Official title: Study 2: Pilot study of incentive-based and media literacy-informed approaches to improve vaping cessation among young adults

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Social/Behavioral
SECTION I

Therapeutic/Non-Therapeutic
Does your research involve a drug, medical device, technique or other intervention or strategy (including means like diet, cognitive therapy, behavioral therapy, exercise) to diagnose, treat or prevent a particular condition or disease: "THERAPEUTIC RESEARCH"?
Yes

1. Title of Protocol:
Study 2: Pilot study of incentive-based and media literacy-informed approaches to improve vaping cessation among young adults

Is a OneChart/EPIC Subject Friendly Short Title needed?
No

2. Responsible Personnel:
A. Principal Investigator (PI):
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C. Participating Personnel:
Buckley, James (James) A - COPH Biostatistics - 860-682-7459 - jabuckley@unmc.edu - alt #: 402-559-4112 - degree: BS - address: Does not work on cam (Zip 4335)

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D. Lead Coordinator:

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E. Coordinator(s):

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Are you adding a clinical trial management group?
No

F. Data/Administrative Personnel:
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G. Are you a student or house officer?
No

3. Funding Source:
Check all that apply and provide the source of the funding.
Cooperative Group:
Center for Clinical and Translational Research (CCTR)
♦ Federal (e.g., NIH) Grant - Provide source: IDeA CTR ECIP
Other Grant:
Departmental funding
Commercial - Provide company name:
Department of Defense
♦ Other - Provide source (e.g. personal funding): faculty funds

4. Deadline for IRB Approval:
Yes - Explain and provide date:

♦ No

5. Contract:
Is there a contract associated with this study?
No

6. Agreements
Is there a Material Transfer Agreement (MTA) associated with this study?
Yes

Identify the other institution(s)
The Division of Laboratory Sciences (DLS) at the Centers for Disease Control and Prevention will analyze the urine samples. We will obtained DLS project approval to process the urine sample collected by submitting following documents.

1. Brief project description
2. IRB package including study protocol, consent form, and IRB approval
3. Prohibit CDC receiving identification form (01375B)

Is there a Data Use Agreement (DUA) associated with this study?
No

Is there a Data Transfer Agreement (DTA) associated with this study?
No

7. Study Sites:
A. Provide the names and locations of all study sites where this research will be conducted under the oversight of the UNMC IRB or Joint Pediatric IRB.
UNMC

B. Will the research be conducted at external sites under the oversight of an external IRB?
No

C. Does UNMC, TNMC, CHMC or UNO serve as the lead site with responsibility for data and/or safety monitoring?
No

D. Does this study involve any international sites where the PI will either; 1) conduct 2) supervise or 3) receive / ship HBM or data to / from UNMC?

No

E. Does this study involve face to face contact with subjects?
Yes

8. Principal Investigator Assurance
The PI understands and accepts the following obligations to protect the rights and welfare of research subjects in this study:

- **All information in this application is complete and accurate.**
- **I will conduct the research as described in the application and the protocol.**
- **I will not initiate any change without IRB approval except when it is necessary to reduce or eliminate a risk to the subject.**
- **I will ensure that all research personnel are qualified and properly trained.**
- **I will fulfill my responsibilities as PI, described in** https://guides.unmc.edu/books/hrpp-policies-and-procedures/page/126-pi-qualifications-and-responsibilities
- **I will follow all applicable HRPP and institutional polices, and all applicable laws, statutes and regulations.**

Michaud, Tzeyu L - 2024-05-08 15:55:24.667

9. Principal Investigator Financial Interest Disclosure
A. As the PI, I declare:
♦ I have no financial interest in this research.
I have a financial interest in this research.

B. As the PI, I understand
♦ I must disclose any change in my financial interest during the course of this research within five (5) business days from the time the change becomes known.

C. As the PI, I certify that:
♦ No Responsible Personnel have a financial interest in this research.
The Responsible Personnel listed below have informed me that they have a financial interest in this research.

D. I have informed all Responsible Personnel that if there is any change in their financial interests during the course of this study it must be disclosed within five (5) business days from the time the change becomes known.

Michaud, Tzeyu L - 2024-05-08 15:55:24.667

SECTION II

PROTOCOL ABSTRACT

1. Provide a brief (less than 2500 characters) abstract of the research protocol. (2500 characters)
This summary should include: 1)) a brief description of the purpose of the study, 2) eligibility criteria, 3) interventions and evaluations and 4) follow-up.
The objective of this pilot study is to evaluate the feasibility and compare the potential effect of different vaping cessation intervention components in addition to evidence-based text-messaging support, including 1) media literacy interactive e-learning lessons, 2) financial incentives, and 3) combined (media literacy + financial incentive) on vaping abstinence among current young adult vapers over a three-month timeframe with the following three specific aims: Aim 1. To assess the feasibility of a multi-component vaping cessation program; Aim 2 To evaluate the preliminary effect of a multicomponent vaping cessation program; and exploratory Aim 3. To Examine the cost-consequence of a multicomponent vaping cessation program. Eligible participants are young adults aged 19-29 and are current vapers (i.e., using e-cigarettes in the past 30 days).We will employ a 4-arm, feasibility randomized trial design to determine the preliminary effect of different vaping intervention components on vaping abstinence over a 3-month timeframe, consisting of a 1-month quitting preparation phase and 2-month abstinence phase. Eligible participants (n=80) will be randomized (in a 1:1:1:1 ratio), using a computer-generated algorithm, to to one of four vaping cessation interventions: 1) Active control: text-messaging support, 2) Media literacy: media literacy + text-messaging support, 3) Financial incentive: financial incentive + text-messaging support, and 4) Combined: media literacy e-learning lessons + financial incentive + text-messaging support, at the baseline visit. Regardless of intervention arms, all enrolled participants will receive receive an evidence-base text-messaging support program for quitting vaping (This is Quitting). Participants will be followed through a 3-month study period including a 1-month quitting preparation phase and a 2-month abstinence phase. All participants will be asked to provide the 5 saliva cotinine samples- at baseline and end-of-study visits and 3 at video calls (remote submissions). Participants who assigned to the financial incentive Combined groups will be provided monetary rewards for submitting saliva cotinine samples during the abstinence period. To examine the feasibility of biomarker testing for toxic exposures, for a subsample of 20 participants, a panel of biomarkers of toxic exposures will be measured at baseline and at the end of study.

PURPOSE OF THE STUDY AND BACKGROUND

2. Purpose of the Study
What are the specific scientific objectives of the research?
This study aims to evaluate the feasibility and compare the preliminary effect of vaping

cessation program consisting of media literacy education and real-time text messaging support and leverage insights from behavioral economics to enhance financial incentives to improve program engagement, and eventually abstinence. Our hypotheses are that 1) the *Combined* arm is associated with improved vaping abstinence to the *Media literacy and Financial incentive* arms; and 2) the financial incentive-related arms (either C*ombined* or *Financial incentive*) enhance engagement compared to the non-incentive related arms.

3. Background and Rationale

Describe the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the information gaps that the project is intended to fill.

