

National Institute for Health Innovation
The University of Auckland

Level 4, School of Population Health
Tamaki Campus
Morrin Road, Glen Innes, Auckland
Private Bag 92019
Auckland
NEW ZEALAND
Telephone: 64 9 923 9884
Facsimile: 64 9 373 1710
Email: n.walker@auckland.ac.nz
www.nihi.auckland.ac.nz

PATIENT INFORMATION SHEET

The SPACE Trial: Smoking relapse prevention among COPD ex-smokers

PROTOCOL NUMBER:	Version 2.0
FUNDED BY:	Health Research Council of New Zealand
INVESTIGATOR:	Dr Natalie Walker
INSTITUTION:	University of Auckland
TELEPHONE:	(09) 923 1751 or 0800 367 644

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

Purpose of the study

We are inviting you to join this study because you have Chronic Obstructive Pulmonary Disease (COPD), you currently smoke cigarettes, and you want to quit smoking. The study is about quitting smoking and preventing relapse back to smoking.

Where will the study be held?

The study will be undertaken in the Auckland region of New Zealand. Interviews will be undertaken at a clinic in Auckland hospital or at University of Auckland, as well as over the phone.

About the study

We plan to recruit 650 people into the study over a 15 month period (from May 2017 to July 2018). You may be in the study for up to 9 months.

If you agree to take part in the study you will receive, from a medical doctor, a prescription for a medicine called 'Champix' (also known as varenicline). You will need to use the medicine for 12 weeks. You will also be called up to six times over the 12 week period and provided with advice and verbal support to help you in your quit attempt. Each call will last about 10 minutes.

Champix is the most effective stop treatment available for smokers wanting to quit, and stay quit. Champix is a small pill that you swallow. It works in the body to help reduce the feeling of reward that you feel after smoking.

If after 12 weeks you have not quit smoking, you will not be able to join the second part of the study. We will however refer you to a smoking cessation service of your choice or another smoking cessation study, so that you can get further help with quitting.

If after 12 weeks you have quit smoking you will be randomly allocated (like the toss of a coin) to one of two groups:

- **Intervention group:** If you are in this group you will get another 12 weeks of Champix, plus another six verbal support calls.
- **Control group:** If you are in this group you will get 12 weeks of a placebo, plus another six support verbal calls. A placebo is a pill that looks and tastes the same as Champix, but does not contain any active substances.

Who can take part in this study?

You can take part in this study if you:

- Smoke cigarettes every day
- Are prepared to make a quit attempt with Champix
- Have a diagnosis of COPD, and your COPD is stable
- Are aged 18 years or over
- Have a landline or mobile phone the researchers can ring you on
- Are living in the Auckland region
- Have tried, but failed, to quit smoking on at least two separate occasions using nicotine replacement treatments, such as patches or gum OR have tried previously to quit smoking using Zyban (also known as bupropion) or Norpress (also known as nortriptyline)
- Are able to provide verbal and written consent to take part

You cannot take part in this study if you have:

- A history of asthma and/or allergies
- A reason why you can't take Champix
- Used Champix in the past 12 months
- A history of serious psychiatric illness or a significant cognitive impairment
- Uncontrolled heart failure, infection or quickly progressive health condition
- A life expectancy of less than 12 months
- Are currently using another medication to help you stop smoking (including e-cigarettes)

What will I be asked to do?

There are two parts to this study – first the quit attempt period and then the clinical trial period.

Quit attempt period (this will involve approximately 650 people):

- If you agree to take part in the study you will be asked to come to a clinic to meet with the study doctor. At the clinic you will be asked to sign a consent form. This consent form is for you to take part in the quit attempt period to see if Champix can help you quit smoking.
- The doctor will ask you some questions about your smoking and your breathing. You do not have to answer all the questions, and you may stop the interview at any time.
- The doctor will also measure your exhaled breath to see how much carbon monoxide you breathe out. This will show how effective your body is at clearing the tobacco smoke out of your system. The test does not hurt or cause any harm. It involves breathing into a small hand-held machine, and takes less than three minutes.
- The doctor will then give you a prescription to take to a pharmacist to get some Champix. You will need to visit the pharmacy once a month for three months to pick up the Champix, as the pharmacist is not allowed to give you all the medicine at once.
- You will need to take the medication every day for 12 weeks.
- You will need to select a quit date (the day you will stop smoking completely), which can be 1-2 weeks AFTER you have started taking the Champix. In other words, you can still smoke while you are taking the first 1-2 weeks of Champix.

