HP00058634-VACCHT to Safeguard CKD Care
NCT03038126
Study Protocol

Evaluation of device(s) for safety or effectiveness or use of a HUD.
Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).
Sample (Specimen) Collection and/or Analysis (including genetic analysis).
Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).

* Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● Yes ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

View: v2_Lay Summary

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

In 2003, the VA started the Care Coordination Home Telehealth (CCHT) system to help improve the health for patients who live far from a VA health center or who require close monitoring. VA healthcare providers decide who is eligible for this system. The CCHT system includes a machine that is installed at home and connects to a patient's home telephone. Each day, the CCHT machine silently and automatically dials a toll-free number to send the medical information the patient has entered into the machine. The information is sent to a secure Internet site so it can be reviewed by the CCHT healthcare team at the Baltimore VA. Examples of medical information patients send through this system include blood sugar levels, blood pressure, and weight.

Patients with all stages of kidney disease are at a high risk of harm related to medical care (called safety events). These safety events may occur outside of the medical system and are often under-reported or under-appreciated. The CCHT system may offer a novel means to track patient-reported adverse safety events in kidney disease, and to reveal new data to healthcare providers that can lead to beneficial changes in treatments. This study will evaluate the VA CCHT system in patients with Chronic Kidney Disease to increase the detection of safety events in this patient population compared to the patients not exposed to the CCHT plan; and determine the impact of this information on clinical care when reported to primary care providers.

In addition, this study will look at caregiver burden among people taking care of a family member or friend with kidney disease.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

View: v2_Justification, Objective, & Research Design

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Purpose: Pre-dialysis chronic kidney disease (CKD) is associated with a high risk of harm related to medical care (adverse safety events). These events may occur outside the purview of the medical system, and hence, are under-recognized. Health information technology (IT) can enhance the detection of such events, and coordinated care can prevent their adverse consequences.

Hypothesis: Coordinated care/home telehealth (CCHT) monitoring of CKD patients, with a CKD disease specific questions and safety-specific decision support, will increase the detection of adverse safety events and, in turn, reduce the need for urgent health resource utilization and associated poor outcomes.

Specific Aim 1: Compare detection of adverse safety events in CKD patients assigned to CCHT vs usual care.
Specific Aim 2: Compare the frequency of urgent health service use and participant satisfaction with CCHT vs usual care group.
Specific Aim 3: Look at caregiver burden among those caring for a family member or friend with kidney disease.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

The study design is a 6-month demonstration pilot randomizing CKD patients to one of two care pathways - CCHT or usual care - as a means to detect adverse safety events and reduce poor outcomes related to these events.

CCHT is comprised of the Veterans Administration (VA) home telehealth system with a guideline-based, CKD-disease-specific questions, augmented laboratory monitoring, and decision support from the VA Renal Inter-disciplinary Safety clinic (RISC).

A secondary subject population, caregivers, will also be included to assess caregiver burden. A cross-section survey, the Zarit Caregiver Burden survey, will be administered to participants' caregivers. The participant will identify whether or not they have a caregiver at home (defined as an unpaid friend or relative that provides care).

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Pre-dialysis CKD is a "fertile" condition for the occurrence of adverse safety events, which, here, is defined as "unintended harm related to health care management rather than a patient's underlying medical condition." As with most chronic diseases, much of the healthcare and medical events associated with CKD occurs outside of the hospital and clinic, where symptoms from adverse safety events might not be detected or reported.

This project builds on the Safe Kidney Care (SKC) study (HP-48532), a prospective cohort of CKD patients, which is innovative in identifying patient-reported safety incidents and actionable safety findings. Findings from the SKC project motivated the founding of the novel Baltimore VA Medical Center (BVAMC) RISC, which will serve as the safety-specific decision support in this project's CCHT intervention.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Current tools used to measure adverse safety events focus on incidents observed within the hospital and medical system (e.g, Agency for Healthcare Quality and Research (AHRQ) patient safety indicators (PSI), trigger method, etc). These established tools are not well-suited to detect adverse safety events pertinent to chronic ailments like kidney disease because medical care for kidney disease largely transcends traditional hospital and medical system boundaries. Health behaviors,

lifestyles and events in the home, work, and leisure environments are important areas to evaluate patient safety in kidney disease. Events that occur in this broader patient-centered universe may not be observed or reported to a healthcare provider because of poor recall, failure for the provider to inquire, or as in the case of the dialysis unit, there may not be a qualified provider on site to receive and process this information.

