

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Improving Adherence to Web-Based Cessation Programs: A Social Network Approach

PROTOCOL NO.: 1R01CA155489-01A1
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SPONSOR: National Cancer Institute (NCI)

INVESTIGATOR: Amanda L. Graham, PhD
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United States

SITE(S): American Legacy Foundation
Schroeder Institute for Tobacco Research & Policy Studies
1724 Massachusetts Avenue NW
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**STUDY-RELATED
PHONE NUMBER(S):** Amanda L. Graham, Ph.D.
202-709-8587

INFORMED CONSENT

ABOUT THE STUDY

You are invited to participate in a research study. The study is called *Improving Adherence to Web-based Cessation Programs: A Social Network Approach*. The research is sponsored by the National Cancer Institute of the National Institutes of Health (NIH) and is being conducted at the American Legacy Foundation, which is located at 1724 Massachusetts Avenue, NW, Washington, DC, 20036. Dr. Amanda Graham is the Primary Investigator.

WHAT IS INFORMED CONSENT?

The purpose of this consent form is to help you decide if you want to be in the study. Please scroll through and read this entire consent form carefully. To join a research study you must give your informed consent. "Informed consent" includes: (1) reading this consent form and (2) asking questions about anything that is not clear. You should not join this research study until all of your questions are answered.

If you have any questions, please contact the study investigator, Dr. Amanda Graham, at EX_Study@becomeanex.org or 202-709-8587.

Things to know before deciding to take part in a research study:

- Taking part in the study is entirely your choice - if you choose not to join the study, you can continue to use the BecomeAnEx website however you wish;
- Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;
- You may withdraw from the study at any time.

If you decide to take part in this research study, you will be able to print or save a copy of this consent form.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to investigate the effectiveness of a smoking cessation website called BecomeAnEx.org when it is used alone, and when it is used along with social network support and/or nicotine replacement therapy (nicotine patch, gum, or lozenge). The study also hopes to identify ways to improve the effectiveness of the BecomeAnEx.org website in helping smokers to quit smoking.

About 6500 subjects are expected to enroll in this study.

WHAT IS INVOLVED IN THE STUDY?

Joining the Study: If you agree to join the study, you will receive an email with a link to an Internet survey. This baseline survey will take about 12-15 minutes to complete and includes questions about your smoking, your health, and your use of the Internet. The survey will determine whether you meet study requirements. **You must complete the survey within 24 hours of receiving the link to join the study.**

Being in the Study: After you complete the baseline survey, and if you meet study requirements, you will be randomly assigned (like a coin toss) to one of four study conditions:

- use of the BeComeAnEx.org website, plus social network support
- use of the BeComeAnEx.org website, plus nicotine replacement therapy
- use of the BeComeAnEx.org website, plus social network support and nicotine replacement therapy
- use of the BeComeAnEx.org website alone

You will not be able to choose which group you are in. In all the study conditions, you can use the BeComeAnEx website however you wish. Depending on which study condition you are assigned to, you may be sent free nicotine replacement therapy (nicotine patch, gum, or lozenge) and/or you may be contacted by other members of the BeComeAnEx website over the next several weeks and months.

Follow-Up Surveys: You will be contacted by email at two different time points by study staff to complete follow-up Internet surveys. If we are not able to reach you by email to complete the surveys, a research assistant will attempt to reach you to complete them over the phone. These follow-up surveys will occur at 3, and 9 months after you join the study. The surveys will ask about your smoking, your health in general, and your feedback about being in the study. Each follow-up survey will take about 12-15 minutes to complete.

At the beginning of the follow-up surveys, you will be asked to provide the name and contact information of someone whom we could call to confirm your smoking status.

The follow-up surveys are a critical part of the study – we need to hear from everyone, even if you are still smoking and/or have not used the website.

Your participation will last about 9 months, if you complete the study.

RISKS AND DISCOMFORTS

Quitting Smoking: If you decide to quit smoking, you may experience mood changes, anxiety, irritability, decreased concentration, restlessness, increased hunger or trouble sleeping. These symptoms usually last for about 1 to 2 weeks after quitting.

Use of Nicotine Patch: There is risk of heart problems for people who smoke while using the nicotine patch. No one should smoke cigarettes or use any tobacco product while wearing the nicotine patch. You may have some skin problems where you put the patch on your body. You may also have an upset stomach if the dose of the patch is too high, or if you smoke while using the patch. You may also dream more when using the patch. You could have an allergic skin reaction to the patch, but this is not very likely to happen. You will be asked to report any side effects/adverse reactions that you may experience by contacting us at EX_Study@becomeanex.org or 202-709-8587. Any side effects/adverse reactions you report will be reviewed by the study physician. You may be asked to discontinue the patch entirely if you develop severe skin reactions. You will be referred to your physician/health care provider if you experience any side effects/adverse reactions.

