Princess Margaret Hospital
University Health Network

Patient Information and (Pharmacotherapy)Consent Form

A Web-based Smoking Intervention for Cancer Survivors (Partnership for Health)

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Sponsor: National Cancer Institute, USA

Introduction

You are currently part of the "Partnership for Health" research study. This study is being conducted by the Dana-Farber Cancer Institute (DFCI). Other hospitals participating in the study are Memorial Sloan Kettering, St. Jude Children's Research Hospital, The Hospital for Sick Children and Princess Margaret Hospital. This study is funded by the National Cancer Institute. About 750 people will be in this study. We plan to enroll 70 people at Princess Margaret Hospital.

Study subjects who are interested in quitting smoking can receive nicotine replacement therapy (NRT), an over-the-counter smoking cessation drug, or Zyban, a prescription smoking cessation drug, through the study. The NRT will be in the form of the patch.

You are receiving this consent form because you have requested free NRT or Zyban as part of your participation in Partnership for Health. This consent form will give you the information you will need to understand why this study is being done and why you are being offered free smoking cessation drugs. It will also describe what you need to do to receive the smoking cessation aides and any possible risks, inconveniences or discomforts that you may have while participating. We also encourage you to ask questions now and at any time. If you decide to receive NRT or Zyban, you will be asked to sign this form and it will be a record of your agreement.

It is up to you to decide if you want to try to stop smoking with the assistance of either NRT or Zyban. You have the right to say no. Your decision will not affect your relationship with the Dana-Farber Cancer Institute or Princess Margaret Hospital.

Why Is This Study Being Done?

This study is being done to learn about the best ways to bring health information to people who have had childhood cancer, leukemia, tumours or similar illnesses. Some study subjects will receive current informational materials in the mail about health, survivorship and smoking. Other subjects will be invited to use a website. The goal of the study is to see which of these methods is a better way to get information about smoking, health issues, and survivorship.

Study subjects will be invited to try to quit smoking, but they are not required to try to quit. To help them quit, we are offering free NRT and Zyban as these drugs may make quitting easier for them. NRT is available at most pharmacies without a prescription. Zyban requires a prescription.

Anyone who uses NRT or Zyban must get clearance from his or her regular doctor. The doctor will sign a form saying that it is medically okay for you to use these drugs. The drugs will be mailed directly to your doctor's office. You will then have to go to your doctor's office to pick up the drugs. If you have any side effect from the drugs, you should go to your regular doctor for care. The form that your doctor signs will also confirm his/her willingness to monitor the side effects of these drugs.

What Other Options Are There?

You may choose not to receive the dose-appropriate supply of NRT or Zyban.

What Is Involved in the Study?

If you choose to receive NRT or Zyban, you will need to give us the contact information for your regular doctor. We will send or FAX a form to your doctor asking him/her to determine whether you can use either of these drugs. The form reminds the doctor of the risks and side effects of these drugs. It also tells your regular doctor that he or she will be responsible for monitoring your care while you are on the drugs

These drugs may or may not help you to quit smoking or to stay quit. When you take your 12-month follow-up survey for the Partnership for Health study, you will be asked if you used the drugs and if they were successful.

How Long Will I Be in the Study?

You will be in the study for about 12 months. If you choose to receive NRT or Zyban, you will be given a dose-appropriate amount of the smoking cessation drug.

What Are the Risks or Discomforts of the Study?

It is up to you if you want to try to quit smoking. If you decide to try and quit, you may experience side effects from quitting. These may include withdrawal symptoms such as mood changes, anxiety, irritability, decreased concentration, restlessness, unusual hunger, trouble sleeping, and constipation.

If you decide to use NRT or Zyban, side effects could include headaches, dizziness, upset stomach, weakness, blurred vision, vivid dreams, mild itching and burning on the skin, diarrhea, insomnia, dry mouth, nausea, and sweating. These side effects are usually temporary. More serious side effects have been noted with Zyban. **Individuals with a history of a seizure disorder, or with medical issues that make them more likely to have seizures, should not use Zyban.**

What Are The Benefits of the Study?

Using the drugs may increase your motivation to quit smoking, may make it easier for you to try to quit, and may make it easier for you to stay quit. Quitting smoking can benefit you in many ways including improved health status and decreased risk for disease. There are also financial benefits to quitting smoking, since the cost of cigarettes is considerable for some people.

What Are the Costs?

There is no cost to you for the dose-appropriate supply of the drugs. The drugs will be sent directly to your regular doctor's office at no cost to you, where you can pick them up. If you and your doctor decide that you should continue on NRT or Zyban after the dose-appropriate supply is gone, you will pay any pharmacy dispensing fees yourself.

