Developing a Team-Delivered Intervention for Smoking and Hazardous Drinking for Primary Care Veterans With Cardiovascular Diseases (CARE)

ClinicalTrials.gov ID NCT05275582

Sponsor VA Office of Research and Development

PI: Julie Gass

Study Protocol

Version Approval Date: 11/20/2023

Overview of CARE-PACT and CARE-PCMHI Study and Research Activities

Conditions

CARE-PACT: Patient aligned care team (PACT) providers will conduct their typical PACT appointment, and at the end will alert the behavioral health education (BHE) to join the appointment. The PACT provider will introduce the BHE; provide education about personalized health risks and outcome expectancies of changing using guided handouts. and encourage engagement with the BHE on the optional self-monitoring portion of CardiovAscular Risk Education – in PACT (CARE-PACT). The BHE will then escort the patient to a new exam room and describe the self-monitoring component of CARE-PACT that will target task self-efficacy. Instructions and materials for self-monitoring will be provided, and participants will be instructed about the follow-up appointments to occur two weeks and four weeks after CARE-PACT.

CARE-PCMHI: CARE-PCMHI is nearly identical to CARE-PACT, except that participants will not participate in the conjoint appointment. Primary Care Mental Health Integration (PCMHI) indicates that the participant will have their normal PACT appointment, and then will be contacted by a member of the study team to schedule a solo appointment with the BHE. At that 25-30 minute appointment, the BHE will provide education about personalized health risks and outcome expectancies of changing using guided handouts. The BHE will then describe the optional self-monitoring component of CARE that will target task self-efficacy. Instructions and materials for self-monitoring will be provided, and participants will be instructed about the follow-up appointments to occur two weeks and four weeks after CARE.

Potential participants will be identified as such:

1) Direct referral from a primary care provider OR a data pull using Corporate Data Warehouse from the VA Informatics and Computing Infrastructure (VINCI) of eligible patients assigned to the provider for care OR
2) research staff will manually "scrub" PACT panels by looking ahead at a provider's scheduled PACT visits in the coming months and looking in each patient's electronic medical record (EMR) to assess for signals of eligibility.
    a. We are request approval to access 10,000 records from these various means (provider panel scrubbing, CDW data pull, or direct referral) in order to meet our eventual recruitment goals.
    b. The primary eligibility criteria will include (a) seeing that the patient carries a diagnosis of a cardiovascular condition in their Problem List or in any of their last 2 years of PACT data encounter codes; (b) screened positive for smoking or hazardous alcohol use at least their two most recent PACT visits (i.e., two positive tobacco use screens or AUDC ≥3 for women or 4 for men on the Primary Care Annual Screeners).

Data from potential participants (i.e., name, contact information, last 4 of their social, whether they are a smoker or drinker, cardiovascular condition(s), and date of pact appointment) will be entered into a password-protected database that will then be used to identify patients to screen for eligibility.

Below is a description of the various CARE intervention and research activities, from the patient's perspective. Each of these will be described in detail below this list.

1. As early as 6 months before PACT appointment: Receive letter regarding study

2. As early as 12 weeks before PACT appointment: Receive telephone call to screen.

3. Between four weeks to one hour before the PACT appointment, 60-minute baseline session in person, via telephone, or via VVC

4. CARE-PACT participants: PACT appointment will include a 5-minute CARE-PACT conjoint appointment

    1. CARE-PCMHI participants: normal PACT appointment without additional conjoint appointment

5. Sometime following PACT appointment: 20-25 minute meeting with the BHE to explain the optional self-monitoring task, set up follow-up visits, and screen for safety

    1. Participants in the CARE-PCMHI condition will be contacted by telephone to schedule this appointment after their PACT appointment. We will attempt to contact them twice by telephone, and if they do not respond to this we will send a letter to them requesting that they contact the study staff to reschedule the appointment. We chose two calls + a letter because this is the standard practice in VA PCMHI clinics for no-shows/missed appointments.