Use of Nicotine Gum: Common side effects of nicotine gum include hiccups, heartburn and other stomach problems especially if chewed too quickly or not chewed correctly. Like other gum-based products, chewing nicotine gum can cause dental fillings to loosen and aggravate other mouth, tooth, and jaw problems.

Use of Nicotine Lozenge: Common side effects of nicotine lozenge include warm or tingling sensation in the mouth or sore throat. Less common reactions include heartburn, mouth pains or severe indigestion.

For Women Only: If you become pregnant during study participation, you must stop using the nicotine patch, gum, or lozenge and inform the study investigator or staff. You also should inform your health care provider if you become pregnant while using the nicotine patch, gum, or lozenge.

You should not participate in this study if you are breast feeding.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to read and submit a new online consent form if this occurs.

BENEFITS

By taking part in this study, you may quit smoking or cut down the number of cigarettes that you smoke which will improve your health, but this cannot be guaranteed.

COSTS

There is no cost to you to join the study or to participate in the study.

PAYMENT FOR PARTICIPATION

You will not be paid for completing the baseline survey. You will be paid \$50 for completing each of the two follow-up surveys. If you do not complete both follow-up surveys, you will be paid for the surveys you complete.

After you complete your 9-month follow-up survey, you will also be eligible to receive a free supply of nicotine replacement therapy, regardless of which treatment group you were assigned to at the beginning of the study.

**** IMPORTANT INFORMATION ABOUT PAYMENT METHOD**

Payment for completing follow-up surveys will be delivered via PayPal, a secure and fast method for online money transfer, or via an Amazon gift code emailed to you. If you select PayPal, your personal financial information is stored securely with PayPal and is never available to study staff. Payment will be delivered from the study to your PayPal account within 48 hours of completing a follow-up survey. The money will then be available for you to move from PayPal to your bank account within 5-7 days.

- If you already have a PayPal account, you will simply need to provide the email address linked to this account.
- If you do not have a PayPal account, you will need to create one at some point before the 3 month follow-up survey. It is free and easy to set up a PayPal account.

To learn more about PayPal, please visit www.PayPal.com. If you are not willing to receive payment via PayPal, you should not join the study.

If you choose to receive an Amazon gift code, you will receive the code at the email address you provide at the end of each survey.

ALTERNATIVE TREATMENTS

You do not have to participate in this study. You can continue to use BecomeAnEx.org however you wish. There are also other quit smoking programs available, such as telephone support available at 1-800-QUIT-NOW and community agencies such as the American Lung Association.

CONFIDENTIALITY

All information collected from you for the study will be kept confidential to the extent of the law. Confidentiality will be protected at all times and several steps will be taken to reduce any risks to confidentiality. Complete confidentiality cannot be guaranteed. All information collected via the Internet will be kept secure using the Secure Socket Layer (SSL) Protocol, the same technology used to encrypt credit card numbers during transmission over the Internet. You will be asked to designate a username and password to access the website. All data will be stored in a database subject to both physical and electronic protection. All participants will be assigned an identification number that will be used to link responses, but no identifying information will be kept with those responses.

Please note that study staff involved in processing your payment for participation will be aware of your identity.

The results of the research study will be shared with other people and will be published in scientific reports; however, your name and the fact that you were in the study will be kept confidential.

The funding agency, the National Cancer Institute, may see your information if it is audited. The federal auditors can use this audit information only for audit or evaluation of the program.

COMPENSATION FOR INJURY

We do not expect any injuries to result from this research study. If an unexpected injury occurs as a result of your participation in this study, you will receive treatment that the American Legacy Foundation considers to be fair and appropriate for that injury, without charge to you. The American Legacy Foundation does not intend to provide you with any other money or payment if this happens. Agreeing to participate in this study does not change any of your legal rights. For more information regarding this provision, please contact Ryan Desrosiers in the Office of Grants Management at the American Legacy Foundation at 202-454-5555.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

The decision whether to be in this study is entirely up to you. Participation is voluntary. Also, if you decide now to participate, you can to change your mind later and withdraw from the study.

There will be no penalty if you decide not to participate, or if you withdraw from the study. The research team may choose to end your participation in this study at any time prior to the completion of the study for any reason.

The researcher will provide you with additional information as it becomes available that may affect your decision to continue in the research study.

SOURCE OF FUNDING FOR THE STUDY

This study is funded by the National Cancer Institute of the National Institutes of Health (NIH).

QUESTIONS

Please contact the study investigator, Dr. Amanda Graham, for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the nicotine patch, gum, or lozenge provided by the study, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not agree to participate in this study unless you have had a chance to ask questions and have gotten satisfactory answers. If you agree to be in this study, you will be sent an email confirmation that includes this consent form with the date and time you entered your information, for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. By entering my initials in the box below, I freely consent to be in this research study.

By agreeing to participate in this study, I have not given up any of my legal rights.