

STUDY PROTOCOL

Effects of a Workplace mHealth Intervention for Smoking Behaviour: A Quasi Experimental Study Protocol

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ABSTRACT

Introduction: Tobacco smoking causes various chronic diseases and adds costs to healthcare systems. The current smoking cessation interventions mostly target smokers who are ready to quit and are reactive in recruitment. Recently, mobile phones have become a new tool for promoting smoking cessation. The aim of this paper is to present a study protocol on a quasi-experimental study investigating the effects of a workplace mHealth intervention for smoking behaviour. **Methods:** A quasi-experimental study will be conducted among employees in an academic institution in Malaysia. The intervention group will receive a theory based WhaSTOP module via WhatsApp and will be compared with the control group (receive usual care). The primary outcomes are stage movement and the number of cigarettes per day. The secondary outcomes include knowledge of smoking, quit attempt, nicotine dependence, 7-day point prevalence of smoking abstinence, and the Transtheoretical Model constructs. A generalised estimating equation analysis will be performed to determine the effects of the intervention. **Discussion:** This protocol will provide a novel method to proactively approach smokers regardless of readiness to quit and to guide them through the stages of change so that they will be ready to take action to quit. This research will also provide insight into whether the intervention can be utilised as an additional tool for smokers at the workplace to quit smoking. **Trial Registration:** The trial was registered with the Iranian Registry of Clinical Trials (Registry Number IRCT20220415054539N1). *Malaysian Journal of Medicine and Health Sciences* (2023) 19(6):340-346. doi:10.47836/mjmh.19.6.44

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INTRODUCTION

Globally, 1.14 billion current smokers were reported by the Global Burden of Disease Study in 2019. Smoking was responsible for 7.69 million deaths and 200 million disability-adjusted life-years worldwide (1). The prevalence of smokers in Malaysia changed only slightly from 22.8% in 2015 to 21.3% in 2019 despite the implementation of various strategies to promote smoking cessation (2). In Malaysia, the largest smoking population consisted of men in the working age group (25–44 years old) (2). Hence, a smoking cessation programme at a workplace is necessary to reduce smoking prevalence (3). Pharmacotherapy, such as nicotine replacement therapy, varenicline or bupropion, behavioural support, and psychological assistance are all effective methods for helping people to stop smoking (4). However, a sizable portion of smokers fail to quit

for a variety of reasons, such as lack of motivation and lack of ongoing support to quit (5). A Malaysian national survey reported that most smokers had low readiness to quit (6). However, most smoking cessation programmes target smokers who are ready to quit and are less effective for smokers with low motivation to quit (7)

According to the World Health Organization's Global Observatory for eHealth, the terms mobile health or mHealth can be defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" (8). Recently, a mHealth intervention for smoking cessation showed promising results (9-11). Text messaging is the most reported method in the literature for mHealth smoking cessation intervention (9). Social media platforms, such as WhatsApp, Facebook, and Twitter have been used as an intervention for smoking cessation since 2015 and have proved to be an effective method (12). Several benefits of mobile phone intervention include it can reach a greater number of participants to provide support to smokers who are unable to attend

smoking cessation sessions in a dedicated facility, the intervention delivery can be automated and fast, involves minimal cost, can be tailored to individual smokers' needs and is very useful in low-resource settings (9).

In Malaysia, WhatsApp instant messaging application is widely used and estimated to have had 25.06 million users in 2021 (13). This indicates that WhatsApp has the potential for use in smoking cessation intervention (10, 11). This app enables the transfer and sharing of text, audio, video, and documents at a low cost. The improved encryption, unlimited use, and ability of a sender to track message delivery or read status are among the advantages of WhatsApp (13). At the workplace, the WhatsApp messenger application is mainly used by present-day employees (14). WhatsApp for smoking cessation intervention at the workplace enables many smokers among employees to be reached proactively regardless of their readiness to quit smoking. Furthermore, it is easier for employees to attend the quit smoking services held in their workplace (15). To the best of our knowledge, a gap in the quit smoking intervention which is a lack of utilisation of WhatsApp as a mHealth intervention for smokers in Malaysia, especially in the workplace setting, exists. We hypothesized that this tailored intervention may help to motivate the smokers to progress through smoking cessation readiness stages of change and subsequently be ready to take action to quit. Later, they can be referred to smoking cessation clinics for further assistance. The aim of this paper is to describe a study protocol on a quasi-experimental study investigating the effects of a workplace mHealth intervention for smoking behaviour.