6. For next 2 weeks after CARE: optional self-monitoring using app/diary
7. 10-minute booster session with BHE using telephone, in-person or VA Video Connect (VVC) format
8. For next 2 weeks: optional self-monitoring using app/diary
9. 10-minute booster session with BHE using telephone, in-person or VA Video Connect (VVC) format
10. Around 6-weeks after PCP appointment, complete 60-minute follow up assessment
11. Around 3 months after PCP appointment, complete 30-minute follow up assessment
12. Around 6 months after PCP appointment, complete 30-minute follow up assessment

PACT Appointment and CARE-PACT Conjoint Appointment: After participants in the CARE-PACT condition complete the baseline assessment, they will complete their normal PACT appointment, including the CARE-PACT conjoint meeting for CARE-PACT participants. During this meeting, Veterans will be introduced by their PACT provider to the BHE, and the PACT provider will go over the relevant handouts to the patient that describe Health Risks and Expectancies related to smoking/drinking and the Veteran's heart condition. The BHE's role is to ensure understanding between the Veteran and PACT provider. The conjoint portion of CARE-PACT will take approximately 5 minutes.

Solo BHE/PCMHI Appointment: Following the PACT appointment, the patient will meet alone with the BHE or PCMHI provider to learn about the at-home self-monitoring app that they can choose to use. Though this is not mandatory, it will be encouraged. The BHE will explain that as part of the CARE trial, Veterans will be asked to complete four weeks of the self-monitoring procedure (~5 minutes per day) and will participate in two telephone or in-person appointments (10 minutes) at the 2- and 4-week mark (more in detail below).

During the solo visit with the BHE, participant safety (i.e., suicidal intent/ideation) will be assessed using the VA's current PCMHI mandated screening and follow-up tools: The Columbia Suicide Severity Index screener, and if positive, VA's full Comprehensive Suicide Risk Evaluation. These measures were chosen as they mirror what would occur in a typical PACT handoff to a PCMHI provider, and therefore if CARE-PACT is eventually implemented in PACT settings, the standard risk assessment protocol will be embedded into its protocol. Should any imminent risk issues be present, a licensed psychologist (i.e., the PI or other CIH psychologists) will be notified and consulted regarding next steps (i.e., if a patient needs to be brought to the emergency department for admission).

4 Weeks Self-Monitoring Protocol: As above, patients will be introduced to and given the option to complete 4 weeks of self-monitoring using a data collection app called Expiwell. Expiwell is an app used for researchers/healthcare systems to deliver assessments and receive data from participants in their natural environment. We will ask participants to complete 1 daily morning assessment (each morning when they wake), which asks questions about the previous day specifically pertaining to health behaviors such as their drinking and smoking. During the day, the app will also (at random intervals) prompt Veterans to respond to 4 assessments. These assessments will also inquire about any recent smoking/drinking, mood, and context (e.g., if the participant is or is not with friends, at work, etc).

Expiwell is available on the app store for participants to download onto their Smartphone If the participant does not have a smartphone, the participant will be provided an iPod to use for the duration of the study. This iPod was purchased specifically for this study, and will have Expiwell already installed. It will also have an admin password which will prevent the participant from downloading additional apps. Participants will be asked to create an Expiwell account (which will ask them to enter their name/email address). In the event that they do want to use the app but do not want to enter their name, we will have a list of pseudonyms and false email addresses that they can use instead. If they choose to create an account either with their real information or with a pseudonym, they will then receive a code from our study team, which will enroll them into our study. Data entered from our study questions will be automatically stored on Expiwell's secure server, and will be downloaded by study staff from this server on a weekly basis. The assessments that we are asking participants to do as part of the study will **contain no sensitive information, will only be identified in the data set by a random ID number, and participants will have the option to delete their data from Expiwell at any time they choose.** Although sensitive information (i.e., name/email address) is asked of participants to create an Expiwell account, this is an optional part of the study and is not VA data, as we will not have access to it and Veteran's are entering the information.

If a participant is not comfortable using the app, we will provide a backup paper-pencil assessment packet for them to complete the assessments. This option will only be offered if a participant expresses that they do not wish to use the app.

