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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE:	RAUORA
PROTOCOL NUMBER:	Version 4.0
FUNDED BY:	Health Research Council of New Zealand
INVESTIGATOR:	Dr Natalie Walker
INSTITUTION:	University of Auckland
TELEPHONE:	(09) 923-9884 or 0800 367 644

Kia ora ra, tenei te tonoa ki a koe.

We would like to invite you to take part in a study called RAUORA. If you have any questions please feel free to ask the investigator at any time.

Purpose of the study

We are inviting you to join this study because you currently smoke cigarettes every day and you want to quit smoking. The study is about comparing two similar medicines to see how good they are at helping you to stop smoking cigarettes.

Where will the study be undertaken?

The study will be undertaken in the central North Island region of New Zealand (defined as the Lakes, Bay of Plenty, Hawkes Bay, Taranaki, Tarawhiti, Whanganui, and Waikato District Health Board regions). All interviews will be undertaken by telephone.

About the study

We plan to recruit 2,140 people into the study from June 2017 until December 2018. One in every three people enrolled will be in the study for 24 weeks. Two in every three people enrolled will be in the study for a year.

If you agree to take part in the study, you will be randomly allocated (like the toss of a coin) to one of two groups:

- **Tabex group:** If you are in this group you will get a prescription for a 12 week supply of Tabex (cytisine) tablets. You'll also be offered a choice of support services to give you advice and support to help you in your quit attempt, for example Tipu Ora.
- **Champix group:** If you are in this group you will get a prescription for a 12-week supply of Champix (varenicline) tablets. You'll also be offered a choice of support services to give you advice and support to help you in your quit attempt, for example Tipu Ora.

Tabex and Champix work in the body to help reduce the feeling of reward from smoking. This action makes it easier for people to quit smoking. Tabex contains cytisine, which is plant-based and found in several New

Zealand plants (including the New Zealand kowhai). Tabex is not currently approved or registered in New Zealand, so is not routinely available. Champix is not plant-based, but has been developed from cytisine.

Who can take part in this study?

You can take part in this study if you:

- Smoke cigarettes every day
- Are Māori or whānau of Māori
- Want to quit smoking in the next two weeks
- Are aged 18 years or over
- Have daily access to a mobile phone that can text and/or email and/or have access to the internet via a computer or smartphone
- Are living in the upper North Island region of New Zealand (defined as the Lakes, Bay of Plenty, Hawkes Bay, Taranaki, Tarawhiti, Whanganui, and Waikato District Health Board regions)
- Have tried, but failed, to quit smoking two or more times using nicotine replacement treatments, such as patches or gum
- Have tried previously to quit smoking using bupropion (Zyban) or nortriptyline (Norpress)
- Are able and prepared to provide verbal consent to take part

You cannot take part in this study if you:

- Are enrolled in another smoking cessation programme or study
- Are currently using another method to stop smoking (including e-cigarettes)
- Have another person in your house that is already part of the study
- Have used Champix or cytisine (Tabex or Desmoxan brand) in the past 12 months

In addition, **the study medicines are not safe for people with certain medical conditions**. You cannot take part in this study if you:

- Are pregnant or breastfeeding
- Have moderate or severe renal impairment (kidney disease or kidney/renal failure)
- Are being treated for active or latent TB (Tuberculosis)
- Have been treated for a heart attack, stroke, or severe angina within the last two weeks
- Have uncontrolled high blood pressure (> 150 mmHg systolic, > 100 mmHg diastolic)
- Have a history of seizures

What will I be asked to do?

- A researcher involved in the study will call you to ask you some questions about your age, gender, education, and iwi, your smoking history and previous quit attempts, your use of alcohol and medicines, and your general health and use of health services.

- The researcher will then transfer the call to a study doctor who will randomly allocate you (like the toss of a coin) to either 12 weeks of Tabex tablets or 12 weeks of Champix tablets. The study doctor will send a prescription for one of these medicines to a pharmacy/chemist of your choice.

- You will be asked to pick up your prescription at this pharmacy/chemist. Your medicine will be free. You will need to take the medicine every day until it runs out. Your quit date will be the 5th day of taking the medicine.

- You will need to visit the pharmacy/chemist once a month for three months to pick you your medicine, as the pharmacist/chemist is not allowed to give you all the medicine at once. Each time your medicine will be free.

- The researcher will also offer you a choice of support services who can give you some advice and support to help you in your quit attempt. This free support can be delivered to you over the phone and/or face-to-face (at a time and place that suits you best). We know that having such support can greatly improve your chances of staying Smokefree.

