiene indices (Silness Loe plaque index(9), Modified gingival index(10) measured at T0,T1,T2,T3
- Patient satisfaction, engagement and interactivity will be assessed using a questionnaire(Annexure 2) filled at(T0), 1 month(T1),(T2) and (T3)
 - Ability to recall will be assessed by taking a recall quiz at T0,T1,T2,T3

STATISTICAL ANALYSIS:

Data analysis will be done using SPSS 23 software. Qualitative variables i.e. gender will be presented as frequency and percentages. Quantitative variables i.e. age will be measured as mean and standard deviation. For intra- and intergroup comparisons of parametric data, the paired sample t-test and independent t-test will be applied, respectively. In cases of non-parametric data, the Mann-Whitney U test will be used for intergroup comparisons.. Reliability of questionnaire will be checked by cronbach's alpha. The level of significance will be set at an alpha level of < 0.05, and 95% confidence intervals.

CONSENT FORM

Comparison of Traditional Instructions Vs AI based Instructions with Customized ChatGPT as Remote Support System on Education of Orthodontic Patients: A Randomized Control Trial

RESEARCH CONDUCTOR:

1. I confirm that I have understood the research information for the above study and have had the opportunity to ask questions
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without any medical care or legal rights being affected
3. I understand that the above research conductor from the Department of Orthodontics, School of Dentistry, Islamabad will have access to my personal details
4. I understand that any data or information used in any publication, which arise from this study will be anonymous
5. I understand that all data will be secured and is covered by Data Protection act
6. I agree that the conductor can contact me on the telephone number mentioned below to arrange an interview at time and location to suit me

Date: -----

Name: -----

Signature: -----

Contact: -----

Address: -----

Witness : -----