Telephone, VVC, or In-Person Booster Sessions: At 2 and 4 weeks post-CARE-PACT, participants will have a 10-minute booster phone call or in-person appointment (their choice). During this booster, they will discuss how the monitoring is going, and what (if any) insights were gained as a result of engaging in the monitoring. If the participant no-shows or does not answer the call, we will make multiple efforts to contact them within the next week to reschedule.

6-Week, 3-, and 6-Month Follow-ups: Participants will be asked to complete follow-up assessments at 1.5, 3, and 6 months following their PCP appointment assessing intention/motivation to change, tobacco and/or alcohol dependence, treatment history and quitting history, and perception of their healthcare team. **The 6 week assessment takes approximately 60 minutes and participants will receive $30. The 3 and 6 month assessments take approximately 30 minutes, for which participants will receive $20 each.** If participants do not respond to phone calls to complete these assessments, they may be sent a letter requesting that they contact the lab. Participants may receive a letter prior to these assessment appointments that remind

Inclusion Criteria [source of data in brackets]

1. Veteran patients ≥ age 18 seen in PACT at the Buffalo VAMC [EMR]
2. Upcoming PACT appointment [EMR]
3. A diagnosis of cardiac disease, including coronary artery disease, hypertension, hyperlipidemia, OR ischemia [EMR]
4. Positive alcohol or tobacco use screen for at least **two consecutive years** (including most recent) for [EMR]:
    a. Smoking (i.e., Answered "Yes" on the Annual VHA Tobacco Use Screening Questionnaire) AND/OR
    b. Hazardous drinking (Alcohol Use Disorders-Consumption [AUD-C] ≥ 4 for men or 3 for women)
5. Currently smokes at least one cigarette per day OR currently scores in a range indicating hazardous drinking on the Alcohol Use Disorders Identification Test (AUDIT) [telephone screen]
6. Currently reports on 1 to 10 scale having no greater than high-moderate (defined as ≥8) intention to change their drinking and/or smoking behavior [telephone screen;]

Exclusion Criteria [source of data in brackets]

1. Disorientation at time of eligibility (i.e., delirium, acute psychosis, dementia, severe intoxication) [EMR, telephone screen, or clinical judgment at the time of the in person appointment]
2. Unable to read or understand English [telephone screen]
3. Non-Veteran status [EMR]

Measures

The following outcome measures for the future larger RCT will be piloted in this study. These will be administered at the Baseline Appointment as well as the follow-up appointment:

1) Readiness to Change Questionnaire: 12-item measure[116] (αs=0.73-0.85) of current intention to change. This scale has been shown to predict future behavior change and has been used in drinkers and smokers. (Main Outcome)
2) Readiness and Confidence: visual analog scale (ruler) for (a) readiness to change smoking and/or drinking behaviors as well as (b) confidence in changing[117]. Rulers such as these have been shown to predict behavior change for tobacco use as well as alcohol use. The rulers will range from 1 (not at all ready/confident) to 10 (very ready/confident to make a behavior change). (Main Outcome)
3) Measures of alcohol quantity/frequency (Secondary Outcome)
4) Subscales *General Quality Assessment* and *Care and Concern* from the Patient Satisfaction Survey[119]: measures perception of quality of care by patients and predictive validity for engaging in healthcare changes. Reliability for the overall scale (α=0.81) and the subscales is high (αs=0.85, 0.88) (secondary outcome).[1]

Data Analysis Plan

Descriptive statistics will be calculated for all patient variables, including demographics, outcome variables, recruitment, feasibility, and survey responses. The primary patient outcomes that we will preliminarily evaluate are readiness to change via a ruler and a questionnaire, and secondary measures include substance use and satisfaction. Primary analysis of these variables will be repeated measures analysis of variance with calculation of both between-groups (CARE-PCMHI vs. CARE-PACT) and within-groups (pre- and post-intervention) effects sizes. Intent-to-treat analyses to account for attrition will be conducted using the last value carried forward methodology which is the recommended method to minimize risk of bias. Though we are statistically underpowered to detect large differences between groups, the statistical methodology described here will be piloted for a larger grant submission. Additional outcomes of this work included looking at descriptive statistics of feasibility of data collection processes, fidelity and training related outcomes, and other feasibility outcomes.

[1] Other measures were collected that were not primary or secondary outcomes.