Home telemonitoring of CKD patients may be able to increase the detection of adverse safety events that occur outside the traditional healthcare system and, in conjunction with coordinated care and decision support, offer new opportunities to reduce their associated poor outcomes using a HIT platform that allows ready dissemination across a national health network.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

View: v2_Supporting Literature

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***
See pages 1-3 of R34 DK102177 attached.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
Works Cited	3/5/2014 12:03 PM	3/5/2014 12:03 PM
1R34DK102177-01_FinalPlan	1/22/2014 9:25 PM	1/31/2014 11:57 AM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

View: v2_Study Procedures

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:
The study procedures for 2 separate study populations, CCHT/Usual Care and Caregivers are described below:

CCHT/Usual Care Subjects:
There will be a total of 3 study visits for each cohort (CCHT and Usual Care). Please refer to the Study Schedule for list of procedures administered at each visit specific to each arm (schedule located in the Additional Documents Section of CICERO and embedded at the end of the Informed Consent Document). Several elements currently employed as part of the Safe Kidney Care (SKC) Cohort Study (HP-00048532) and VA RISC assessment will be employed in the study procedures.

CONSENT/RANDOMIZATION VISIT FOR BOTH STUDY GROUPS:

This visit will take place at the RISC or ERI clinic at the Baltimore VA or in the VA GRECC. At this time, the informed consent will be administered and, a baseline visit will be scheduled. At the baseline visit, the randomization envelope will be unsealed revealing the participant's assigned arm.
1) Usual Care or
2) Intervention group with access to the Care Coordination Home Telehealth (CCHT) system.

For participants assigned to the CCHT intervention group, study staff contact the VA CCHT program manager to coordinate system installation in the participant's home (per the standard VA procedures) to occur approximately 2 weeks of the consent visit. (See "CCHT Protocol" below).

Approximately 2-6 weeks after the consent, the baseline visit will occur for both CCHT and usual care participants. Study participation ends approximately 6 months later. Clinic visits will occur at the ERI, RISC, or GRECC center depending on space at the time of visit. Study procedures for the CCHT Group and the Usual Care Group are described below (also see CICERO study schedule).

Questionnaires/Procedures conducted for research purposes include:
- Demographic questionnaire,
- Medical history questionnaire,
- Self-reported safety events (SRSE) questionnaire,
- Medication inventory (including both over-the counter (OTC) and prescription drugs),
- Lawton Independent Activities of Daily Living Survey
- Montreal Cognitive Assessment (MoCA) - series of questions that measure concentration, language, and memory.
- Short physical performance battery (SPPB) - sit in a chair, then stand, then sit back down for a total of 5 times; stand normally with feet touching and then stand with one foot in front of the other: timed walk 13 feet two times
- Anthropometric measurements: height and weight and waist measurement
- Laying down and standing blood pressure and pulse
- Fasting labs at Baseline, Visit Months 3 and 6- Renal Function Panel (albumin, calcium, Co2, chloride, creatinine, glucose, phos Po4, Potassium, sodium, BUN, eGFR; and Hemoglobin). A hemoglobin A1C will be collected at the baseline and 6-month visit only. All blood tests/results may be considered non-research as well. Nevertheless, the labs are obtained at the VA Laboratory with results available in CPRS for provider use.

- Safety education session using materials posted on www.safekidneycare.org, i.e. high potassium foods, medications to avoid (See attached Safety Curriculum Slides in additional documents)
- Safety Assessment completed by a clinician (either MD or NP)
- Hypoglycemia Fear Survey
- Hypoglycemia Score Survey

CCHT Protocol: The CCHT system will be the standard health kiosk appliance employed through the VA CCHT program with hardwire linkage to peripherals including scale, automated blood pressure cuff, and glucometer (Health Buddy® T400 Telehealth System, Bosch Health Systems, Palo Alto, CA). The machine will be provided to participants who are randomized to this management study arm. The appliance is approximately 9 × 6 inches in size and plugs into a telephone line and an electrical outlet. A light on the appliance blinks when disease relevant questions and information for the daily session are available. Vital signs from linked peripherals are automatically stored. The appliance silently and automatically dials a toll-free number to send the participant entered information to Health Buddy® System's HIPAA compliant secure Internet site where it becomes immediately available to the CCHT staff for review on the Health Buddy® computer portals at the BVAMC. The appliance uses very little power and never disrupts an incoming or outgoing call.

