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Participant Information Sheet

Trial title:	ASCEND-II: A randomised trial to assess the effectiveness and safety of combining nicotine patches with e-cigarettes (with and without nicotine) plus behavioural support, on smoking cessation.
Ethics committee ref:	15/NTA/123
Lead investigator:	Associate Professor Natalie Walker National Institute for Health Innovation, University of Auckland 09 923 9884
Project Manager:	Tomasz Kurdziel National Institute for Health Innovation, University of Auckland 09 923 1571

We invite you to take part in a trial looking at three different treatments to help you quit smoking. The trial is funded by the Health Research Council of New Zealand. It is being run by researchers at the University of Auckland.

We are doing our research across New Zealand. You may be eligible to take part if you smoke cigarettes and plan to quit in the next two weeks.

Whether or not you take part is your choice. If you decide not to, you don't have to give a reason.

This Information Sheet will help you decide what to do. It tells you why we are doing the trial, what it involves, the benefits and risks, and what would happen after the trial ends. The researcher will go through this with you to answer any questions. You do not have to make your choice today. Before you decide you may want to talk about the trial with other people, such as family, whanau, friends, or healthcare providers. Feel free to do this.

If you agree to go ahead, you will be asked to give your verbal consent.

What is the purpose of the trial?

This is a study about quitting smoking. We want to find out if the current most popular, proven quit smoking treatment (the nicotine patch) is more effective at helping people quit when used alone or in combination with e-cigarettes.

What exactly are the products being tested?

E-cigarettes are electronic devices that let the user inhale nicotine with less harmful chemicals than found in tobacco smoke. They contain water and propylene glycol (a non-toxic food additive, also used in asthma inhalers) or glycerol (vegetable oil). Nicotine can be added to this mixture. When heated it forms a mist that looks like smoke and can be breathed in.

In New Zealand e-cigarettes with nicotine are not allowed to be sold – that's because there is not enough information about them. We have approval from the government to use e-cigarettes with nicotine in this study, so we can get the information the government needs to make informed decisions.

Nicotine patches stick onto your skin. They release nicotine at lower levels than you would get from smoking a cigarette. Nicotine patches are the main treatment in New Zealand for helping people to quit smoking.

Who can take part in this trial?

You can take part if you:

- smoke and want to quit in the next two weeks
- Are aged 18 years or over
- Have a landline or mobile phone the researchers can ring you on
- Are living in New Zealand
- Are willing to use a nicotine patch or a nicotine patch and an e-cigarette to help quit smoking

You cannot take part in this trial if you have any of the following:

- You are pregnant or breastfeeding
- You have used an e-cigarette for more than one week in the last year for quitting smoking
- You use nicotine patches, gum, lozenges, mouth sprays, inhalers or tablets
- You are enrolled in a quit smoking programme
- You use a non-nicotine based quit smoking treatment e.g. Zyban (bupropion), clonidine, nortriptyline or Champix (varenicline).
- You have a history of severe allergy and/or poorly controlled asthma
- You have had a heart attack, stroke or severe angina in the last two weeks
- Another person in your household is already in this trial

What will the trial involve?

We are inviting 1809 people who want to stop smoking to take part in this three year trial. Each person will be in the study for 6 months.

If you decide to take part, a researcher will phone you up to ten times to ask about your use of the trial product, and your smoking and quitting. Each call will take between 10-20 minutes.

For the trial to work we need your commitment to the follow-up phone calls.

At the first phone call the researcher will explain the trial and check that you meet the entry criteria.

You will be asked for your verbal consent to take part. You will then be picked at random to join one of three groups:

- Group 1: Nicotine patch: People will be asked to wear one nicotine patch every day for 12 weeks. We will ask you to not use an e-cigarette.
- Group 2: Nicotine patch plus nicotine-free e-cigarette: People in this group will be asked to wear one nicotine patch daily for 12 weeks, plus use an e-cigarette which doesn't contain nicotine. The e-cigarette can be used at any time.
- Group 3: Nicotine patch plus nicotine e-cigarette: People in this group will be asked to wear one nicotine patch every day for 12 weeks, plus use an e-cigarette which contains nicotine. The e-cigarette can be used at any time.

