

Study Informed Consent and Assent Forms

Official Title: Vaper to Vaper: A Multimodal Mobile Peer Driven Intervention to Support Adolescents in Quitting Vaping (V2V)

NCT#: NCT05140915

IRB Approval Date: December 12, 2022

University of Massachusetts Chan Medical School
Committee for the Protection of Human Subjects in Research

ASSENT TO PARTICIPATE IN RESEARCH

Vaper to Vaper (V2V): A Multimodal Mobile Peer Driven Intervention to Support Adolescents in Quitting Vaping

Principal Investigators: Drs. Rajani Sadasivam and Lori Pbert

1. My name is Dante Simone.
2. We are asking you to take part in a research study because we are trying to learn more about vaping in high schools.
3. If you agree to be in this study, you will be asked to:
 - Give us your home address, phone, cell phone, and phone numbers of three people who might be able to help reach you if we can't, and the best times and days to reach you.
 - Complete a survey today. The survey will ask you about your use of and attitudes towards vaping, marijuana, or tobacco. We will give you a \$25 gift card for completing this survey.
 - Receive written brochures that talk about quitting vaping.
 - Complete a survey and give us a sample of saliva at six months. The survey will ask you the same questions that we are asking you today. For the saliva sample, we will ask you to hold a small sponge in your mouth for about 2 minutes. The saliva sample is used only to determine the amount of nicotine in your body. It will not be used for DNA retrieval or to see if you have used any other type of drugs. We will give you a \$25 gift card for completing this survey and giving us a saliva sample.
4. One of the risks of being in this study is that your personal information (like your name or phone number) could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected. If we learn that you plan on hurting yourself or others, we will have to let someone, like the school nurse, know. We will also make a referral to the school nurse if you are highly stressed or depressed, based on some of your answers on study surveys.
5. A potential benefit of being in this study is preventing personal health risks that can be caused by vaping. You are helping to develop vaping interventions for teens.
6. Please talk this over with your parents/guardians before you decide if you want to participate. We have sent a letter to all parents/guardians of students at your school letting them know about the study and asking them to tell us if they didn't want their son or daughter to be part of it. But even if your parents/guardians want you to be part of the study, you can still decide not to do this.

7. Your participation is completely voluntary. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop. Your care in the school health clinic and your grades will not be affected by whether or not you decide to be in this study. You can stop or withdraw at any time.
8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me at (508) 856-8384 or ask me next time.
9. You will be given a copy of this form for your records.

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 - Complete a survey today. The survey will ask you about your use of and attitudes towards vaping, marijuana, or tobacco. We will give you a \$25 gift card for completing this survey.
 - Receive text messages about quitting vaping over the next six months. You may also be asked during these six months to talk about vaping with peer coaches.
 - Complete a survey and give us a sample of saliva at six months. The survey will ask you the same questions that we are asking you today. For the saliva sample, we will ask you to hold a small sponge in your mouth for about 2 minutes. The saliva sample is used only to determine the amount of nicotine in your body. It will not be used for DNA retrieval or to determine if you have used any other type of drugs. We will give you a \$25 gift card for completing this survey and giving us a saliva sample.
 - Give a one-hour interview at six months. We will ask you how you felt about the text message content and how easy or hard it was to use the system.
4. One of the risks of being in this study is that your personal information (like your name or phone number) could be lost or exposed. This is very unlikely to happen, and we will do everything to make sure that your information is protected. If we learn that you plan on hurting yourself or others, we will have to let someone, like the school nurse, know. We will also make a referral to the school nurse if you are highly stressed or depressed, based on some of your answers on study surveys.
5. A potential benefit of being in this study is preventing personal health risks that can be caused by vaping. You are also helping develop vaping interventions for teens.
6. Please talk this over with your parents/guardians before you decide if you want to participate. We have sent a letter to all parents/guardians of students at your school letting them know about the study and asking them to tell us if they didn't want their

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**UNIVERSITY OF MASSACHUSETTS CHAN MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Vaper to Vaper (V2V): A Multimodal Mobile Peer Driven Intervention to Support Adolescents in Quitting Vaping (H00021082)

Sponsor: National Institutes of Health (NIH)

Investigators: Rajani Sadasivam, PhD and Lori Pbert, PhD

368 Plantation Street

Worcester, MA 01605

Daytime Phone Number: (508) 856-8384

Consent Version: 2.0

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

KEY INFORMATION

You are being invited to participate in a research study because you are enrolled in grade 9-12 at one of the four high schools that are participating in our study.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. Your care in the school health clinic and your grades will not be affected by whether or not you decide to be in this study.

The main question this study is trying to answer is how can we best develop a program to support adolescents to quit vaping?

If you join this research, you will be asked to give us your home address, phone, cell phone, and phone numbers of three people who might be able to help reach you if we can't, and the best times and days to reach you. We will also ask you to complete a survey today, receive written brochures that talk about quitting vaping, complete a second survey after six months, and give us a sample of saliva at six months.

You may not want to be in this study if you are uncomfortable with: Sharing your private information with researchers.

Risks: We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

Benefits: We cannot promise any benefits if you take part in this research. Your participation will help us to gain knowledge that may help support adolescents to quit vaping in the future. However, there is no direct benefit to you.

