

Manuscript Title:

“Getting Every Smoker to Participate and Quit” V2.0 Personalised Smartphone App for Smoking Cessation in Malaysia: A Randomised Controlled Pilot Trial Protocol

Trial registration number:

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<https://www.isrctn.com/ISRCTN91299538>

1. Introduction

Today, tobacco smoking remains the most conspicuous public health threat. Worldwide, about 1.3 billion people smoke tobacco, which accounts for more than 8 million deaths every year (World Health Organization, 2024). There are currently around 4.8 million Malaysian smokers (21.3%) aged 15 years and above (Institute for Public Health Malaysia, 2024). As nicotine contained in tobacco is addictive, (U.S. Department of Health and Human Services, 2020; World Health Organization, 2024) a more comprehensive and targeted smoking cessation effort is needed to curb this addiction.

In Malaysia, the established cessation aids that are currently available range from evidence-based recommendations (e.g., nicotine replacement therapies (NRT)) (Raw et al., 1999) to affordable healthcare interventions (e.g., brief advice from a healthcare provider, telephone helplines, printed self-help materials) (West et al., 2015). However, overall tobacco consumption among Malaysians remained prevalent and plateaued (around 20%) for more than a decade (Institute for Public Health Malaysia, 2024). There are numerous types of cessation aids available, but limited access and adherence to existing cessation support services, such as keeping up with in-person interventions, are common obstacles (Haskins et al., 2017; Iacoviello et al., 2017). Novel cessation aids like smartphone smoking cessation apps (SCAs) can greatly support existing cessation methods as they are extremely convenient and versatile (Paay et al., 2015).

Digital technologies are ever more pervasive in the daily lives of people who smoke (Hoepfner et al., 2016). As such, SCAs can be an ideal mHealth intervention to aid people who smoke to quit more effectively, as it is constantly within reach. Furthermore, there is evidence that smokers who intend to quit use their smartphones more frequently than those who have no intention to quit (Borrelli et al., 2015).

1.1 SCA effectiveness

SCAs' content ranges from information-based only (self-help booklets); multifunctional apps equipped with assistive functions (eg, tracking, alarms, games, community features) to combined apps that provide both information and assistive functions to encourage and motivate users to quit smoking (Seo et al., 2022). As the usage of smartphones intensifies, there has been a concomitant increase in the number of SCAs made available (Bennett et al., 2015). Since 2012, SCAs have been addressing accessibility barriers as they serve as digital interventions with high population reach (Whittaker et al., 2019). In 2013, there were over 400 English-language SCAs (Abroms et al., 2013) and by 2020, there were 1543 available in both the Apple and Google Play app stores (Seo et al., 2022).

Although smartphones may facilitate cessation at any instant as users have access to them at all times, only a few SCAs have been reported to be efficacious in smoking abstinence (BinDhim et al., 2018; Bricker et al., 2020; Crane et al., 2018). Presently, comprehensive reviews of studies evaluating the effects of SCAs have found that evidence to determine the effect of the apps was insufficient (Barnett et al., 2020; Haskins et al., 2017; Regmi et al., 2017; Whittaker et al., 2019). The main reasons SCAs were limited in assisting in smoking reduction and cessation were poor quality and low adherence, as well as a large degree of variety in the app content and engagement strategies (Barnett et al., 2020; Rajani et al., 2019). Design elements that can improve motivation, autonomy, personal relevance, tailoring, and

optimisation may be crucial to fostering SCA engagement (Gowarty et al., 2020; Perski et al., 2017).

Research has also shown that personality traits are associated with the adoption and use of mobile apps (Stachl et al., 2020; Xu et al., 2016). A large-scale study to understand the impact of personality traits on mobile app adoption utilising Big Five Personality Traits found that personality traits have a significant impact on the adoption of different types of mobile apps (Xu et al., 2016). Another recent study suggested that everyday smartphone behaviour can allow for inferences on individual personality traits based on Big Five Personality Traits and that research in behavioral sciences and personality psychology could benefit from including these diverse behavioral indicators (Stachl et al., 2020). SCAs that are scientifically developed with a customised approach to fit the needs of each smoker are beneficial for cessation (Hoeppner et al., 2016; Paay et al., 2015).

