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Mobile application-based support for treatment of patients with gum disease

Submission date
21/02/2024

Recruitment status
No longer recruiting

Registration date
28/02/2024

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Encouraging patients to effectively remove plaque from above the gumline and control factors that contribute to oral disease requires them to understand how to maintain good oral hygiene. This study aims to assess the effects of using a mobile application to help manage gingivitis (gum inflammation) and periodontitis (serious gum infection).

Who can participate?
Women aged between 35 and 55 years with either gingivitis or periodontitis.

What does the study involve?
Participants are randomly allocated to either the control group (plaque removal and dental health education) or the test group (plaque removal and dental health education + mobile application). The test group participants are instructed to download and install mobile apps. For every visit, clinical periodontal parameters are recorded and displayed inside the app to ensure that the participants are aware of whether their periodontal condition has improved or deteriorated. Additionally, the app serves as a daily dental hygiene reminder for users as well as a constant source of education and motivation for periodontal health maintenance. Instructions on how to perform the proper way of brushing and the use of complimentary dental hygiene tools, notably interdental brushes and dental floss, are given simultaneously with the daily reminder sent for users through the app, twice a day (every morning and night). Moreover, dental health education is given to users three times a week in the form of interactive posters. Clinical parameters (e.g. gum bleeding), cognitive scores and a checklist of oral hygiene procedures are assessed at 1 and 3 months after the intervention.

What are the possible benefits and risks of participating?
The researchers expected improvement in clinical parameters, cognitive, and psychomotor aspects. There were no side effects or adverse events.

Where is the study run from?
Universitas Indonesia (Indonesia)

When is the study starting and how long is it expected to run for?
April 2021 to December 2022

Who is funding the study?
Ministry of Education, Culture, Research and Technology (Indonesia)

Who is the main contact?
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Additional identifiers

Protocol serial number
091241221

Study information

Scientific Title
Mobile application-based support for periodontal treatment improves clinical, cognitive, and psychomotor outcomes: a randomized controlled trial study

Study objectives
Mobile application-based support for periodontal treatment improves clinical, cognitive, and psychomotor aspects more than conventional dental health education

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/01/2022, The Dental Research Ethics Committee, Faculty of Dentistry, Universitas Indonesia (Jl. Salemba Raya IV, Jakarta Pusat, 10430, Indonesia; +62 (0)2131906289; etikrisetfkg@ui.ac.id), ref: 01/Ethical Approval /FKGUI/I/2022

Primary study design
Interventional

Study design
Interventional double-blinded randomized controlled clinical trial

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Improving clinical, cognitive, and psychomotor aspects of patients with gingivitis or periodontitis

Interventions
Participants were listed and evenly distributed between the test (professional mechanical plaque removal including scaling and root planing and dental health education [PMPR-DHE] + mobile application) and control (PMPR-DHE alone) groups by a masked researcher who was not involved in the clinical examination. A periodontal mobile application intervention was only implemented for participants who belong to the test group. First, the participants were instructed to download and install mobile apps. For every visit, clinical periodontal parameters, which were recorded, were displayed inside the app to ensure that the participants were aware of whether their periodontal condition had improved or deteriorated. Additionally, the app served as a daily dental hygiene reminder for users as well as a constant source of education and motivation for periodontal health maintenance. Instructions on how to perform proper way of brushing and the use of complimentary dental hygiene tools, notably interdental brush and dental floss, were given simultaneously with the daily reminder sent for users through the app, twice a day (every morning and night). Moreover, dental health education were given to users three times a week in the form of interactive posters.

Intervention Type
Mixed

Primary outcome(s)
1. Clinical periodontal parameters: probing pocket depth (PPD) measured using periodontal probe UNC-15 and visual inspection on six tooth surfaces, namely the distobuccal, mid-buccal, mesiobuccal, distolingual, mid-lingual, and mesiolingual surfaces of all teeth, except for the third molars, and the average probing depth value was measured at baseline, 1 and 3 months
2. Clinical periodontal parameters: bleeding on probing (BoP) measured using periodontal probe UNC-15 and visual inspection by assessing the presence of bleeding lasting up to 30 seconds, the BoP was recorded during the PPD measurement at baseline, 1 and 3 months

3. Clinical periodontal parameters: oral hygiene index (OHIS) measured using a disclosing agent and visual inspection which stained plaque and calculus on all tooth surfaces to be evaluated at baseline, 1 and 3 months
4. Cognitive scores recorded by using pretest questions at baseline and post-test questions during the evaluation visits at baseline, 1 and 3 months
5. Psychomotor scores assessed using a checklist form of oral hygiene procedures at baseline, 1 and 3 months

Key secondary outcome(s)
Microbiology periodontal complexes measured using next-generation sequencing (NGS) at baseline, 1 and 3 months

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Gingivitis or periodontitis subjects
2. Aged between 35 and 55 years
3. Had never received periodontal therapy only during the previous 6 months
4. Android system-based smartphone users

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 Years

Upper age limit
55 Years

Sex
Female

Total final enrolment
40

Key exclusion criteria
1. Systemic conditions related to periodontal disease such as cardiovascular disease, oral cancer, respiratory tract infection, and diabetes
2. Pregnancy or breastfeeding
3. On medication from a health provider
4. Current smokers

Date of first enrolment
21/01/2022

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
Universitas Indonesia
The Periodontics Clinic
Dental Teaching Hospital
Faculty of Dentistry
Jl. Salemba Raya IV No 2
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Sponsor information

Organisation
Universitas Indonesia

Funder(s)

Funder type
Government

Funder Name
Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi

Alternative Name(s)
Ministry of Education, Culture, Research, and Technology, Ministry of Education, Culture, Research, and Technology, Republic of Indonesia, Kemdikbudristek, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, Republik Indonesia, Indonesia Ministry of Education, Culture, Research, and Technology, Indonesian Ministry of Education, Culture, Research, and Technology, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, MECRT, Kemdikbudristek

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality. However, if only needed, the researchers can provide the patients' informed consent to participate in this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/04/2024	08/03/2024	Yes	No