Alternatives: This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

Why is this research being done?

The purpose of this research is to develop a program to support adolescents to quit vaping.

How many people will take part in this research?

About 80 adolescents who attend four local high schools will take part in this research.

How long will I be in this research?

You will actively be in this research for about six months.

What happens if I say yes, I want to be in this research?

Joining this study is not required. It is up to you. A signed copy of this form will be given to you. You are free to change your mind and choose not to be a part of the study at any time. Your care in the school health clinic and your grades will not be affected by whether or not you decide to be in this study. You are required to complete this consent form if you agree to be in the study.

If you agree to be in this study, you will be asked to:

- Give us your home address, phone, cell phone, and phone numbers of three people who might be able to help reach you if we can't, and the best times and days to reach you.
- Complete a survey today. The survey will ask you about your use of and attitudes towards vaping, marijuana, or tobacco. We will give you a \$25 gift card for completing this survey.
- Receive written brochures that talk about quitting vaping.
- Complete a survey and give us a sample of saliva at six months. The survey will ask you the same questions that we are asking you today. For the saliva sample, we will ask you to hold a small sponge in your mouth for about 2 minutes. The saliva sample is used only to determine the amount of nicotine in your body. It will not be used for DNA retrieval or to see if you have used any other type of drugs. We will give you a \$25 gift card for completing this survey and giving us a saliva sample.

Will you be collecting any specimens from me?

Yes. We will collect a sample of your saliva. The saliva sample is used only to determine the amount of nicotine in your body. It will not be used for DNA retrieval or to see if you have used any other type of drugs.

Could being in this research hurt me?

There is a risk that someone could get access to the data we have stored about you (like your name, date of birth, address, telephone number, and your email address). We believe the chance that this will happen is very small, but we cannot make guarantees.

Will being in this research help me in any way?

We cannot promise any benefits if you take part in this research. Your participation will help us to gain knowledge that may help support adolescents to quit vaping. However, there is no direct benefit to you.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

Will it cost me any money to take part in this research?

No, there is no cost to you.

Will I be given any money or other compensation for being in this study?

Yes. You will receive two \$25 gift cards for completing the surveys and giving us a saliva sample.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study investigator(s) as soon as you are able.

The University of Massachusetts Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Follow the directions of the research staff.
- Call the research team at (508) 856-8384, or email at Dante.Simone@umassmed.edu, if you have any questions.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. This is called withdrawing. Your decision will not result in any penalty or loss of benefits. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you.

Can I be removed from the research without my approval?

The person in charge of the research study or the sponsor can take you out of the study even if you do not want to leave. This may happen if the study is stopped by the funder or the University of Massachusetts IRB.

How will my information be stored and when will it be destroyed?

We will keep your personal information (like your name, date of birth, address, telephone number, and your email address) separate from your research data. Only the study team will have access to your contact information and will not share it with anyone else.

We will keep paper documents under lock and key. We will keep research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will keep research-related records for a period of 3 years after the study has ended. It is possible that we might use the research data in other future research. We may also share data with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

We will not keep or store your saliva samples. Research staff will enter the level of nicotine from your saliva sample into our secure database, using your participant ID as an identifier, and destroy the samples.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, the University of Massachusetts Chan Medical School may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address.

Your research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor.
- People who work with the research sponsor.
- Federal and state government agencies, such as NIH state auditors.
- The University of Massachusetts Chan Medical School and UMass Memorial Health Care, including the Institutional Review Board (IRB) and research, billing, and compliance offices.

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy. We may break confidentiality as part of a safety plan, in order to report current symptoms that need medical attention to emergency services. If we learn that you plan on hurting yourself or others, we will have to let someone, like the school

nurse, know. We will also make a referral to the school nurse if you are highly stressed or depressed, based on some of your answers on study surveys.

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceeding.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

Will you share any results with me?

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

Signature of adult research participant

Date

Printed name of adult research participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent

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You may not want to be in this study if you are uncomfortable with: Sharing your private information with researchers or replying to interview questions about vaping.

Risks: We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.

Benefits: We cannot promise any benefits if you take part in this research. Your participation will help us to gain knowledge that may help support adolescents to quit vaping in the future. However, there is no direct benefit to you.

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Will you be collecting any specimens from me?

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Could being in this research hurt me?

Some risks include feeling uneasy about participating in the interview. You do not have to answer any questions that you are not comfortable answering, and you can stop the interview at any time. There is also a risk that someone could get access to the data we have stored about you (like your name, date of birth, address, telephone number, and your email address). We believe the chance that this will happen is very small, but we cannot make guarantees.

Will being in this research help me in any way?

We cannot promise any benefits if you take part in this research. Your participation will help us to gain knowledge that may help support adolescents to quit vaping. However, there is no direct benefit to you.

What other choices do I have besides taking part in this research?

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Will it cost me any money to take part in this research?

No, there is no cost to you.

Will I be given any money or other compensation for being in this study?

Yes. You will receive two \$25 gift cards for completing the surveys and giving us a saliva sample.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study investigator(s) as soon as you are able.

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The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

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You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

Signature of adult research participant

Date

Printed name of adult research participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent