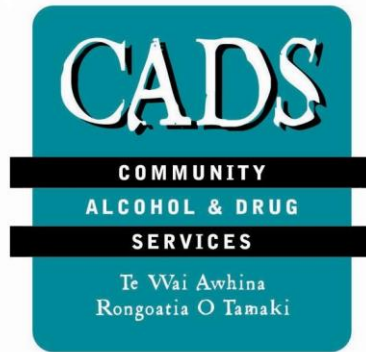


Funding

The STATUS Trial is funded by a three-year grant from the Health Research Council of New Zealand. The study e-cigarettes and e-liquid have been purchased from NZVapor.

The STATUS trial is registered in the Australian New Zealand Clinical Trial Registry (ANZCTR): ACTRN12616001355460p. The Universal Trial Number is U1111-1186-7693. The trial is also registered with Awhina Knowledge Management Centre, Waitemata DHB.

Ethics approval for the trial (reference 16/STH/153) was granted by the Southern Health and Disability Ethics Committee.



Want to know more?

Phone us on 0800 367 644

Email: statustrial@auckland.ac.nz

Website: <https://status.nihi.auckland.ac.nz/>

Facebook: @STATUSTrial

Next issue

FIRST PARTICIPANTS RANDOMISED

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

E-CIGARETTES

What are e-cigarettes, are they effective smoking cessation aids and how safe are they?

SOCIAL MEDIA

How do we use social media to promote the STATUS trial?



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P1 / Quick Refresher

What is the STATUS trial, why is the study important, and who can sign up? This newsletter provides a quick refresher.



P2 / Meet the Team

The STATUS Trial is a collaboration between the National Institute for Health Innovation and Waitemata District Health Board.



P3 / Trial treatment

STATUS involves three types of quit smoking treatment – Champix, Zyban and e-cigarettes with nicotine.



P4 / How can you help?

Read more about what you can do to help with recruitment in your service.

STATUS Trial

AUGUST 2017

NEWSLETTER / ISSUE 1

RECRUITMENT STARTED

The STATUS Trial is now open for all users of Community Alcohol & Drug Services and Community Mental Health Services in Auckland who want to quit smoking.

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 bupropion or nicotine e-cigarettes, plus behavioural support, on smoking abstinence in people in treatment for co-existing conditions.

Why is the study important?

The burden of smoking-related illness is greatest in those with the highest prevalence of smoking, including people with mental health or drug and alcohol addiction. A recent audit of CADS showed that at least two-thirds of users currently smoke. The proportion smokers in the NZ population with a mental illness has increased from 27% in 1996 to

47% in 2012. Switching to other types of nicotine products or combining effective treatments for smoking cessation has been shown to increase quit rates. These approaches to treatment have not been integrated nor trialed among people with co-existing problems – yet this group of people has the most to gain should such simple changes of available treatment lead to improved cessation efficacy.

Who can participate in the study?

Users of CADs and CHMS 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 Champix in the past year. If clients are interested they can call the researchers on **0800 367 644**.

“

The STATUS Trial evaluates the effect and safety of combining varenicline with bupropion or e-cigarettes with nicotine

”

Meet the Team

The STATUS Trial is conducted by researchers at the National Institute for Health Innovation (NIHI), University of Auckland. The trial is led by **NIHI Director Professor Chris Bullen**.

STATUS was designed in close collaboration with Dr **Susanna Galea**, Service Clinical Director and Consultant Psychiatrist at CADS Auckland (WDHB), Dr **David Newcombe**, senior lecturer in Alcohol and Drug Studies and over 15 years’ experience working in the addiction sector in NZ and Australia, and Dr **George Laking**, cancer specialist, Māori health expert and advisor in the NZ tobacco control field.

The team at NIHI

Professor **Chris Bullen** is an international expert in smoking cessation, particularly use of e-cigarettes. Chris acts as the study doctor in the STATUS trial. This means he determines if a participant is eligible to enter the study and he closely evaluates any adverse health events which may occur during the trial.

Associate Professor **Natalie Walker** leads the Addiction programme within NIHI and has nearly 20 years’ experience in the design, conduct, and analysis of large community-based trials. She currently leads three HRC-funded trials in the field of smoking cessation.

Dr **Marjolein Verbiest** is a research fellow at NIHI with a background in Health Psychology and Public Health, in particular smoking cessation care.