MATERIALS AND METHODS

Study design and setting

A two-arm parallel group quasi-experimental study will be conducted among employees from a large public university in Malaysia. The university is situated in an industrialised state on the west coast of Peninsular Malaysia consists of six campuses: (1) Puncak Alam Campus (A), (2) Puncak Perdana Campus (B), (3) Dengkil Campus (C), (4) Shah Alam Campus (D), (5) Sungai Buloh Campus (E), and (6) Selayang Campus (F) in Selangor state.

Eligibility criteria

The study population will consist of employees who are current smokers, have smartphones with internet connections, use WhatsApp at least four days a week, can understand the Malay language, and are willing to commit to the programme. In this study, a current smoker is defined as an individual who smokes cigarettes or tobacco products, or who concurrently smokes both cigarettes or tobacco products and e-cigarettes, such as vape and/or pod (dual user). Employees who are currently in any smoking cessation programme, have mental health issues/impairment, or are unable to give

informed consent will be excluded during screening.

Recruitment

An invitation letter and email will be sent to the Head of the Department of each campus and later will be disseminated to all staff members. Furthermore, other recruitment strategies will be adopted, including an individual staff invitation via email, recruitment poster advertisement to be displayed at the office buildings, e-poster advertisement to be disseminated via the department's staff WhatsApp groups, and office phone call to individual staff for an invitation to join the study. Those agreeing to participate will be screened for inclusion and exclusion criteria. Systematic sampling will be conducted to obtain the required number of participants at each campus after obtaining their informed consent. The recruitment process started at the end of 2022 and continued until it reached the minimum required sample size. No blinding of participants will be implemented for those administering the interventions or assessing the study outcomes.

Allocation

All the participants will be allocated into either the intervention or control group based on their workplace (according to which campus they work). Participants recruited in Campuses A, B, and C will be allocated to the intervention group and those in Campuses D, E and F will be designated as the control group. The campuses are far apart with a minimum of 20 kilometres from each other to minimise study contamination.

Sample size

The sample size was calculated based on the 24.1% improvements in the stage of smoking behaviour at one-month post-intervention in the intervention group from a previous study using a confidence interval (CI) of 95% and power of 80% (16). The calculated sample size is 54 for each arm. Considering a 30% attrition rate, the targeted sample size is 70 per group. Thus, the total minimum required sample size should be 140 participants.

Intervention

The WhaSTOP mHealth intervention module consists of 13 educational and motivational short videos (with an average duration of < 3 minutes each) on topics about smoking behaviour and cessation in the local Malay language (Table I). The videos employ texts in a positive and neutral tone, background scenes relevant to the content, and background music. Each video will conclude with encouragement for participants to engage in self-reflection on their smoking behaviour or a motivational text to increase their readiness to quit. The WhaSTOP intervention was developed by researchers and field experts and tailored to the Transtheoretical Model (TTM) of behaviour change theory. The TTM theory has been widely used as a basis in many smoking cessation intervention programmes (17, 18). The TTM

suggests that smokers need to be provided with an appropriate intervention according to their readiness to quit to be effective in helping them move through the stages and change their behaviour (17). This intervention aims to help smokers to progress across the stage of change and subsequently take action to quit smoking either with professional assistance (counselling or pharmacotherapy) or without.

The module content was based on scientific literature, manual and guideline for smoking cessation (19-21). The module content was validated for relevancy by seven experts in the field of public health and tobacco control, health promotion and smoking cessation services provider. The item content validity index (I-CVI) was satisfactory with results of ≥ 0.86 (22). The face validity was analysed for clarity and comprehension among ten smokers. The module achieved a satisfactory level of item face validity index with an I-FVI of ≥ 0.9 (23).

The intervention group will receive the usual care (smoking cessation pamphlet) at baseline and followed by three to four videos each week for four weeks. They will continue for another four-week follow-up period. The researcher will send individual WhatsApp messages containing Canva Pro link of the video to each participant. The participants will be required to click the link to watch the video within two to three days. They will be encouraged to respond afterwards by providing any comments or enquiries related to smoking via WhatsApp message to the researcher throughout the two months study period.

