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Effectiveness of a personalised smoking cessation smartphone app among Malaysian adult smokers

Submission date
13/01/2023

Recruitment status
No longer recruiting

Registration date
02/03/2023

Overall study status
Completed

Last Edited
24/10/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
GEMPAQ V2.0 is the enhanced version of a smoking cessation smartphone app that has been designed and developed by the Nicotine Addiction Research Group (NARCC), University of Malaya Centre for Addiction Sciences (UMCAS) for Android smartphone version 5.0 and above, according to user-centered design processes. The smoking cessation app has been specifically tailored to suit the smoker's need to quit smoking based on the Big Five Personality traits which are Extroversion (E), Agreeableness (A), Conscientiousness (C), Neuroticism (N), Openness to Experience (O). GEMPAQ V2.0 is an evidence-based, prevention-focused, cost-effective (free) and scalable intervention to reduce smoking, which is a major modifiable behavioural noncommunicable disease risk factor.
The aim of this study is to evaluate the effectiveness of GEMPAQ V2.0. Today, advances in mobile technologies can help overcome obstacles to smoking cessation such as accessibility and adherence. The rise of smartphone usage has made low-intensity interventions such as the smartphone app a readily acceptable self-help tool. Mobile or smartphone apps may assist in smoking cessation through behavioural modification, dissemination of information and advice on medication usage.
It is hoped that GEMPAQ V2.0 will help smokers find suitable smoking cessation app modules to aid them in smoking reduction and/or cessation. Available in both Bahasa Malaysia and English, GEMPAQ V2.0 directs smokers to the appropriate smoking cessation strategy based on their personalities and preferences. The information from this study will help in treating future patients to quit smoking.

Who can participate?
Adult smokers aged 18 years and above who smoke cigarettes at least monthly and have smoked 100 or more cigarettes in their lifetime, and intend to quit smoking in the next 30 days

What does the study involve?
Before starting the study, the researchers will make sure that participants are suitable and eligible to participate in this study and confirm their age, whether they are a smoker or not, and have an Android smartphone. Participants will be guided to download, install and use all

features in the apps as stated in the module, then they use the application accordingly. There are no specific restrictions in this study and participants can continue their normal daily routine.

What are the possible benefits and risks of participating?
It is hoped that the GEMPAQ V2.0 will help smokers find a suitable smoking cessation module to aid them in smoking reduction and/or cessation.
There is no side effect to your health by taking part in this study. However, the smartphone's performance might be slower as the app is downloaded. The app consumes 25MB of the smartphone's storage.

Where is the study run from?
Universiti Malaya (Malaysia)

When is the study starting and how long is it expected to run for?
February 2022 to September 2024

Who is funding the study?
Universiti Malaya's grant: Malaysia's Tobacco Control Policy Evaluation Program Grant RU001A-2021 (Malaysia)

Who is the main contact?
Professor Dr Yee Hway Ann @ Anne Yee, anne.yee@monash.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Medical Research Ethics Committee, University of Malaya Medical Centre (MREC UMMC), Malaysia MREC ID No: 2022428-11196; National Medical Research Register, Malaysia NMRR Research ID: RSCH ID-22-03835-EYB

Study information

Scientific Title
A randomized controlled pilot trial of a personalised version compared to a basic (reduced) Smoking Cessation Smartphone App – GEMPAQ V2.0 “Getting Every Smoker to Participate and Quit” among Malaysian adult smokers

Acronym
GRCT V2.0 (GEMPAQ Randomized Controlled Trial V2.0)

Study objectives
It is hypothesized that smokers using personalised GEMPAQ V2.0 as a smoking cessation app intervention will have higher 30-day point prevalence abstinence (PPA) after 3 months than those using the basic (reduced) GEMPAQ V2.0 version.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/08/2022, Medical Research Ethics Committee, University of Malaya Medical Centre (MREC UMMC; 3rd floor, Menara Utama, Pusat Perubatan Universiti Malaya, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 2022428-11196

Study design
Single-centre 3-month double-blinded randomized controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Up to 286 eligible participants will be screened and randomly assigned to the two arms of this study.