While using the CCHT appliance at home, participants will record the following vital signs: a daily recording of pre-meal, post-void, undressed weight (6-8am), and bidaily post-medication blood pressure and pulse (7-9am and 6-8pm), both seated and standing, and a morning, pre-prandial, post-medication FS blood glucose and a repeat FS glucose prior to the evening meal (7-9 am and 6-8 pm). These readings will be transmitted daily to the CCHT office via the health kiosk and safety events will be reported directly to the participant's VA healthcare provider.

Event Ascertainment for all study participants:
Ascertainment of ED visits, hospitalizations, and death will be accomplished through review of medical event self-reported safety events form obtained at final study visit (6 months) for all study participants with retrieval of medical event records from utilized EDs and hospitals of reported admissions. It is expected that since study participants are veterans seen at the BVAMC, about 70% of service utilization will be through BVAMC with the remainder at non-VA facilities (based on SKC experience). Data elements to be included will be ICD-9 codes, and admit and discharge dates. Secondary outcomes will include change in renal function as determined by changes in eGFR from baseline to final visit. Similarly changes over the study period will be determined for weight, as a measure of fluid intake, and HbA1c, as a measure of glucose control.

Data Acquisition Protocol:
Acquisition of safety events-
There will be two types of safety events recorded in this study: 1) patient-reported safety incidents and 2) actionable safety findings

1. Patient-reported safety incidents-
Patient-reported safety incidents will be transmitted to the SC via in-center study visit Self-Reported Safety Event (SRSE) survey or telephone communication. All Patient-reported safety incidents will be recorded on a standardized safety case report form (safety CRF) allowing for uniform documentation of such events via all three mechanisms and across both study arms.

2. Actionable safety findings-
Participants assigned to the CCHT study arm will be observed using standard procedures for data monitoring of vital signs, weights, and FS glucose by the core CCHT staff and their clinical protocol. These actionable safety findings will be ascertained via clinical readings submitted by CCHT transmission and available for review via the CCHT office by core staff and SC. CCHT staff are qualified VA nurses and health specialists trained to monitor data readings via established CCHT computer work stations (in BVAMC Annex) to identify clinical values that fall outside established ranges and for the purpose of identifying patients with poor control, or non-adherence, along with safety events as defined in this protocol. The standard procedures foster adherence and communication with primary provider staff when a medication or management change is deemed necessary. The core CCHT staff will oversee CCHT clinical data with regular review of study participants assigned to the CCHT arm with specific attention to safety thresholds (see pg. 10 Table 5 of R34 DK102177 for actionable safety finding thresholds). CCHT core staff will ensure identification of findings defined as actionable safety findings and report safety events to the PI and SC.

Data transmission-
When safety events are detected by CCHT clinical staff or with review by SC (either patient-reported safety incidents and actionable safety findings), the RISC management and decision support team in the Baltimore VA (see pg 9, Figure 6 of R34 DK102177) will be notified using person-to-person transfer or fax.

A similar review of all other study-related data including patient-report safety incidents, medication additions or deletions, and laboratory abnormalities obtained on participants in both the CCHT and usual care arms (based on their respective scheduled in-center visits) will be conducted by SC at in-center visits and with clinical labs with recording of all safety events on the safety CRF.

Caregiver Subjects:
At the baseline study visit, the study coordinator will ask the participant (from the CCHT/Usual Care population) if they have a caregiver at home (defined as an unpaid family member or friend that proviced care to them). If a caregiver exists, the coordinator will then provide the participant with a sealed packet that will include the Zarit Caregiver Burden Interview survey, a self-addressed and stamped envelope, and instructions to omit their name, address, or other personal identifiable information from the survey. They will ask that the caregiver complete the survey (which will take approximately 15-20 minutes) at home and return via mail using a self-addressed envelope that we will provide.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

The usual care protocol is designed to be consistent with routine CKD management. After the consenting/randomization visit, usual care group participants will be provided with telephone contact to referring providers in the ERI clinic or general clinics and toll-free telephone contact for general BVAMC RN counseling. The former will be available for complaints or incidents that they feel should be addressed by medical staff or new medication prescriptions that require approval for use in CKD and the latter will be available for emergent health need.

3 * Describe the duration of an individual participant's participation in the study:

CCHT/Usual Care Subjects:
Duration of study participation is estimated to be 6 months.

Caregiver Subjects:
Completion of the Zarit Caregiver Burden survey is estimated to take approximately 15-20 minutes. That is the only requirement of the caregiver's participation in the study.