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**Participant Information Sheet/Consent Form**

**Health/Social Science Research** -*Adult providing own consent*

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| **Title** | Modif-i Tobacco Trial: A clinical trial of a “brain-training” smartphone app to assist tobacco cessation |
| **Short title** | Modif-i Tobacco trial |
| **Project Sponsor** | Eastern Health |
| **Principal Investigator** | Professor Victoria Manning |

**1 Introduction**

You are invited to take part in this research project, which is called “*Modif-i Tobacco Trial: A clinical trial of a “brain-training” smartphone app to assist tobacco cessation*”*.* You have been invited because you are a current tobacco smoker residing in Victoria who would like to try to quit smoking. The research project tests a smartphone app called “*Modif-i*”. We want to test whether using this app:

* helps people avoid smoking
* reduces craving for tobacco
* and reduces reactions to tobacco-related images.

This research project will compare a version of *Modif-i* that includes “brain-training” designed to reduce impulses to smoke, to a version that includes a similar “brain-training” task that is not designed to change these impulses. This type of study is called a ‘randomised controlled trial’, which means that, if you agree to participate, you will be randomly assigned to one version of the app or the other. You will have a 50% chance of receiving either version. This is so we can compare the results of people who do each version of the app. This will help us find out whether the training has a positive impact, so that we know whether or not it is helpful to provide it to people who are trying to quit smoking tobacco. The randomisation is done automatically when you install the app, and we will not be able to tell you which version you receive. This is so your response to the training is not influenced by knowing which version you are using.

This participant information sheet tells you about the research project and explains what it would involve for you if you decide to take part. Please read this information carefully. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed below.

**2 What does participation in this research involve?**

If you agree to participate in this research, you will first be asked to complete an online survey that takes approximately 10 minutes. This is to collect some general information about you and your history of use of tobacco and other nicotine products, as well as asking questions to measure your tobacco craving and well-being. This survey will also ask you to set a quit date in the next week, when you will attempt to stop smoking.

After you complete this online questionnaire, you will receive an SMS with a link to download the “Modif-i” app from the App Store or Google Play, and an access code to use the app. Since we are using “Twilio”, a US-based messaging service, to send automatic SMSs for this project, this message will come from a US phone number (+1 270-516-1439). To install and use the app, you need to be using a smartphone that has an Android or iOS (Apple) operating system. To ensure the app functions well, please ensure that your phone operating system has been updated within the last year.

After you have entered your access code, the app will display instructions for how to use it. You will also be asked to answer some brief questions about recent tobacco use. Before doing the first session of brain-training, you will also be asked to complete a short (~3-minute) test of your responses to smoking-related pictures, and other non-smoking related pictures.

You will then be asked to complete your first session of the brain-training task. The “brain-training” in both versions of the app is a brief (3-5 minute) game-like task which requires you to try to control your attention to pictures, some of which are smoking-related, and some of which are not. The only major difference is that, in one version of the app, the “brain-training” task is designed to try to change mental reactions to tobacco images which may be involved in craving. In the other version of the app, the training is not designed to do this.

For the first 4 weeks, *Modif-i* will send regular notifications to remind you to use it. Using the app only requires a few minutes of your time per week. For the first 4 weeks, you will also be asked to enter information about whether you have smoked any tobacco each week. Completing this weekly questionnaire is likely to only take an additional 2-3 minutes.

After 4 weeks, the app will ask you to repeat the 3-minute test of your response to pictures. When you complete this, you will then receive an SMS (from the US phone number noted above) with a link to complete additional online questionnaires and tests which will take approximately 10 minutes. These include questions about use of tobacco and other nicotine products, craving, physical and mental wellbeing, and your impressions of the app. You will be sent a gift voucher by SMS (from the US phone number) for completing this survey. To encourage you to complete the weekly questions about tobacco use in Modif-i (at the end of week 1, 2, 3, and 4), the voucher for completing the 4-week follow-up survey will be $30 if you also completed all 4 weekly question tasks in Modif-i, but will only be $20 if you had not completed all 4 weekly tobacco use question tasks in Modif-i.

After the 4-week follow-up questionnaires, you will have free access to use the brain-training task in *Modif-i* if you want to, but the app will no longer send notifications reminding you to use it each week. However, three months after you download the app, you will receive an SMS from the US phone number with a link to complete a final online follow-up survey which will ask you about use of tobacco and other nicotine products, craving, and physical and mental health and wellbeing. We anticipate the 3-month follow-up survey will take approximately 10 minutes. We will send you a $20 gift voucher for completing the 3-month follow-up survey.

Collecting these follow-up questionnaires is very important for us to be able to measure whether the app is effective. A member of the research team may contact you by phone or using other contact details you provide to remind you to complete the follow-up if you have not completed it within a few days after receiving the notification. Gift cards will be sent during working hours, so be aware that there may be a delay in sending them if you complete the follow-ups in the evening or on a weekend.

The chart below summarises what participation involved if you agree to participate:



**3 Do I have to take part in this research project?**

Participation in this research is voluntary. If you do not wish to take part, you do not have to. If you decide to participate, you can still withdraw from the research at any time. You can stop using the app or delete it from your phone, and you can stop answering questionnaires. If you no longer wish to be contacted about the research, you can also inform the research team using the contact details listed below (see “Contacting the research team” section). Please be aware that if you cease participating in the research, we will retain any data you already provided, to use in our analyses to help us understand whether or not the app is helpful, unless you specifically instruct us not to retain these data. If you do not want us to retain your data, you will need to contact the researchers to inform them of this.