In this study, participants in the pre-contemplation, contemplation, and preparation stages at baseline will receive all 13 videos for four weeks. These videos aim to provide education and motivation on smoking cessation. Each video will be ended with a motivational sentence or question asking participants to do self-reflection on their smoking behaviour. For example, asking participants to think why they smoke and what is their barrier for quitting. The participants in the preparation stage will be included in this video intervention to reinforce their knowledge and motivation to be more confident and prepare them to proceed to the action stage.

After completing the videos, participants will be reassessed at the end of week 4. During the four-week follow-up, the participants will receive two to three WhatsApp messages sourced from the video package and tailored to the participants' stage to initiate conversation and to maintain contact between participants and the researcher. The researcher will provide feedback to any participants' enquiries. The researcher will also enquire about each participant's number of cigarettes smoked per day in week-2 and week-6 via WhatsApp's message. The control group will receive only the usual care alone at baseline followed by an eight-week follow-up period.

Quality control

To minimise study contamination, the participants will be instructed not to share any messages received with anyone. Also, the participants from both intervention and control groups will be recruited from campuses located in different districts. Only smokers that agree and are willing to fully commit to the study will be recruited to increase compliance with the intervention. The participants will be advised to adhere with the intervention procedure. This includes watching and understanding each content of the WhaSTOP intervention during the study period.

A blue-coloured double-tick sign or any message response from the participants will indicate that the message has been opened. Participants will also be encouraged to reply to the message after completing each video. Moreover, obtaining workplace support from the supervisor is essential. The privacy and confidentiality protection of the health-related data are ensured by the WhatsApp provider. In ensuring intervention fidelity, the researcher underwent a two-month training in a government quit smoking clinic.

Outcomes and assessments

Baseline characteristics

The participants baseline characteristics will be collected using a set of self-administered questionnaires in Malay language. The sociodemographic characteristics will include age, gender, ethnicity, education level, and monthly income. The job characteristics will consist of job category, years of service, shiftwork, and job stress. Stages of change, number of cigarettes per day, age of smoking initiation, nicotine dependence level, previous quit attempts, and TTM constructs will be the smoking characteristics collected.

The job stress level will be measured by a self-administrated Malay version Job Stress Level Inventory (JSLI) (24). It has 18 items comprising of two factors namely Behavioural Symptoms and Motivational Symptoms. The JSLI is reliable and valid instrument with the overall Cronbach alpha coefficient score of 0.93 showed a strong reliability for the two factors. Each item is scored using a 5-item Likert type scale (1 = never, 2 = seldom, 3 = sometimes, 4 = often, and 5 = always). Then, the total score of all items will be classified into low (scores of 17 to 39), moderate (scores of 40 to 61) and high (scores of 62 to 85) level of job stress (24).

Primary outcomes

The primary outcomes will be the stage movement and the number of cigarettes per day.

i) Stage movement

The stage movement is defined as the proportion of participants progressing through the Stages of Change

algorithm. The outcome will be recorded as either pre-contemplation, contemplation, preparation or action stage. The participants need to choose only one answer from the three options given: (1) not thinking of quitting (pre-contemplation stage), (2) seriously thinking of quitting in the next six months (contemplation stage), or (3) seriously thinking of quitting in the next 30 days (preparation). The participants who stop smoking starting on day-1 up to six months will be categorised into action stage (18). However, no participants will be classified into maintenance stage as this study will only occur within a 6-month timeframe.

ii) Number of cigarettes per day

Participants will self-report the number of cigarettes smoked per day in the past week. They will be instructed to write down number of cigarettes they smoked daily in a smoking diary provided to them.

Secondary outcomes

The secondary outcomes will be the number of quit attempts, 7-day smoking abstinence, knowledge of smoking, nicotine dependence level, and TTM constructs (temptation to smoke, decisional balance, and impact of smoking).

i) Number of quit attempts

Participants will self-report the number of quit attempts during the study period.

ii) 7-day smoking abstinence

Participants will self-report 7-day smoking abstinence during the study period.