- As with any medicine, people can have side effects. For the first 14 weeks of the study you will need to go online to a website to record how many tablets you take, and note how the tablets make you feel. We will send you a free text every day for the first four weeks of the study, and then every week for the next 10 weeks, to remind you to go to the website to record how you are feeling. You can free text back 'Stop' to turn

these texts off if you wish. You can also call us at any time on this free phone number (0800 367 644) if you feel you have any urgent concerns about the medicine you are using.

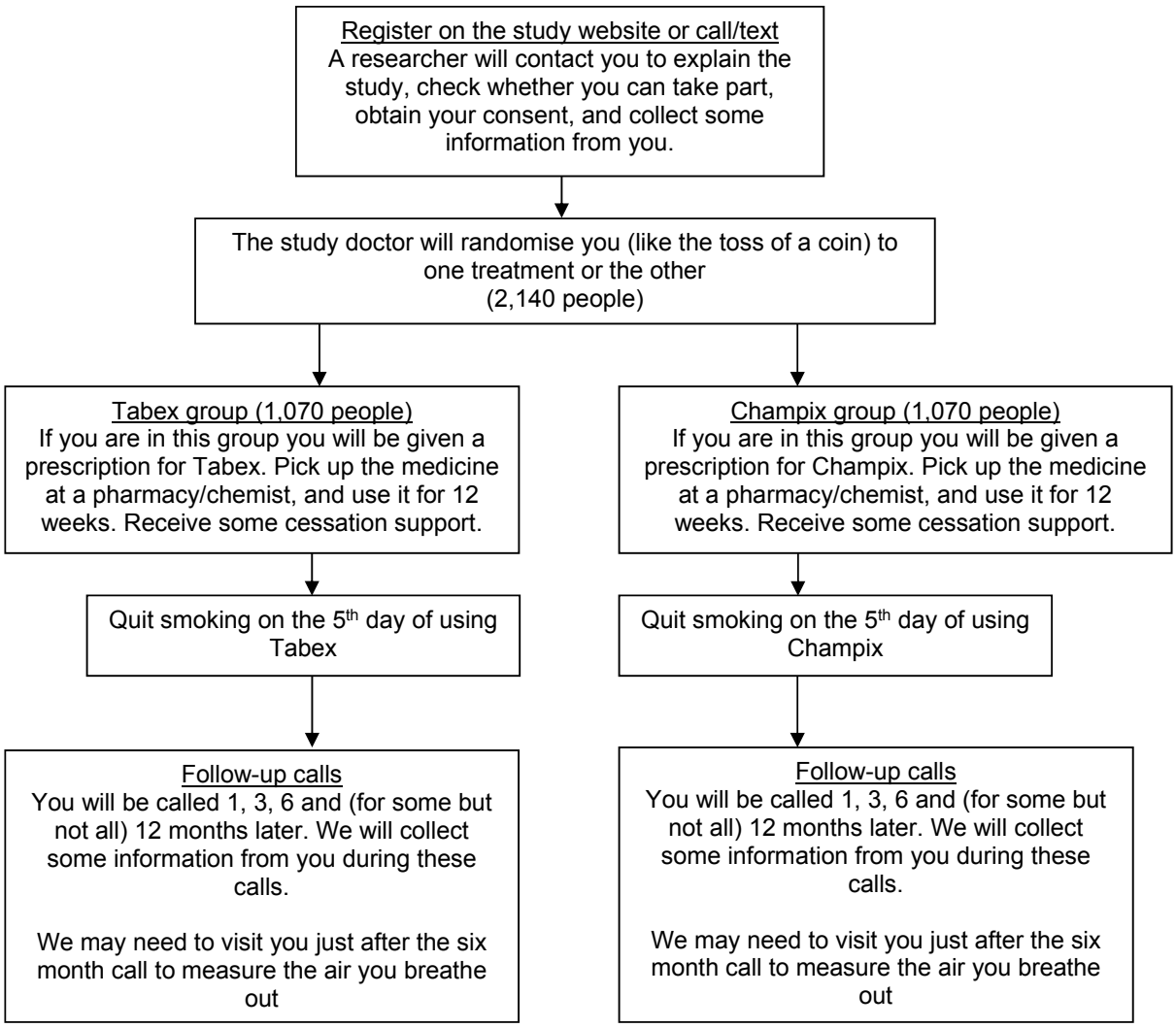
- You will be called by a researcher again at one, three and six months after your quit date. They will ask questions about your smoking, the use of the medicine you have been given and how it makes you feel, and your general health and use of health services. You don't have to answer all the questions, and you may stop the interview at any time.