Vaping has become a public health crisis among youth/young adults.[1] In 2020, an estimated 19.2% of U.S. high school students and 9.4% of young adults aged 18-24 years old reported current use of e-cigarettes.[2,3] For these emerging vaping products with varying devices and nicotine formulations, the health effects of vaping and vaping cessation remains largely unknown.[4] E-cigarette use among young people may also increase the risk of nicotine addiction and transition to cigarette smoking, marijuana, and other substance use.[5,6] In 2020, 53.4% of current young e-cigarette users reported intention to quit vaping, and 67.4% reported having tried to quit vaping,[7] but failed attempts to quit vaping remained high.[8] Very limited evidence-based vaping programs have been developed,[9] and the program reach continues to be an implementation issue for evidence-based programs (EBPs), especially among youth/young adult populations.[10]

Contingency management is an established behavioral intervention in which individuals receive reinforcement (e.g., financial incentives) contingent upon biochemically verified abstinence.[11] Incentives have been used to encourage healthy behaviors,[12] and as an implementation strategy to improve EBP reach and engagement.[13] Moreover, social support has been integrated into smoking interventions to promote cessation.[14] Notably, family and friend use is one of the top reasons for youth to use e-cigarettes[15], and vaping for entertainment is common among young vapers.[16] Studies have shown that peer support can be an effective strategy in increasing social support and promoting abstinence in smoking cessation, especially among young people.[17,18] Although there is clear evidence that social support and financial incentives individually improve smoking cessation rates in mixed population,[19] little is known regarding their individual and collective effect on vaping cessation program reach and effectiveness, especially targeting the young adult population.[10,20]

CHARACTERISTICS OF THE SUBJECT POPULATION

4. Accrual

A. Is this study conducted solely at sites under the oversight of the UNMC IRB (e.g.

UNMC, Nebraska Medicine, CHMC, UNO)?
Yes

1. How many subjects will need to be consented (per group, as applicable) in order to achieve the scientific objectives of the research?
We will recruit 80 young adult current vapers aged 19-29 to test a four-arm pilot trial (*Active control*, *Media literacy*, *Financial incentive*, and *Combined*) with n=20 for each arm.

2. What is the statistical or other justification for the total number of subjects described above?
As this is a pilot feasibility study, and as the rule of thumb, it was suggested that a minimum sample size of 12 subjects per treatment arm or a total sample size of 70 in order to reduce the imprecision around the estimate of the standard deviation for a pilot trial. Accordingly, the sample size of 80 for this study would be sufficient to assess the preliminary effectiveness of financial and social incentives as well as determine the feasibility and ability to scale interventions to a larger group.

3. How long do you estimate it will take to accrue the required number of subjects?
We estimate that it will take about 3-4 months to accrue the required number of subjects.

5. Gender of the Subjects
A. Are there any enrollment restrictions based on gender?
No

6. Age Range of Subjects
A. Will adults be enrolled ?
Yes

1. What is the age range of the adult subjects?
Young adults aged 19-29

2. What is the rationale for selecting this age range?
As vaping is prevalent in youth and young adult population, the objective of this study is to test the application of financial and social support to improve the reach, engagement and retention of the vaping cessation program consisting of education lessons and text-messaging support program, which are developed and tested specially among youth and young adult populations.
In general, young adults are referred to adults aged between 18-20 years-old. In Nebraska, an individual is considered an adult when he/she reach the age of 19.

B. Will children (18 years of age or younger) be included in this research?
No

1. What is the justification for excluding children from participating in this research?
Research is irrelevant to children (e.g. disease or condition rarely encountered in children).
Knowledge being sought in the research is already available for children or will be obtained from another ongoing study.
♦ A separate study in children is warranted and preferable.
Insufficient data are available in adults to judge the potential risk in children.
Other. Explain.

7. Race and Ethnicity
Are there any subject enrollment restrictions based upon race or ethnic origin?
No

8. Vulnerable Subjects
A. Will prisoners be included in the research?
No

B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.
Decisionally-impaired persons
Critically ill patients
Students of the investigator
Employees of the investigator
Educationally disadvantaged individuals
Socially or economically disadvantaged individuals
Individuals with a stigmatizing illness or condition
Individuals from a marginalized social or ethnic group
Other.
♦ No vulnerable subjects will be specifically recruited

9. Inclusion Criteria
What are the specific inclusion criteria?

- Aged 19-29
- Self-report current e-cigarette users (in the past 30 days)
- Have access to internet/video chat/SMS text message
- Are interested in quitting vaping in the next 30 days

10. Exclusion Criteria
What are the specific exclusion criteria?

- Must meet all the inclusion criteria
- Self-report as currently pregnant or planning to become pregnant in the next 3 months
- Already involved in vaping cession programs (either behavioral or medical intervention)

11. Pregnancy and Contraception Requirements
A. Are women of child bearing potential (WOCBP) included in this research?
Yes

a. Are there any specific contraception requirements for subjects?
No

1. Provide justification for absence of contraception requirements
♦ There are no interventions that are likely to be of risk to a fetus
Investigational drug(s) is (are) not systemically absorbed
Investigational drug(s) is (are) systemically absorbed, but there is no evidence from human studies, or from clinical experience, that there is risk to a fetus
Other

B. Are pregnant women included in this research?
No

1. Provide justification for excluding pregnant women
Investigational drug(s) is (are) absorbed systemically, and there is evidence from animal or human studies, or from clinical experience, that there is risk to a fetus **OR** investigational drug(s) is (are) absorbed systemically, and there is a well-understood mechanism of action that may result in risk to a fetus
Intervention includes a procedure expected to be of risk to a fetus (eg, exposure to ionizing radiation, maximal exercise test)
Research is not relevant to pregnant women (e.g. disease or condition rarely encountered in pregnant women)
Knowledge being sought in the research is already available for pregnant women or will be obtained from another ongoing study
♦ A separate study in pregnant women is warranted and preferable
Physiology of pregnancy precludes generalization to other populations
Other - explain

2. Describe how pregnancy status will be assessed (eg, self-report, urine pregnancy test, blood pregnancy test) and the frequency of monitoring during participation in the research.
Enrolled participants will self-report and contact the research team when they become pregnant at any time during the study period. They will be disenrolled from the study.

3. Describe the plan should a female subject, or the partner of a male subject, become pregnant while research interventions are on-going (or during the period that contraception is required following the completion of the intervention).
Enrolled participants will self-report and contact the research team when they become pregnant at any time during the study period. They will be disenrolled from the study.

C. Are breast feeding women excluded in this research?
No

Provide justification for the inclusion or exclusion of breast feeding women.
As this is a incentive-based (financial and social) enhanced vaping cessation study, there will not be therapeutic interventions or treatments other than educational lessons and support programs. Breastfeeding should not be impacted.

METHODS AND PROCEDURES

12. Methods and Procedures Applied to Human Subjects
A. Are there any evaluations or tests that will be performed for the purpose of determining subject eligibility which would not be routinely conducted as part of standard clinical care of the prospective subject?
Yes

1. Describe the evaluations or tests to determine subject eligibility
Interested potential participants will complete an online screen survey (RedCap link embedded in the recruitment email), to determine their eligibility based on the inclusion and exclusion criteria.