In tandem, “Getting Every Smoker to Participate and Quit” - GEMPAQ, a novel mHealth SCA has been designed by a team of researchers from the Nicotine Addiction Research Collaborating Group (NARCC) of the Universiti Malaya Centre for Addiction Science Studies (UMCAS), grounded on Big Five Personality Traits (McCrae & Costa, 1997). The primary aim is to improve usage and engagement levels by personalising smoking cessation modules according to the smoker’s personality traits in both English and the national language, Bahasa Malaysia; the first in the country. This mHealth app has been developed to enable the adaptation of smoking cessation modules to smokers’ personality traits to ensure a more targeted and effective approach in helping people who smoke to reduce and quit smoking.

2. Methods and analysis

2.1 Study design

This is an automated, double-blind, pilot randomised controlled trial (RCT) to assess the uptake and usability of a personalised SCA–GEMPAQ V2.0 – full version as the intervention, compared to a placebo/control, which is a reduced basic version of the same app. A single app has been developed (Fig. 1), integrated with baseline and follow-up questionnaires in both sub-apps: the intervention and control apps.

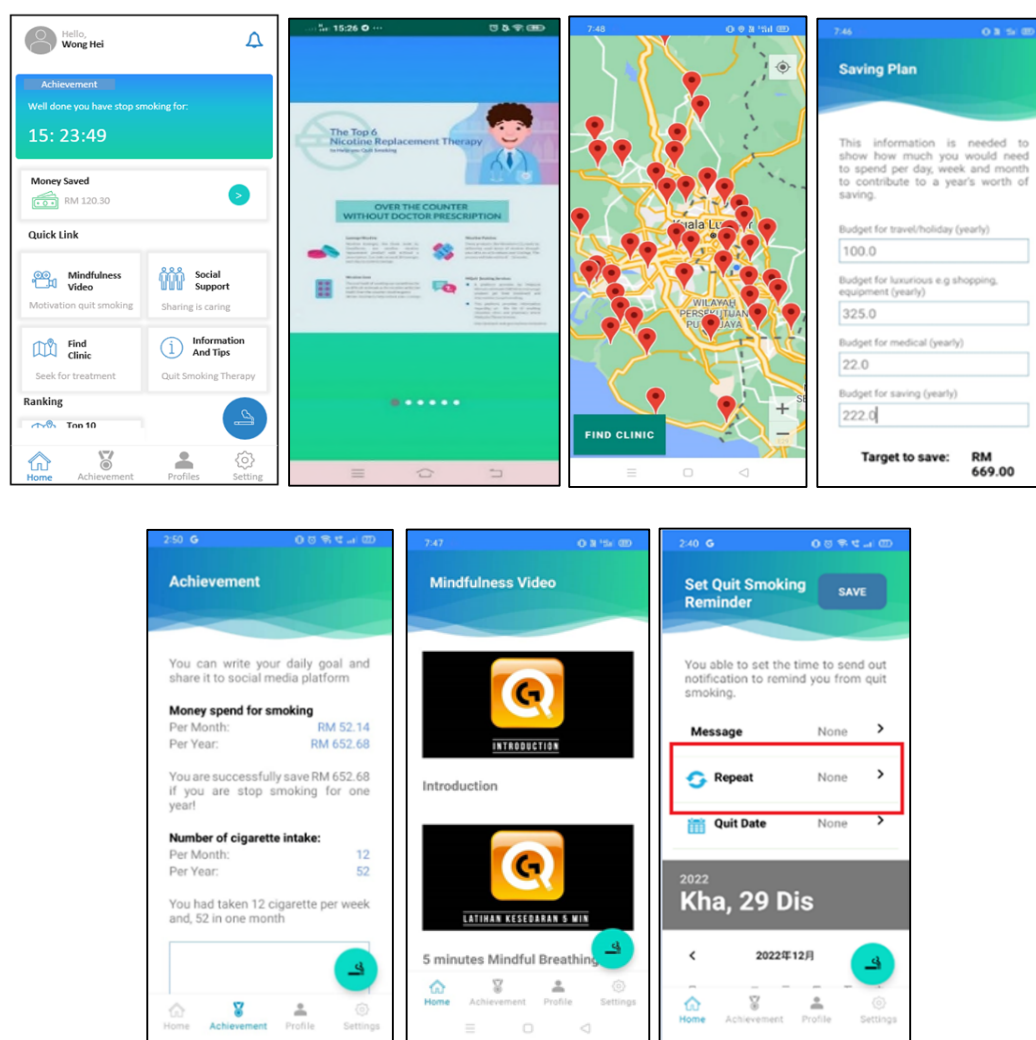


Fig. 1. Screenshots of GEMPAQ V2.0 app (A landing page, B Information & Tips, C Tracking the Nearest Clinic, D Target to Save – saving plan, E Target to Save – Achievement, F Mindfulness, G Quit Reminder)

This study will be performed in agreement with the Declaration of Helsinki. The entire study app content design participants' information statement and their consent, was reviewed by and approved by the Medical Research Ethics Committee, Universiti Malaya Medical Centre (MREC ID#2022428-11196). This study is also registered with the National Medical Research Registry of Malaysia: NMRR ID-22-02155-KUI, and the International Standard Randomised Controlled Trial Number (ISRCTN) Registry (United Kingdom): ISRCTN91299538.

2.2 Trial design and randomisation

A project team member who is not participating in the data analysis and research will randomise eligible participants to have an equal probability of being allocated to the intervention or control group using a computer-generated 1:1 ratio simple randomisation procedure with no strata or blocks. Participants and all the other investigators will be blinded to the group allocation (double-blind). The protocol follows the Consolidated Standards of Reporting Trials (CONSORT) - EHEALTH checklist (Eysenbach, 2011). See Fig. 2 for a CONSORT diagram for the proposed study design.