- You will be called up to six times over the 12 week period (each call will be 10 minutes long) and provided with advice and verbal support about quitting.
- After 12 weeks you will be called by a researcher who will ask if you are smoking or not. If you have NOT QUIT smoking the researcher will talk to you about other possible ways to quit smoking, and will refer you to a cessation support service of your choice or another smoking cessation study. You will then finish the study. If after 12 weeks, you HAVE QUIT smoking, the researcher will ask you to attend the study clinic again (within a week of the call).

Trial period (this will involve 262 people):

- At the clinic the doctor will again measure your exhaled breath to see how much carbon monoxide you breathe out. This will show how effective your body is at clearing the tobacco smoke out of your system, and will indicate your success in quitting smoking. If your carbon monoxide reading is high the doctor will talk to you about other possible ways to quit smoking, and will provide you with some extra help or refer you to a cessation support service of your choice. You will then finish the study.
- If your carbon monoxide reading is low the doctor will obtain your written consent to come into the second part of the study – called the 'trial period'. They will then ask you some questions about your smoking behaviour in the past 12 weeks and your breathing. You do not have to answer all the questions, and you may stop the interview at any time.
- The doctor will randomly allocate you (like the toss of a coin) to receive either Champix or a placebo. **You or your doctor will not know which treatment you will get.**
- The doctor will provide you with the medicine you have been allocated – you will not need to go to a pharmacy to get it. You will need to take the medication every day for 12 weeks, according to the instructions shown on the medicine.
- A researcher will call you six times over the 12 week period to provide you with advice and verbal support about preventing relapse back to smoking.
- A researcher will call you three months then six months later and ask you some questions about your smoking and your breathing. You do not have to answer all the questions, and you may stop the interview at any time.
- If you are still smoke-free when we call you at three and six months, a researcher will need to meet you at a place that suits, to measure your exhaled breath to see how much carbon monoxide you breathe out.

Contact times

During the study you will need to attend the study clinic once or twice so we can collect some information from you. The clinic will be at either the (i) The Clinical Research Facility, Level 4 – Building 502, 85 Park Road, Grafton, Auckland or (ii) National Institute for Health Innovation, Level 4, School of Population Health, Tamaki Campus, The University of Auckland, 261 Morrin Road, Glen Innes, Auckland 1072. There is free parking available for both clinics, and good access using public transport. We will also phone you three times so we can collect some information from you. The table below tells you what to expect at each visit or phone call and how long each visit or phone call will take.