2. Are any of these evaluations or tests performed prior to obtaining informed consent?
Yes

B. Describe the research plan, including all procedures, interventions, evaluations and tests.
Study design

This study employs a pilot, 4-arm randomized clinical trial (RCT) design. Individuals who meet the eligibility criteria will be randomized (1:1:1:1) to receive one of the following interventions with a 1-month quitting preparation phase and a 2-month abstinence phase:
1) Active control-
Participants in this arm will receive an evidence-based text-messaging support
2) Media literacy-
Participants will receive media literacy e-learning lessons and an evidence-based text-messaging support
3) Financial incentive-
Participants will receive financial incentive intervention and an evidence-based text-messaging support
4) Combined-
Participants will receive media literacy e-learning lessons, financial incentive, and an evidence-based text-messaging support program

During the 1-month quitting preparation phase, participants assigned to the *Media literacy* and *Combined* arms will be instructed to complete media literacy e-learning lessons. All participants will be instructed to complete the registration and setup text-messaging support program and begin preparing for quitting and be familiar with the remote saliva cotinine sample submission procedure for the abstinence phase. The 2-month abstinence phase starts with the day after the self-designated quit date (not later than the 1-month quitting preparation phase), where participants will engage with 3scheduled video calls at Week 6, Week 8, and Week 10 to conduct and submit a remote saliva cotinine testing result. The content of a video call is described as follows:

- At each video call, participants will be asked to submit a remote saliva cotinine sample to track their abstinence progress. Each call should take less than 20 minutes.
- During the video call, the research team will check-in with participants, and participants will then be instructed on how to complete the remote saliva cotinine sample submission as follows: (1) participants will open the new, labeled packaging for each testing kit while on the video call to ensure they are using a new test each time; (2) participants will be asked to write down the participant id, test number, date, and time on the test kit; and (3) participants will take a picture, including participant id, test number, date, and time for verifying the final results and provide the final results (approximately 10-minute processing time) and picture to the research team member before ending the call.

All participants will receive an evidence-based active text-messaging support program (i.e., This is Quitting; https://truthinitiative.org/thisisquitting).

For quality improvement and future modification and adoption of the multi-component vaping cessation program, we will conduct an exit interview (n=8-12; n=2-3 from each arm based on first available participants) via a video call, with participants to identify the feasibility, facilitators, and barriers of implementing the proposed interventions. Participant who have completed the end-of-study assessment will be contacted by research staff for their willingness to participate in the exit interview. The interview will take place after the Week 12 visit based on participant's availability via a zoom meeting. Therefore, the total participating time in the study is roughly 14-16 weeks. The interview will be audio-recorded and transcribed in order to produce an accurate transcript of the discussion. Each participant in the exit interview will receive a $25.00 giftcard. The interview will last less than 30 minutes.

Participant enrollment process

Interested potential participants will complete an online screen survey (RedCap link embedded in the recruitment email; and less than 5 minutes to complete), to determine their eligibility based on the inclusion and exclusion criteria. Once potential participants have been deemed as eligible through screening questions, participants will be asked if they would like to participate. If they agree, they will be asked to indicated the times and days that participants would be available to attend the in-person session to complete the informed consent, intake process, including providing saliva sample, urine sample (only for 20 participants who volunteer to be in the biomarker measurement group), and completing the baseline survey (less than 20 minutes to complete), consisting of demographic information, vaping history, vaping experience/behavior, exposure to Tobacco Marketing and Marketing Influences, social efficacy, UPPS impulsive behavior scale, money choice question, and nicotine dependence index (Penn State Cigarette Dependence Index). After completing all the tasks at the baseline session, a randomization algorithm will be utilized to decide which interventions (*Active control*, *Media literacy*, *financial incentive*, and *Combined*) that a participant will be assigned to.

If an interested patient contacts the research team because of the recruitment flyer or other mode outside of the recruitment email,(e.g., see the flyer in the community), the research staff, listed on the IRB protocol, will conduct the phone screening using the same Redcap link for the screening survey to determine his/her eligibility. To make sure that the consenting process is consistent throughout the study, if the individual is eligible, the research staff will schedule the individual for an in-person baseline visit to complete all the activities mentioned above.

To examine the feasibility of biomarker testing for toxic exposures, for a subsample of 20 participants (n=5 participants will be recruited from each intervention group until fulfilled), a

panel of biomarkers of toxic exposures will be measured at baseline and vaping abstinence, including 1) cotinine and hydroxycotinine, and 2) creatinine. See our paper for biomarkers and clinical relevance.[21] Given that we are testing out the feasibility and estimating the possible costs of biomarker testing of toxic exposure among young adult vapers and based on the budget for the project, we decide n=20 would be sufficient to determine the feasibility and scalability of biomarker testing in a future large-scale study. Of note, the biomarker analysis will be done by the CDC, and the PI and research team also recognize that no samples will be collected or sent prior to an MTA being in place with the CDC. The biomarker testing of toxic exposure is solely for research purpose and thus the results will not be share with the participants.

Goal setting

Each participants will be asked to choose a quit date after completing the media literacy e-learning lessons (only for participants who are assigned to *Media literacy* and *Combined* arms) and registration for the text message app within the 1-month quitting preparation phase. Participants could choose to set up an earlier quit date, however, the latest quit date is the day after the 1-month quitting preparation phase. Participants will be asked to sign a pre-commitment pledge to strive to achieve their abstinence goal during the 2-month abstinence phase. Pre-commitment has been demonstrated to motivate behavior change.

Vaping cessation interventions:

1. Text-messaging support program- This is quitting

Grounded in social cognitive theory, This is Quitting is an evidence-based, free mobile program from Truth Initiative designed to help young people quit vaping. The program is fully automated and interactive and developed based on the best practice of smoking cessation among young people. To establish or reinforce perceived social norms and social support around quitting, a majority of messages come from other users who have submitted them to the program.

To enroll in This is Quitting, enrolled participants will text DITCHVAPE to 88709. The first messages they receive will ask for their age and product usage so that they are able to receive relevant messages. Users receive one age-appropriate text-message per day tailored to their enrollment date or quit date, which can be set and reset via text message. Users with a quit date receive one week of messages prior to that date and at least eight weeks of messages after their quit date.

The program is written in first-person, positioned as a nonjudgmental, supportive friend to the user. It is anchored around key constructs from the Social Cognitive Theory. For example, to build self-efficacy, users receive messages that are designed to bolster confidence (eg, Matt says: Just trust the process. Its hard at first but it gets easier with time. And don't get down on yourself, every day is a new day. We all believe in you here.). To establish or reinforce perceived social norms and social support around quitting, a majority

of messages come from other users who have submitted them to the program (edited by Truth Initiative personnel where appropriate). These messages reference the author and are designed to convey that many other young people are quitting and that the user is not alone (eg, Ashley says: You can do it we are all in this together. You're not the only one whos thought about quitting.). To support observational learning, users receive messages with strategies from other young people (eg, Dalton says: Remember that stress can be dealt with in other ways! Try meditating or even writing down what the problem is and then figure out solutions. You dealt with hard things before you started to vape, and you still can.) To grow behavioral capability, users receive messages that suggest concrete evidence-based skills and strategies users can practice (eg, Have your friends supported your quitting? Reply YES or NO. {{If user responds NO}} Practice - like actually say out loud in front of a mirror at home or in your car - how you'll turn down a JUUL if they offer it to you.). Like this example, many of the messages are interactive in nature, encouraging users to engage with the program.
Participants will still have access to the app after they completed the study.

