NDARC
National Drug & Alcohol Research Centre
The Difference is Research

UNSW
THE UNIVERSITY OF NEW SOUTH WALES

PARTICIPANT INFORMATION STATEMENT

Research project title:

Desmoxan (Cytisine) and Champix (Varenicline) for smoking cessation – The CESSATE study.

1. What is the research study about?

You have been invited to take part in this research study. This study aims to evaluate the cost-effectiveness between two smoking cessation products, Desmoxan and Champix. This study will see if a 25-day course of Desmoxan, a medicine derived from a plant is as effective as Champix, another smoking cessation medicine for helping smokers to stop smoking.

2. Why am I receiving this information?

You have received this information because you have indicated that you would like to know more about this study. Please ensure that you read all of the information provided in this document. A research team member will contact you soon to discuss further about the study and check your eligibility to participate. In the meantime, if you have any questions about the study you can contact a member of the research team using the contact details provided at the end of this document.

3. Do I have to take part in this research study?

Your participation in this study is voluntary. If you don't want to take part, you don't have to. You can withdraw your consent at any time. Your decision will not affect your relationship with Quitline or the University of New South Wales (UNSW) or any other organisation. You can decline to answer any question/s or parts of questions during interviews.

4. Who are the researchers & Who is funding this research project?

This research is being conducted by Professor Michael Farrell, Dr Ryan Courtney and Dr Dennis Thomas from UNSW. The project coordinator's contact details are provided at the end of this document. The study interviews will be conducted by an independent organisation, theSocial Research Centre (SRC), who is working with the UNSW research team on this study. Our study doctor will oversee participant study enrolment, and ensure the smoking cessation products offered as part of this study are appropriate for you. The study medication will be mailed from a Central Pharmacy (Chemist Warehouse). This study is funded by the National Health and Medical Research Council (NHMRC).

5. Who can participate in this research?

In order to take part in this research you must meet the following criteria:

- You are currently smoking and you are interested in quitting smoking using medications;
- You are 18 years of age or older;
- You have access to a phone (land line or mobile);
- You are able to provide verbal consent; &
- You are willing to complete baseline and follow-up interviews.

6. You cannot take part in this study if you meet the following criteria:

- You are pregnant or breastfeeding or planning to become pregnant in the next 7 months;
- You have had a hospitalisation for arrhythmia (heart rhythm disorder), heart attack, stroke or severe angina (heart pain) in the last three months;
- You have been diagnosed with hyperthyroidism or pheochromocytoma (a tumour of adrenal gland)
- You are a current user of nicotine replacement therapy products (e.g. patches, gum, lozenges, inhaler, mouth spray, etc.) or other smoking cessation medications such as Zyban (buproprion), nicotine electronic cigarette, clonidine or nortriptyline;

- You are currently enrolled in another smoking cessation programme or another cessation study;
- You are currently using either cytisine (Desmoxan or Tabex) or varenicline (Champix); &
- You have known hypersensitivity to the active ingredient or any other ingredients contained in the study medicaton. The active ingredient in Desmoxan is cytisine. The other ingredients in Desmoxan capsule include microcrystalline cellulose; maize starch; anhydrous colloidal silica; magnesium stearate. The active ingredient in Champix is varenicline. The other ingredients in Champix tablet include microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate.

7. Precautions and warnings

When using Desmoxan and/or Champix a caution is indicated for the following disease conditions: : psychiatric illness, ischemic heart disease, heart failure, cerebrovascular diseases (e.g. stroke), blood vessel (or artery) problems (atherosclerosis – thickening or stiffing of blood vessels), hyperthyroidism, diabetes mellitus (high blood sugar level), kidney and liver problems, pheochromocytoma (a tumour of adrenal gland), hypertension (high blood pressure), active gastroesophageal reflux disorder (GERD) or peptic ulcer disorder and people with history of seizures (epilepsy). If you have any of these conditions, you will be evaluated by a study doctor over phone before enrolling in the study.

8. What are the possible risks, side-effects and/or discomforts?

When you give up smoking you may experience symptoms associated with nicotine withdrawal, such as agitation, anxiety, depression and disturbed sleep. Taking Desmoxan or Champix when you stop smoking may reduce these symptoms. However, both of these medicines may have some side effects.

