

COMPUTER PROGRAM FOR TEEN ALCOHOL AND DRUG USE

1. *WHY IS THIS STUDY BEING DONE?*

You are being asked to be part of a research study. This study will look at whether a new computer program can help teens (ages 12-18 years) stop using alcohol and drugs. This study may also help us to build a better computer program for teens in treatment for alcohol or drug use. You are being asked to be part of this study because you are in treatment for alcohol or drug use. This study is being run by the XXXX. This study is paid for by the XXXX.

This study will take place at XXXX. We plan to have XX teens take part in the study.

2. *WHAT WILL YOU BE ASKED TO DO IN THIS STUDY?*

If you take part in this study, you will be randomly placed (like by the flip of a coin) into one of two groups: (1) Regular Treatment or (2) Treatment That Includes a New Computer Program.

(1) Regular Treatment. If you are in the regular treatment group, you will get the regular treatment at the XXXX. This is the treatment you would normally get if you were not a part of the research study.

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(2) Treatment That Includes a New Computer Program. If you are in the treatment that includes a new computer program group, you will be able to use a new computer program once a week for 12 weeks. Each computer session should last about an hour. You also will get the regular treatment at the XXXX. However, you will be asked to replace one session of regular care (like a one-on-one or group session with the counselor) with the computer session each week.

During the computer sessions, you should learn about things like: getting along with others, solving problems, finding a job, alcohol or drug use, how to set goals, fun things to do without alcohol or drugs, and dealing with anger. You do not need to know how to use a computer to use the new computer program.

You can do the computer sessions on a computer at the XXXX or at home. You will get a username and password to use the program. You will be reminded by email and/or phone to complete one session each week for the 12 weeks of this study.

Your XXXX counselor will be able to see if you are completing computer sessions.

If your parent or caregiver agrees to be in this study AND if you are in the computer program group, your parent/caregiver can do 4 sessions on the computer program. If this is the case, your parent/caregiver will be asked to sign a separate consent form to participate. Your parent/caregiver will do these sessions separately from the sessions you do on the computer.

Questions: No matter what group you are in, you will be asked to answer some questions before starting the study, and then 4 weeks, 8 weeks, and 12 weeks after joining the study. You also will be asked to answer these questions 1 month after finishing the study.

The questions will ask about: alcohol and drug use, crime, mood, health, school, and work. You also will be asked about how ready you are for treatment and how happy you are with treatment. These questions should take about 1½ - 2 hours each month.

Urine Tests: No matter what group you are in, you will be asked to give some urine before starting the study and twice per week during the 12 weeks of the study. You also will be asked to give some urine 1 month after finishing the study.

The urine you give us will be tested for drugs (including opioids, cocaine, benzodiazepines, propoxyphene, amphetamines and marijuana). A research staff person who is the same sex as you may watch you give the urine.

Breath Tests: No matter what group you are in, you will be asked to give a breath sample (by breathing into a breathalyzer) before starting the study and twice per week during the 12 weeks of the study. You also will be asked to give a breath sample 1 month after finishing the study. Your breath will be tested for alcohol.

3. HOW LONG WILL YOU BE IN THIS STUDY?

You will be in this study for 12 weeks. About 1 month after you finish the 12 week study, we will ask you to come back for a visit. The total time you will be asked to be in the study is about 4 months.

4. WHAT ARE THE RISKS TO BEING IN THE STUDY?

One risk of being in this study is that you may get bored in the study. Also, you may feel uncomfortable answering questions about things like alcohol and drug use.

Another risk of being in the study is that, even though we will try very hard to keep your information private, someone may see you being in this study or learn that you are in this study.

Another risk is that you may have wanted to be in a different study group or think that a different study group might have helped more as part of treatment.

Another risk of participating in this study is that you may feel uncomfortable being watched while giving urine samples. You might feel frustrated if your parent/caregiver chooses to or not to take part in some study sessions.

5. WHAT ARE THE GOOD THINGS ABOUT BEING IN THE STUDY?

One good thing about being in this study is that you could learn new ways to stop using alcohol or drugs. Also, you may learn how alcohol or drugs can change your life. You also can help us see whether a computer program can help teens stop using alcohol or drugs.