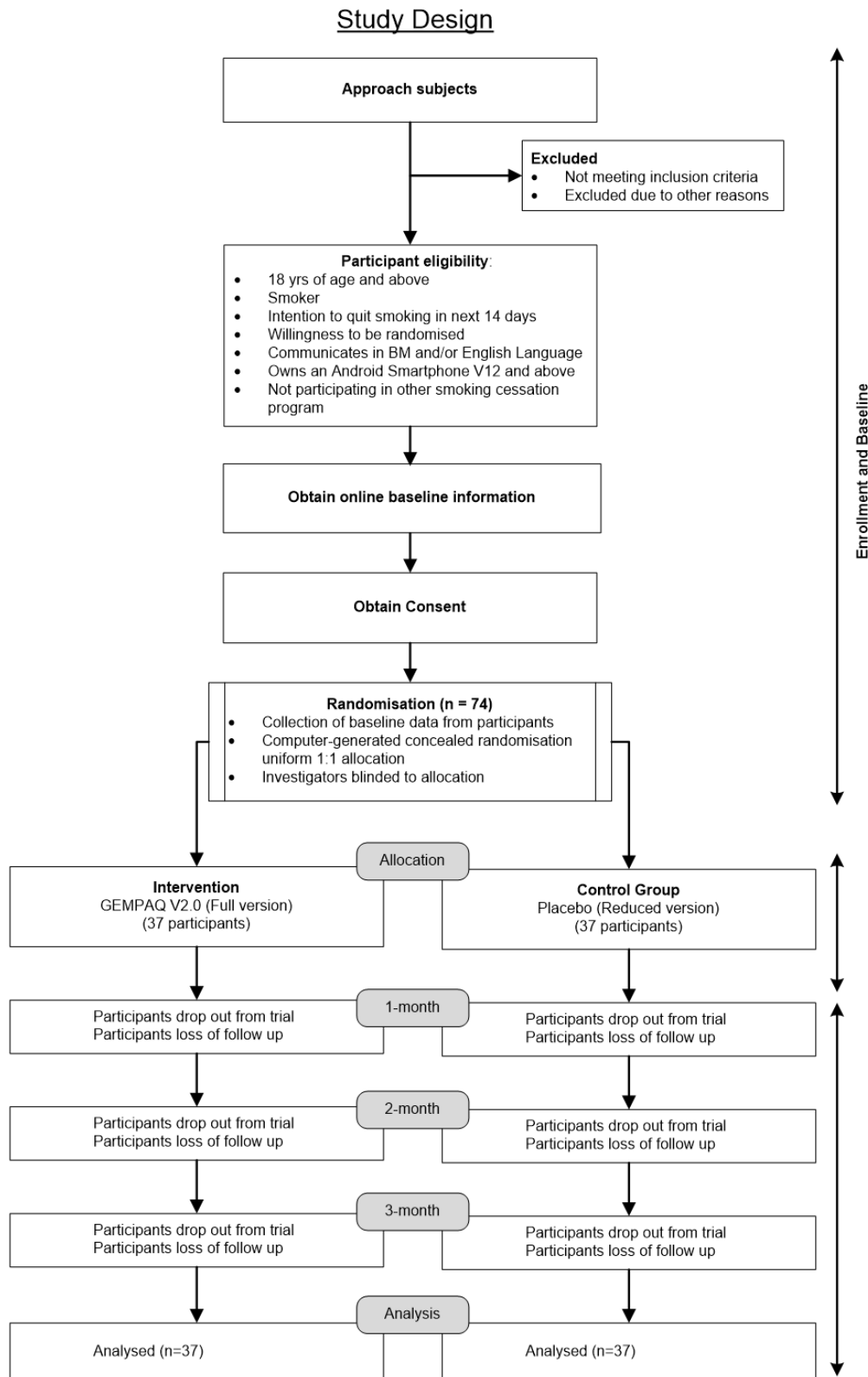


Fig. 2. Consolidated Standards of Reporting Trials (CONSORT) - the trial flow chart

2.3 Study participants

This study has been promoted since March 2023 and participants will be recruited via online methods. Potential participants' suitability will be assessed by completing an online eligibility questionnaire. If eligible, they will be sent the respective Android application package (APK) accordingly and requested to download the app at no charge. Each user will register by creating their own login identity and password. Non-eligible participants will receive a 'thank you' study decline message. Both groups will receive equal incentive credit payments for participation.

2.3.1 Inclusion and exclusion criteria

The participants that will be included in this study are smokers who live in Malaysia that smoked at least five cigarettes daily for the past 12 months, as consistent with cessation trials (Civljak et al., 2013), aged 18 years old and above, owns an Android version 12.0 and above smartphone, volunteers who provide consent, has the intention to quit smoking in the next 14 days and communicates in Bahasa Malaysia and/or English. Participants who are cognitively impaired and those participating in another smoking cessation program will be excluded.

2.3.2 Recruitment and data collection

Upon setting up the login, the app will require the user to provide consent before proceeding to complete the baseline questionnaire which comprises a personality test, Fagerström Test for Nicotine Dependency (FTND) test (Heatherton et al., 1991) and sociodemographic characteristics. The app is integrated with online baseline questionnaires, both intervention and control sub-apps, as well as automatic follow-up for the 1, 2 and 3-month questionnaires to assess the outcome.

As this study is fully automated, not being able to ensure that some users may download the app from another device is an unavoidable limitation. However, the audit trail can identify the user's identity and monitor all activities that have been performed in the app based on their login credential. Although this may not completely eliminate the possibility of contamination but will aim to reduce it. Reminder notification will be sent to the user to complete the baseline and subsequent 1, 2 and 3-month follow-up questionnaires.

