COVER PAGE

Title of the study: Social Influence Strategies during a Web-based Smoking Prevention Intervention for Adolescents: NIDA R00 Protocol

NCT number: NCT02703597

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

RESEARCH PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE:

Social Influence Strategies during a Web-based Smoking Prevention Intervention for Adolescents: NIDA R00 Protocol

PERSON(S) CONDUCTING THE RESEARCH:

PARENTAL PERMISSION

Please read this document carefully before you decide to give permission for your child to participate in this research study. **Your child's participation is voluntary, and they can decline to participate, or withdraw at any time, with no consequences**.

Purpose of the research study:

We are doing this study to find ways to improve the health of Florida adolescents. We are asking children who are 11- to 18-years-old (also called an adolescent) and visiting one of the participating after-school programs to participate in this study.

In particular, we would like to learn how adolescents react to an interactive health website and health related group activities so we can design more effective health programs.

The research study is not school and will not affect grades or teacher interaction.

Your child will not miss any activities from the regular school day.

If your child is pregnant, they will not be eligible to participate in this study.

Location of research during COVID-19:

Due to COVID-19, the research team will work with the site staff to ensure that COVID guidelines are enforced when conducting research when at the site.

If the after-school program is not allowing people to be at the facility, we will conduct research study remotely with participants by using Zoom. Depending on the group your child is placed in, they may complete health related group activities through a website with video-conferencing capabilities.

What your child will be asked to do in the study:

First, your child will be asked to complete 2 surveys with questions about their mood and how they feel about themselves, their opinion about health, and a description of their friendships.

They will get the chance to use a website and they may be asked to participate in group activities. We will spend about an hour, once a week for 5 weeks, going through the website and group activities.

Half-way through the program and 3 to 4 weeks after the program, your child will be asked to complete the surveys one more time.

Time required:

The study period is 2 months and 1 week for the Fall semester, and 2 months and 1 week for the Spring semester.

The first day of the study, during Week 2 of the study, the last week of the study, and 3 to 4 weeks after the study has ended, each of the 2 completed surveys will take about 20 minutes to complete.

Study sessions using the ASPIRE website and/or group activities will occur once a week for 4 weeks. An extra 5th session may be needed for completion. Each session should last about 1 hour.

The interview session should last about 1 hour.

Participation in this study will be over after the fourth survey or the interview is completed.

Number of people who will be in the study:

Up to 376 adolescents will be enrolled in this study.

Risks and benefits:

There is a potential risk for loss of confidentiality; however, appropriate steps will be taken to protect your child's information.

Surveys may contain questions that are sensitive in nature, such as their mood and how they feel about themselves, their tobacco use habits. Your child may refuse to answer any question that makes them feel uncomfortable.

Although the study is not designed to explore such issues, if Dr. Khalil or research staff obtain credible evidence that participant shows signs of distress or self-harm, Dr. Khalil or staff will address this by reporting it through the Florida Abuse Hotline or the National Suicide Prevention Lifeline.

By taking part in this study, your child may learn more about general health information, ways to stay healthy, and how to maintain a healthy lifestyle. Future adolescents may benefit from what is learned. There is no additional direct benefit from participating in this study.

Additional Information about the Research Study:

If you give permission to your child to take part in this study, you will complete up to 4 parts of this study during their after-school program in your absence:

Part 1: For Part 1, your child will complete a survey about their demographics, skills with games, attendance of social events, personality, their mood and how they feel about themselves, their tobacco use habits, and opinions about health and the internet.

Part 2: For Part 2, your child will complete a survey about their friends at the after-school program. They will be asked who their friends and peer leaders are at the program. The survey should take about 20 minutes to complete. For Part 2, you will also participate in an orientation session to learn about the study details. The orientation will be in the form of a presentation and a group activity.

Part 3: For Part 3, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group. Your child will have a 1 in 2 chance of being in either Group A or Group B.

Both Group A and Group B will use a website called A Smoking Prevention Interactive Experience (ASPIRE). The ASPIRE website has been designed for adolescents and has videos, activities, and health information facts about the effects of smoking, the benefits of meditation, and healthy living. Your child will complete 1-hour sessions using the ASPIRE website once a week for 4 weeks. In case your child does not complete ASPIRE by the 4th session, they may continue for an extra 5th session.

If your child is in Group B only, in addition to using the ASPIRE website, they will also complete health-related group activities on paper about the effects of tobacco

use. Researchers will form groups by pairing together participants who are not likely to use tobacco with those who are more likely to use tobacco. If in group B, you may be asked to submit a recording in the form of a photo or video securely to research staff, although this is not a requirement to participate in the study.

During Week 2 of the study, the last week your child is on the study, and 3 to 4 weeks after the study has ended, your child will complete the 2 surveys they completed during Part 1 and Part 2.

If you are in Group A and you do not receive the activities during the Fall semester, you will then receive them during the Spring semester.

If you receive the activities during the Spring semester, you will complete surveys right before you start the activities, the last week you do the activities, and 3 to 4 weeks after the activities have ended.

