

Technology-Based Prevention for Adolescents in Primary Care

NCT03489434

Informed Consent/Assent

September 16, 2021

Georgia State University
Assent Form for Minors

Title: Technology-Based Prevention for Adolescents in Primary Care

Principal Investigator: Amanda K. Gilmore, PhD

Sponsor: National Institute on Drug Abuse

Subject's Age: _____ years

Subject's Name: _____

Information About This Study:

Why are you being asked to be in this study? You are 14 to 18 years old and recently attended a doctor's visit.

Why is this study taking place? We are trying to learn if an online program for teens is helpful.

What will happen if you take part in this study? You will be asked to answer some questions. Then we will either give you the teen program or not. It will be random what you get, like a flip of a coin. Then we will ask you to answer surveys afterwards.

Will any part of this study make me feel uncomfortable? There are no common risks and discomforts expected in this study, but it might make you feel uncomfortable. If we find out that you are being hurt or might hurt yourself, we have to tell the authorities and your parents in order to keep you safe.

Will I be compensated for my time and effort? You will receive a \$5 gift card for doing the screening survey even if you are not eligible or do not finish the study. You will receive a \$30 gift card for completing the baseline survey. Then you will receive \$40 for completing a follow-up survey in 1 month, a \$45 gift card for doing the survey in 3 months, and a \$50 gift card for doing the survey in 6 months. You will also receive an extra \$5 for each survey if you complete it in a week, and an extra \$10 if you complete all the surveys. If you get the online program, you will receive an extra \$10.

Can I change my mind about being in the study at any time? Yes.

For subjects 11 to 17 years old: if you agree to be in this study, please sign your name below.

Signature of 11 to 17-year-old Subject

Date

Signature of Researcher soliciting assent

Date

Georgia State University
Guardian Informed Consent

Title: Technology-Based Prevention for Adolescents in Primary Care

Principal Investigator: Amanda K. Gilmore, PhD

Sponsor: National Institute on Drug Abuse

Introduction and Key Information

- We are asking your teen to be in a research study. It is up to you and them to choose if they want to join the study because they are under 18. You both must agree.
- The reason for this study is to learn if a program to prevent teen substance use and sex is helpful.
- Your teen will be asked to answer some questions to see if they can be in the study. If they can, we will ask them more questions. All questions will need to be answered alone, without you being able to see their answers. Then we will either give them the online teen program or not. It will be random what they get, like a flip of a coin. Then we will ask them to answer surveys afterwards.
- Their role in the study will last about 30 minutes for a survey and 10-15 minutes for the program (if they get it) today. Later, it will last 30 minutes for a survey online in 1 month, 30 minutes for a survey online in 3 months, and 30 minutes for a survey online in 6 months.
- The risks of being in this study include:
 - If we find out your teen has been sexually assaulted, that they have sexually assaulted someone, or if they might hurt themselves or others, then we might have to tell you, their doctor, and the police or the Department of Social Services in order to keep them and others safe.
 - It is possible that we could lose or someone could steal your teen's information. But we are doing everything we can to make sure that is unlikely.
- This study may not help your teen personally. Overall, we hope to gain information from the study to help make programs better for teens like them. The program might help their health, though.
- If you or your teen do not wish to take part in this study, they can choose to not join the study.

Purpose

The reason for this study is to learn if a program for teens is helpful. Your teen is being asked to be in this study because they are aged 14 to 18 and saw their doctor recently. We will ask 120 teens to be in this study.

Procedures

If you and your teen decide they join the study, they will:

1. ...be asked some questions about their substance use to see if they can join the study. We will keep this information private.
2. If they are eligible and want to join the study, they will be asked some questions about their substance use and sexual experiences in an online survey.

3. After answering questions, we will either give your teen the online teen program or not. It is an online program that takes about 10-15 minutes. They will read information, watch videos, and answer interactive questions.
4. Then we will ask them to answer surveys 1 month, 3 months, and 6 months afterwards—again, in private, without anyone seeing their answers.
5. Today's activities might take up to an hour if they are eligible for the study (but only 15 minutes if they are not eligible), then each later survey will take about 30 minutes each.

Future Research

Researchers will remove information that may identify your teen and may use their data for future research. If we do this, we will not ask for any additional consent from you or your adolescent.

Risks

It is possible that this study may make your teen feel upset. We have made the teen program with input from other teens and doctors, so we do not think it will upset them. No injury is expected from this study, but if you believe your adolescent has been harmed, contact the research team as soon as possible (call Dr. Gilmore at 404-413-1416). If we find out your teen has been sexually assaulted, that they have sexually assaulted someone, or if they might hurt themselves or others, then we might have to tell you, their doctor, and the police or the Department of Social Services in order to keep them and others safe. Georgia State University and the research team have not set aside funds to compensate for any injury.

