

What can you do?

All professionals working within CADS, CMHS and NGOs in the Auckland metropolitan region can inform their smoking clients about the trial.

We have free recruitment material that can help you with this, such as flyers and posters. These have been distributed throughout CADS, CMHS and NGOs. If you would like to order additional flyers or posters for your service please call us on 0800 367 644 or send us an email statustrial@auckland.ac.nz.

Also contact the research team if you would like to promote the trial via your newsletter or social media channels. The study team would be very happy to come to your service and inform your team about the trial or to attend support groups and inform your clients in person.

If you are a community support worker or key worker of a client who is part of the trial, you can help your client by making sure they pick up and use their Champix tablets. You don't have to provide any additional quit smoking support – as part of the trial, a researcher will call your client on a regular basis to provide behavioural support. If clients report any side effects of using the study treatment, please call us on 0800 367 644 or send us an email statustrial@auckland.ac.nz.

FLYERS
POSTERS
SOCIAL MEDIA
COMMUNITY
SUPPORT GROUPS
TEAM MEETINGS
NEWSLETTERS
CONFERENCES
NEWSPAPERS
RADIO

Funding

The STATUS Trial is funded by a three-year grant from the Health Research Council of New Zealand.

The e-cigarettes and e-liquid have been purchased from NZVAPOR. NZVAPOR is not involved in the design, conduct or analysis of the trial, but will provide on-line and phone support to participants regarding use of their allocated e-cigarettes. The e-cigarettes to be used in the trial and NZVAPOR (including the Managing Director) have no links with the tobacco industry.

The trial is registered in the Australian New Zealand Clinical Trial Registry: ACTRN12616001355460p. The Universal Trial Number is U1111-1186-7693. Ethics approval for the trial (ref 16/STH/153) was granted by the Southern Health and Disability Ethics Committee. The trial is also registered with Awhina Knowledge Management Centre, Waitemata DHB, and has been approved by the Auckland DHB Research Review Committee.



Next issue

RECRUITMENT UPDATE

The next issue will provide an update about the number of randomised participants.

CHAMPIX

Is Champix safe? What are common side effects and what can you do about them? Find out more in the next issue.

SOCIAL MEDIA

How do we use social media to promote the STATUS trial? Read more in the next issue.

Contact us

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P1 / What's happening?

The STATUS study team has visited CADS & CMHS teams across Auckland. Find out what has happened in your service.



P2 / Trial re-design

The STATUS trial was originally designed as a three-arm trial. Read why the team has dropped the bupropion arm.



P3 / E-cigarettes

What are e-cigarettes, are they effective smoking cessation aids and how safe are they? Find out the basics.



P4 / Recruitment

How is recruitment going? This newsletter provides a first overview of the number of clients who have expressed interest.

STATUS Trial

OCTOBER 2017

NEWSLETTER / ISSUE 2

RECRUITMENT in WDHB, ADHB and NGO mental health and addiction services across Auckland



What is the STATUS Trial?

The STATUS trial is an HRC-funded randomised controlled trial that aims to evaluate the effectiveness and safety of combining varenicline with nicotine e-cigarettes, plus behavioural support, on smoking abstinence in people in treatment for mental illness and/or addictions.

Who can participate in the study?

Registered clients of CADs and CMHS in the Auckland region, who smoke daily and are willing to quit may be eligible for the trial. Participants need to be at least 18 years of age, live in Auckland, have tried to quit twice before using nicotine replacement treatment, and have not used varenicline in the past year. If clients are interested they can call the researchers on 0800 367 644.

“ The STATUS trial evaluates the effectiveness and safety of combining varenicline with nicotine e-cigarettes in people in treatment for mental health illness or addiction who do not quit smoking after two weeks of varenicline treatment ”

From three to two-arm trial: Varenicline plus bupropion arm removed

Since our last newsletter in August 2017 the STATUS trial steering group has decided to make a substantial change to the trial design.

WHAT WAS CHANGED?
The STATUS trial was originally designed as a three-arm study. Participants who did not quit smoking or reduced the number of cigarettes they smoke a day by half or more, after two weeks of varenicline were randomised to receive another 10 weeks of only varenicline, or varenicline combined with either a nicotine e-cigarette or bupropion. However, after careful consideration the study team decided to remove the varenicline plus bupropion arm.

WHY DID THE TRIAL DESIGN CHANGE?
The change addresses some concerns expressed by clinicians about combining varenicline with bupropion. A large number of screened participants who could potentially have been randomised to the varenicline plus bupropion arm were taking other psychoactive medications or have medical histories that raised concerns about the addition of bupropion to their current medications. As such, these people could not be included in the study. Also, by removing this arm from the study the sample size needed will decrease. This will make achieving the required number of participants to demonstrate a difference between the two groups, if one exists, more feasible.



“The change addresses some concerns expressed by clinicians about combining varenicline with bupropion ”

WHAT WILL THIS MEAN?
The change does not affect the 'adaptive' design of the study, whereby participants are only randomised after two weeks up-titration of varenicline if they have not already quit or cut down their baseline cigarettes per day by half or more. This feature remains as a novel aspect of the study. Although a number of participants were already screened for eligibility when the decision was made, fortunately no participants were randomised. They were re-consented and will stay in the trial.

The changes have been approved by the Southern Health and Disability Ethics Committee and SCOTT. The trial has approval to proceed in WDHB and ADHB facilities, with those who have consented prior to the change first being contacted for re-consent to the new protocol.

What’s happening?