Desmoxan is a medicine derived from a plant; Cytisus Laburnum (Golden Rain), which has been used in Europe for over 50 years as a smoking cessation product. It does not contain any nicotine, but is similar in structure to nicotine. Desmoxan is currently not commercially available within Australia. The most common side effects reported in previous studies were gastrointestinal disorders (mainly nausea, vomiting, stomach ache, dry mouth and dyspepsia) and sleep disturbance. If you take more than the recommended dose of Desmoxan you may experience nausea, vomiting, pupil dilation, racing heart rate and general weakness. These feelings will disappear if you reduce to the recommended levels. It is considered safe and does not affect your ability to drive or operate machinery.

Champix is a smoking cessation medication widely used in Australia. Mood disturbance, nausea, headache, insomnia, sleep disturbance, abnormal/vivid/strange dreams and constipation are the commonly reported side effects.

A small percentage of people have changes in mood or behaviour that are not typical for them when stopping smoking, with or without treatment. These may include depression, agitation, aggression, self-harming or suicidal thoughts or behaviour, and hallucinations (seeing, hearing or sensing things that are not there). If you have any symptoms that are not experienced in the past you should stop taking the study medications immediately and you should advise the research team and your General Practitioner. You also may experience the following side effects while taking Desmoxan or Champix fatigue, malaise, tiredness, lacrimation, changes in appetite (mostly increased appetite), increased body weight, headaches, dizziness, irritation, heaviness of the head, sleep disorders (sleeplessness, drowsiness, strange dreams, nightmares, somnolence), mood swings, anxiety, problems with concentration, decreased libido, increased or decreased heart rate, increased arterial blood pressure, dyspnoea, increased coughing up, dryness in the mouth, excessive salivation, gastrointestinal disorders (stomach ache, nausea, vomiting, constipation, diarrhoea, flatulence, heartburn), burning of the tongue, changes in taste, muscle pains, rash, increased sweating, reduced skin elasticity, increased activity of aminotransferases (certain type of hepatic enzymes).

Women who are pregnant or breastfeeding should not take these medications. It is recommended that you be on contraception whilst taking either of these medications to reduce the risk of pregnancy.

If you experience any side effects from medications during the treatment, please notify the research team on the toll-free number 1800 290 612 or email the project co-ordinator Dr Dennis Thomas on cessate@unsw.edu.au.

If you have concerns about these potential side effects please seek further information from the product information sheet (will send to you along with medication) or please speak to your regular doctor or pharmacist or call 1800 290 612 to speak to the research team for advice. You

can also contact Poison Information Centre on 131126 (24 hours support) and after hours GP Helpline on 1800 022 222, if you require any urgent support.

Both medications should be stored safely out of reach of children, and animals.

9. What are the possible benefits to participation?

You will receive free access to Champix or Desmoxan during the study period and we hope that either medication will assist you to stop smoking.

10. What are the benefits to other people in the future?

We hope that the study will help to develop the most effective program for helping smokers to quit.

11. What does participation in this research require?

The main components of the study are summarised in the below table:

Procedure	**What will happen and for how long?**
Treatment groups	This study will randomly assign (like tossing a coin) each study participant to one of the two study treatments, Desmoxan or Champix. The random allocation is important to meet the study objectives. **If you are in Desmoxan group:** We will send you a 25-day supply of Desmoxan capsules, Desmoxan information statement and dosing schedule. 25-day supply is sufficient to complete the full course of Desmoxan treatment. You need to stop smoking completely on the 5th day of treatment. You need to follow the dosage regimen exactly as described in the information statement. **If you are in Champix group:** We will send you an initiation pack of 4-week supply of Champix tablets, Champix information statement and dosing schedule. You need to stop smoking completely on the 8th day of treatment. You will also receive a continuation pack of 8-week supply of Champix provided you have started to use the initiation pack and completed at least one check-in call (see below check-in call section for more details). You need to follow the dosage regimen exactly as described in the information statement.
Telephone interviews	3 telephone interviews will occur in a 7-month period. A baseline interview followed by 2 follow-up interviews that will occur at 4 months and 7 months from the baseline interview. Each interview will be conducted by an interviewer from the Social Research Centre. Each interview will take 20-30 minutes and we will ask you some questions about your current smoking status, quitting experiences, problems associated with treatments etc. You will receive $40 for completing each interview and this will be mailed to you immediately after completing each interview.
Check-in calls	You will receive two check-in calls from the research team following the completion of your first interview. Each call will take approximately 10 minutes and will include questions regarding progress with quitting, health concerns, use of medication etc.
Carbon Monoxide breath test	If you report that you have quit smoking at 7 months you may be asked to do a carbon monoxide breath test to confirm your smoking status. The breath test involves blowing into a machine, a bit like doing a random alcohol test. This will be done either by you visiting the trial coordinating centre or having a researcher attending your house to perform this test. You will receive $40 for doing this test.
Pharmaceutical Benefit Scheme (PBS) and Medicare Benefits Schedule (MBS) linkage	If you are enrolled in the study, you will also receive a consent form seeking your permission to access your PBS and MBS claims history. PBS information includes details of the medicines you have brought that were subsidised by the Australian Government and MBS information includes details about the Medicare services that you have used that were subsidised by the Australian Government. Return of this form is optional and you can still participate in this study if you chose to decline.