2. Media literacy e-learning lessons
Developed by the research team at university of Nebraska Medical Center and partner with Tobacco Education & Advocacy of the Midlands (TEAM), the TEAM No Vaping, including 3 modules and will take about 30 minutes to complete, covers topics regarding what e-cigarettes are and how they work, how nicotine and nicotine addiction affects the brain and behavior, how to prepare to quit vaping, developing a quit plan and how to deal with cravings and relapse. The program focuses on changing knowledge, attitudes and beliefs related to e-cigarette use, as well as emphasizing vaping related media literacy. The 3 modules can be accessed through a website (Lesson 1:https://webmedia.unmc.edu/eLearning_open/COPH/Dai/VapingPrevention1/; Lesson 2:https://webmedia.unmc.edu/eLearning_open/COPH/Dai/VapingPrevention2/; and Lesson 3:https://webmedia.unmc.edu/eLearning_open/COPH/Dai/VapingPrevention3/). Enrolled participants will be asked to complete the self-paced 3 modules at their leisure time within the 1-month quitting preparation phase. At the end of each modules, participants will be instructed to complete a short quiz to indicate the completion and/or understanding of the education materials. The education lessons are mainly developed for vaping cessation-related research studies targeting youth or young adults.

3. Financial incentive
- Participants will earn $3 for each saliva cotinine sample submission regardless of positive or negative results after the quit day (an assessments at Week 6, Week 8, Week 10, and Week 12, during the abstinence phase)
- Participants will earn additional escalating rewards for each negative sample- $7 for Week 6, $12 for Week 8, $17 for Week 10, and $22 for Week 12 (2 months after the

target quit date). The bonus starts at $7 and increase by $5 for each subsequent negative cotinine sample (i.e., $7, $12, $17, and $22). A reset contingency will be used. That is the reward amount will be returned back to original $7 if there is a missing or positive saliva cotinine sample
- Participants could earn a total possible payment of $70 with a total of 4 submissions of cotinine samples, including 3 remote submissions and one in-person submission (Week 12)
- Participant will receive all the earning at the Week 12 visit for a one-time payment.

Measurement
All participants will need to attend in-person baseline visit and Week 12 visits to complete saliva samples and urine samples (only 20 participants who volunteer) collection and complete survey questionnaires. Each in-person is expected to take 1-1.5 hours to complete the activities.

Participants will be given iScreen test kits (iScreen; Alere, Watham, MA) during the baseline session and complete their first saliva cotinine samples in-person. Participants will also complete saliva samples remotely during the 3 scheduled live video calls.

The baseline and end-of-study surveys will be conducted on the Redcap platform using the study iPad, hosted on a secure server at UNMC at the in-person baseline and Week 12 visits.

Participants will complete their first and last saliva cotinine samples in-person during the baseline and final visits. Meanwhile, participants will also download the This is Quitting app at the baseline visit and set up the account with the target quit date (not later than 30 days from the baseline visits). For the remaining check-in sessions (i.e., scheduled live video calls which are mainly for remote saliva sample submissions- a total of three submissions), participants will be instructed during live video call on how to complete the saliva cotinine sample submission with the following procedures.
- Participants will open the new, labeled packaging for each testing kit while on the video call to ensure they are using a new test each time
- Participants will be asked to write down the participants id, test number, date, and time on the test kit
- Participants will take a picture, including participant id, test number, date, and time for verifying the final results and provide the final results and picture to the research staff before ending the call (approximately 10-minute processing time)

The study period consists of an 1-month quitting preparation phase followed by a 2-month abstinence phase. There will be 3 check-in video calls (and thus 3 remote saliva sample submission) for all participants. At each video call, participants will follow the above

instruction to submit a saliva cotinine sample. Each remote video call will take no longer than 20 minutes.
Live, synchronous video calls will be scheduled based on the assigned intervention groups for the next two months for check-in and to submit a remote saliva cotinine sample as described above. For the 1-month quitting preparation phase, participants will be instructed to complete media literacy education lessons (only for participants who are assigned to *Media literacy* and *Combined* arms) and the registration of the text-messaging program (i.e., This is Quitting) and will be instructed not to quite but begin preparing for quitting. They will also be familiar themselves with the remote saliva cotinine sample submission process.

For the participants who are volunteer to be at the biomarker measurement group for providing urine samples (n=20), they will be given instructions on where and how to provide a urine sample to test for five classes of biomarker levels as described above.

Survey instrument

1. Screening survey
2. Baseline and end-of-study survey, including demographic, vaping history, vaping experience/behavior, attempt to quit, Penn State Nicotine Dependence Index, exposure to Tobacco Marketing and Marketing Influences, UPPS impulsive behavior scale, money choice question, and self-efficacy about not to vape, and wheezing and related respiratory symptoms

Primary outcome

- **biochemically verified vaping abstinence** (negative results- will be cut-off < 30 ng/mL[71]), measured by saliva cotinine samples at the Week 12 visit.

Secondary outcome

1. Nicotine abstinence: bi-weekly/monthly saliva nicotine abstinence results (positive vs. negative) will be obtained using the iScreen test kit (https://stat-technologies.com/product/alere-iscreen-for- cotinine/#:~:text=The%20Alere%20iScreen%C2%AE%20OFD,nicotine)%20in%20human%20oral%20fluid.) after the target quit date for 2 month in addition to baseline and Week 12 saliva cotinine samples. Saliva sample/results will be collect in person at baseline and Week 12 visits and remotely via live video calls during the abstinence phase. The remote saliva sample collection will follow the instruction below:

- Participants will open the new, labeled packaging for each testing kit while on the video call to ensure they are using a new test each time
- Participants will be asked to write down the participants id, test number, date, and time on the test kit
- Participants will take a picture, including participant id, test number, date, and time for verifying the final results and provide the final results and picture to the research

staff before ending the call (approximately 10-minute processing time)
All participant will need to provide a saliva sample at the in-person baseline and the Week 12 visits and at remote video calls (Week 6, Week 8, and Week 10).

2. Biomarkers of toxic exposures: Twenty participants who are assigned the biomarker measurement group will need to provide the urine sample at the in-person baseline (Week 0) and Week 12) visits at the UNMC clinical research center (CRC). The nurse research coordinator at CRC would assist with the urine sample collection. The biomarker classes may include: 1) cotinine and hydroxycotinine, and 2) creatinine. The biomarker testing of toxic exposure is solely for research purpose and thus the results will not be share with the participants.

3. Engagement, assessed by: a) proportions of media literacy e-learning lessons completed at the end of the quitting preparation phase (Week 4), and b) proportions of participants who submitted the remote saliva cotinine sample at each scheduled time-point at Week 12;
4. Nicotine dependence index, measured by the Penn State E-cigarette Dependence (PSECD) index at baseline and Week 12;
5. Media literacy, measured by the vaping media literary scale at baseline and Week 12.
4) Self-reported vaping abstinence, assessed by the question In the past 30 days, did you vape at all, even a puff of someone else? at Week 12.

Exploratory outcomes
We will collect intervention cost data using all program invoices related to program implementation and survey questionnaire to estimate the cost-effectiveness of the program. For example, we will calculate the incremental cost per additional completing the vaping cessation program, the incremental cost per additional abstinence case across study arms.

C. Select any of the following that apply to the research:
Phase I study
♦ Randomization
Placebo (or non-treatment arm)
Washout
Sensitive surveys or questionnaires
None of the above

Option chosen: Randomization
Describe randomization process and schedule
Participants will be assigned following a randomization table created by the study statistician after completing the consent process and baseline survey on the REDCap platform. To

ensure an even distribution of participants between the four intervention groups, eligible subjects will be randomly assigned to one of four intervention groups using a computer generated randomization table created by the study statistician. We will recruit 5 participants from each intervention group (until fulfilled) for the biomarker measurement group.
Upon randomization, research staff will review the intervention component based on the intervention group that they are assigned to with the participants and provide instruction and materials for the followup sessions.

