H-35254- CHOICES4HEALTH: A TABLET BASED INTERVENTION TO PREVENT SUBSTANCE-EXPOSED PREGNANCY IN PRIMARY CARE

Background

You are invited to take part in a research study because you are a woman of child-bearing age. Please read this information and feel free to ask any questions before you agree to take part in the study. Your participation is entirely voluntary and you can refuse to participate without penalty or loss of benefits to which you are otherwise entitled.

This research study is funded by National Institutes of Health

Purpose

This study is being conducted because we want to compare the effects of three interventions: CHOICES4Health delivered by a counselor (C4H-C), CHOICES4Health delivered by a computerized tablet, and Brief Advice (BA). Up to 240 women will take part in this study. This research will give us evidence as to which approach is best for helping women avoid substance-exposed pregnancies by reducing alcohol and marijuana use, increasing use of effective contraception and encouraging smoking cessation.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston.

Initial Interview: After giving written consent to take part in this study, a research assistant will conduct an interview that should last approximately 45 minutes. Subjects will include frequency and quantity of substance use, contraceptive practices, smoking practices and prior use of substance abuse treatment services. Questionnaires and other research materials will be used to help gather this information. Also, you will be asked questions about education, income, religion, family composition and marital status. You will be asked to provide saliva samples to be tested for nicotine and THC, the active component in marijuana. Briefly, the collection of the sample requires that you place the saliva swab in your mouth for approximately 2 minutes to absorb your saliva, place the swab into the container included in the package, seal the container tightly and then hand it back to the interviewer. The results of these tests are for research purposes only and your name will not be included on the saliva sample.

Interventions: You will participate in one of the following interventions designed to help you make changes in risky behaviors.

1. Brief Advice/Treatment As Usual (BA): You will receive advice and educational material from the research assistant (RA) about womens health. In addition, as part of your visit for medical care, you may be asked by your health care provider (physician, nurse, physician assistant, or nurse practitioner) about your use of alcohol or tobacco and your sexual activity and any contraception you are using. Depending on your responses, your healthcare provider may provide advice for changing these behaviors, including recommendations for additional services.

2. CHOICES4Health-Counselor (C4H-C) Intervention: The CHOICES4Health intervention will consist of the following:

Two counseling sessions conducted by a trained counselor. These sessions will focus on your drinking, smoking (tobacco and marijuana), sexual activity and your contraceptive practices. These sessions will include a discussion of options and plans for changing behaviors you may want to change.

A contraceptive consultation at an appropriate community clinic. This consultation will include a discussion of contraception options and, if desired, a prescription for contraception.

Referral to a smoking cessation program.

CHOICES4Health counseling sessions will be audio recorded using digital recorders. This will be done to provide oversight and ensure that study counselors are correctly using the techniques designed for this intervention. Your name will not appear on the digital audio recording file. Only your first name may be heard on the recording. No other personal identifying information will be associated with the digital file. The digital file will be stored on password protected computers. No one other than study staff will listen to the digital recordings. Like other materials collected for the study, the digital recordings are confidential and every effort will be made to protect your privacy. The digital recordings will be retained on the password protected computer for possible future analysis.

3. CHOICES4Health-Tablet (C4H-T) Intervention: The CHOICES4Health intervention delivered on a computer tablet will consist of the following:

Two counseling sessions delivered by an animated narrator on a tablet computer. The same two-session intervention goals, components, and motivational style of delivery described in C4H-C will be adapted for inclusion in the tablet version of the intervention so that C4H-T mirrors the C4H-C intervention.

A contraceptive consultation at an appropriate community clinic. This consultation will include a discussion of contraception options and, if desired, a prescription for contraception.

Referral to a smoking cessation program.

Follow-up Sessions: Interview sessions similar to the initial interview will occur at 3- and 9-months after the initial study interview. In addition, there will be a brief phone assessment at 6 months. You will be asked to provide saliva samples (like at the initial interview) to test for nicotine and THC at the 3 and 9 month interviews.

Project Duration:
This study should take approximately 4 years to complete. Your participation will be for 9 months. Actual time required is outlined below:
1) The Initial Interview will take between 45 minutes to 1 hour.
2) The two intervention sessions will be between 45 minutes and 1 hour each.
3) The contraceptive consultation should last between 20 to 30 minutes.
4) The follow-up interview at 3 months will take about 45 minutes to 1 hour.
5) The follow-up interview at 6 months will be a brief phone check in interview that will take about 5 to 10 minutes.
6) The follow-up interview at 9 months will take about 45 minutes to 1 hour.

The total number of hours over the 9 months of your participation in the study will be between 4 hours and 5 ½ hours. It is important that you seriously consider whether you want to commit yourself to the full time requirement of this study before you make a decision about whether you can complete the requirements.

In addition, if you chose to participate in the optional smoking sessions at Harris Health System (Fresh Start), the program has four 1-hour sessions and you may attend as many as you wish. Alternatively, you may decide to participate in the Quitline Fax Referral program, which offers 3 or more telephone counseling sessions, linkage to community-based smoking cessation programs, access to the nicotine replacement therapy patch and recorded tips on quitting. Again, you may decide to access any or none of these services.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Other: Audio digital recordings of intervention sessions.

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, UT: Health Science Center - Houston, and NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA) and their representatives.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, Data and Safety Monitoring Board, HCHD: Harris County Hospital District, UT: Austin, and UT: Health Science Center - Houston may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Mary Marden Velasquez
The University of Texas at Austin
School of Social Work
1 University Station, D3510
Austin, Texas 78712-0359

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts
Risks to you as a participant in this study are considered minimal. Though unlikely, you may experience distress caused by answering questions about mental health, alcohol use, smoking and drug use, sexual behavior, or potential harm to a fetus. Should this occur, you will be encouraged to consult with the principal investigator, Dr. Mary M. Velasquez, to discuss avenues for managing your distress. You may also be referred to a Harris Health System provider for further attention. You will be asked to

provide saliva samples at different times during the study. There are no known risks of producing saliva samples. No individual other than research staff will have access to both the results of the lab work and your personal information. In addition, we take careful steps to protect your confidentiality.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: to reduce risky alcohol, marijuana, and tobacco use, and to increase your use of effective contraception, reducing your overall risk of a substance-exposed pregnancy. Findings from this study may also help other women reduce such risks in the future.. However, you may receive no benefit from participating.

Alternatives
You may choose to not participate in this study.

Subject Costs and Payments
You will not be asked to pay any costs related to this research.

Participants will receive compensation in the following amounts: $75 for the initial interview, $20 for participation in the second CHOICES4Health session (if applicable), $50 for the 3- month interview, and $75 for the 9-month interview. There will not be any compensation for the brief 6-month telephone check-in assessment. No reimbursement is offered to you for hospital and/or physician costs. You bear primary financial liability for all hospital and physician costs.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ALICIA ANN KOWALCHUK, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ALICIA ANN

KOWALCHUK at 713-798-4491 during the day and KIRK VON STERNBERG at 512-779-3313 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

In the event of injury resulting from this research, Baylor College of Medicine and the Harris Health Systems are not able to neither offer financial compensation nor absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

HARRISHEALTH SYSTEM

IRB Number: H-35254
Approval Date: 09-05-2019
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