A Pilot Trial Comparing NicoBloc to Nicotine Lozenges: Initial Acceptability and Feasibility Trial

3/27/2019

NTC:300001370

CONSENT FORM

TITLE OF RESEARCH: **A Pilot Trial Comparing NicoBloc to Nicotine Lozenges: Initial Acceptability and Feasibility Trial**

IRB PROTOCOL: **300001370**

INVESTIGATOR: **Karen Cropsey, Psy.D.**

SPONSOR: **Department of Psychiatry and Behavioral Neurobiology**

Supported by: **NicoBloc, plc**

Purpose of the Research

You are invited to participate in a research study conducted by Karen Cropsey, Psy.D. that will compare the effects of two different interventions, nicotine lozenges or NicoBloc, in reduction or cessation of smoking. Richard Shelton, MD, will provide medical supervision. This study is 16 weeks in duration. You are being asked to participate in this study because you are a current smoker. Both of the interventions used are available over-the-counter and without prescription. This study will enroll 50 participants from the Birmingham community.

Explanation of Procedures

This is a study designed to see if counseling plus nicotine lozenges or NicoBloc will be effective in quitting smoking. The counseling is focused around your experience of using these smoking cessation interventions, including how the use of them may help you quit smoking, side effects, and smoking cessation expectancies. If you are eligible to be in the study, you will be randomized (like the flip of a coin) into one of two groups. If you are in the NicoBloc group you will use one drop of NicoBloc (which will block 33% of tar and nicotine) on your conventional cigarette and then will smoke this cigarette during Session 1. If you are in the nicotine lozenge group, you will be given either a 2 or 4mg lozenge to use in session, depending on how soon you smoke upon awakening. You will try the NicoBloc or the nicotine lozenge during your counseling session and talk about it. Things discussed will include your expectations of the method to reduce or stop smoking, how it may help, and side effects. You will be asked to fill out forms about your smoking behavior, demographics, medical information, and a sheet that requires you to provide your contact information as well as two other individuals that we can contact about you. This contact sheet will be updated at every visit. Some of the questionnaires will be repeated at every visit and others will be repeated less frequently. See the chart below for details. **If you are a woman of child bearing potential you will be asked to give a urine sample to test for pregnancy.** At each visit you will have a carbon monoxide (CO) test where you will blow into a machine (like an alcohol breathalyzer), which will tell us how much CO is in your lungs as a result of smoking. We are asking you to attend a baseline visit, four weekly intervention sessions and three follow-up appointments. **You are being asked to go as long as you can without smoking the day of your study sessions.**

At the **baseline visit** (Session 0) you will be asked to complete several commonly used questionnaires. You will have a CO test and a urine drug screen. If you are a woman of child bearing potential you will be asked to give a urine sample to test for pregnancy. **You will be asked to go as long as you can without smoking on the day of your Session 1.** Each session will begin with the completion of several self-report measures and you will have a CO test.

NicoBloc Group

At **Session 1** (Week 1), you will use one drop of NicoBloc (which will block 33% of tar and nicotine) on your conventional cigarette and then will smoke this cigarette in session. Following smoking, you will discuss the effects of the NicoBloc on your withdrawal, cravings, and overall enjoyment of their cigarette. To bolster your NicoBloc experience, you will be provided with NicoBloc to use between sessions to get used to the NicoBloc and to make practice quit attempts.

Sessions 2 and 3 are similar to Session 1 except you will use more NicoBloc product during the session and will be instructed to use the product between sessions. For example, in in session 2, you will use 2 drops on their cigarettes (which blocks about 66% of tar and nicotine) and then smoke. Similarly, in Session 3 you will use 3 drops of NicoBloc which is equivalent to blocking 99% of the tar and nicotine exposure from a cigarette. You will discuss your experiences and expectancies for NicoBloc to help you quit.

At **Session 4** you will discuss your experiences using NicoBloc and will set a quit date prior to your 8 week visit.

You will return at **8 and 12 weeks** at which time the intervention will be complete.

A final one month follow-up at **Week 16** will examine how well you did without the NicoBloc.

