RESEARCH CONSENT FORM

Basic Information

Title of Project: Records for Alcohol Care Enhancement (RACE) Study, R33 Phase

IRB Number: H-42631 NCT# NCT05492942

Sponsor: NIH/National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Principal Investigator: Dr. Emily Hurstak

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Study Phone Number: 617-358-1443

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a clinician in the general internal medicine primary care clinic at Boston Medical Center (BMC) who we expect will be in your current clinical role in the practice for a minimum of 18-months and who may provide clinical care for patients with alcohol use disorder (AUD). We are conducting a four-group randomized control trial to test the feasibility and effectiveness of electronic health record enhancements (Best Practice Advisories and Clinical Decision Supports) combined with various additional supports (access to a clinical care nurse manager, population health manager, or both) for improving identification and management of unhealthy alcohol use in primary care patients at BMC.

If you agree to participate in the study, you will be randomly assigned to receive one of four interventions: (1) best practice advisory (BPA) (only); (2) BPA and population health manager (PHM); (3) BPA and clinical care manager (CCM); (4) BPA and PHM and CCM. Your involvement in the research study will last up to 18 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are loss of confidentiality and inconvenience related to time required to participate in the intervention. You may not benefit from participation in this study, but it is also possible you will benefit from increased support for the management of patients with AUD in your panel. You will find more information about risks later in this form.

Purpose

BMC and BU Medical Campus IRB
IRB NUMBER: H-42631
IRB APPROVAL DATE: 03/28/2023

The research aims to improve recognition of unhealthy alcohol use, management of AUD, and services provided to patients with AUD by leveraging recent updates made to the risky alcohol use and alcohol use disorder BPAs within the Boston Medical Center (BMC) electronic health record (EHR), and provide targeted supports to primary care clinicians – specifically a clinical care manager (CCM) and population health manager (PHM). The trial will compare the use of the 1) BPA alone (only Epic-based clinician prompting and clinical decision support); 2) BPA + PHM; 3) BPA + CCM; and 4) BPA + PHM + CCM, to determine which of the four interventions is most effective at increasing rates of initiation and engagement in AUD treatment, as well as other clinical processes and outcomes such as referral to AUD specialty care.

Ultimately, the goal of the study is to gather evidence that could lead to better clinical outcomes for patients with AUD such as less heavy drinking, access to evidence-based treatments for AUD, fewer alcohol-related emergency department visits, and less alcohol-related morbidity and mortality.

What Will Happen in This Research Study

You will be one of approximately 130 clinicians who will be asked to participate in the study.

The study will assess patient initiation and engagement in treatment for alcohol use disorder (a national quality of care measure) through a four-group randomized control trial. We will ask you to participate in the following study activities:

- Provide us with your contact information
- Complete a brief socio-demographic survey (~5 minutes) at the beginning of the study
- Be randomized to one of the four intervention assignments up to 18 months
- Complete a brief follow-up survey (~5 minutes or less) when you are concluding your time in the study

After all participating clinicians have been enrolled in the study, the study team will randomly assign each clinician participant to one of the following intervention groups. Of note, all clinicians will have access to the existing BPA and clinical decision support (Smart Set) for risky alcohol use and alcohol use disorder (AUD) as described below in #1 (BPA only).

1. **Best Practice Advisory** (**BPA) Only**: Access to the existing Epic BPA and Clinical Decision Support (Smart Set) for Risky Alcohol Use and Alcohol Use Disorder (AUD). In this BPA-only group, you will have continued access to the existing Epic BPA for risky alcohol use and alcohol use disorder. It will continue to operate routinely, wherein you will receive prompting when you open an Epic record for an encounter with a patient who has risky alcohol use, or a possible or confirmed alcohol use disorder. From the BPA, you will have the option to open a Smart Set which contains clinical decision support for diagnosis and management of risky alcohol use and AUD.