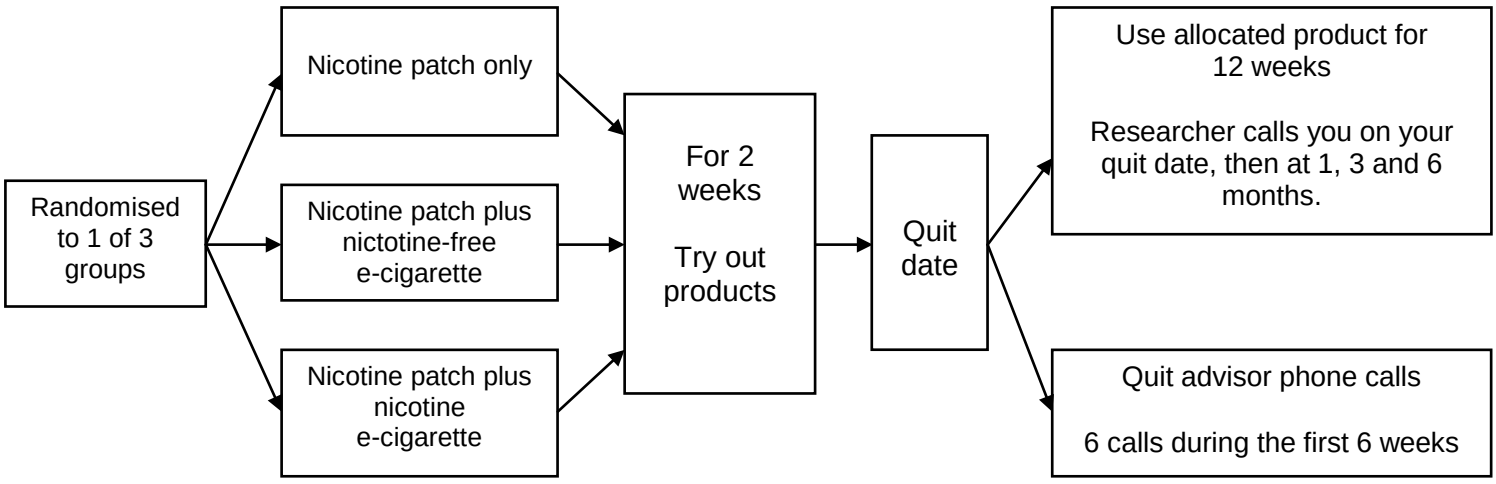
Nobody in group 2 or 3 will know whether their e-cigarette has nicotine or not until after the trial.

After you have been picked for a group, we will send you the products to help you stop smoking. You will need to set a date to quit, sometime within the next two weeks. We ask that you try out the products for two weeks, so you get used to handling them.

On your quit date you need to stop smoking and only use the products you have been given. You need to use these for 12 weeks.

We will call you on your quit date, then one, three andsix months later. At each phone call we will ask you about whether you have quit, use of the products we gave you, and how many cigarettes you are using (if by chance you are still smoking). You do not have to answer all the questions, and you can stop the interview at any time.

The picture below will give you an idea about the trial design.



Quit advisor phone calls

Everyone will be phoned by a quit advisor at least six times during the first six weeks of your quit attempt. Their job is to give you support, tips and advice to help you get through the quitting process. Each call is about 10 minutes long.

If you quit smoking

If you quit smoking we may ask to meet in person at a time and place convenient for you. At this visit we will measure the amount of carbon monoxide you breathe out. This will show how effective your body has been at clearing the tobacco smoke out of your system. People who smoke have higher amounts of carbon monoxide in their breath than non-smokers.

The test does not hurt or cause any harm. It involves breathing into a small machine, and takes less than three minutes.

Sub-studies

We may contact you during the trial to see if you are interested in further research about stopping smoking and e-cigarettes. Whether or not you take part is your choice. If you don't want to, you don't have to give a reason.

What are the benefits and risks of this trial?

Possible benefits

The trial products may help you get over nicotine withdrawal and quit smoking. By doing this, you will be helping other people in the future who want to quit smoking.

Possible risks

When you reduce the amount of cigarettes you smoke or stop smoking you take in less nicotine. Nicotine is the main chemical in cigarettes that makes tobacco addictive. You may experience nicotine withdrawal symptoms; for example agitation, anxiety, feeling down and disturbed sleep. The products we are looking at in this trial will help reduce these symptoms. The symptoms themselves will go away over time.

Nicotine patches are safe medicines that have few side effects. They can sometimes cause headache, irregular heartbeat, coughing, hiccups, nausea, and redness and itching of the skin where the patch has been. E-cigarettes are also a safe product. E-cigarettes can sometimes cause mouth and throat irritation, and dry cough. These symptoms usually go away after several weeks use. Because both products contain nicotine they should be stored out of reach of children and animals.

As with any medicine people can have side effects we don't know about. If this happens or you feel unwell during the trial you should contact your GP before taking any new medicines yourself. It is important that when you see any doctor or pharmacist you tell them you are in the trial, especially if they wish to give you any other medication. This is to make sure they do not give you any medicine that could disagree with the products we are looking at. If the doctor or pharmacist has concerns they should ring the ASCEND-II project manager on 09 923 1751.

Will it cost anything to take part in this trial?

No, the nicotine patches and e-cigarettes will be made available at no cost.

What if something goes wrong?