If you do not receive the activities during the Spring semester, you will complete surveys at the beginning the Spring semester, and 13 weeks later.

Part 4: For Part 4, 3 to 4 weeks after the study has ended, 30 participants from Group A and 30 participants from Group B will be invited to participate in an interview. If your child chooses to participate in the interview, they will be asked to describe their experience with the ASPIRE program and the group activities.

The interviews and the intervention sessions will be audio and video recorded to assess your child's experience with the program.

If your child has concerns about completing the surveys or sessions, they are encouraged to contact Dr. Khalil or staff (contact information above).

In this study, your child will be asked about certain behaviors that they may not want to share with their parents or legal guardians (general mood and tobacco use). Their answers will be kept confidential and their parents or legal guardians will not be provided their answers.

Study Tasks Due to COVID-19:

If the afterschool program is allowing members to meet in-person, research staff will work with the afterschool program staff to ensure COVID guidelines are enforced when conducting research at the site.

If an afterschool program does not allow their members to meet at the site in-person, participants will be able to complete study tasks remotely. Research staff will connect with participants via phone or Zoom. Participants in group B will complete health-related group activities via a website.

Confidentiality:

If you give permission for your child to participate in this study, the study Principal Investigator, Dr. Khalil, will collect and use confidential information about your child for research purposes.

During the surveys and interview, your child will be asked for their name and mailing address, without asking for any other personal information that could identify them. However, appropriate steps will be taken to minimize this risk and protect your child's information.

Immediately after each questionnaire or interview, participant names will be matched with code numbers. Your child's responses will become anonymous. The link between names and code numbers will be kept confidential in a separate document only available to Dr. Khalil. However, the links between code numbers and names will be discarded immediately after all questionnaires and interview have been linked to each other, and no longer than 1 year after the study has ended. Other than for group assignment, the research team will not directly be making effort to identify responses, and we will use the links only for matching questionnaires across times. During the interviews, we will ask your child to refrain from mentioning anyone's name or any other identifying information. In case identifying information is mentioned, study staff will erase the segment that mentions the identifying information. Should you submit a recording of the completed off-site activity, we will ask you to capture the videos and photos without having a non-participant in the recording. If a non-participant is visible in the recording, the recording will be censored to remove the non-participant. We will use the mailing address to mail compensation.

Only Dr. Khalil and research staff will have access to identifiable or individual responses. All study data files will be server-maintained with limited access by using passwords and logins restricted to study staff. In case of online data collection, data files will be stored in a password-protected and secure cloud. All physical study data files will be stored in an encrypted and password protected hard drive, physically locked at the Department of Health Outcomes and Biomedical Informatics at the University of Florida.

All study information will be reported in aggregate form, and study participants will not be identified in any public reports or documents.

Although the study is not designed to explore such issues, if Dr. Khalil or research staff obtain credible evidence that a participant shows signs of abuse, they will have to address child abuse/neglect by reporting it through the Florida Abuse Hotline (1-800-96-ABUSE). This Hotline will provide all reports to the Florida Department of Children and Families.

Although the study is not designed to explore such issues, Dr. Khalil or research staff will address suicidal ideation by asking the participant to immediately call the National Suicide Prevention Lifeline (800-273-8255), where immediate action can be taken. The PI will also report such an incident to the Florida Department of Children and Families. Child abuse/neglect, suicide risk, and any other adverse event will be reported to the National Institute on Drug Abuse and the institution.

Dr. Khalil and research staff will be able to identify responses because names will be provided, but after checking for any evidence of abuse or suicidal ideation, only codes will be used to match data sets. After data matching, your child's information will be anonymous.

Data storage during COVID-19 quarantine:

Due to COVID-19 quarantine, study data files will be saved in the secured server network of the Health Outcomes and Biomedical Informatics Department.

All data collected from participants in group B when completing the web-based health-related group activities will automatically be stored in a password-protected secure cloud.

Compensation:

During the Fall semester, as compensation for your child's time and effort for Part 1 and Part 2 of the study, they will receive $5 in cash or gift card. At session 2 of ASPIRE, mid-intervention, your child will receive $10 in cash or gift card. At the last session of ASPIRE, your child will receive $15 in cash or gift card. After the last survey and/or interview, your child will receive $20 in cash or gift card.

During the Spring semester, if in Group A, as compensation for your child's time and effort for Part 1 and Part 2 of the study, they will receive $5 in cash or gift card. At the last session of the intervention, they will receive $10 in cash or gift card. 2 to 3 months after the intervention, after completing a survey, they will receive $15 in cash or gift card. Six to 7 weeks after the intervention, after completing a survey, they will receive $15 in cash or gift card. During the Spring semester, if in Group B, as compensation for your child's time and effort for Part 1 and Part 2 of the study, they will receive $5 in cash or gift card. 13 weeks later, after completing a second survey, they will receive $10 in cash or gift card. As compensation the parent/legal guardian will receive $20 in cash or gift card.