Benefits

This study is not made to benefit your teen, but if they get the teen program it might help their health. It might also give them more information about substance use prevention and healthy relationships. Overall, we hope to learn how to make programs better for teens like yours.

Alternatives

The alternative to taking part in this study is to not take part in the study.

Compensation

Your teen will get a \$5 gift card for doing a survey to see if they can join the study. They will get a \$30 gift card for doing a survey today. They will get a \$40 gift card for doing a survey in 1 month. They will get a \$45 gift card for doing a survey in 3 months. They will get a \$50 gift card for doing a survey in 6 months. They will also get a \$5 bonus for each survey if they complete it within a week, and a \$10 bonus if they get the teen program. They will also get an extra \$10 for completing all the follow-up surveys.

Voluntary Participation and Withdrawal

Your teen does not have to be in this study. If you or they decide to be in the study and change your minds, you all have the right to drop out at any time. Your teen may skip questions or stop participating at any time. This will not cause them to lose any benefits to which they are otherwise entitled.

Confidentiality

We will keep your adolescent's records private to the extent allowed by law. We expect your adolescent to complete the study procedures in privacy (without oversight from you, their guardian). The following people and entities will have access to the information your adolescent provides:

- Amanda Gilmore
- Research assistants on the team who are trained in research confidentiality including Dr. Elizabeth Mosley
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)
- National Institute on Drug Abuse

We will use a participant ID number rather than your adolescent's name on study records. The information they provide will be stored on secure computers and in locked cabinets.

- The key linking your teen's participant ID to their name will be destroyed at the end of the project once all data have been de-identified.
- Surveys are being collected over the internet. Data sent over the Internet may not be secure, so we will work to protect your teen's data through encryption. We will not be collecting IP addresses from where they take the surveys.
- The health information your teen gives us will be used in this research study. We will remove all information that can identify them. If you and your adolescent decide you want to be in this study, it means that you agree to let us use and share their personal health information for the reasons we have listed in this consent form.
- While we are doing this research, the research team may use only the personal health information that your adolescent has given us (for example, name, date of birth, and contact information such as telephone number, email address, and social media accounts).
- Your teen's personal health information may be shared by the people or places we have listed, but it will be shared in a way that does not fall under the protection of federal regulations that apply to the privacy of health information. This research may be published and shown to other researchers, but we will take steps to make sure that your teen cannot be identified.
- If you sign this consent form you are letting us use your teen's personal health information until the end of the study. You and they can say that you or they do not want us to use their personal health information after we have collected it. If you or they decide you don't want us to use the information anymore you must write a letter to Dr. Gilmore asking us not to use the information. If you don't want us to use the information anymore, we will stop using it, but any information that we have already used in the study will not be removed.
- You will not be able to look at or get a copy of your adolescent's health information that they gave us while we are doing the research.

If your teen tells us they have been sexually assaulted and it has not been reported to the appropriate location (Department of Social Services or Law Enforcement depending on the perpetrator), then a

research staff supervised by a mental health professional will meet with them (virtually or in-person) to report the assault and to provide any needed referrals for treatment. We will also tell their doctor.

When we present or publish the results of this study, we will not use your teen's name or other information that may identify them. 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.

Contact Information

Call or email Dr. Amanda K. Gilmore at 404-413-1416 or at agilmore12@gsu.edu, or Dr. Elizabeth Mosley at 470-219-8153 or emosley@gsu.edu.

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you think you have been harmed by the study

The IRB at Georgia State University reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, concerns, problems, information, input, or questions about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

Consent

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Parent/Guardian/Caregiver

Date

Principal Investigator or Researcher Obtaining Consent

Date

Georgia State University
Informed Consent

Title: Technology-Based Prevention for Adolescents in Primary Care

Principal Investigator: Amanda K. Gilmore, PhD

Sponsor: National Institute on Drug Abuse

Introduction and Key Information

- You are invited to take part in a research study. It is up to you to decide if you would like to take part in the study.
- The purpose of this study is to learn if a program for teens is helpful. The program is about teen alcohol and drug use, sexual assault, and sexual risk.
- You will be asked to do the following: You will be asked to answer some questions. Then we will either give you the online teen program or not. It will be random what you get, like a flip of a coin. Then we will ask you to answer surveys afterwards.
- Your role in the study will last about 30 minutes for a baseline survey, 10-15 minutes for the program (if you get it), 30 minutes for a survey online in 1 month, 30 minutes for a survey online in 3 months, and 30 minutes for a survey online in 6 months.
- The risks of being in this study include:
 - If we find out you are being hurt or if you might hurt yourself, we have to tell the authorities/police to keep you safe.
 - It is possible that we could lose or someone could steal your information. But we are doing everything we can to make sure that is unlikely.
- This study is not necessarily designed to benefit you personally. Overall, we hope to gain information from the study to help make programs better for teens like you. The program might help your health, though.
- If you do not wish to take part in this study, the alternative is to not consent and not participate in the study.

