

**Evaluating the real-world effectiveness of varenicline and burpropion
for long-term smoking cessation (MATCH) Study
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Q 1: What is the purpose of this study?

A: The purpose of the study is to measure the long-term quit rates associated with bupropion and varenicline treatment in a real-world setting, outside clinical trials.

Q 2: What is the rationale for this study?

A: Smoking rates remain high in Ontario, although it is proven that smoking can lead to serious health conditions and cost t our health care system. Prescription medications, Zyban® (bupropion) and Champix® (varenicline), can help with quitting smoking. But, their effects in general population is limited by a combination of factors. Distributing Nicotine Replacement Therapy to a large number of people in general population approaches have been successful for nicotine replacement therapy. However, bupropion and varenicline can make a greater impact since research studies have been shown them to be more effective.

Q 3: Who is conducting this study and what is the affiliated institution involved?

A: This research study is being conducted by Dr. Laurie Zawertailo, a scientist at the Centre for Addiction and Mental Health, and her group. The study is funded by the Global Research Awards for Nicotine Dependence.

Q 4: How many participants will be involved in this study?

A: About 1500 participants from Ontario will participate in this study.

Q 5: What do I need to be able to participate in the study?

A: You need to be a smoker and you will need a valid e-mail address that you check regularly in order to participate in this study. Specifics of eligibility criteria cannot be disclosed to participants. Your eligibility is determined based on the initial questionnaire answered by you. Please note that the primary mode of contact for this study is through e-mail. Any study material will be e-mailed to your email address. You will also receive the follow-up questionnaires via e-mail. You can obtain a free email address by visiting Yahoo! mail or Hotmail.

Q 6: Are there any in-person visits?

A: No, there are no required in-person visits with the study investigators for this study. The primary mode of contact for this study is through e-mail. Any study material will be e-mailed to your email address. You will also receive notification to complete the follow-up questionnaires via e-mail. All the information is collected online via the MATCH study portal.

In addition, study medication and saliva sample kits are sent to participants by mail. Saliva samples are also sent back by participants through mail and received by study investigators.

You are only required to take the Letter to the Doctor and the Standard Script to your family doctor sometime within **5 weeks** of enrolling in the study. Your doctor will have to sign the Standard Script and fax the Prescription to the Pharmacy to be filled. You are also encouraged to continue seeing your doctor for additional support if needed.

Q 7: What happens after the initial questionnaire if I am determined to be eligible? Will I need to see my family doctor to decide if I can participate in this study?

A: Study eligibility will be determined once you complete the initial questionnaire online through the study portal. However, you need to see your family doctor, who will decide if it is safe to prescribe you the assigned study medication. At this time, you are encouraged to discuss your concerns regarding your medical history and any other medications you take with your family doctor.

Q 8: Can I take part in this study if I live outside Ontario?

A: No, unfortunately, this study attempts to look at quitting smoking in Ontario patients only.

Q 9: What are the study treatment groups and medications?

A: The study provides 12 weeks of bupropion or varenicline to help you quit smoking. Once you provide consent and are determined eligible, you will be randomly assigned to either bupropion or varenicline.

Q 10: Am I guaranteed to receive free medication for quitting smoking if I agree to take part in this study? Are there any placebo groups?

A: Once you provide consent and are determined eligible, you will be randomly assigned to either bupropion or varenicline. There are no placebo groups. However, you will have **5 weeks** after enrollment date to take the Standard Script and Letter to Doctor and get the prescription for the assigned medication signed by your doctor and faxed to the study pharmacy. You may not receive the medication if your doctor, based on your medical history or based on his/her discretion, chooses not to prescribe you the study medication.

Q 11: What happens if I do not visit my doctor or if my doctor does not prescribe me the assigned study medication?

A: If you do not visit your doctor to have the Standard Script signed after successful enrollment in the study or if your doctor chooses not to prescribe the assigned study medication, we will still attempt to contact you with the same follow-up questions as other participants. The information we collect from you will be used to compare to the

information we collect from those who have visited a doctor and are prescribed the medication. You are free to use other methods to aid your quit attempt.