- Two in every three people taking part will also be called again 12 months after their quit date, and will be asked some questions about their smoking.

- If you have quit smoking when we call you at six months, we will ask to meet you at a time and place that suits you best, to measure the air you breathe out.

Study design

Please look at the picture below which will give you an idea about how the study works.



Why do you need to measure the air I breathe out?

A sample of the air you breathe out will be taken using a device that measures carbon monoxide. This test will confirm whether you are smoking or not. The test does not hurt or cause any harm, and takes less than three minutes. It involves breathing out into a small, hand-held machine (like to the one in the picture). We get a result immediately from the machine. No breath sample is stored.

Some iwi disagree with the taking of samples, out of respect for whakapapa. Your iwi may advise you to consult with them prior to participating in the study. You might like to discuss the possibility of your participation in the study with your whānau, and let them know if you do decide to participate.

Contact times

A researcher will phone you four or five times during the study to collect some information from you. This table tells you what to expect at each phone call.

Call	1	2	3	4	5
Stage	Randomisation	One month after quit day	Three months after quit day	Six months after quit day	Twelve months after quit day
Approximately how long will the call take?	30 minutes	10 minutes	10 minutes	10 minutes	10 minutes
Study explained	Yes				
Checking to see if you can take part, and if so consent obtained	Yes				
Measure the air you breath out				Only if you say you have quit smoking	
Questions about your smoking	Yes	Yes	Yes	Yes	Yes
Questions about the study medicine		Yes	Yes	Yes	Yes
Questions about your health and use of health services	Yes		Yes	Yes	Yes

Will participating in the study affect my healthcare?

Your GP (and/or any medical specialist you have been seeing) will continue to care for you during the study. We will send them a letter to say you are participating in the study and whether or not you have quit smoking at six months. Your healthcare will not be affected by participating in this study.

The study doctor may need to talk to your GP to check if it's OK for you to use the study medicine. The study doctor may also need to talk to them if you think the medicine is making you feel unwell in any way during the study. Only the study doctor will talk to your GP, no-one else. We would need your permission to talk to your GP. But it's up to you. You can decide not to give us permission – it is your choice.

Will I be paid?
No, people are not usually paid for participating in clinical studies.

Will it cost me anything to be in the study?
No. Everything in this study is free – the call with the researcher and study doctor and the medicines to be used in this study will be free. All text message reminders we send you are free, and it will be free for you to text us back.

Benefits
- The study medicines may help you quit smoking.
- If you stop smoking your health will improve and the risks of having serious health problems in the future will also reduce.
- Quitting smoking will improve the health of whānau who spend time around you.
- You will be helping other people in the future who want to quit smoking.

Potential risks and discomforts
- Reducing the amount of cigarettes you smoke or quitting, reduces or stops the amount of nicotine you consume.
- This may lead you to experience nicotine withdrawal symptoms, such as agitation, anxiety, feeling down or disturbed sleep.
- These feelings are quite common when people quit smoking, and they will go away over time.
- The medicines we are using in this study help reduce these feelings.
- However, medicines themselves may cause some side effects for some people.
- Tabex and Champix are a similar type of medicine. We know a lot about the side effects of Champix. These may include:
    - Difficulty sleeping (insomnia): about 1 in every 10 people
    - Feeling like vomiting (nausea): about 3 in every 10 people
    - Headache: about 1 in every 10 people
    - Vivid dreams: about 1 in every 10 people
- We know less about the side effects of Tabex. Side effects may include:
    - Gastro-intestinal effects, such as having a dry mouth, feeling like vomiting (nausea), having a sore stomach or indigestion: about 1 in every 10 people.
- Any side effects usually pass within a few days of weeks; nausea may be reduced by eating smaller meals rather than large meals.
- **If you have major changes in behaviour or thinking, anxiety, psychosis, mood swings, agitation, aggression, depressed mood, suicidal thinking and suicidal behaviour, you should stop taking the study medicine you have been allocated. You should contact your GP immediately and also ring us on 0800 367 644**
- It is important that you tell your doctor or pharmacist/chemist that you are in the trial, especially if they wish to give you any other medication so as to avoid any medication interactions.
- If the doctor or pharmacist has any concerns they should ring us on 0800 367 644.
- If you have any serious side effects we will need to send your GP a letter explaining what has happened. This is so the information is kept on your medical records and your doctor can offer you on-going support (if need be).