2. **BPA plus population health managemen**t (**BPA+PHM**): Access to the existing Epic BPA and Clinical Decision Support for Risky Alcohol use and AUD (see description above in #1 (BPA Only)) plus access to a population health manager (PHM). You will be supported by a population health manager who will access an existing registry of patients with possible or confirmed alcohol use disorder to examine outcomes and quality metrics for patients with alcohol use on your patient

panel. The PHM will send you quarterly reports with summaries of data that show the numbers and percentages of patients on your panel who need additional screening for alcohol use care, as well as the number and percentage of patients on your panel with AUD who have initiated and engaged in treatment for their AUD. The PHM may send you a weekly message via Epic messaging about higher-risk patients (patients who were recently seen in the acute care setting or by BMC Faster Paths for alcohol-related health conditions) for whom outreach may be beneficial. In addition to sending you information about the high-risk patient(s), the PHM will send the General Internal Medicine (GIM) front desk staff an Epic message regarding high-risk patient(s) to facilitate scheduling a GIM visit with the patient within two weeks of their new AUD encounter, and copy you on the staff message. If you choose to participate in the RACE study, the clinic administrative staff may become aware of your participation in the study as they may receive Epic messages from the PHM regarding scheduling requests for your patients. You will only receive a weekly report IF you have patient(s) who meet criteria for high-risk outreach as above. The PHM may share aggregated and de-identified data that may be reviewed in group meetings with clinical teams. Data reviewed may include the number and percentage of patients screened, with unhealthy alcohol use, with AUD, with an AUD-related visit beyond the encounter when the diagnosis was initially made, with prescription of AUD medication, and who were referred to and/or are receiving AUD counseling at BMC or AUD specialty care.

3. **BPA plus clinical care management (BPA+CCM):** Access to the existing Epic BPA and Clinical Decision Support for Risky Alcohol use and AUD (see description above in #1 (BPA only)) plus access to a clinical care manager (CCM). You will be supported by a nurse clinical care manager who can assist in identifying patients who need further assessment, and will assist in conducting outreach to those patients regarding alcohol use care. The CCM will communicate with you through Epic messaging and in-person to discuss and decide on potential care plans, and then assist in implementing those plans. The CCM has expertise on how to provide appropriate alcohol-related clinical care to patients and can help patients navigate the complex care system. Further assistance by the CCM may include facilitating evidence-based AUD prescriptions for your sign-off, assuring adequate refills, finding, selecting and coordinating specialty AUD care, and contacting patients to make appointments, or other navigation support.

4. **BPA plus population health management plus clinical care management (BPA+PHM+ CCM):** Access to the existing Epic BPA and Clinical Decision Support for Risky Alcohol use and AUD (see description above in #1 (BPA only)) plus access to a population health manager (PHM) and clinical care manager (CCM). You will be supported by a population health manager as described in #2 (BPA+PHM) above, and supported by a clinical care manager as described in #3 (BPA+CCM) above.

The research team will notify you by email about which group you have been assigned to, and if randomized to groups 2, 3, or 4, you will be contacted by the PHM or CCM as described below. Data to assess the study's primary, secondary, and other outcomes will come from Medicaid claims data and Epic data accessed via the BMC clinical data warehouse. In addition, to reduce the number of questions we ask during the socio-demographic survey, we will collect publicly available demographic information about you such as your title or highest degree completed to have more in-depth demographic information about clinicians in GIM.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

The primary risk for participating in the RACE study is inconvenience related to the time required to participate in the intervention. The risk of inconvenience is minimal.

Inconvenience may occur due to time spent engaging in the intervention activities with the CCM and PHM. It may be inconvenient for you to take time to review reports and messages from the population health manager and/or clinical care manager, and to facilitate and provide additional patient care that otherwise might not have been provided.

How much or when you engage with the PHM and CCM will be up to you and is entirely voluntary. Additionally, participating in this study is voluntary, and you are free to stop participating in the study at any time. If you decide that you want to stop being in the study, we ask that you let us know. If you have an unanticipated departure from the BMC clinical practice but continue to consent to participate in the study, we will send you one additional follow-up survey.

Potential Benefits

You may not experience any direct benefits from being in the study. However, you may benefit from increased clinical support for your patients with AUD. The primary goal of this research is to collect information about the scientific questions asked in this study. Society, medical science, and the health care system may benefit from the information obtained about advancements to EHR and care innovations provided by the BMC primary care clinic. Particularly, the study has the potential to improve the quality of care for patients with AUD.

Costs

There are no costs to you for being in this research study.

Payment

You will be offered a $25 ClinCard (e.g., similar to a visa gift card) for enrolling in the RACE study.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a

CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research or overseeing the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information or asking us to share your information.

If you agree to be in the study, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Kara Magane at 617-358-1369.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study

_____ _____
Signature of subject Date