iii) Knowledge of smoking

Knowledge of smoking will be measured using a self-administered Malay version of the Global Adult Tobacco Survey (GATS) 2011 questionnaire by World Health Organization (25). The GATS questionnaire consists of ten sections. In this study, only knowledge on smoking section will be used. The participants will be asked four questions, with 11 sub questions for question number 2: "1) Based on your knowledge or beliefs, does smoking tobacco causes serious illness? 2) Based on your knowledge or beliefs, does smoking tobacco causes the following illness: i) stroke, ii) heart attack. iii) lung cancer, iv) oral cancer, v) premature birth, vi) throat cancer, vii) miscarriage, viii) gangrene, ix) bladder cancer, x) stomach cancer, xi) osteoporosis; 3) Do you believe cigarettes are addictive? 4) Based on your knowledge or beliefs, does consuming 'smokeless tobacco' cause serious illness?" Participants will need to answer either "Yes" or "No" or "Don't know" for each question and sub question. The correct answer for all questions will be "Yes" and will be given score of 1. Score 0 will be allocated for answers "No" or "Don't know". The highest score will be 14. A higher total score indicates a higher level of smoking knowledge (26).

iv) Nicotine dependence level

The nicotine dependence level will be measured using the Malay version of the Fagerstrom Test for Nicotine Dependence (FTND-M) (27). The FTND-M had moderate internal consistency with a Cronbach's alpha of 0.67. It consists of six questions with the total score ranging from 0 to 10. A higher score indicates a higher dependence level.

v) TTM constructs (temptation to smoke, decisional balance, and impact of smoking)

Temptation to smoke, decisional balance, and impact of smoking will be measured by a self-administered 26-item Malay version of the TTM questionnaire (28). The Malay translated questionnaire was validated and a reliable instrument with acceptable value of Cronbach's alpha coefficients (internal consistency) for decisional balance (pros of smoking: 0.84; cons of smoking: 0.76) and temptations to quit smoking (positive/social: 0.89; habit/addictive: 0.54; negative/affective: 0.85). The entire questionnaire was based on a 5-point Likert-scale. The score for each construct (temptation to smoke, decisional balance, and impact of smoking) will be the average score for each item within each construct (28).

The WhaSTOP mHealth intervention usability

The usability of WhaSTOP intervention in terms of the capability of the mobile apps to deliver their purpose, effectiveness, efficiency, and user satisfaction will be assessed by the participants in the intervention group at the end of week-4 study period using a Malay version of the System Usability Scale (SUS) for the Assessment of Mobile Apps (also known as Skala Kebolegunaan Aplikasi Mudah Alih in Malay language) (29). It consists of 10 items measured using a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The score of each item is summed and then multiplied by 2.5 to obtain the total score ranges from 0 to 100. A system or product scored value of ≥ 68 is considered as having a good usability. The Cronbach alpha value was 0.85, similar to the original English version, indicating that the Malay translated SUS questionnaire is a reliable tool for assessing the usability of a mobile app (29).

Data collection

The baseline data will be collected after the participants enrolled have in the study. The primary and secondary outcomes will be measured three times; during baseline measurement, at week-4 and at week-8. An additional two data collection timepoints will be added for the number of cigarettes smoked per day during week-2 and week-6 via WhatsApp message to maintain regular contact with the participants. Two methods of data collection will be used for self-administered questionnaires. The participants may choose between using paper and pencils or a Google form to respond to the baseline questionnaires during recruitment and will only complete the Google form to the other time-

point measurements (week-4 and week-8). The study is estimated to last for four months (Fig. 1).