Users will be asked about their age in the eligibility questionnaire. If the self-reported age is under the eligible age for the study, then the user will not be randomised. The user's responses will be sent automatically to the study's database. Participants can submit the response to any question only once and even if they delete and reinstall the app, their responses to previous questions are kept.

2.4 The intervention

The intervention app consists of eight modules, of which four core modules will also be provided to the control app: Information and Tips, Find Clinic, Social Support and Achievement. The next four personalised modules comprise - Target to Save, Mindfulness Videos, Super Quit (Top 10 Warriors) and Quit Reminder. Fig. 3 describes the functions of each module according to the availability in both the intervention and control apps.

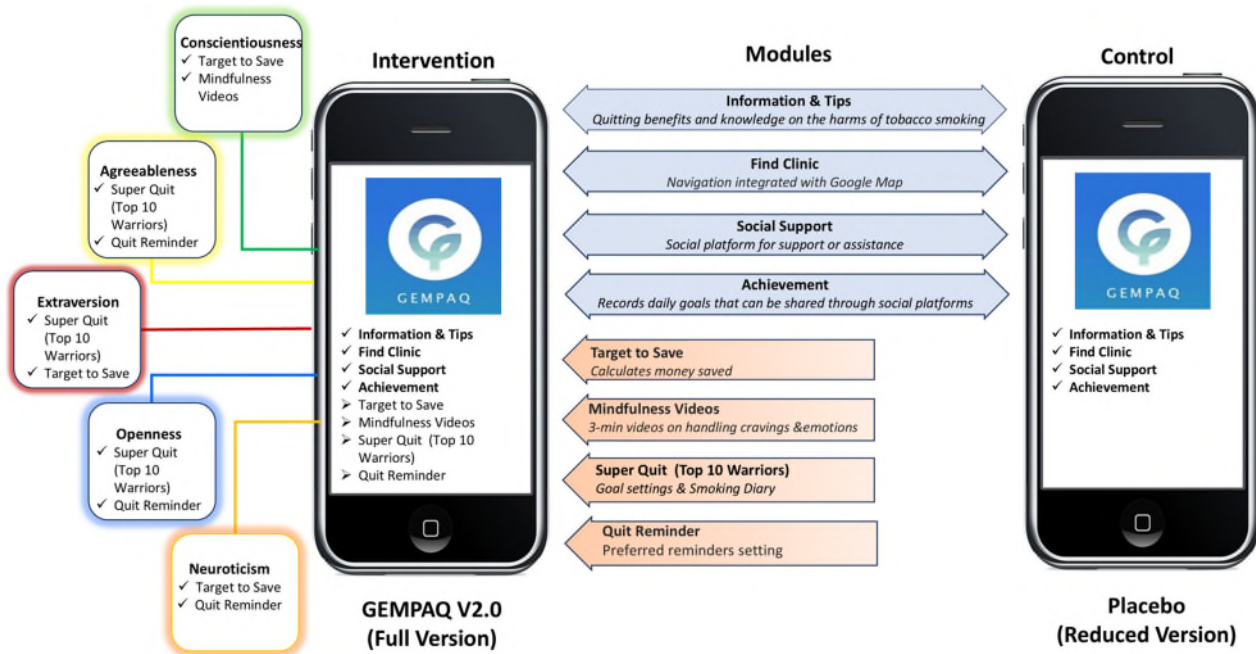


Fig. 3. GEMPAQ V2.0 Modules

To the best of our knowledge and from our user experiences as conducted in GEMPAQ V1.0 App preliminary testing, we have used the principles of clarity, convenience, consistency and courtesy in the UX and UI design for this app in a way to make it user-friendly and attractive. Once the user has completed their personality questionnaire online, their personality traits will be auto-calculated according to the Mini International Personality Item Pool (mini-IPIP) (Donnellan et al., 2006) to enable personalised SCA modules to be released accordingly. The results will be displayed, and the preferred modules according to their top two dominant personality traits will be made available to the user immediately. The preferred module selection according to the Big 5 Personality Traits – conscientiousness, agreeableness, extraversion, openness and neuroticism (McCrae & Costa, 1997) are derived from an algorithm based on results from an earlier feasibility mapping pre-post study on the GEMPAQ V1.0 App (Yusoff et al., 2022).