Nicotine Lozenge Group

At **Session 1**, participants who receive nicotine lozenge (mini lozenge) will be given either a 2 or 4 mg lozenge to use in session, depending on how soon you smoke after waking. If you smoke within 30 minutes of waking, you will start with the 4 mg lozenge; more than 30 minutes, you will start with the 2 mg lozenge. Similar to NicoBloc, you will use the lozenge in session and will discuss the effects of using the lozenge in session.

Sessions 2 and 3 are similar to Session 1. You will be given lozenges between sessions and will be instructed to use the product between sessions.

At **Session 4**, you will discuss your experiences using the lozenges and will set a quit date prior to your 8 week visit.

All Sessions, after the four week intervention, you will be given an additional 8 weeks of medication (NicoBloc or Lozenge) in four week allotments to use for a sustained quit attempt.

Thus, both groups will receive the medication for 12 weeks total to make a quit attempt. All participants will continue to receive medication and monitoring for side effects, regardless of their medication adherence. Study visits occur at baseline (Week 0), intervention Weeks 1-4,

You will return at **8 and 12 weeks** at which time the intervention will be complete.

A final one month follow-up at **Week 16** will examine how well you did without the nicotine lozenges.

Study Assessment Schedule	**BL**		**Post-Randomization Assessment Schedule**						
Measures or Procedures compensation)	**Day 0 ($10)**	**RANDOMIZATION**	**WK1 S1 ($20)**	**WK2 S2 ($20)**	**WK3 S3 ($20)**	**WK4 S4 ($20)**	**WK8 ($40)**	**WK12 ($40)**	**WK16 1 MO F/U ($40)**
Screening Questionnaire	X								
Demographics	X								
Urine Drug Screen	X								
Urine Pregnancy Test (if female)	X					X	X		
Smoking History	X					X	X	X	X
Treatment Expectancies	X		X	X	X	X	X	X	X
Weekly Smoking Behavior	X		X	X	X	X	X	X	X
Tobacco Use Calendar Weekly	X		X	X	X	X	X	X	X
NRT Lozenge Use Calendar Weekly				X	X	X	X		
NicoBloc Use Calendar Weekly				X	X	X	X		
PSS – 10 Item Questionnaire	X		X	X	X	X	X	X	X
Stanford Expectancies for Treatment Scale	X					X	X	X	X
Belief and Attitudes about Medication Scale	X					X	X	X	X
TAA Questionnaire	X		X	X	X	X	X	X	X
SAQ Questionnaire	X						X	X	X
ARME Questionnaire	X		X	X	X	X	X	X	X
ANL Questionnaire	X		X	X	X	X	X	X	X
ANB Questionnaire	X		X	X	X	X	X	X	X
CFS Questionnaire	X						X	X	X
FTND Questionnaire	X						X	X	X
WISDM Questionnaire	X						X	X	X
QSU Questionnaire	X		X[1]	X[1]	X[1]	X[1]	X[1]	X	X
MNWS Questionnaire	X		X[1]	X[1]	X[1]	X[1]	X[1]	X	X
TSS Questionnaire								X	X
CEQ Questionnaire								X	X
Side Effects				X	X	X	X	X	
***Carbon Monoxide* (CO)**	X		X	X	X	X	X	X	X
Intervention Adherence				X	X	X	X	X	X
Alliance Questionnaire						X			
Alliance Questionnaire Therapist						X			
Adverse Events				X	X	X	X	X	
Serious Adverse Events				X	X	X	X	X	

Note: BL=Baseline Assessment; S=session; WK=week; [1]All participants will complete these surveys twice (at the beginning and end of session) during sessions 1-8.

Risks and Discomforts

You may have some side effects from taking the nicotine lozenge. The side effects occur in about 10% of the population who receive the medications. The side effects are generally mild and well-tolerated. The NRT products that we are using are available over-the-counter without a prescription and have been on the market for years without serious problems.

The most common side effects are dry mouth, agitation, insomnia, headache, nausea, constipation, weight loss, and tremor. Most of these side effects disappear within a couple of weeks of starting the medication. There are no known side effects associated with the use of NicoBloc.