Mental Health Awareness Week

9-15 October was Mental Health Awareness week. The STATUS trial team used this opportunity to bring the trial to the attention of service providers, clients and the wider public around Auckland. We promoted the trial on the AUT Mental Health Awareness Seminar and went along several ADHB clinics including Manawanui Oranga Hinengaro, Buchanan Rehab Centre, the St Lukes clinic, Pregnancy & Parenting, and the Auckland Opioid Treatment Service in Pitman House.

NGO service providers

Recruitment has started in NGO services across Auckland. Lindsay Yuille (Nurse Manager, Fairleigh Lodge) invited the STATUS team to attend the INNOVATE and NAVIGATE meetings to talk about the trial. We were also invited by Dan Crozier (Service and Relationship Manager, Pathways) to meet with several service providers of Pathways in the Henderson District.

ADHB mental health and addiction

After locality approval from the ADHB was received, Jane Galea-Singer (ADHB, Smokefree Coordinator) initiated recruitment for STATUS in the ADHB clinics.



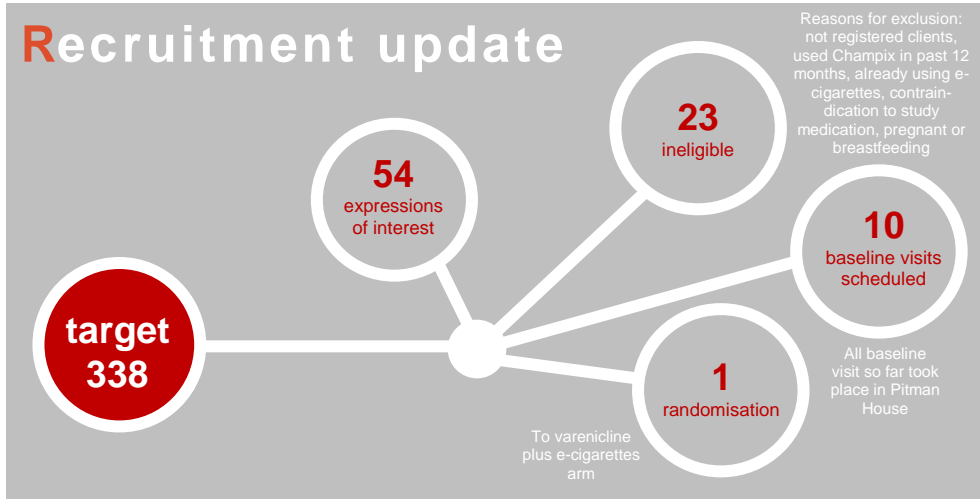
Did you know... Facts about e-cigarettes

All STATUS participants receive a 12-week course of varenicline (Champix®) plus six behavioural support phone calls as is the standard for usual quit smoking support. After two weeks of treatment, those that have not quit smoking and those who have not reduced their smoking by half or more will be randomly allocated (like the toss of a coin) to either A) continue with varenicline only for 10 more weeks, or B) start combining varenicline with an e-cigarette for 10 weeks. **What do you need to know about e-cigarettes?**



“E-cigarettes are both efficacious for smoking cessation when delivering nicotine and highly acceptable to patients who smoke and who are undergoing treatment for other addictions ”

Recruitment update



>> VISIT THE STUDY WEBSITE FOR MORE INFORMATION AT [HTTPS://STATUS.NIHI.AUCKLAND.AC.NZ](https://status.nihi.auckland.ac.nz)

WHAT IS AN E-CIGARETTE?

E-cigarettes, or vapes, are hand-held devices that, when activated by the user, produce a visible cloud of aerosol made up of droplets of liquid containing propylene glycol and glycerine, flavours and usually (and in the STATUS trial) nicotine, for inhalation. ***They do not burn tobacco like a conventional cigarette. The products we are using in this trial have been purchased from a local NZ company. There is no involvement by the tobacco industry.***

HOW DOES AN E-CIGARETTE WORK?

A fully set up e-cigarette has a charged battery, a tank full of liquid (popularly known as juice or e-liquid) and a coil. When you press the button the battery delivers power to the coil. Because this is made of thin metal it quickly heats up, and so does the liquid in contact with it. Almost instantly, the coil is surrounded with a small, but dense, cloud of vapour. When the user takes a puff, air is drawn in through the air holes and over the coil. This pulls the vapour up to the mouthpiece, allowing more liquid to evaporate. The coil will carry on creating vapour until the airflow stops. Most vapers inhale for up to five or six seconds. When they exhale, a big cloud of vapour is usually visible.

HOW SAFE ARE E-CIGARETTES?

One previous NZ trial with 657 participants led by Professor Chris Bullen found no difference in adverse events at six months between e-cigarette users and nicotine patch users. No mental health related adverse events have been detected in any previous e-cigarette trial. Some health risks may emerge from long-term use of e-cigarettes but, given what is known about the constituents of the vapour produced by e-cigarettes, it is generally agreed that in the unlikely event of health effects occurring, they would be minor in comparison to continued smoking.

DO E-CIGARETTES HELP PEOPLE QUIT SMOKING?

Overall, trials to date show that e-cigarettes with nicotine are an effective aid for smoking cessation. The effect is probably similar to that of other forms of nicotine replacement therapy. E-cigarettes are also shown to be very popular among people who smoke and who are undergoing treatment for other addictions, an important feature because of the typically low uptake of conventional smoking cessation treatment in this population. Secondary analysis of our previous e-cigarette trial found that among smokers with mental illnesses, e-cigarettes with nicotine had similar efficacy to (and were preferred over) conventional nicotine patches.