A Pilot Trial to Prevent Intoxicated and Impaired Driving Among Adolescents

Study Protocol

NCT04959461

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1. PURPOSE OF THE STUDY

a. Brief Summary

The purpose of this study is to evaluate the efficacy of a single- session web-intervention called webCHAT in reducing impaired driving among teens enrolled in driver education.

b. Objectives

We hope to learn whether providing webCHAT reduces alcohol and cannabis use and intentions to engage in impaired driving.

c. Rationale for Research in Humans

The purpose of this study is to test the efficacy of a behavioral intervention called webCHAT compared to usual driving school services.

2. STUDY PROCEDURES

a. Procedures

When the PI was at RAND, RAND staff conducted the qualitative focus groups and interviews with staff and teens. RAND will no longer be conducting research on human subjects. The activities described in 2a will only be Stanford's role.

All measures will be collected via WebCHAT, which is a system designed by the 3C Institute.

BETA-TESTING/DEBRIEFING INTERVIEWS
Stanford is interested in recruiting 8 to 10 15.5-17 year old adolescents attending behind-the-wheel classes at two driving schools who report having access to a computer or smartphone, and are within a month of taking their licensing exam. The purpose of their involvement is for them to provide feedback on our materials prior to starting our RCT phase of the study. Driver education staff will provide parents a flyer or show a powerpoint slide with the study project's website to sign up for the study. Parents go to the website to review study details and sign written informed consent if they would like their teen to participate. Parents then provide their teen's contact information, teens receive project information, complete a screener, and then sign assent if eligible. At this point, a Stanford staff member will contact the teen to assess eligibility, send them the online consent and baseline survey. After the teen participant completes the baseline

survey, they can view the webCHAT intervention online (single session), and then will complete a phone debriefing interview with a Stanford staff member. Teen participation is complete after this interview.

RCT PROCEDURES
Similar to the beta-testing, parents and teens will be recruited in the same manner. After the teen completes their baseline survey, they will be randomized to webCHAT or usual care. If assigned to webCHAT, they can also complete the 20-minute self-guided web-intervention in that sitting. Teens then would complete online surveys 3 and 6-months after baseline.

COORDINATION & DATA COLLECTION
Our research coordinator (Kat Nameth) at Stanford site will be responsible for all recruitment and data collection of WebCHAT participants. We will have monthly meetings with the other sites to update and plan for recruitment, update on enrollment, any concerns and unanticipated or adverse events. All conversations will be documented via a WebCHAT meeting minutes document, that is centrally stored in a secure location on Box. Any protocol modifications or interim findings that are to be made or discovered will also be discussed at these meetings amongst the full research team to ensure updates are consistent with both sites. RAND will no longer be participating in any human subject research.

RECRUITMENT
Parents can go to the webCHAT website to consent and provide their teen's contact information

b. Procedure Risks

Parents provide informed consent and teens provide assent. Both parents and teens are informed that participation in the study does not affect services they receive at the driving school. In addition, we use validated measures we've used in more than a decade of adolescent substance use research. All teens receive driving school education about safe driving as part of their licensure requirements.

c. Use of Deception in the Study

N/A

d. Use of Audio and Video Recordings

Prior to the RCT, we will beta-test the webCHAT intervention with 8- 10 teens who will test the program and provide feedback. The feedback interview will be audio recorded.

e. Alternative Procedures or Courses of Treatment

N/A. This is not a trial conducted in a clinical setting.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

N/A. This is not a trial conducted in a clinical setting.

g. Study Endpoint(s)

Participants will complete surveys via WebCHAT at 3 and 6-months after baseline. The study is a pilot study with a small sample and we need the full sample to have adequate statistical power to determine significant findings.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

This same intervention has been evaluated in-person in primary care and uses principles and techniques from our prior research for the past 20 years. These studies have found reduced substance use and related consequences.

b. Findings from Past Animal Experiments

N/A

4. PARTICIPANT POPULATION

a. Planned Enrollment

8-10 teens for beta-testing the intervention, 150 teens for the RCT Teens 15.5-17 yo enrolled in driver education schools

b. Age, Gender, and Ethnic Background

15.5-17 yo, all genders/race/ethnicity

c. Vulnerable Populations

8-10 teens for beta-testing the intervention, 150 teens for the RCT. We will conduct parental/guardian informed consent.

d. Rationale for Exclusion of Certain Populations

N/A

e. Stanford Populations

N/A

f. Healthy Volunteers

Teens could be healthy volunteers

g. Recruitment Details

Parents attend orientation upon signing up their teen for behind-the-wheel lessons. At that orientation or upon signing them up, driving staff will share a flyer about the study that includes the study website parents can read about the study. All adolescents in the study are required to have parental/guardian consent. Upon parental consent and providing teen contact information, teens will be contacted by a Stanford staff member and described the

study. They will then be given access to an online assent form to sign, will participate in the screening questionnaire, and then complete baseline.