Intervention arm: personalized GEMPAQ V2.0 app version (smoking cessation smartphone app) – two auto-released modules based on the personality of the participant
Control arm: basic (reduced) GEMPAQ V2.0 app version (smoking cessation smartphone app) – just the Information and Tips module.

Participants will have an equal probability of being allocated to the intervention or control group using a computer-generated simple randomization procedure via Microsoft Excel. Simple random allocation of individuals between the different intervention groups will be carried out most conveniently by using a computer. For example, in Microsoft Excel, the instruction '= RANDBETWEEN (1,3)' will produce a random number between 1 and 3, i.e. each of the numbers 1, 2, or 3 has an equal chance of being generated. Participants will be blinded to group allocation and will not be aware of the control or intervention condition throughout the trial. Investigators will also be blinded to group allocation until the completion of the trial after the initial analysis of the primary and secondary outcomes.

This study will evaluate the efficacy of the GEMPAQ V2.0 app in smoking reduction and cessation as well as the usability and level of engagement among smokers. A two-arm parallel RCT will be conducted to evaluate the GEMPAQ V2.0 app. The primary aim of this initial evaluation will be to determine the efficacy of the personalised GEMPAQ V2.0 app version in reducing smoking prevalence among smoking adults after 3 months. Secondary aims include examining the usability and level of engagement of end-users. More proximal outcome measures of cessation behaviour will be examined as well. Two modules based on the personality of the participant will be automatically released upon completion of the personality questionnaire which will be administered online at GEMPAQ V2.0 start-up. The control group will be exposed to a basic (reduced) GEMPAQ V2.0 app version. Follow-up will be done for 30-day point prevalence quit rates upon completing the intervention 3-month period. Investigators and data collectors will be blinded to the group assignments. The protocol is in accord with the CONSORT-EHEALTH checklist. All self-reporting survey questionnaires will be administered online via the GEMPAQ V2.0 app according to:
1. Demographic, Fagerström Test for Nicotine Dependence (FNTD), Personality (Mini IPIP), Cessation behaviour at Baseline
2. Fagerström Test for Nicotine Dependence (FNTD) at end of 1st month (30 days)
3. Fagerström Test for Nicotine Dependence (FNTD) at end of 2nd month (60 days)
4. Fagerström Test for Nicotine Dependence (FNTD), Nicotine Withdrawal, Cessation behaviour, mHealth App Usability (MAUQ) Questionnaire: Ease of Use, Interface and Satisfaction, Usefulness at end of 3rd month (90 days)

Intervention Type
Behavioural

Primary outcome(s)
1. Nicotine dependence is measured using Fagerström Test for Nicotine Dependence (FNTD) at baseline and end of 1, 2 and 3 months
2. Smoking abstinence in the last 30 days will be asked at the end of 3 months

Key secondary outcome(s))
Usability, level of engagement and satisfaction of GEMPAQ® V2.0 usage is measured using mHealth App Usability (MAUQ): Ease of Use, Interface and Satisfaction, Usefulness at the end of 3 months

Completion date
28/09/2024

Eligibility

Key inclusion criteria

1. Participants aged 18 years and above
2. Participant volunteers and provides consent
3. Participant has the intention to quit smoking in the next 30 days
4. Participant owns an Android version 5.0 or above smartphone
5. Participant is able to communicate in Bahasa Malaysia and/or English

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
152

Key exclusion criteria
1. Participants who are unfit or chronically ill
2. Participating in another smoking cessation programme

Date of first enrolment
01/03/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Malaya
Jln Profesor Diraja Ungku Aziz
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya Malaysia Tobacco Control Policy Evaluation Program Grant RU001A-2021

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Associate Professor Dr Anne Yee (annyee17@um.edu.my).

The type of data that will be shared: Anonymized data
Dates of availability: After completion and publication of the study, after 31/08/2025.
Whether consent from participants was required and obtained: Consent will be obtained.
Comments on data anonymization: Data shared will be coded, with no PHI included.
Any ethical or legal restrictions: Approval of the request and execution of all applicable agreements (i.e. any material transfer agreement) are prerequisites to the sharing of data with the requesting party.
Any additional comments: No.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/10/2025	24/10/2025	No	No
Protocol file	version 2.0		13/05/2025	No	No