What if something goes wrong?
If you were injured in this study, which is very unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What are my rights?
Your participation in this study is entirely voluntary (your choice). You do not have to take part.

If you agree to take part in the study, you should only use the stop smoking medicine we have given you – not any other stop smoking medicine. If you chose to stop using the medicine before all the tablets are gone, we would still like to contact you at six months to see if you have quit smoking. If you withdraw from the study we would like to use your information up to the point you withdraw.

All information that you provide will be strictly confidential. No material that could identify you will be used in any reports on this study. The information will be kept at the National Institute for Health Innovation, the University of Auckland. All computer records will be password protected and paper records stored in a secure storage facility. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994.

During the study only the RAUORA researchers and the study monitor will have direct access to your information. Representatives of the ethics committee may also require access. This access will only be to check the accuracy of the information collected for the study, and the information will remain confidential.

As a participant you have the right to access your information and to correct your information in the study documents. If you wish to do this, then just ask us when we contact you.

If we learn of any new information about Tabex or Champix that will have a positive or negative effect on your health, we will inform you as soon as possible.

What will happen when the study has ended?

We hope to finish collecting all the information for the study by May 2019. We will then analyse the data, and publish the findings in a medical journal. At the earliest, this publication will be available at the end of 2019. We will then notify you of the results by email or post.

We will keep your information for 10 years after the study is completed.

Your data may be used in a study called a meta-analysis. This type of study collects individual participant information from studies that are similar to this one. If we do share your data for such a study, you would not be able to be identified. We may also be asked to submit individual participant data to a clinical trial register, in order to have the results published in a well-known journal. If we are required to submit data to such a register, you would not be able to be identified.

Who do I contact for more information or if I have concerns?

If you want to talk to someone who isn't working on the study, you can contact a health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Mēnā he pakirehua tāu, whakapāngia mai a Eru George

(For Māori health support please contact Eru George):

Phone: 07 348 1199 extn 8950
Email: eru.george@lakesdhb.govt.nz

RAUORA has received ethics approval from the Southern Health and Disability Ethics Committee. You can contact the Health and Disability Ethics Committee (HDEC) on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Thank you

Verbal Consent Form

RAUORA

A randomised trial to compare two medicines (Tabex and Champix) that can help people quit smoking.

I have had the study explained to me and I understand it.

I have been offered the chance to talk with my whānau/ family and/or Doctor to help me ask questions and understand the study before taking part.

I have been given enough time to decide whether or not to take part in this study.

I give verbal consent to take part in this study.

I understand that taking part in this study is my choice, and I may withdraw from the study at any time.

I consent to the research staff collecting information about my health. I understand I have the right to access and, if needed, to correct my information.

I understand my responsibilities as a study participant and I agree to use only the study products I have been allocated (Tabex or Champix).

I understand that I need to go to a pharmacy/chemist once a month for three months to get the medicine, and I will do this.

I agree to accept study-related telephone calls at a telephone number of my choice. If needed, researchers can leave messages about the reason for calling.

I understand there may be risks associated with the study medicines.

I understand my taking part in this study is confidential and that nothing that could identify me personally will be used in any reports.

I understand that a monitor or members of the ethics committee may review my study records to check the accuracy of the information collected for the study.

I understand this study is covered under ACC compensation.

I understand I may be asked to give an exhaled breath air sample to a researcher if I stop smoking.

If I decide to withdraw from using the study medicines, I agree to be contacted for the follow-up phone calls.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used.

I understand that information may be shared with other studies or registers but that no information that identifies me personally will be used.

I wish to receive a summary of the results from the study. The results will not be available until 2019.	Yes ☐	No ☐
I agree to the study doctor calling my GP to check medical information in relation to my participation in this study (if needed), and to talk to them if I think the study medicine is making me feel unwell in any way during the study. GP's name: _____ GP's Practice Name:_____	Yes ☐	No ☐

Declaration by member of research team:

I have given a verbal account of the research project to the participant, and have answered their questions. I believe the participant understands the study and has given verbal informed consent to take part. I will ensure the participant is sent a copy of the Participant Information Sheet and Informed Consent Form.

Participant's name: _____

Researcher's name: _____

Researcher's contact phone number: _____

Date of verbal consent: _____

Declaration by study medical doctor:

I have checked the information provided by the participant	Yes ☐	No ☐
I have talked to the participant's usual doctor about the person's involvement in the study	Yes ☐	No ☐
I believe that the study medicines are suitable for them to use.	Yes ☐	No ☐

Study doctor's name: _____

Study doctor's signature: _____

Date: _____