D. Identify:

1. All procedures, interventions, evaluations and tests performed solely for research purposes (eg, administration of an investigational drug or a new psychological assessment instrument; randomization)

- We will administer a set of educational lessons about vaping cessation that discuss what e-cigarettes are and how they work, how nicotine and nicotine addiction affects the brain and behavior, how to prepare to quit vaping, developing a quit plan and how to deal with cravings and relapse.
- We will facilitate participants to download and enroll in the evidence-based vaping cessation support text-messaging program (This is quitting, https://truthinitiative.org/thisisquitting)
- We will administer monetary incentives based on engagement (submitting saliva samples at Week 6, Week 8, and Week 10), and the efforts with vaping cessation (abstinence results).
- We will evaluate nicotine levels in the body for program efficacy via 5 saliva sample (2 at in-person baseline and Week 12 visits and 3 at check-in video calls at Week 6, Week 8, and Week 10); and two urine cotinine tests for biomarker of toxic exposure (only for 20 participants in the biomarker measurement group) at in-person baseline and Week 12 visits)
- We will administer a set of screening questions, baseline/end-study surveys, and vaping-related symptom questionnaires (e.g., wheezing and related respiratory symptoms)-only for 20 participants assigned to the biomarker measurement group).
- For quality improvement and future modification and adoption of vaping cessation programs, we will conduct an exit interview with participants (n=8-12; n=2-3 from each arm based on first available participants) who have completed the final study visit through a video call. We will assess the feasibility, facilitators, and barriers to participation and engagement in the study's vaping cessation interventions.

2. All procedures, interventions, evaluations and tests performed for clinical indication but more frequently than they would be if the subject was not participating in the research (eg, extra blood tests; additional radiology exams)

None.

E. Describe briefly the statistical methods used to analyze the data (or reference the appropriate section of the detailed protocol or grant).
Summary statistics will be reported for all participants and further stratified by each group. Group difference will be compared using chi-square test for categorical variables and ANOVA test for continuous variables. Multivariable regression analysis will be performed to compare the intervention effects, adjusted by age, gender, race/ethnicity. Statistical analysis will be performed using STATA 16.0 (College Station, TX) with $p< 0.05$ to be significant.

F. Does this study involve the collection of blood, urine, saliva or other human biological material (HBM)?
Yes

1. Does this research involve genetic testing including Genome Wide Association Studies (GWAS), Whole Genome Sequencing (WGS) or Whole Exome Sequencing (WES)?
No

G. Does this study involve the creation of a tissue bank for future unspecified research? This includes un-used (excess) blood, urine, or tissue, obtained for clinical indication or for research, or additional human biological material collected specifically for future research.
No

DRUGS, BIOLOGIC DRUGS AND DEVICES

13. Drugs and Biologic Drugs
1. Does this research involve the use of drugs or biologics?
No

14. Devices
1. Does this research involve a medical device(s) (including an in vitro device [IVD] (assay), and medical software)?
Yes

A. Check all that apply:
FDA approved (or cleared) device
FDA unapproved device
♦ In Vitro Device (IVD)

Option chosen: In Vitro Device (IVD)
1. Is the IVD 1) in the laboratory research phase of development, 2) not represented as an effective in vitro diagnostic product and 3) labeled with: "For Research Use Only. Not for use in diagnostic procedures."
No

Option chosen: In Vitro Device (IVD)
a. Is the IVD being shipped or delivered for product testing prior to full commercial marketing and labeled with "For Investigational Use Only. The performance characteristics of this product have not been established."
No

Option chosen: In Vitro Device (IVD)
2. Is the IVD being used in a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure?
No

Option chosen: In Vitro Device (IVD)
3. Is the IVD (a) invasive, or does it (b) require an invasive sampling procedure that presents significant risk; or does it (c) by design or intention introduce energy into a subject?
No

CONFIDENTIALITY AND PRIVACY

15. Confidentiality and Privacy
A. Describe where research data will be stored. Check all that apply.
Box@unmc.edu (secure UNMC or UNO designated cloud-based storage site)
♦ Microsoft Office 365 application (including SharePoint, OneDrive for Business, Teams or Streams) (UNMC, UNO or NU system instance) (secure UNMC or UNO designated cloud-based storage site)
Other secure UNMC or UNO designated cloud-based storage site - describe:
OnCor Clinical Trial Management System (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
CCORDA database (biostatistics) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
♦ RITO-hosted databases (for example, REDCap, CV-QOR, Onchem Trials, XNAT) (secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO)
Nebraska Medicine PACS (for image files) (secure server at UNMC, CHMC, Nebraska

Medicine, and/or UNO)
Other secure server at UNMC, CHMC, Nebraska Medicine, and/or UNO - describe:
On an NSRI or designated high security .gov storage site
On a VA-approved storage vehicle for a VA-approved study
On a remote secure server and/or database maintained by the sponsor accessible through the internet
On a secure server and/or database hosted and maintained by another institution accessible through the internet
On a device or mobile application provided by the sponsor to upload data to a coordinating center or central database
On a device or mobile application being developed by a sponsor or by a UNMC, CHMC or UNO investigator
On a device or mobile application that connects to the internet through UNMC or NM network (wired or wireless)
On an encrypted, password protected portable computer, or flash drive
Other - describe:
In hard copy (other than signed Consent Forms)

B. Will any of the following subject identifiers be recorded (at any time) in association with the research data?
Yes

1) Indicate the subject identifiers that will be recorded. Check all that apply.
♦ Name
♦ DATES (e.g. date of study visit, date of sample collection, birth, admission, discharge)
♦ Postal address information: street address, city, county, precinct, ZIP code
♦ Telephone numbers
Fax numbers
♦ Electronic mail addresses
Social Security numbers
Medical Record numbers
Health plan beneficiary numbers
Account numbers
Certificate/license numbers
Vehicle identifiers and serial numbers, including license plate numbers
Device identifiers and serial numbers
Web Universal Resource Locators (URLs) Internet Protocol (IP) address numbers
♦ Biometric identifiers, including finger and voice print
Full face photographic images [and any comparable images]

No Identifier

2) Will a unique subject identifying number (e.g., S1, S2, S3), characteristic or code be used to link data to any of the identifiers listed above?
No

3) What is the justification for recording the specific subject identifiers listed above? Check all that apply.
♦ Schedule appointments
Collect continuous clinical information from the medical records
♦ Follow-up with subjects
Link stored tissue with subject identification for it to be withdrawn in the future if requested
♦ Compensation
Other. Explain.

4) How long will the subject identifiers be maintained in association with the research data?
Subject identifiers will be removed following the study completion.

5) How will all of the identifiable research data be destroyed (e.g., all identifiers stripped from the data and destroyed, hard copies shredded etc) when the identifiable data is no longer required?
All identifiable research data will be deleted and removed from all computers that it is stored in with the assistance of UNMC ITS.