Quitting smoking is also associated with withdrawal symptoms including feeling sad or depressed mood, increased appetite or weight gain, difficulty concentrating, irritability, insomnia, restlessness, anxiety, decreased heart rate, and cravings. Please inform the physician or study staff if you experience any of these side effects. Under rare circumstances, if symptoms are severe, please visit your nearest emergency room or dial 911 and stop taking the lozenges. If this should occur, please contact the study doctor after you have been treated.

As with other interventions with a behavioral/psychological component, some participants may be uncomfortable answering personal questions on questionnaires or talking about personal information during an intervention session.

There is also the risk of loss of confidentiality. Every effort will be made to minimize this risk.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Information for Women of Childbearing Potential and/or Men Capable of Fathering a Child

We do not know if the NRT product will affect mother's milk or an unborn fetus. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study. Women will be screened monthly for pregnancy using a urine pregnancy test. If you become pregnant during the trial you will be taken off the study medication. Results of all pregnancy tests will be provided to you on site immediately.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a method to avoid pregnancy that works well or you must not have sex.

Unless you cannot have children because of surgery or other medical reasons, you must agree to use an effective form of birth control while taking the study drug. Effective birth control includes

birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant.

Benefits

The study interventions may help you to quit smoking. It is unknown if this intervention will help you abstain from smoking in the future. You may not benefit directly from taking part in this study. However, this study may help us better understand how to help people quit smoking in the future.

Alternatives

The alternative is to not participate in the study. If you do not want to be in the study you can get smoking cessation treatment by your primary care doctor who can prescribe medication for you to help you quit. There are also free quit line services to help you quit smoking and we can give you those phone numbers if you are interested.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB), the NIH, the FDA, and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Office for Human Research Protections (OHRP). The results of the research may be published for scientific purposes. However, your identity will not be given out.

Your anonymity will be protected in any research papers and presentations that result from this work.

In certain instances, researchers may disclose voluntarily, without your consent, information that would identify you as a participant in a research project in the following cases: (1) wanting to harm yourself, (2) wanting to harm other people, or (3) reports of child or vulnerable adult abuse.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent for the following reasons:

- The study doctor thinks it is necessary for your health or safety
- You have not followed study instructions
- Administrative reasons require you to stop

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All drugs, exams, and medical care related to this study will be provided to you at no cost during the 16 week study period.

If you require standard medical care, the costs of your standard medical care will be billed to you and/or your insurance company in the usual manner. If you want to keep taking the medication after our study has ended, you will be responsible for the cost of continuing the medication.

Payment for Participation in Research

You will be paid for your participation in this study. Overall, you have the opportunity to receive up to $210. You will receive $10 for your baseline visit and $20 each for sessions 1 through 4. After session 4, you will receive $40 for week 8, 12, and 16. You will be given a Greenphire ClinCard, which is a reloadable gift card. In order to be paid through ClinCard we require that you provide your social security number (SSN). At each visit, your compensation will be loaded onto your card. Please allow up to 2 weeks for processing of compensation.

Payment for Research-Related Injuries

UAB and NIH have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Text Messaging

In the event that we cannot reach you by phone, we use text messages for appointment reminders, if you miss an appointment, and/or if we need to reach you concerning the study. We will not include any of your personal health information in these text messages, and the

messages will state they are from the UAB research study. Please indicate below if you agree to receive text messages regarding the study.

_____ Yes, I agree to receive text messages concerning this study.

_____ No, I do not agree to receive text messages concerning this study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact the principal investigator Karen Cropsey, PsyD. She will be glad to answer any of your questions. Dr. Cropsey's number is 205-975-7809. The study medical doctor, Richard Shelton, MD, may also be reached during office hours at 205-975-9295 or after hours by paging him at 205-934-3411 for any medical questions.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number: 300001370**
Research Protocol: A Pilot Trial Comparing NicoBloc to Nicotine Lozenges: Initial Acceptability and Feasibility Trial **Principal Investigator: Karen Cropsey, Psy. D.**
Sponsor: UAB Department of Psychiatry & Neurobiology

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____
Relationship to the participant: _____