h. Eligibility Criteria

i. Inclusion Criteria

15.5-17 yo teens participating in driver education at one of the collaborating schools and a month away from taking their licensing exam

ii. Exclusion Criteria

Non-English speaking outside age range

i. Screening Procedures

After consent and assent, teens will be screened on the CRAFFT, a 6-item measure that asks if they ever ridden in a CAR driven by someone (including yourself) who was "high" or had been using alcohol or drugs; used alcohol or drugs to RELAX, feel better about themself, or fit in; used alcohol or drugs while they were by themself, or ALONE; FORGET things they did while using alcohol or drugs; their FAMILY or FRIENDS told them they should cut down on their drinking or drug use; or if they ever gotten into TROUBLE while they were using alcohol or drugs. A score of 2 or higher (2 yes responses) is considered positive. The sample will be stratified such that teens screening positive will represent 40%, negative 60%. If eligible, teens will complete assent, and then can complete their baseline survey and be randomized to webCHAT (or beta test it).

j. Participation in Multiple Protocols

Participants will not be enrolled in more than one study. No other research are being conducted at the driving schools.

k. Payments to Participants

Beta-test: $[redacted] for beta testing webchat, competing baseline, and phone interview RCT: $[redacted] for the baseline, $[redacted] post-session (webCHAT), $[redacted] for the 3-month follow-up, $[redacted] for the 6-month follow-up, and then a $[redacted] completer bonus if they finish all assessments.

l. Costs to Participants

N/A

m. Planned Duration of the Study

2-3 years (ending 8/31/2024 if no-cost extension year). Screening is estimated to take less than five minutes, assessments between 20-30 minutes, and webCHAT between 20-30 minutes. Analysis of data is estimated at three months.

5. RISKS

a. Potential Risks

i. Physical well-being

None foreseen

ii. Psychological well-being

Teens may feel embarrassment/discomfort by survey items that ask about driving under the influence attitudes and behaviors.

iii. Economic well-being

None foreseen

iv. Social well-being

None foreseen

v. Overall evaluation of risk

Low

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b. Procedures to Minimize Risk

Informed consent, teen assent, voluntary nature of the study ensures that adolescent participants are aware of what they are disclosing and how that information will be used. Data will not be shared with parents or the driving school body and all data will be analyzed in aggregate, de-identified. This ensures there is no way that a participant could face civil or criminal liability for information disclosed during our study. Discomfort with disclosure. Staff who collect survey data will be coached by Dr. Osilla on how to respond to embarrassment or discomfort in an appropriate and compassionate manner. Participants will also be encouraged to contact the project PI in the event of a later adverse reaction and will receive specific written (in the form of a project description and PI's contact business card) and verbal instructions during the project consent procedures about how to do so, if needed.

We are collecting sensitive information, such as use of alcohol, tobacco, and other illegal drugs. Parents and youth are informed of the content before the survey is administered and parents must give permission for their son or daughter to participate. In addition, youth may choose to refuse to complete the survey or answer any question that may make them uncomfortable during the actual survey.

Mandatory reporting. One serious adversity a participant may encounter is the possibility that staff must report to authorities the instances of physical abuse, neglect or threat of physical harm among participants to themselves or others. To anticipate these concerns, the project has established procedures and guidelines to respond to risk disclosures and crisis situations. Research staff will be trained to recognize risks or crises that require immediate reporting response.

Each of the possible adverse events is described in detail, including background, criteria for emergency action, and non-emergency action. Please note that these emergency procedures will be discussed in detail with each site to ensure that we collaborate with them on these procedures and follow clinic procedures in that setting. For example, AAA

sites may prefer that we check in with them before we contact emergency services, such as calling 911, so that they are fully informed of the situation.
One potential risk is breach of confidentiality related to collection of sensitive information. Contact information will be transported directly to STANFORD and locked in a secure project room and when data entered, stored only on SRG's secure server. Risk of disclosure is unlikely, but if it were to occur, would involve only address and phone information – no social security numbers, driver's license numbers or any other highly sensitive information is being collected.
Surveys are completed via internet and will not contain personal identifiers. The link file will be stored electronically on SRG secure server and will be accessible only by SRG's project staff.
Parents and driving school staff may have interest in an individual's data; however, they are informed that findings are only described in general summaries and that they will not have access to an individual's data at any time, and that driving school services will not be affected by research participation or non-participation.

c. Study Conclusion

All surveys are online and not interviewer administered - thus, the chances of risk/safety disclosure to research staff are low. In the even research staff are on the phone with a teen at risk of harm to self or others, they will call 911 and/or conduct a warm transfer to the National Suicide hotline.

6. BENEFITS

Tools for preventing impaired driving and not using substances in risky situations.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.