12. Can I have other treatments during this research projects?

You are free to take any non-smoking cessation medications as required. It is important to inform the research staff about any treatments or medicines you may be taking, including over the counter medications, vitamins or any other alternative treatments. It is also important to inform your doctor or pharmacist that you are participating in this study and taking these medications if you visit them during the study period. You must not take any other smoking cessation medications other than those supplied to you during your participation in the study.

13. What if I want to withdraw from the research study?

You may withdraw at any time. If you wish to withdraw, please complete the "Withdrawal of Consent Form" and post to us via reply-paid envelope. Also, you can withdraw from the study by contacting the research team via phone, text message or email using the contact details provided at the end of this document.

14. What will happen to information about me?

Information participants give will help guide future quit programs and approaches to help people quit. Non-identifiable group data will be presented in scientific journals and at research conferences. The data collected at the Social Research Centre will be stored in an electronic database on password protected computers. The data will be transferred to the UNSW databases on a regular basis using a secured file exchange portal. The data will be stored at UNSW in a re-identifiable format for a period of 15 years. Your interest in participating future research studies will be sought during the screening interview and if you are interested, your contact details will be stored in a separate password protected computer database at UNSW.

15. What will be done to make sure my information is confidential?

All information you provide will be stored securely on the study database (data will be encrypted while on transfer and at rest) and electronic password protected files. Your contact details will be used for research purposes only i.e. contacting you about the study. Such information remains confidential and will not be given to any other persons.

16. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of this research in a variety of ways. All information published will be done in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by sending an email to cessate@unsw.edu.au or contacting the research team via our toll-free study number 1800 290 612. The results will also be made available via the school's website (http://ndarc.med.unsw.edu.au/).

17. What should I do if I have further questions about my involvement in the research study?

If you require further information about the study or need to speak to a research team member please contact our toll-free number 1800 290 612.

18. What will happen next?

A research team member will contact you soon to discuss the study further, check your eligibility to participate and obtain your verbal consent to participate in the study. In the meantime, if you would like to get the support at the earliest, you are free to contact the study toll-free number provided below. You can also inform the research team if you don't want to be contacted further.

19. Study related supports and contacts
Study toll-free number 1800 290 612
Reporting adverse events (side effects) 1800 290 612
Poison Information Centre 131126 (24 hours support)
After hours GP Helpline 1800 022 222
Quitline 13 7848

The project coordinator can be contacted at the below address;

Dr Dennis Thomas
02 93850249
Project coordinator
National Drug and Alcohol Research Centre
University of New South Wales,
Sydney, NSW 2052
d.thomas@unsw.edu.au

20. What if I have a complaint or any concerns about the research study? If you have any concerns or complaints about the project or the way it is being conducted, and would like to speak to someone independent of the project, please contact the Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (phone 02 9385 6222, fax 02 9385 6648, email humanethics@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed of the outcome.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the Desmoxan and Champix smoking cessation study and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, Quitlines or any other organisation.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

Project coordinator:	Dr Dennis Thomas
Email:	cessate@unsw.edu.au
Phone:	1800 290 612
Postal Address:	University of New South Wales National Drug and Alcohol Research Centre Building R3 22-32 King Street Randwick NSW 2031