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Using artificial intelligence to improve patient understanding and acceptance of orthodontic treatment

Submission date 03/12/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/12/2025	**Overall study status** Completed	
Last Edited 12/05/2026	**Condition category** Oral Health	

Plain English summary of protocol

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Effect of AI-enhanced visual simulations and explanations on patient understanding and acceptance of orthodontic treatment: a randomized controlled trial

Acronym
AIOPA

Study objectives
1. To determine whether AI-enhanced communication increases treatment acceptance within 14 days of consultation compared with standard consultation.
2. To assess differences in patient comprehension scores between AI-enhanced and standard consultations.
3. To compare decisional conflict, decisional regret, satisfaction, and trust in the clinician between groups.
4. To measure differences in consultation duration and clinician workload.
5. To explore whether demographic or clinical variables (age, sex, education, electronic health literacy (eHealth literacy), malocclusion severity, treatment type) modify the effect of AI-enhanced communication.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/11/2025, Ethics Committee of the College of Dentistry, University of Sulaimani (Old Campus – Madam Mitterrand Street, College of Dentistry, University of Sulaimani, Sulaimani, 46001, Iraq; +964 772 544 7528, +964 770 157 8705; dentistry.ethics@univsul.edu.iq), ref: CoD-EC-25-0104

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Patient understanding and acceptance of orthodontic treatment

Interventions

Participants will be allocated in a 1:1 ratio using a computer-generated randomisation sequence with concealed allocation via sealed opaque envelopes opened only at the time of consultation. Outcome assessors will remain blinded to group assignment.

Control group (Standard consultation): The orthodontist explains the patient's condition and treatment options using the diagnostic records (photos, radiographs, tracings, and models) together with a generic printed brochure about orthodontic treatment and appliance care.

Intervention group (AI-enhanced consultation): Patients receive all elements of the control consultation plus AI-generated visual simulations, plain-language explanations (Kurdish) and a digital take-home summary via QR code. Consultation duration is kept similar between groups.

AI-Generated Visual Simulations
Individualized treatment simulations will be generated using 3Shape OrthoAnalyzer™ software, version 2025.1 (3Shape A/S, Copenhagen, Denmark). The software integrates AI-based algorithms trained on extensive orthodontic datasets to simulate predicted outcomes of malocclusion correction.
Baseline diagnostic records, including intraoral and extraoral photographs, lateral cephalograms, and digital study models obtained via intraoral scanning, will serve as input data. The system produces:
- 2D before–after overlays superimposed on facial and intraoral photographs,
- 3D interactive digital models illustrating predicted tooth alignment and occlusal changes, and
- Animated treatment progression sequences that demonstrate key transitional stages and the anticipated final result.

To ensure consistency and reliability, all simulations will be generated following standardized parameters embedded in the software (e.g., correction of crowding, overjet reduction, arch coordination). Each simulation will be reviewed by the investigator for clinical plausibility prior to presentation. During the consultation, patients will view the simulation on a tablet, and a secure QR code will be provided to access the same materials at home.

The simulations are intended exclusively as decision-support and communication tools to enhance patient comprehension and confidence; they do not replace the orthodontist's diagnostic judgment or definitive treatment planning.

Total duration of intervention: Each participant receives a single orthodontic consultation session (with or without AI-enhanced communication depending on the allocation arm).

Total duration of follow-up: 14 days after the consultation, during which treatment acceptance and secondary outcomes are assessed.

Intervention Type
Behavioural

Primary outcome(s)
1. Treatment acceptance measured using Binary yes/no response questionnaire at 14 days post consulatation

Key secondary outcome(s)

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. New patients attending for an initial comprehensive orthodontic consultation.
2. Age 18–40 years (representing the core orthodontic patient population who are legally capable of providing informed consent and making independent treatment decisions.)
3. Index of Orthodontic Treatment Need (IOTN-DHC ≥ 3, indicating moderate to severe need).
4. Ability to read and understand Kurdish (Sorani).
5. Able to provide informed consent.

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previous comprehensive orthodontic treatment within the last 5 years.
2. Emergency cases requiring urgent pain or trauma management.
3. Patients with cognitive, hearing, or visual impairments that preclude participation in surveys or comprehension tests.
4. Patients who cannot complete follow-up (e.g., no phone or digital access for the 14-day follow-up survey).

Date of first enrolment
15/12/2025

Date of final enrolment
21/03/2026

Locations

Countries of recruitment
Iraq

Sponsor information

Organisation
University of Sulaimani

ROR
https://ror.org/00saanr69

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		22/09/2025	12/05/2026	No	No