2.5 The control

In the control app - placebo, which is the reduced basic version of GEMPAQ V2.0, four modules as described in Figure 3 will be provided: Information and Tips, Find Clinic, Social Support and Achievement. After the same stipulated period, the app will automatically stop the data collection and then participants may access the app for as long as they want.

3. Measures

Primary outcome

1. Self-reported abstinence rate at 1 month, 2 months and 3 months
2. Self-reported nicotine dependence level at 1 month, 2 months and 3 months

Secondary outcomes

1. Examine the feasibility of GEMPAQ V2.0 by measuring engagement levels:
 - a. App utilisation
 - b. Overall usefulness
 - c. Overall satisfaction
2. Examine smokers' personality traits association with GEMPAQ V2.0.

Table 1. Participant surveys and time points when they will be administered (all participants)

Measure	Screening	Baseline	1-month	2-month	3-month	Purpose
Eligibility & Enrollment (12 items)	X					Eligibility & Enrollment
Demographic (6 items)		X				Exploratory
Smoking History & Quit Activity (6 items)		X				Exploratory
Quit Resources (1 multiple choice item)		X			X	Exploratory
Personality – Mini IPIP (20 items)		X				Exploratory & Stratification
Intervention Usage (8 items)			X	X	X	Primary Outcome
mHealth Application Usability Questionnaire- MAUQ (18 items)					X	Primary Outcome
Nicotine Dependence – FTND (6 items)		X	X	X	X	Secondary Outcome
Smoking Cessation – 7 & 30 days PPA (2 items)			X	X	X	Secondary Outcome

Measures will be collected accordingly from baseline and will be followed up at 1, 2 and 3 months (see Table 1). We will record the quit date and the end date of the follow-up, 3 months after either the quit date or the date lost to follow-up. Tobacco abstinence will be self-reported (not even a single puff since the quit date) as biochemical validation of smoking status will not be done due to difficulties in obtaining samples for interventions for smoking cessation (Baskerville et al., 2018; BinDhim et al., 2018; Crane et al., 2018). Furthermore, the Society for Research on Nicotine and Tobacco (2002) guideline for assessing outcomes in smoking cessation studies does not recommend biochemical verification when there is no close contact or interaction between participants and the study team. Even though the absence of biochemical

verification may result in some under-reporting of smoking, this should not differ between the intervention and control groups, so this should not impact the test of effectiveness.

If the participant relapses, then the current number of smoked cigarettes collected will be compared to their baseline. The participants will be required to complete the final survey, which includes the use of other quit resources, GEMPAQ V2.0 App usage review and mHealth App Usability (MAUQ) Questionnaire (Zhou et al., 2019). Participants may select either English Language or the national language (Bahasa Malaysia) to complete the online surveys. Surveys conducted in the national language – Bahasa Malaysia will use relevant translated and validated questionnaires (Anne Yee et al., 2011; Leong et al., 2019; Mustafa et al., 2021).

3.1 Sample size

A priori sample size calculation was performed using the G*Power program which showed that the minimum number of participants required in each group according to repeated measures analysis of variance with power ($1-\beta$) of .80, an effect size of $f = .175$, three measurements, and a significance level of $\alpha = .05$, is 54 based on previous studies (Baskerville et al., 2018; Bricker et al., 2014; Bricker et al., 2020). As the main focus of this pilot RCT is on the usability of GEMPAQ V2.0 in assisting adult smokers to reduce and quit smoking, the study's sample size is powered to show differences in usability, operationalised as the number of times participants opened their assigned app.