Purpose

The reason for this study is to learn if a program for teens is helpful. You are being asked to be in this study because you aged 14 to 18 and you recently went to a visit with your doctor. 120 teens will be asked to be in this study.

Procedures

If you decide to take part, you will:

1. ...be asked some questions about your drug and alcohol use on an online survey. We will keep this information private.
2. ...be asked some questions about your sexual experiences on an online survey. We will keep this information private unless you tell us that you were sexually assaulted or that you sexually assaulted a child.
3. The following procedures are experimental: After answering questions, we will either give you the online teen program or not.

4. We will ask you to answer questions online at the beginning of the study, in one month after you do the program, three months after, and six months after using an online survey.

Future Research

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

Risks

There is the possibility that participation in this study may make you feel upset. We have designed the teen program with input from other teens, so we do not think it will upset you. No injury is expected from this study, but if you believe you have been harmed, contact the research team as soon as possible (call Dr. Gilmore at 404-413-1416). If we find out you are being hurt or if you might hurt yourself, we have to tell the authorities/police to keep you safe. Georgia State University and the research team have not set aside funds to compensate for any injury.

Benefits

This study is not designed to benefit you personally, but if you get the teen program it might help your health and give you more information about substance use prevention and healthy relationships. Overall, we hope to gain information from the study to help make programs better for teens like you.

Alternatives

The alternative to taking part in this study is to not take part in the study.

Compensation

You will receive a \$5 gift card for screening for this study even if you are not eligible or do not finish.

You will receive a \$30 gift card for completing the baseline survey for this study.

You will get a \$40 gift card for doing a survey in 1 month.

You will get a \$45 gift card for doing a survey in 3 months.

You will get a \$50 gift card for doing a study in 6 months.

You will also receive a \$5 bonus for each survey if you complete it in a week, and a \$10 bonus if you get the teen program. You will also receive an extra \$10 for completing all the follow-up surveys.

Voluntary Participation and Withdrawal

You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop participating at any time. This will not cause you to lose any benefits to which you are otherwise entitled.

Confidentiality

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Amanda Gilmore

- Research assistants on the team who are trained in research confidentiality including Dr. Elizabeth Mosley
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)
- National Institute on Drug Abuse

We will use a participant ID number rather than your name on study records. The information you provide will be stored on secure computers and in locked cabinets.

- The key linking your participant ID to your name will be destroyed at the end of the project once all data have been de-identified.
- Note that surveys are being collected over the internet. You should be aware that data sent over the Internet may not be secure, so we will work to protect your data through encryption. We will not be collecting IP addresses from where you take the surveys.
- The health information you give us will be used in this research study. We will remove all information that can identify you. If you decide you want to be in this study it means that you agree to let us use and share your personal health information for the reasons we have listed in this consent form.
- While we are doing this research, the research team may use only the personal health information that you have given us (for example, your name, date of birth, and contact information).
- Your personal health information may be shared by the people or places we have listed, but it will be shared in a way that does not fall under the protection of federal regulations that apply to the privacy of health information. This research may be published and shown to other researchers, but we will take steps to make sure that you cannot be identified.
- If you sign this consent form you are letting us use your personal health information until the end of the study. You have the right to say that you do not want us to use your personal health information after we have collected it. If you decide you don't want us to use your information anymore you must write a letter to Dr. Gilmore asking us not to use your information. If you don't want us to use your information anymore, we will stop using it, but any information that we have already used in the study will not be removed.
- You may not be able to look at or get a copy of your health information that you gave us while we are doing the research; however you will be able to look at or get a copy at the end of the study.

When we present or publish the results of this study, we will not use your name or other information that may identify you. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contact Information

Contact Dr. Amanda K. Gilmore at 404-413-1416 or at agilmore12@gsu.edu, or Dr. Elizabeth Mosley at 470-219-8153 or emosley@gsu.edu.

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you think you have been harmed by the study

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Consent

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant (if 18 years)

Date

Signature of Parent/Guardian/Caregiver (if under 18 years)

Principal Investigator or Researcher Obtaining Consent

Date