Q 12: For how long do I need to take the medication provided?

A: The study provides 12 weeks of bupropion or varenicline to help you quit smoking. The instructions for the assigned medication will be provided to you by your doctor and/or the study pharmacist. This is the standard course of treatment for smoking cessation and you are encouraged to use all of the medication to increase your chances of remaining abstinent.

Q 13: How will I receive my medication? Is the medication provided free of charge?

A: Once your doctor decides it is appropriate for you to take the assigned study medication and the signed prescription's fax is received by the study pharmacy, they will fill the prescription and mail the medication to you.

Q 14: Will a pharmacist be involved in this study and how will I have my questions regarding the study medication answered?

A: Once the study pharmacist receives the signed Prescription and verifies it, he/she will fill the medication and mail it to your mailing address. The pharmacist will call you at the time of dispensing the medication to discuss possible allergies, your current medications and to offer counseling.

Q 15: How long after the doctor faxes the signed prescription to the research pharmacy will the pharmacy call for counseling on my assigned medication? And how many times will the pharmacy call back if I am not able to take the call the first time?

A: The pharmacy will call on the same day the signed prescription is received. If they cannot get a hold of you the first time they call, they will try to contact you a few times by phone and email. The medication will not be mailed out to you unless the phone counseling has been completed.

Q 16: How long does it take for the medication to be processed by the pharmacy, mailed, and received by me?

A: It will take about 3-5 business days from the day the counseling is completed for the medication to be processed, mailed, and received by you. If you have not received your medication within a week of the phone counseling, please contact us by sending an e-mail to match.study@camh.ca.

Q 17: How long does this study run and will I be contacted again after initial enrollment?

A: This study will attempt to follow the participants for just a little over a year after enrollment. You will have **5 weeks** from the enrollment date to visit your family doctor and get the Standard Script signed and faxed by your doctor. Then, the medication will be mailed to you and you will need to take the assigned study medication for 12 weeks. You will be contacted by e-mail approximately **4, 8 and 12 weeks** after starting your medication to fill out the follow-up questionnaire. We will also contact you with similar questions **6 and 12 months** later via e-mail. The follow-up questionnaires are a very important part of your participation in the study as we need to know how the smoking cessation medication that was provided to you affected your smoking behaviour. If you agree, we may contact you in the future to invite you to participate in other studies at the Centre for Addiction and Mental Health. If you would prefer not to be contacted for participation in future research, this will not affect your participation in this study.

Q 18: How many follow-up questionnaires will I need to answer and what will they be about?

A: You will be contacted by email **9, 13 and 17 weeks after enrolling** (this is approximately 4, 8 and 12 weeks after starting treatment, assuming that you have visited a doctor within 5 weeks of enrolling). The purpose of the follow-up questionnaires is to ask you a few questions to see how you are doing with your attempt to quit smoking. We will also contact you with similar questions **6 and 12 months later**. This is an important way of measuring the effectiveness of providing these smoking cessation treatments free of charge.

Q 19: Are there any additional supports provided, other than the study medication?

A: You will receive weekly motivational emails for 12 weeks, starting on the 5th week after you are enrolled and are determined eligible. The e-mails will include tips on several things other than the medications that you can do to help you quit smoking. You are also encouraged to continue seeing your doctor for additional support if needed.

Q 20: Do I need to provide any biological samples?

A: Yes, we will mail you a kit at so you can provide some of your saliva (approximately half a teaspoon) as a sample for biochemical confirmation of current smoking status. You may also be mailed a saliva kit during the study (at about 4 weeks) and again at 6 or 12 months to confirm your smoking status.

Q 21: Am I responsible for the cost of mailing my saliva sample back to study investigators?