6. HOW WILL YOU KEEP MY CHILD'S INFORMATION PRIVATE?

If you agree to be in this study, your personal information will be kept private and will not be given out without your written permission, except as stated here or unless the law requires it.

Your name will not be in any publication.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to give information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from giving out information about your involvement in this research if you want to. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from voluntarily disclosing information that would identify you as a participant in the research project, but it would only be released according to both the strict confidentiality procedures of XXXX and the rules of ethical research practice under the following circumstances:

- If you tell the researcher that you are planning to harm yourself or someone else, we would have to tell the staff at XXXX or the appropriate agencies without your permission. Also, if you tell us that someone is hurting you, we may have to tell the authorities without your permission.
- If you tell the researcher something that could help with your treatment at XXXX, we will ask for your permission to share this information with the staff at XXXX.

7. HOW MUCH WILL YOU GET PAID IN THIS STUDY?

If you agree to be in the study, you will get \$XX in gift cards for answering questions before joining the study. You also will get \$XX in gift cards for answering questions 4 weeks, 8 weeks, and 12 weeks after starting the study. You also will get \$XX in gift cards for answering questions 1 month after finishing the study. You will get the gift cards immediately after answering the questions at each appointment. You could get a total of \$XX in gift cards for answering questions in this study.

You will get \$XX in gift cards for each urine and breath sample that you give immediately after providing the samples. This is on top of the gift cards for completing questions. If you give urine and breath samples before joining the study, twice per week for the 12 weeks of the study and 1 month after finishing the study, you could get \$XX in gift cards.

If you answers questions at all scheduled appointments and give all of the requested urine and breath samples in this study, you can get a total of \$XX in gift cards.

You can get the same amount of gift cards whether you are in the regular treatment group or in the treatment that includes a new computer program group.

8. WILL BEING IN THIS STUDY COST ANYTHING?

There is no cost to you for being in this study. Your insurance company or any third party payer will be responsible for any treatment or other services received at this clinic that is not part of the research study.

9. ANY QUESTIONS?

The researcher has answered to the best of his or her ability all the questions you have now and will answer any questions you have in the future. If you have any questions later about the study, please contact the Principal Investigator for this project, XXXX, at (XXX) XXX-XXXX. If you want to talk to anyone about this research study because you think you have not been treated fairly, or think you have been hurt by joining the study, or you have any other questions about the study, you can call the Principal Investigator, XXXX, at (XXX) XXX-XXXX or XXXX at (XXX) XXX-XXXX. You also can call **XXXX of XXXX at (XXX) XXX-XXXX**. Either the researcher or XXXX or IRB office will answer your questions and/or help you to find medical care for an injury you feel you have suffered. The XXXX and the XXXX, and the Federal Government do not have any program to provide compensation to you if you experience injury or other bad effects which are not the fault of the investigators.

10. BEING IN THE STUDY IS VOLUNTARY

Being in this study is voluntary. You may choose not to be in the study and you may still continue to receive the same treatment from XXXX. Choosing to be in the study or not will not affect your care at XXXX in any way.

Also, you can choose to withdraw from the study at any time before completing it. You may withdraw from the research study at any time by telling a research staff that you do not want to be in the study anymore. Your choice to leave the study early will not impact your treatment at XXXX in any way.

Informed Consent Signature Form – Participant Aged 18

IF I SIGN THIS FORM, WHAT DOES IT MEAN?

This is a consent form. If you sign this form, it means that you have read and understood this form. It also means that all of your questions have been answered.

You understand the following:

- You will either get regular treatment at XXXX or treatment at XXXX that includes a new computer program.
- You will be asked to answer questions and give samples of urine and breath.
- You will be in this study for 12 weeks, and then come in one time about 1 month after finishing the study.
- You can get up to \$XX in gift cards for being in the study.
- You will be given a copy of this form to keep.
- You know that you do not have to be in this study.
- If you agree to be in the study, you can change your mind and stop at any time.
- You know that being in this study has nothing to do with the care you get at the XXXX. You will be treated the same whether or not you agree to be in the study.
- Your name will not be used on any questionnaires or other data: only a code number will be used.
- All of your information will be kept in locked files that only research staff can get to.
- We have a Certificate of Confidentiality to help protect your privacy.

Participant Signature

Date

Interviewer Signature

Date