**4 What are the possible risks of taking part?**

The training tasks in the app involve viewing tobacco-related images. The questionnaires include questions about tobacco cravings, smoking, and mental health. Some people might find these training tasks or questionnaires upsetting or that they increase craving for tobacco. We believe this risk is small, but if you feel distressed or experience increased cravings, you can contact the following smoking cessation and mental health telephone and online support services:

* Quitline: free confidential smoking cessation counselling service that operates 8am-8pm Monday to Friday. To speak to a Quitline counsellor, you can either:
	+ Phone 13 78 48
	+ Text ‘call back’ to 0482 090 634
	+ Visit https://www.quit.org.au/request-callback/ to book a time for Quitline to call you
* Lifeline:
	+ Free and confidential crisis hotline, available 24/7: phone 13 11 14.
	+ Online chat is also available from 7pm - 4am: lifeline.org.au/get-help/online-services/crisis-chat

**5 What are the possible benefits of taking part?**

By participating in this research, you will help researchers identify whether this easily-accessible approach to treatment is useful for the many people who want to quit smoking. However, we cannot guarantee that you will receive any benefits from this research. However, some past research suggests that, for some people, regularly reporting whether or not they have used tobacco (e.g., by answering the questions in the app) may help them reduce smoking. Past research in people trying to quit alcohol use also suggests that the type of “brain-training” used in one of the 2 versions of the app can reduce likelihood of relapse, and some studies suggest it might help reduce smoking too. However, there is not enough evidence to clearly say if this brain-training works for people trying to quit tobacco use, or whether it works when it is delivered in a smartphone app, so we cannot say whether either version of the brain-training is likely to benefit you.

**6 Could this research project be stopped unexpectedly?**

Although unlikely, this research project may be stopped unexpectedly for a variety of reasons, for example if technical problems arise with the computer servers or databases used by *Modif-i*. It is likely that after we have completed this research, this version of this app may become unavailable or may be replaced by a newer version. If this occurs, the version of the app on your phone may stop working.

**7 What happens when the research project ends?**

Once we have finished this project, we will make a summary of our key findings available on the Turning Point website. It will be written in non-technical language. Please be aware that we will be collecting data for approximately 1 year, and it will take additional time to analyse data, so it may be more than a year before findings are publicly available.

We also intend to publish the findings of this study in scientific journals and to present the findings at scientific conferences. Publicly presented data will only include numerical data and statistical analyses about the whole group of participants. It will not include individual descriptions of you or any information which may identify you. No individuals will be identified in any reporting of this study. If student researchers are involved in the project, they may use these data in their thesis.

**8 What will happen to information about me?**

Any information obtained in connection with this research project that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. A serious and imminent threat to harm yourself or others may be subject to reporting to a third person. Any information concerning the protective safety of children is subject to reporting to relevant authorities.

Questionnaire data will be stored in a secure Monash University REDCap database only accessible to the research team, which is protected with two-factor authentication. These data in the REDCap database will be labelled with your phone number. Throughout your participation in the study we will send you REDCap survey links and reminders using the Twilio SMS messaging service, which is hosted in the USA. As such, your phone number (but no other data) will be used by Twilio. The only data that Twilio holds is metadata about SMS messages and calls, and this data is scrubbed by an automated process that REDCap runs every 120 seconds. This means that your phone number and survey responses are not stored by Twilio.

Data collected within the Modif-i app will be stored on a secure Google Cloud Platform (GCP) cloud server protected with two-factor authentication which is only accessible by the research team and the app developers (Monash University eSolutions). Data in the GCP database will be labelled with the access code you use to activate Modif-i and this database will not include any details that identify you. A list of which access codes correspond to which phone numbers will be stored in REDCap so that we can link data between the different databases at the end of the project.

Once the project is completed, the research team will download data from these databases and store it on Turning Point shared drives only accessible to the research team. Following completion of the study, researchers will delete phone numbers and any other identifying information from the data collected. The deidentified data will be stored on the Turning Point shared drive for at least 7 years following publication of the last paper arising from this study, or 7 years after the final report to the ethics committee, or 7 years after final reporting of outcomes on a clinical trials registry, whichever occurs latest. These de-identified data may be used for other analyses not described in this information sheet and may be combined with data from other studies for this purpose, but these data would not be shared outside the research team without further approval from Eastern Health.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. However, given that data will be de-identified at the close of the study, we cannot guarantee that we will be able to locate this information for you should you wish to access it once this project is complete.

**9 Who is organising and funding the research?**

This project is funded by a grant from the Victorian Medical Research Acceleration Fund, which is funded by the State of Victoria Department of Health, as well as funding from Eastern Health. This project was initiated by Professor Victoria Manning. The research is being conducted by Eastern Health in collaboration with Monash University, Cancer Council Victoria, Deakin University, and Flinders University.

**10 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Eastern Health HREC.Their contact details are provided below.

**11 Further information and who to contact**

* **General information:**

If you have any questions about the research, need technical support with the app, or if you wish to provide feedback regarding the app or the research, or wish to withdraw from the research, you can contact the research team using the following details:

* phone or SMS: 0477 274 465.
* Email: modif-i-techsupport@monash.edu

You can also email the principal investigator, Professor Victoria Manning at victoria.manning@monash.edu

* **Reviewing HREC approving this research and HREC Executive Officer details**

If you wish to speak to the human research ethics committee that reviewed and approved this trial, you may contact the Eastern Health Human Research Ethics Committee on (03) 9895 3398 or email them at ethics@easternhealth.org.au.

**Consenting to participate in the research**

Since participation in this research is voluntary, you do not have to participate if you do not want to. If you tick the box below which indicates that you consent, you are telling us that you:

* Understand what you have read
* Consent to take part in the “Modif-i” online surveys and tests
* Consent to download and use the “Modif-i” app
* Consent to the use of your survey responses, test data, and “Modif-i” app data as described above

Please tick one of these options:

* I understand what I have read and consent to take part in the research project as described.
* I do not wish to take part in the research project.