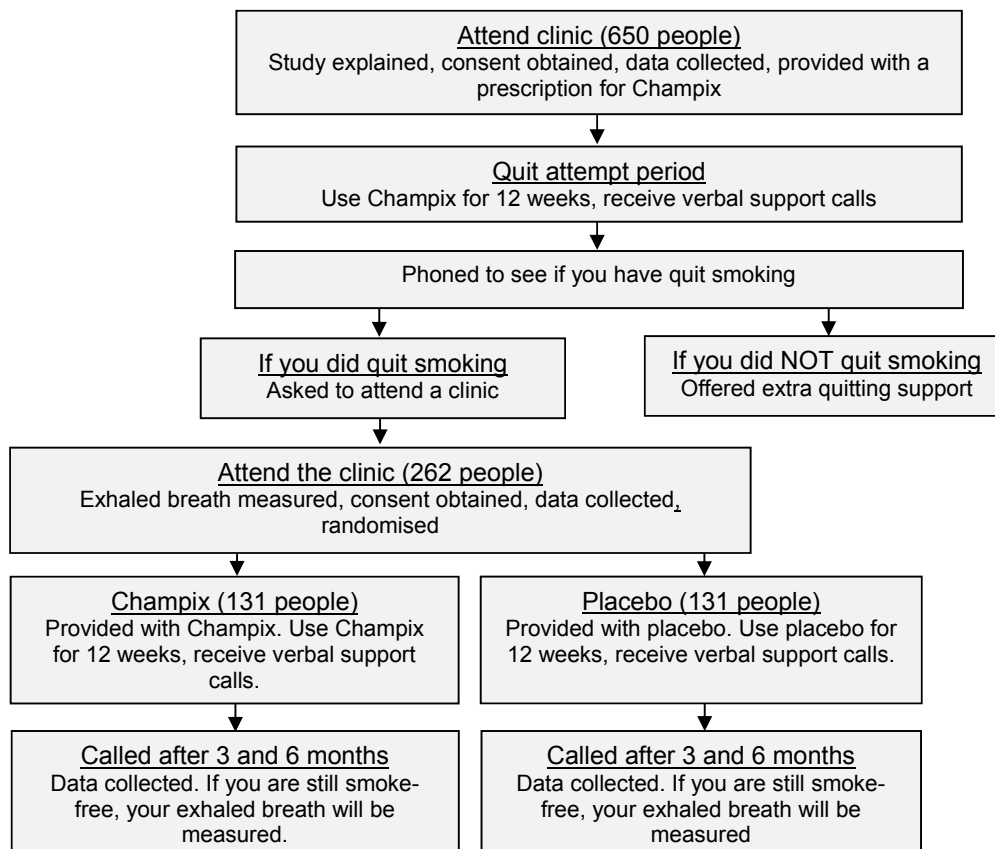
Contact points	Start of quit attempt	End of quit attempt	If you have quit smoking after 12 weeks of treatment*	Three months later	Six months later
How will we talk to you?	Face-to-face at a clinic	By phone	Face-to-face at a clinic	By phone	By phone
How long will it take?	40 minutes	10 minutes	25 minutes	15 minutes	15 minutes
Study explained, consent obtained	Yes		Yes		
Eligibility checked	Yes	Yes	Yes		
Exhaled breath tested	Yes		Yes	Only if you are still not smoking	Only if you are still not smoking
Randomised			Yes		
Information about your smoking collected	Yes	Yes	Yes	Yes	Yes

Information about your health collected	Yes	Yes	Yes	Yes	Yes
---	-----	-----	-----	-----	-----

*We will call you before the clinic visit to see if you have quit smoking. Only those people who have quit will need to come to the clinic

Study design

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



Will participating in the study affect my healthcare?

Your usual doctor (any specialist who you have been seeing or your GP) will continue to care for you during the study. We will send them a letter to say you are participating in the study. Your healthcare will not be affected by participating in this study.

Will I be paid?

No, people are not usually paid for participating in clinical studies. However, we will offer you a \$10 petrol or food voucher to reimburse you for your time travelling to and from each study clinic.

Will it cost me anything to be in the study?

No. The medicine to be used in this study will be free.

What if I don't want to participate?

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

Do you need to talk to my usual doctor (GP)?

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

Benefits

- The study medicine 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 your family/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 medicine we are using in this study will help reduce these feelings.
- However, medicines themselves may cause some side effects for some people.
- The side effects of Champix 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
- Any side effects usually pass within a few days; 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 a health professional immediately and also ring us on 0800 367 644.
- It is important that you tell your doctor or pharmacist 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.

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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 pills are gone, you can still remain in the study. 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 SPACE Trial researchers and the study monitor will have direct access to your information. If you experience any serious side effects to the study medicine we will need to share this information with the study safety committee and the pharmaceutical company (Pfizer) – you will not be identified in this process. Representatives of the ethics committee may also require access to your information 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 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 April 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 Tākuta Hōri Laking
(For Māori health support, please contact Dr George Laking):

Phone: 022 124 8262
Email: georgeL@adhb.govt.nz

The SPACE Trial has received ethics approval from the Northern Health and Disability Ethics Committee (16/NTA/148) on the 21st September 2016. You can contact the Health and Disability Ethics Committee (HDEC) on:

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

Thank you