How will Confidentiality and privacy be protected?

1. What information will be collected, used, and shared as part of this study?

In order for you to receive the drugs, we will need to collect information including your name and the name of your regular doctor. However, your name will not be present on the records that indicate your choice to receive these drugs. Study staff will take several steps to protect your privacy. You will be given a code that will be used instead of your name or other identifying information on all of your study materials. The cross-list matching names and codes

will be kept in a password-protected computer file at DFCI. All data will be kept in a locked file drawer. All project file cabinets and computer databases are secured within offices that are locked when not in use. Only study staff will be able to see your information. We will keep this code in order to maintain a link between you and the information about you collected during this study. The coded information, without your name attached, may be shared with others outside the research.

2. Why will my information be used and shared?

The main reasons we will use and share your information are:

- to conduct and oversee the research study
- to make sure that this study meets legal, institutional, and accreditation requirements

3. Who will use or share the information about me that is collected by the research team?

We will share your information (without personal identifiers such as your name) with people at the Dana-Farber Cancer Institute, Memorial Sloan Kettering, St. Jude Children's Research Hospital, and Princess Margaret Hospital. We may share your information with other researchers outside of these institutions. We may also share your information (without identifiers) with people outside of these institutions who are in charge of the research, pay for or work with us on the research study.

Your information may also be shared with members of the Institutional Review Board/Research Ethics Board (IRB/REB). These are the people who review and oversee research studies and study data to assure that the studies are safe and being well managed.

4. With whom may my information be shared?

We will protect the information about you that we have access to, and will take care to maintain your privacy as much as possible. We may, however, need to share this information with the following people or groups so that they can carry out their duties related to this study:

- Federal Agencies, such as the Department of Health and Human Services (the DHHS), the National Cancer Institute/National Institutes of Health (the NCI/NIH) and the Office for Human Research Protections (the OHRP)
- Individuals outside the hospital that provide services, for example, a transcriptionist.

Those who receive your information may share it if they are required to do so by US or Canadian law. These other groups may not be required to obey the federal privacy rules that the hospital and researchers must follow. The results of this study may be published in a medical book or journal or used for teaching purposes. However, neither your name nor other identifiers will be used in any publication or teaching material without your specific permission.

5. How long will my information be used or shared?
Your information will be kept for at least seven years after the study has ended. It will be destroyed by shredding the paper copies and deleting the computer files. We will destroy identifying information once this study is complete.

6. Your Signature
You have the right not to sign this form. If you do not sign the form, you cannot receive the free drugs to help you quit smoking. You may, however, continue using the Partnership for Health materials you have already received.

WHAT ARE MY RIGHTS:

- You have the right to not participate in this study.
- If you change your mind about participating, please contact us about your decision. We may still need to use the information we have already collected. Once you tell us that you do not want to participate, we will not ask you for any other information.
- Receiving NRT or Zyban through this study is your choice. You can choose not to get them or not to use them. You may also stop using them at any time

Whom do I contact if I have questions about the study?

We encourage you to ask questions about the study or your role as a participant at any time. If you have questions about the study, please call Dr. David Hodgson, the Principle Investigator at (416) 946-2126.

If you suffer a research-related injury or would like advice regarding your rights as a research participant, please call Dr. Ronald Heslegrave, Chair of the University Health Network Research Ethics Board at (416) 340-4557.

This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under any pressure to enroll in this study or to continue to participate in this study.

This person is not involved with the research project in any way and calling him will not affect your participation in the study.

Documentation of Consent

My signature below indicates my willingness to receive smoking cessation drugs through this study and my understanding that I can refuse them or stop using them at any time. It also indicates my understanding that it is my responsibility to work with my regular doctor related to side effects or other problems I encounter with the drugs.

_____ _____

Patient signature Date

I, _____,

(print your name)

have read and agree to all of the above information. I give the Dana-Farber Cancer Institute permission to send an appropriate supply of the **patch** or **Zyban** (please cicle one) to my regular doctor, listed below.

I currently smoke _____ (how many) cigarettes a day.

Date of Birth: _____

Name of Family Doctor: _____

Family Doctor's Address: _____

_____

_____

Family Doctor's Phone: _____

Certification from person obtaining consent:

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered any questions regarding the study to the best of my ability.

1. _____ I do not have a financial conflict of interest with this proposal.
2. _____ I do have a financial conflict of interest with this proposal but it is within the de minimus as defined by the PHS guidelines (less than $10,000).

Signature of Person Obtaining Consent: _____
Printed Name of above: _____
Date: