HIV and Alcohol Research center focused on Polypharmacy (HARP) Pilot 1

ClinicalTrials.gov ID NCT05560932
Sponsor Yale University
Information provided by Yale University (Responsible Party)

Consent Form

Approved February 10th, 2023

Information Sheet

Research Study Summary

- We are asking you to join a research study.
- Approximately 50 subjects will be asked to participate.
- The purpose is to learn how to help people who take 5 or more medications, and drink alcohol decrease their use of alcohol and or medications to decrease their bothersome symptoms. We are also interested in learning how to communicate personal health risks associated with alcohol and medication use.
- Study activities include:
    - Completing a fingerstick blood test on your own, which we will provide instructions for, that measures recent alcohol use. This may take up to 20 minutes.
    - Completing a survey regarding bothersome symptoms, alcohol and current medication use. This should take 5-10 minutes.
    - Participating in a first telephone call with the clinical pharmacist, who will briefly review your medications and discuss possible associations between your bothersome symptoms and your use of alcohol and medications. This may last up to 45 minutes.
    - Keep track of changes in your alcohol consumption, medications, and bothersome symptoms using a worksheet that we provide.
    - Participate in a second follow-up telephone call two weeks after the first call to discuss how things are going. This should last no longer than 30 minutes.
    - After the follow up telephone call, complete a brief follow up survey. This should take 5-10 minutes.
    - 30 days after the follow-up telephone call, complete another fingerstick blood test and follow up survey. This should take no longer than 30 minutes.
    - Finally, we MAY recontact you to participate in a final interview with one of our colleagues to speak with you about your experience with the study. This interview will take approximately 30 minutes.
- Without the final interview, your involvement will require approximately 2.5 hours. If you are chosen and participate in the final interview, the total time will be 3 hours.
- There may be some risks from participating in this study.
    - You may experience some discomfort from the fingerstick.
    - You may feel emotional discomfort as a result of completing the surveys.
    - The clinical pharmacist will be speaking with your VA HIV clinician prior to her phone call with you regarding:
        - Any of your medications that have significant interactions with each other or with alcohol.
        - Symptoms that you may have consistent with alcohol use disorder.
    - There is also the possible risk of loss of confidentiality.

- The study may have no direct benefits to you. Nevertheless, we hope that through the intervention, you will experience some relief from bothersome symptoms related to your alcohol and/or medication use. We also hope that the tools and skills we discuss will help you decrease your alcohol consumption and talk with your provider about your medications. We hope to benefit others by better understanding how to communicate with patients about their health risks.
- You do not give up any of your legal rights by giving your verbal agreement to participate.
- You will be paid for taking part in this study:
  - Prior to the first telephone call with the clinical pharmacist:
    - You will receive a $25 gift card for returning an adequate first fingerstick blood test.
    - You will receive a $25 gift card once you return the first survey.
  - After the second telephone call with the clinical pharmacist, we will ask you to complete and return a follow up survey. You will receive a $25 gift card when we receive this survey.
  - 30 days after the follow up telephone call with the pharmacist, we will ask you to complete and return another follow up survey and blood spot test. You will receive a $25 gift card for returning the survey and another $25 gift card for returning an adequate second blood spot test.
  - If you complete all the activities above, the total value of the gift cards that you receive for this study will add up to $125.
  - In addition, if you are selected and agree to participate in the final interview, you will receive an additional $50 gift card, meaning the total value of the gift cards that you receive for this study will add up to $175.
  - You are responsible for paying local, state, and federal taxes for the payments you receive for this study. Taxes are not withheld from your payment.
- Taking part in this study is your choice. You can choose to take part, or you can choose to not take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with the VA and your provider. You do not give up any of your legal rights by giving your verbal agreement to participate.

If you are still interested in participating, I can tell you more. Be sure to ask me questions about anything you do not understand.

Shall I continue? Yes No

What information will you collect and how will you keep it safe and private

The information we will collect is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). This law means that we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, you can speak with the VA Privacy Officer at 932-5711 ext 4109 or 6391.

The specific information that we will collect, use, and share, includes:

- Your entire medical record from the VA
- Sex
- Date of birth
- Research study records
- Records about phone calls made as part of this research
- Records about your study visits

All of your responses will be held in confidence. Only the researchers involved in the study and those responsible for research oversight will have access to any information that could identify you. These individuals are all required to keep all information confidential and include:

- The Principal Investigator, the study coordinator, and members of the research team
- The US Department of Health and Human Services agencies
- Representatives from - the - Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants) responsible for ensuring research compliance.
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study.
- Data and Safety Monitoring Boards and others authorized to monitor the study

We have obtained a Certificate of Confidentiality from the Federal Government. This protects your privacy by allowing us not to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

All research information will be secured in locked files (hardcopy) or on a secure server (digital). We may share information about you with other researchers for future studies, but we will not use your name or any personal identifiers.

We will do our best to make sure your information stays private. If we share information with people who do not have to follow the Privacy Rule, agreements are in place with these individuals and/or companies that require that they keep your information confidential. Let us know if you have questions about this.

Why must I agree to the use of my information?

By giving us permission to use your health information, you will allow researchers to use and disclose your information for the purposes of this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose the health information collected during this study will never expire. However, you may withdraw or take away your permission at any time. You can do this by telling the study staff or by writing to Amy C. Justice, MD, PhD VA Connecticut Medical Center 950 Campbell Ave West Haven Ct 06516.

If you withdraw your permission, you will not be able to stay in this study, but the care you get from your regular healthcare provider will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

The study doctors also have the right to end your participation in this study for any of the following reasons: 1) if it would be dangerous for you to continue, 2) if you do not follow study procedures, or 3) if the sponsor funding the study decides to end the study.

Will I hear about New Findings?

We may learn things during the study that you may need to know. We can also learn things that might make you want to stop participating. If so, you will be notified.

How may my data be used in the future?

Identifiers will be removed from the private information and biospecimens that are collected. After those identifiers have been removed, the information and biospecimens could be used for future research studies or could be distributed to another investigator for future research without additional informed consent from you or your legally authorized representative

What if I am Injured?

If you are injured as a result of this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance with study procedures. Emergency and ongoing medical treatment will be provided as needed.

Who should I contact if I have questions?

If you have questions or if you have a research-related problem, you can call the Principal Investigator at 203-932-5711 x3541. If you have any questions about your rights as a subject, you may contact the Chairman of the Human Studies Subcommittee at 203-932-5711, extension 3350. If you have any complaints, concerns or pertinent questions regarding the conduct of this study, or if you have any questions about compensation for injury, you may contact the Human Studies Coordinator in the Research Office at 203-937-3830.

Do you consent to participate in the study? Yes No

Do we have permission to contact you for the additional interview? Yes No

Do we have your permission to recontact you for future studies? Yes No