C. Will research data that contain subject identifiers be disclosed to:
Other investigators at UNMC, NM, UNO or CHMC who are not listed in Section I of this application?
No

2. Investigators outside of UNMC, NM, UNO or CHMC?
No

3. Will research data that contain subject identifiers be disclosed to any commercial sponsor or contract research organization (CRO), or to any other external organization or entity (e.g., NCI cooperative groups)?
No

D. What provisions will be in place to protect the subject's privacy? Check all that

apply.
♦ Ensuring that only personnel listed on the IRB application Section I.3(A-E) are present during the consent process.
♦ Ensuring that the fewest number of individuals possible are aware of the subject's participation in the research.
♦ Ensuring that the research activities are performed in as private of a place as possible.
Other. Explain.

E. Does this research involve data banking at UNMC, NM, UNO or CHMC, or by an outside organization (e.g. NCI Cooperative Group, pharmaceutical company) for future research that is not related to this study?
No

RISK/BENEFIT ASSESSMENT

16. Potential Risks
What are the potential risks associated with each research procedure, intervention, evaluation and/or test? If data are available, estimate the probability that a given harm may occur and its potential reversibility.
The risks associated with the measurements proposed in this study are minimal; these tests are not different from tests used in standard care for smoking/vaping/substance use individuals. Th saliva and urine nicotine samples are both non-invasive. The risks associated with the vaping cessation program consisting of education lessons and text-messaging support program (i.e., This Quitting) are minimal. Online questionnaires, live video call, and/or financial incentive may make participants uncomfortable, but they may choose not to answer any question, participate in the video call, or receive final rewards. Participants may experience some withdrawal symptoms due to initiating quitting. Moreover, for participants whose response for the mental health related question are above the threshold, the research team will provide resource at Nebraska Family Helpline at 888-866-8660.

In addition, the potential risk includes possible loss of confidentiality, which our team will strive to avoid by using de-identified data during statistical analysis, only giving individuals listed in this protocol access to the data collected, and storing all data on a password-protected
computer.
Moreover, the risk of participation in the exit interview is minimal.The information shared with the study investigator or staff will be kept confidential to the fullest extent of the law, and the final reports will not include any identifying information.Some participants may be

uncomfortable in an interview setting though the focus on ways to improve cessation is not a highly reactive topic. There are also risks to the privacy and confidentiality of audio recordings. The seriousness of this risk is low. We believe the benefits to provide input to refine the vaping cessation program that can help improve young adult abstinence outcomes far outweigh the risks. These risks will be presented to the participants prior to participation, and if the subject is interested in study participation, informed consent will be obtained.

17. Risk Classification
What is the overall risk classification of the research?
♦ Minimal risk
Greater than minimal risk

18. Minimization of Risk
A. Describe how the subjects of the research will be monitored by the investigators and other research personnel to ensure their safety.
The PI and the research team will be responsible for monitoring all aspects of the study and ensure the trial is conducted according to the approved protocol. Serious adverse events will be reported in a timely manner to the research team, if disclosed by a participant. Reports on participation, engagement, retention, and participant flow will be provided to the PI for review on a weekly basis. In addition, during the 3 scheduled video calls (Week 6, Week 8, and Week 10), research staff will check in with participants to see if there is any question-related to the conduct of the study.

In addition, subjects will be notified that they may stop at any time if they feel any discomfort during the cessation process, and report any adverse events to the research team via email or the phone call.
For participants who participate in the exit interview, they will be informed before the interview that participation is voluntary and they may stop the interview at anytime.

B. Describe how the data collected will be monitored to ensure the safety of subjects. Identify who will perform the ongoing data and safety analysis, and describe the frequency of data analysis. If there is an independent Data and Safety Monitoring Board (DSMB) provide the charter, or describe (1) the composition of the DSMB membership, (2) the frequency of DSMB meetings and reports.
Though participation in the intervention conditions and completion of assessment points are of minimal risk and participants are not masked, the study will monitor participation, engagement, and retention throughout the study period. The PI and the research team will be responsible for monitoring all aspects of the study and ensure the trial is conducted according to the approved protocol. Data will be reported to the PI and be reviewed together

with the research team to ensure the study is moving forward at the proposed rate. Serious adverse events will be reported in a timely manner to the research team, if disclosed by a participant. Reports on participation, engagement, retention, and participant flow will be provided to the PI for review on a weekly basis.
Due to the low risk of the intervention program and the pragmatism of the pilot trial, the data and safety monitoring board will not be appointed. However, the data safety and monitoring plan will be tabulated and presented to the PI and the research team on a monthly basis. Participants will be asked to report any adverse events with the participation in the vaping cessation program at any time during the run-in phase and abstinence phase of the proposed trial or the contact with the research team. Participant reports on adverse event rates and participant receipt of intervention components will be reviewed by the PI and the research team on a monthly basis. Any deviations from participation, engagement, and retention projections will be discussed within the research team for review and possible action.
Given the low risk of adverse events as a result of participation in this study, it is unlikely that the rates of these events will necessitate stopping the trial. Nonetheless, the research team will monitor the rates of participant disclosure of any adverse events and report unexpectedly high rates to the IRB.

C. Describe the auditing plan for research conducted. Identify who will conduct the audits and specify the audit frequency.
The PI will review the data once a week to ensure it is being carried out according to the protocol submitted in this IRB application.

D. Describe the specific subject withdrawal criteria.
Individual subjects will not be removed from the research by the investigator unless they request to be removed from the study.

Moreover, participants will not be removed from the study if they do not complete acertain percentage of the required research procedures (do not complete education, do not register for the app, do not answer phone calls, etc.).

E. Describe the stopping rules for the research (e.g., the specific criteria for halting or early termination of the study).
Given the low risk of adverse events as a result of participation in this study it is unlikely that the rates of these events will necessitate the stopping of the trial. Nonetheless, we will monitor the rates of adverse events and report unexpectedly high rates to the IRBs. Other potential reasons to discontinue the trial, in an extreme case, could be: 1) that the treatment demonstrates a large magnitude of benefit, 2) that early in the trial we will be able to determine that there is no likelihood of demonstrating a treatment effect, 3) poor

recruitment, or 5) poor retention of participants.

F. Describe plans and resources available to promptly address any subject injury.
Participants that experience a research-related injury will be encouraged to contact their primary care physician and contact PI or the research staff immediately. PI and the research team will review the case and communicate with participant's primary care physician for any followup.
In addition, participants will be asked to report any adverse events with the participation in the vaping cessation program at any time during the quitting preparation and abstinence phases of the proposed trial or the contact with the research team. Participant reports on adverse event rates and participant receipt of intervention components will be reviewed by the PI and the research team on a monthly basis. Any deviations from participation, engagement, and retention projections will be discussed within the research team for review and possible action.

19. Potential Benefits to the Subject
Is there the prospect for direct benefit (eg, research on diagnosis or treatment of disease)?
Yes

Describe potential benefits to the subjects that may reasonably be expected from participation in the research, if any. If there are therapeutic and non-therapeutic components of the research, address anticipated benefits to subjects that may reasonably be expected from each of these components.
Benefits may include complete cessation or reduction of use of tobacco and nicotine from e-cigarettes.

20. Potential Benefits to Society
Describe the potential benefits to society that may reasonably be expected to result from this research.
As there is limited research on how incentive-based and media literacy-informed approaches to facilitate vaping cessation (especially among young adults), this study may lead to novel multi-component interventions to increase the vaping abstinence rates.