Your child's and the parent's payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your child's information which will include their name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You child and the parent will be randomly

assigned a specific identification (ID) number to protect your identity. If you have any problems regarding your payment contact the study coordinator.

Source(s) of funding for the research:

This study is funded by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH)

May the researcher(s) benefit from the research?

We may benefit professionally if the results of the study are presented at meetings or in scientific journals.

Withdrawal from the study:

Your child may choose not to take part in this study. You and your child are free to withdraw consent and to stop participation in this study at any time without consequence.

For the surveys and interviews, your child can decline to answer any question they don't wish to answer.

If your child withdraws, will their information be used or discarded?

Your child's information will be used for research, up until they choose to withdraw from the study.

Can the researcher(s) withdraw your child from the study? If so, on what basis?

The researchers may withdraw your child from the study if their safety may be compromised, when the study is being closed by Dr. Khalil, the University of Florida, or NIH, or if your child is non-compliant with required study procedures.

If you wish to discuss the information above, please ask questions now or contact one of the research team members listed at the top of this form.

If you have any questions regarding your child's rights as a research participant, please contact the [redacted]

AGREEMENT:

Parent/Adult Legally Representing the Participant. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection and use of data for the person named below as described above for research purposes. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the participant.

_____ _____

Consent & Authorization Signature of Parent/Legal Representative

Date

_____ _____

Print: Name of Legal Representative

Print: Relationship to Participant:

_____

Print: Name of Participant:

CHILD ASSENT

Please read this document carefully before you decide to participate in this research study. **Your participation is voluntary, and you can decline to participate, or withdraw at any time, with no consequences**.

Purpose of the research study:

Our research team is trying to learn how adolescents like you react to an interactive health website and health related group activities so we can design more effective health programs.

The study should take 2 months and 1 week during the Fall semester, and 2 months and 1 week during the Spring semester.

If you are pregnant, you will not be eligible to participate in this study.

What will be asked from you:

If you decide to participate, first, you will be asked to complete 2 surveys with questions about your mood and how you feel about yourself, your opinion about health, and a description of your friendships.

You will get the chance to use a website and you may be asked to participate in group activities. We will spend about an hour, once a week for 5 weeks, going through the website and group activities.

Half-way through the program and 3 to 4 weeks after the program, you will be asked to complete the surveys one more time.

If you do not receive the activities during the Fall semester, you will then receive them during the Spring semester.

If you receive the activities during the Spring semester, you will complete surveys right before you start the activities, the last week you do the activities, and 3 to 4 weeks after the activities have ended.

If you do not receive the activities during the Spring semester, you will complete surveys at the beginning the Spring semester, and 13 weeks later.

Method of completing study tasks during COVID-19 quarantine:

Because of the COVID-19 quarantine, you will complete the ASPIRE program, questionnaires, and possibly an interview online.

You may complete group activities using a website that shares your webcam and audio with others completing the group activities.

Confidentiality:

For the group discussions, other than the researchers and those in your group, no one will know your answers, including your teachers or your parents. Everyone in the group will be asked not to share what they learn with anyone outside the group.

For the surveys, other than the researchers no one will know your answers, including your teachers, classmates, or parents.

Although the study is not designed to explore such issues, if your answers show that you feel you may hurt yourself, the researchers will ask you to speak with a professional who can help you.

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 disclose 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 have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

Risks and benefits:

There are no known risks to participation, and most teens actually enjoy the website and activities.

If you don’t like a question, you don’t have to answer it and, if you ask, your answers will not be used in the study.

If you do not feel well during the study, please make sure to speak with a research staff member immediately.

By taking part in this study, you may learn more about health and ways to stay healthy. Other teens like you may benefit from what is learned in this research.

Whatever you decide, this study will not affect your grades in class.

Compensation:

During the Fall semester, as compensation for your time and effort in the study, you will receive $5 in cash or gift card for the first time you take the surveys. Half-way through the program, you will receive $10 in cash or gift card. At the last session of the program, you will receive $15 in cash or gift card. After the last survey and/or interview, you will receive $20 in cash or gift card.

During the Spring semester, if you receive group activities, as compensation for your time and effort for Part 1 and Part 2 of the study, you will receive $5 in cash or gift card. At the last session of the intervention, you will receive $10 in cash or gift card. 2 to 3 months after the intervention, after completing a survey, you will receive $15 in cash or gift card. Six to 7 weeks after the intervention, after completing a survey, you will receive $15 in cash or gift card. Your parent or legal guardian will also receive $20 in cash or gift card.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity. If you have any problems regarding your payment contact the study coordinator.

Withdrawal from the study:

You do not have to be in this study if you don't want to and you can quit the study at any time.

By signing below, your parent or legal guardian said it would be OK for you to participate in this study.

If you have any specific questions about the study, please ask questions now, or you may contact Dr. Khalil or one of the research team members listed at the top of this form.

AGREEMENT:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent).

_____ _____

Assent Signature of Participant Date