A: No, the saliva kits mailed out to you will contain the return envelope, with the return address label, and paid postage stamp. All you need to do is to place your saliva sample in the return envelope and send it by mail.

Q 22: What are the benefits of participating in this study?

A: The benefit of participating in this study is that you will receive the medication free of charge, which may increase your chances of quitting smoking and stopping smoking is the single most beneficial thing that smokers can do to improve their health.

Q 23: Are there any financial benefits to me if I participate in the study?

A: For compensation for your time and effort in sending in your saliva sample, you will be mailed a \$10 gift card once we receive your baseline saliva sample back in mail. You will also receive additional \$25 gift cards for each additional saliva sample we request, once we receive them in mail.

Q 24: Are there any risks in participating in this study?

Using Zyban (bupropion) or Champix (varenicline) for quitting smoking is approved by Health Canada. The risk is that there are some possible side effects of Zyban (bupropion) and Champix (varenicline). The most common side effects of bupropion are dry mouth and insomnia in about 5% of users. The major side effects, which are clinically significant, are seizures (1 in 1000 users), hypertension (in less than 5% of users) and rash (in 1% of users). These conditions are all reversible. The most common side effects of Champix (varenicline) are nausea, abnormal dreams, constipation, flatulence and vomiting in 30, 13, 8, 6 and 5% of users, respectively. They are reversible and usually not severe. As you may have heard in the media that some people who were taking Champix have experienced some psychiatric symptoms. These symptoms have not been proven to be caused by Champix, but Health Canada has endorsed a public announcement about this issue that we ask you to read carefully.

You may find this announcement at:

http://www.pfizer.ca/en/our_products/products/bulletin/152?ProductBulletinID=25

In the event that you suffer an injury as a direct result of participating in this study, normal legal rules on compensation will apply. By signing the consent form you are in no way waiving your legal rights or releasing the investigator from their legal and professional responsibilities.

Q 25: What happens if I have an adverse reaction to the study medication?

A: Using Zyban (bupropion) or Champix (varenicline) when quitting smoking is approved by Health Canada. You are encouraged to discuss your medical history, your current medications and any other concerns with your family doctor when you visit him/her to get the Prescription signed. This is to avoid possible adverse reactions. You

can also share your concerns with the study pharmacist at the time of phone counseling. Additionally, you can contact the study investigators with your concerns in this regard. Moreover, the follow-up questionnaire will collect information about side effects you may have experienced and we will advise you to stop medication if side effects are serious. If the adverse reactions are interfering with your daily activities, you are free to withdraw from study at any point if you wish not to continue with taking the assigned medications.

Q 26: What happens if I stop taking the medication at any point during treatment? Can I be excluded from the study?

A: In case of serious adverse reaction to assigned study medication, you will be asked to stop taking the medication. However, we will continue to ask you with the same follow-up questions as other participants. The information we collect from you would be used to compare to the information we collect from those who have used all 12 weeks of medication.

Q 27: Will personal information about me be kept confidential?

A: Your answers to the questions are confidential to the full extent permitted by law and will be available only to the study investigators. As part of continuing review of the research, your records may be assessed on behalf of the Research Ethics Board at CAMH. A person from the research ethics team may contact you to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain your confidentiality to the extent permitted by law. The information you provide will not be made available to anyone else without a court order or your written permission. Any reports or publications based on this study will not mention your name or identify you in any way. You will be provided with an email address and telephone number to contact us, if you have any questions about the study. You will be informed in a timely matter of any new information or changes to the study that may affect your willingness to participate. Please remember that your participation is voluntary and you may withdraw your consent at any time.

Q 28: Is my participation voluntary? What happens if I no longer wish to take part in the study?

A: Taking part in this study is entirely voluntary. You may decide not to take part or you may decide to take part and then change your mind. Even if you consent to participate, you are free to withdraw from the study at any time and for any reason and without affecting your future medical treatment. If you withdraw from this study, all biological samples will be destroyed. However, we will keep any results and clinical information collected up to that point.