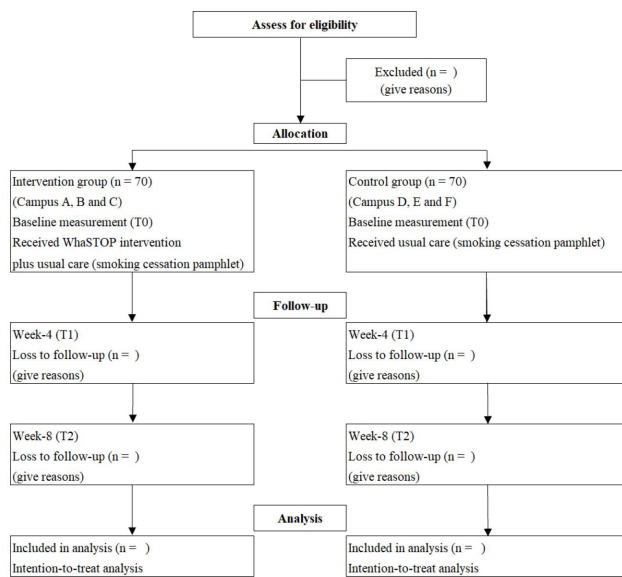


Figure 1: Study flow diagram for WhaSTOP quasi-experimental study

Data management

The privacy and confidentiality of the participants will be strictly maintained. Each participant will be allocated a unique anonymous research identification number (ID). The participants' names and data will be stored on a password-protected researcher's laptop and linked only with their respective research ID for this research. Only the researchers will own and be able to access the data. Upon study completion, the data on the computer will be transferred into an external hard disc, and the data on the computer will be erased. External disc and any hardcopy data will be stored in a researcher's locked office. The data will be kept for a minimum of three years after the study completion and later will be erased.

Data analysis

The data will be stored in Microsoft Excel and the IBM Statistical Packages for Social Sciences (SPSS) version 28 software will be utilised for data analysis. Data will be transferred into SPSS and cleaned accordingly. Both descriptive and inferential statistics will be applied as appropriate. Descriptive statistics will be used to describe the participants' characteristics in the intervention and control groups. Continuous data will be presented in mean (standard deviation (SD)) and median (interquartile range (IQR)), while categorical data in frequency (n) and percentage (%). Graphical and statistical methods will be used to assess the distribution of continuous data.

Inferential analyses will be used to compare baseline characteristics between the intervention and control groups. It will be analysed using a chi-squared test for categorical variables, and for a continuous variable, an independent t-test or Mann–Whitney U test will be used.

The effectiveness of the WhaSTOP intervention will be analysed using the generalised estimating equation (GEE) analysis to compare within and between-group differences (the intervention and control groups) while controlling for other covariates. The intention-to-treat (ITT) analysis method will be adopted to handle non-response participants and any missing data to reflect the real-world scenario accurately. The significance level for all statistical tests will be set at $p < 0.05$ with a 95% CI.

Ethics approval

The study has been approved by the Universiti Teknologi MARA (UiTM) Research Ethics Committee, Malaysia (REC/06/2021 (MR/381)) and will be conducted following the Declaration of Helsinki and the Malaysian Good Clinical Practice Guidelines. Informed consent will be obtained from all subjects involved in the study.

DISCUSSION

This paper describes a protocol of an intervention study investigating an innovative method of mHealth intervention to approach smokers regardless of stage of readiness to quit. It will provide insight into whether this intervention can serve as an additional resource to support smoking cessation among employees in an academic institution..

The study's strengths lie in the mHealth module, which was developed based on the TTM, and this aspect will contribute to its effectiveness in producing the desired outcomes (18). The module contents were prepared in the local Malay language to accommodate the participants. In addition, the intervention adopts a proactive approach to reach smokers who do not come to the clinic as the intervention is regardless of time and location (11). This can especially be beneficial for employees who are unable to attend a stationary smoking cessation session, for instance, due to pandemic restrictions, tight work schedules or work commitments. The potential reach of mHealth intervention is great as it could easily be expanded to reach many smokers at a low cost (11, 15). The utilisation of this intervention among employees will give support to the implementation of a smoke-free workplace policy (30).

Several potential limitations may be present in this study. First, there may be a selection bias due to a lack of randomisation. Hence, the participants will be allocated into either an intervention or control group based on the campuses they work. Second, there is a risk of study contamination. This study will attempt to ensure intervention fidelity by recruiting participants from different campuses for the intervention and control groups and by instructing participants not to share the videos with others. Third, based on participants' use of self-reported outcomes measures, there is a potential for information bias to arise.

An effective and proactive workplace smoking cessation intervention is necessary to promote and deliver smoking cessation education and give motivation for them to take real action to quit (15). It is expected that participants in the intervention group will progress through the stage of readiness and are more likely to start taking action towards smoking cessation.

CONCLUSION

This protocol outlines the methodology for a quasi-experimental study in intervention using WhatsApp in the workplace, targeting employees who smoke. If the WhaSTOP intervention is determined to be effective, it can be used at a workplace to promote and deliver smoking cessation education and give motivation for the employees to take real action to quit smoking. The results of this study may assist in the future development of online-based workplace smoking cessation programmes regardless of the stage of readiness to quit. Suggestions for further research may include comparing this WhaSTOP intervention module with other traditional or digital health interventions, such as web-based applications or automated reply systems across different regions or countries and with different age groups and populations.

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