Photo: Rita George, Tomasz Kurdziel, Kelly Zhong, Natalie Walker & Marjolein Verbiest

“STATUS will be the largest trial of its kind so far anywhere in the world in people with mental health and addictions who smoke”

The project management team consists of **Tomasz Kurdziel** who is a senior project manager and **Rita George** who is the project coordinator. Both are responsible for the day to day running of the trial.

Varsha Parag is a senior biostatistician on the study and has extensive experience in the statistical design elements and analysis of randomised trials in general and smoking cessation intervention trials in particular.

Kelly Zhong is the research assistant working on the trial. She is the first point of contact for service users if they express interest in the study. Kelly informs them about the study and has regular contact with all study participants, both in person (during the baseline clinic visit) and by phone. Kelly has a background in Psychology and ensures that participants receive regular behavioural support by phone.

First participants enrolled

Photo: Professor Chris Bullen



PITMAN HOUSE

June 2017 we started recruitment in Pitman House. The first participants have now been enrolled in the study. After a screening phone call in which their eligibility was confirmed, a face-to-face visit was scheduled in the clinic to do the informed consent, collect baseline data, and prepare the quit smoking attempt.

CADS SOUTH

Chris Bullen has also visited other CADS teams across Auckland in the past few weeks. One of them was the CADS South team. They are very supportive of the trial and keen to help us with recruitment. We aim to ramp up recruitment in this area in the upcoming weeks.

TUPU

The research team also liaised with the TUPU team who provide Alcohol and Drug & Gambling services for Pacific clients across Auckland. The clinicians are keen to inform their clients about the trial. We hope start the first baseline visits in their clinics soon.

Trial Treatment

Champix, Zyban and e-cigarettes

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. Those that have not quit smoking after 2 weeks of treatment and those who have not reduced their smoking by half or more will be randomly allocated (like the toss of a coin) to one of the three intervention groups.



“No smokers left behind - in order to reach New Zealand’s smokefree goal in 2025 we need to focus on priority populations”

How can you help?

All professionals working within CADS and CMHS in the Auckland region can inform their smoking clients about the trial. We have recruitment material that can help you with this, such as flyers and posters. These have been distributed throughout CADS.

If you would like additional recruitment material for your service please let us know on 0800 367 644 or statustrial@auckland.ac.nz.

VARENICLINE PLUS BUPROPION

Participants randomised to this group will continue their varenicline treatment for a further 10 weeks and start combining it with bupropion (Zyban®). Bupropion is an atypical anti-depressant that acts in part as a non-competitive antagonist of neuronal nicotinic acetylcholine receptors but also via other pathways such as inhibition of noradrenaline-dopamine reuptake.

VARENICLINE PLUS E-CIGARETTE

Participants in this group will start using an e-cigarette with nicotine together with their varenicline treatment. In a previous study, e-cigarettes with nicotine had similar effects to (and were preferred over) conventional nicotine patch among smokers with mental illness.

VARENICLINE ONLY

Participants in this group (control group) will continue their use of varenicline for a further 10 weeks. In the general population and, to some extent, among smokers with co-existing conditions, there is growing evidence that varenicline use leads to better quit rates than nicotine replacement therapy, bupropion or nortriptyline.

Interested in taking part in a study about quitting smoking?

We are looking for people who are using **mental health and addictions services**, and who smoke tobacco and want to quit smoking, to take part in a clinical trial called **STATUS**. The trial involves the use of several stop smoking medications and e-cigarettes.

We are looking for people who:

- Smoke daily and want to quit
- Are users of mental health and addictions services
- Live in the Auckland region
- Are at least 18 years of age
- Have access to a telephone (mobile and/or landline)
- Have tried to quit twice before using nicotine replacement treatments (e.g. patches, gum etc.)
- Have not used an e-cigarette for more than one week in the last year
- Are prepared to use Champix®, Zyban® or an e-cigarette to help them quit smoking

If you fit all of these criteria and are interested in the study, we'd love to hear from you.

Contact us

Freephone: 0800 367 644

Free text: "your name" + "STATUS" to 4073

Email: statustrial@auckland.ac.nz

Website: <https://status.nihi.auckland.ac.nz/>

Facebook: @STATUSTrial

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