If you were injured in this trial you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You would have to lodge a claim with ACC, which could take some time to assess. If your claim was accepted, you would 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 trial won't affect your cover.

What are my rights?

You do not have to take part in this trial. If you do not take part, your healthcare will not be affected in any way. If you agree to take part, you can stop taking the trial products at any time, or withdraw from the trial at any time. If you stop taking the trial products, we would still like to contact you at follow-up phone call times to see if you have quit smoking. If you withdraw from the trial we would like to use your information up to the point you withdraw. However you do have the right to access your data and/or to remove it from the study.

The trial files and all information you provide will be strictly confidential. No material that could identify you will be used in any reports on this trial. 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 facility. All future use of the information will be strictly controlled as per the Privacy Act, 1994.

During the trial only the ASCEND-II researchers and the trial monitor will have direct access to your information. Representatives of Medsafe or the ethics committee may also require access. Medsafe are in charge of making sure medicines and medical devices are acceptably safe. This access will only be to check the accuracy of the information collected for the trial. The information itself will stay confidential.

You have the right to access and, if needed, to correct your information in the trial documents. Ask the researcher how to do this. You also have the right to services of an appropriate standard. This means that if we learn of any new information about nicotine patches or e-cigarettes that will have a positive or negative effect on your health, we will tell you as soon as possible.

What happens after the trial?

When all participants have completed the trial, the data will be analysed and published. At the earliest, this will be about 3½ years after the first person started on the trial. We will advise you of the results by email or post. If you are in the e-cigarette group we will tell you whether your e-cigarette had nicotine or no-nicotine. We may be asked to submit individual data to a clinical trials register in order to have the results published. If we are required to submit data to such a register, you would not be able to be identified.

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

Your data may be used in a type of study called meta-analysis. This type of research collects individual information from all trials of smoking cessation. If we were to share your data for such a study, 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 trial, 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

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this trial on:

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

This clinical trial is registered on the ClinicalTrials.gov website NCT02521662.

Verbal Consent Form

ASCEND-II

A randomised trial to assess the effectiveness and safety of combining nicotine patches with e-cigarettes (with and without nicotine) plus behavioural support, on smoking cessation.

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Researcher to ask the participant the following questions and tick to indicate their agreement to the following

I have had the trial explained to me and I understand it.	Yes ☐	No ☐
I have been offered the chance to talk with my whanau/ family or GP to help me ask questions and understand the trial before taking part.	Yes ☐	No ☐
I have been given enough time to decide whether or not to take part in this trial.	Yes ☐	No ☐
I am willing to give verbal consent to take part in this trial.	Yes ☐	No ☐
I understand that taking part in this trial is my choice, and I may withdraw from the trial at any time.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health. I understand I have the right to access and, if needed, to correct my information in the trial documents.	Yes ☐	No ☐
I understand my responsibilities as a trial participant and I agree to use only the trial products I have been allocated. (Patch only or patch and e-cigarette).	Yes ☐	No ☐
I agree to accept telephone calls from the ASCEND-II researchers at a number of my choice and, if needed, to let researchers leave messages about the reason for calling (i.e. smoking cessation support) at this number.	Yes ☐	No ☐
I agree to set a quit date, within 2 weeks	Yes ☐	No ☐
I understand there may be minimal risks associated with the trial products.	Yes ☐	No ☐
I understand my taking part in this trial is confidential and that nothing which could identify me personally will be used in any reports. Information may be shared with other studies or registers but no information that identifies me personally will be used.	Yes ☐	No ☐
I understand that a monitor or members of Medsafe or the ethics committee may review my trial records to check the accuracy of the information collected for the trial.	Yes ☐	No ☐
I understand this trial is covered under ACC compensation.	Yes ☐	No ☐
I understand I may be contacted to see if I would like to take part in further research about smoking cessation and e-cigarettes. This would be my choice.	Yes ☐	No ☐
I understand I may be asked to give an exhaled breath air sample to a researcher if I stop smoking.	Yes ☐	No ☐
If I decide to withdraw from using the trial products, I agree to be contacted for the follow-up phone calls.	Yes ☐	No ☐
If I decide to withdraw from the trial, I agree that the information collected about me up to the point when I withdraw may continue to be used.	Yes ☐	No ☐
I understand that a written copy of the information sheet and consent will be sent to me in the post or by email. I know who to contact if I have questions about the trial in general.	Yes ☐	No ☐
I wish to receive a summary of the results from the trial. The results will not be available until late 2018.	Yes ☐	No ☐

I agree to my GP being told I am involved in this trial. 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 trial and has given informed consent to take part.

I will ensure the participant is given a copy of the Participant Information Sheet and Informed Consent Form.

Participant's name: _____

Researcher's name: _____

Role in Project: _____

Researcher's contact phone number: _____

Date of verbal consent: _____