ALTERNATIVES TO PARTICIPATION

21. Alternatives to Participation
1. Describe the likely care the subject would receive <u>at this institution</u> were he/she not to participate in the research. If there are more than one reasonable courses of treatment briefly describe.

UNMC offers a nicotine dependence clinic (cigarettes, dip, other forms of nicotine products) that has dependence counseling services with a qualified professional. Clinicians at this clinic offer counseling, pharmacotherapy (nicotine replacement therapy), and lung screening for high-risk patients. Services are offered at a cost.

2. Is the potential benefit of the research at least as good as the potential benefits of the alternatives described above?
Yes

3. Are there any reasonably available alternatives outside this institution which would have the potential for providing benefit to the subjects outside the research context?
Yes

a. What are the reasonably available alternatives?
Other institutions have similar nicotine dependence clinics similar to the clinic described above.

4. Would any of the study procedures or courses of treatment in the protocol be available to the subject if they elected not to participate?
Yes

a. Explain.
Participants who choose not to participate or withdraw from the study, will still have access to the SMS text-based quitting support program (This is Quitting), and cotinine testing (saliva samples).

5. Would the research intervention be available outside the context of research?
Yes

6. Are there any treatments that the subject would be denied as a consequence of participating in research that he/she would have received had he/she not participated?
No

7. How do the risks of the research compare with the risks of alternative procedures or courses of treatment described above?
There are some risks associated with pharmacotherapy (nicotine replacement) treatment that may be applicable to the treatment options mentioned above. Given that this study simply includes ono-invasive interventions- media literacy e-learning lessons, text-messaging support programs, and financial incentives, the risk of research is minimal or

comparable to the risk of alternate procedures.

FINANCIAL OBLIGATIONS AND COMPENSATION

22. Financial Obligations of the Subject
A. Who will pay for research procedures, interventions, evaluations and tests? Check all that apply.
Sponsor
♦ Grant
CRC, CCTR
Costs or fees waived by Nebraska Medicine, UNMC- P, CHMC or CSP
Department/Section funds
♦ Other. Explain faculty fund

B. Will any of the research procedures, interventions, evaluations and tests described above be charged to the Subject, the Subject's health insurance, or Medicare/Medicaid?
No

C. Are there any other financial obligations that the subject will incur as a result of participating in the study?
Yes

1. Provide additional detail
While signing up for the text-messaging support program, participants will be responsible for standard data/text messaging rates.

23. Compensation to the Subject for Participation
A. Will the subject receive any compensation for participation?
Yes

1. Describe the form of compensation, dollar amount (if applicable) and the prorated compensation plan (if applicable).

- All participants will receive $25 worth Visa giftcard each for attending the in-person baseline (Week 0) and end-of-study (Week 12) sessions .
- Moreover, for 20 participants who volunteer to provide the urine samples, they will receive additional $10 for completing the urine sample at baseline (Week 0) and end-of-study (Week 12) visits ($20 total).
- For participants who are assigned to*the Financial incentive*or*Combined* groups, they

can have additional possible earning of $70. Participants will save up all the earning until the end of study for a one-time payment (via visa giftcards).

- In total, participants who assigned to the *Active control*or*Media literacy* groups will receive up to $50 payment ($70 if they are also in the biomarker measurement group).
- Participants who are assigned to the*Financial incentive*or*Combined* groups will receive up to $120 ($140 if they are also in the biomarker measurement group).
- Participants who participate in the exit interview will receive $25 Visa giftcard.

PRIOR REVIEW

24. Prior IRB Review
A. Has this study (or one substantially similar) been previously submitted to the UNMC IRB (or the Joint Pediatric IRB) and then withdrawn by the investigator for any reason?
No

B. To the best of your knowledge, has this study (or one substantially similar) been considered by another IRB and disapproved?
No

SUBJECT IDENTIFICATION & RECRUITMENT

25. Method of Subject Identification and Recruitment
A. Will prospective subjects learn about the research and then contact the investigator about participation (for example, in response to a print, electronic, radio or television advertisement; referral by a clinician or other specifically for this research)?
Yes

1. If so please describe how prospective subjects will become aware of the research (for example, by a print, electronic, radio or television advertisement, or thru another mechanism)?
Study participants will be identified and recruited via email through MyChart/Epic at University of Nebraska Medical Center (UNMC) in addition to recruitment flyers distributed in the community. In addition, we will also supplement the EHR potential participant list by social media recruitment strategies (e.g., Facebook advertisement to the Omaha metropolitan area) if we are not able to reach our recruitment goal (n=80) with the EHR list. We will recruit 80 young adults aged 19-29 years old.
We will work with UNMC EHR data access core to identify a potential participant pool. A recruitment/screening email will be sent to patients aged 19-29 with an opt-in for research indication through the Epic patient portal. The email and the flyer will ask if participants are

interested in participating in the study and provide contact information for any questions. If an interested patient contacts the research team because of the recruitment flyer or other mode outside of the recruitment email, the interested patient will be sent the recruitment/screening email to keep the consenting process consistent throughout the study. The recruitment/screening email will include a link to a REDCap with the screening questions to determine their eligibility. Interested individual will complete a brief online screening to determine their eligibility.
In the social media recruitment strategy, the Facebook advertisement information will include a URL link to the REDCap screening survey. Similar to the EHR list recruitment strategy, interested potential participants will be instructed to compete the screening survey to determine their eligibility. The recruitment and enrollment process after completing the screening survey is identical across EHR list and social media recruitment strategies. We will work with VCR recruitment team to implement the social media recruitment strategy.

2. Who will be responsible for receiving these inquiries from prospective subjects?
The project coordinator and/or PI will be responsible for receiving these inquiries from prospective subjects.

3. Will prospective subjects be screened for eligibility prior to informed consent?
Yes

a. What information will be collected prior to informed consent?
Interested individuals will complete an online screening through RedCap to determine their eligibility prior to informed consent. Screening questions includes current age, frequency of vaping, access to internet/video chat/SMS text message or not, and intention/desire to quit.

B. Will the investigator make the initial contact with the potential subject to tell him/her about the research (for example, by contacting existing or past previous patients or research participants; or by contacting prospective subjects thru school records, or thru support groups or other Interest Groups; or thru use of the Hospital Opt-In Database)?
Yes

1. How will prospective subjects be identified?
We will work with UNMC EHR data access core to identify a potential participant pool. A recruitment/screening email will be sent to patients aged 19-29 with an opt-in for research indication through the Epic patient portal.

2. Will potential subjects be screened for eligibility prior to informed consent?
Yes

a. What information will be collected prior to informed consent?
Interested individuals will complete an online screening through RedCap to determine their eligibility prior to informed consent. Screening questions includes current age, frequency of vaping, access to internet/video chat/SMS text message or not, and intention/desire to quit.

b. By whom?
Interested individuals will complete an online screening through RedCap by themselves to determine their eligibility prior to informed consent. If an interested individuals contacts the research team because of the recruitment flyer or other mode (e.g., social media) outside of the recruitment email (e.g., see the flyer in the community), the research staff, listed on the IRB protocol will conduct the phone screening using the RedCap to determine his/her eligibility. If the individual is eligible, the research staff will obtain a verbal consent from the individual and enroll him/she in the study and email him/her a copy of informed consent.

c. Does that person have ethical access to information about potential subjects?
Yes

i. Describe
We will work with UNMC EHR data access core to identify a potential participant pool. A recruitment/screening email will be sent to patients aged 19-29 with an opt-in for research indication through the Epic patient portal. All study personnel will complete required CITI training. Except the recruitment email sent to potential participants, the research will not make the initial contact.

