

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

Submission date 21/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2024	Condition category Oral Health	<input type="checkbox"/> 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?
Dr Benso Sulijaya, benso.sulijaya87@ui.ac.id, bensosulijaya@gmail.com

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Interventional double-blinded randomized controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2021

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

Age group

Adult

Lower age limit

35 Years

Upper age limit

55 Years

Sex

Female

Target number of participants

40

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

Jakarta Pusat

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Sponsor information

Organisation

Universitas Indonesia

Sponsor details

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Sponsor type

University/education

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**Publication and dissemination plan**

Planned to publish in a high-impact peer-reviewed international-indexed journal

Intention to publish date

01/03/2024

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