Although digital health studies hold promise for significant cost and time advantages, such studies typically suffer higher participant attrition, ranging from 20% to 50% (Daniore et al., 2022; Lüscher et al., 2017; Scott-Sheldon et al., 2016). Therefore, a minimum of 74 participants (37 participants for each group) were recruited with 35% attrition consideration, in order to achieve statistical power.

3.2 Statistical analysis

The analysis will be performed as per protocol – complete case analysis (CCA) and intention to treat (ITT), assuming that all participants remained in their treatment group as randomised. As high drop-out rates are sometimes even considered a typical characteristic of internet interventions, especially internet-based unguided self-help interventions, including those for smoking cessation (Eysenbach, 2005), multiple imputations (MI) (Rubin, 2004) and last observation carried forward (LOCF) (Hedeker et al., 2007) will be utilised to handle missing smoking status data, which is often caused by participant drop-out before follow-up measurements can take place.

As this study uses automated electronic data collection, there will be no missing values in the baseline data and other survey questionnaires; the app also includes a data integrity check to prevent users from entering invalid data (e.g. maximum age is 99). Generalised estimating equations analysis will be used to verify the efficacy of the intervention on the repeated measures outcomes; the binary logistic outcome variables (1, 2 and 3-month for both 7-day and 30-day point prevalence abstinence) and ordinal logistic outcome variables (1, 2 and 3-month nicotine dependence levels), with and without adjustment for participants' baseline characteristics. Further analyses include: the app usability outcomes and the correlation of smokers as app users' personality traits and the app usage.

3.3 Strengths and limitations

This pilot RCT is fully automated with no human intervention as it utilises smartphone capabilities. Automated methods decrease the cost and are less labor-intensive to manage. Limitations of this study may include incentive-caused bias and the possibility that participants can use two or more devices, or who know each other, might know about the other sub-app.

Although measures have been placed to minimise these, we cannot eliminate such possibilities. At present, as the app has been prepared in the English Language and the national language, Bahasa Malaysia, it will not be able to support smokers who only communicate in Chinese or Indian languages – the other Malaysia’s major ethnic groups.

Ethical considerations

This study will be performed in agreement with the Declaration of Helsinki. The entire study app content design participants’ information statement and their consent, was reviewed by and approved by the Medical Research Ethics Committee, Universiti Malaya Medical Centre (MREC ID#2022428-11196). This study is also registered with the National Medical Research Registry of Malaysia (NMRR ID-22-02155-KUI).

As this study is fully automated, and the investigators have no direct contact with the participants, the consent will be electronically obtained. All obtained data will be anonymised by substituting codes as participant identifiers and thus cannot be linked back to the participants. After the completion of the study, the data will be retained for the stipulated period securely by the Principal Investigator and will be destroyed at the end of the required retention period.

Dissemination

The results of the trial will be published in peer-reviewed journals according to the CONSORT statement.

This study has been registered in the International Standard Randomised Controlled Trial Number (ISRCTN) Registry (United Kingdom):

ISRCTN91299538 <https://doi.org/10.1186/ISRCTN91299538>

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Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and all the survey protocols and all materials, including the survey questionnaires, were approved by the Medical Research Ethics Committee, University of Malaya (MREC ID#2022428-11196) and registered with the National Medical Research Registry of Malaysia (NMRR ID-22-02155-KUI). This study has been registered in the International Standard Randomised Controlled Trial Number (ISRCTN) Registry (United Kingdom): ISRCTN91299538 <https://www.isrctn.com/ISRCTN91299538>

Informed Consent Statement

Informed consent will be obtained on the web survey from all study participants before completing the survey.

Data Availability Statement

Data obtained through this study may be provided to qualified researchers with an academic interest in tobacco control. Data or samples shared will be coded, with no PHI included. Approval of the request and execution of all applicable agreements (i.e. a material transfer agreement) are prerequisites to the sharing of data with the requesting party.

The datasets generated during and/or analysed during the current study are/will be

available upon request from the Principal Investigator, Associate Professor Dr. Anne Yee

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