3. How will potential subjects be approached and invited to participate?
The research team will work with UNMC EHR data access core to identify a potential participant pool. A recruitment/screening email will be sent to patients aged 19-29 with an opt-in for research indication through the Epic patient portal.
Potential participants may also see the Facebook advertisement and complete the screening survey included in the advertisement.

a. Describe the process of initial contact
A recruitment/screening email will be sent to patients aged 19-29 with an opt-in for research indication through the Epic patient portal.

b. Who will make the initial contact?
Except the recruitment email sent to potential participants, the research will not make the initial contact.

c. Does that person have ethical access to information about potential subjects?

Yes

i. Describe
All study personnel will complete required CITI training. Except the recruitment email sent to potential participants, the research will not make the initial contact.

C. Will this study be listed in the clinical trial registry at www.clinicaltrials.gov?
Yes

1. Provide the NCT#.
NCT05586308.

2. Identify who holds the NCT#
♦ PI
Sponsor

OBTAINMENT OF INFORMED CONSENT

26. Waiver or Alteration of Informed Consent
A. Is a complete waiver or alteration of consent requested?
No

27. Waiver of Signed Consent
Is a waiver to obtain signed consent requested?
No

29. Process of Informed Consent
A. When will the prospective subject/parent(s)/guardian(s)/LAR be approached relative to their/the subject's actual participation in the study?
Approximately 10 days prior to the baseline visit, individuals that are interested in participating in the study will be mailed an initial packet with the informed consent, and a letter with instructions for their initial visit. The information on the consent will also be reviewed at the baseline visit.

B. Where will informed consent be obtained, and how will the environment be conducive to discussion and thoughtful consideration?
All interested individuals will have the opportunity to review and sign the informed consent at home, prior to their initial visit. To ensure that all potential participants have a strong understanding of the study, there will be a presentation of the information contained on the

consent form and, if the individual has questions about what is stated in the informed consent, he/she will have the opportunity to discuss those questions with a member of the research team on a one-on-one basis. The individual may then choose to sign or not to sign the informed consent.

C. Who will be involved in the process of consent and what are their responsibilities?
At the baseline visit, trained research assistants/staff will review the informed consent and answer any questions the patient may have. Once the informed consent is signed, a research assistants/staff will conduct the baseline activities, including completing the survey questionnaires, and providing saliva and urine samples.

D. Is there any limitation on the amount of time allotted to the process of consent?
No

E. How will the process of consent be structured for subjects who are likely to be more vulnerable to coercion or undue influence?
Participants will be given time to ask questions about the consent process and provide feedback on their understanding of the study and procedures. Participants will also have the opportunity to discuss participation with family or friends.

F. Will non-English speaking subjects be enrolled in this research?
No

Provide justification for exclusion of non-English speaking subjects
At this time the study materials including the SMS text-messaging cessation support and media literacy e-learning lessons are only available in English.

G. How will it be determined that the subject/parent(s)/guardian(s)/LAR understood the information presented?
After the reviewing the consent document together with the study staff, potential participants will be ask to articulate in their own words what the study is about, and what they might be asked to do to participate. Only when the study staff is satisfied the subject comprehends all of the elements of informed consent will they sign the consent form.

31. Information Purposely Withheld
Will any information be purposely withheld from the subject during the research or after completion of the research?
No

RESOURCES

33. Describe the resources available to safely conduct this study at <u>each</u> study sites specified in Section I.7.

- UNMC Clinical Research Center The Clinical Research Center for in-person baseline and end-of-study visits
- REDCap platform for conducting survey

LITERATURE REVIEW

34. References

Provide a full listing of the key references cited in the background (Section II.3). The references should clearly support the stated purpose of the study.

1. Murthy VH. E-cigarette use among youth and young adults: a major public health concern. *JAMA pediatrics*. 2017;171(3):209-210.
2. Cornelius ME, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults - United States, 2020. *MMWR Morb Mortal Wkly Rep*. Mar 18 2022;71(11):397-405. doi:10.15585/mmwr.mm7111a1
3. Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. E-cigarette Use Among Middle and High School Students - United States, 2020. *MMWR Morb Mortal Wkly Rep*. Sep 18 2020;69(37):1310-1312. doi:10.15585/mmwr.mm6937e1
4. U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. *Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health*. 2016;
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SECTION III

SUBMISSION DEADLINE

A. Full Board Review:
The IRB meets twice monthly, on the first and third Thursday of the month, with the exception of January and July when the IRB meets only on the third Thursday of the month. No more than 15 applications (e.g., initial review of a new study, re-review of a tabled study) will be reviewed at each meeting. All reviews are performed on a first-come first-served basis. The IRB meeting schedule and deadline dates can be found on the IRB website at www.unmc.edu/irb.

B. Expedited Review
Applications that qualify for expedited review have no submission deadline and can be reviewed independent of the IRB meeting schedule. Call the Office of Regulatory Affairs for assistance in determining if your study meets the requirements for expedited review.

ADDITIONAL REVIEW REQUIREMENTS

Final IRB approval and release of studies is contingent upon approval by the following UNMC committees or departments. Check the appropriate boxes:
UNMC and NM - Pharmacy & Therapeutics (P&T) Committee (Required for studies involving drugs)
Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) (Required for studies involving cancer)
Institutional Biosafety Committee (IBC) (Required for studies involving the use of gene transfer and vaccines)
Investigational Device Review Committee (IDRC) Review by the IDRC is required for all protocols involving the use of investigational or marketed devices
Billing Grid (Required for all studies involving billing for hospital/clinic services)
Coverage Analysis (Departments requiring this analysis have been specified by the Organization)
Conflict of Interest (COI) Management Plan (Required for all studies with declared COI by study personnel)
♦ **Sponsored Programs Administration (SPA)/UNeHealth** grants and contracts
Pathology approval for collection of tissue samples required for this study
Radiation Committee Approval
Other Review
None of the above organizational requirements apply to this study

SECTION IV

COVID-19

Human Subjects Research Safety Plan
For studies involving face-to-face encounters, the research team under the responsibility of the principal investigator will agree to comply with the following safety measures:

1. **Masking of the researcher(s) during a face-to-face encounter**
2. **Cleansing of any surface and/or equipment utilized before and after a subject encounter**
3. **The Biosafety Officer (jenna.mckenzie@unmc.edu) will be notified if obtaining saliva, nasal, sputum or stools samples to ensure safe collection, handling, and processing plan is in place**
4. **Suggest addressing the current health of the subject before commencing face-to-face research via questions below:**
    - **Have you or anyone in your household tested positive or had a fever, chills, cough, shortness of breath, diarrhea, nausea, vomiting, recent loss of taste or smell, tiredness or fatigue, or muscle aches? If yes, the monitor will not be allowed on campus.**
    - **Have you recently traveled to an area with a widespread outbreak or had close contact with a person known to have COVID-19, MERs-CoV or Ebola?**
    - **Have you traveled outside of the country within the past month? If so, where did you travel and when did you return?**
    - **Have you had a recent SARS-COV-2 antibody test or nasal swab and if so when and what were the results?**

♦ I acknowledge this requirement.