PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Title: **Effects of Family Sodium Watcher Program on Outcomes in Heart Failure Patient-Family Caregiver Dyads**

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	2/11/2020
NCT Number:	NCT03560206
IRB Number	46045
Coversheet created:	9/28/2021

Statistical Analysis Plan

Specific Aim 1: Repeated measures analysis of variance (ANOVA) will be used to assess differences between intervention and control groups on outcomes variables over time. Post-hoc analysis will be based on Fisher's least significant difference procedure for pairwise comparisons. Baseline comparisons between those who dropped out and those who completed all three waves of data collection will be determined using two-sample t-tests or chi-square tests, and the rate of retention will be compared between the two treatment arms using the chi-square test of association to assess whether differential drop-out occurred.

Specific Aim 2: Kaplan-Myer survival analysis with a logrank test will be used to make an overall comparison between time to rehospitalization or death event between intervention and control groups. Cox proportional hazards model will be used to estimate the hazard ratio of intervention effect on the prediction of the end-point of rehospitalization or death compared to usual care group, while controlling potential compounding factors.

IRB Approval
2/11/2020
IRB # 46045
IRB6

PROTOCOL TYPE

Which IRB

(•) Medical ( ) NonMedical

Protocol Process Type

( ) Exemption
(•) Expedited (Must be risk level 1)
( ) Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If you select the wrong IRB Type and/or your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or go to ORI's "Getting Started" web page. If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 **prior** to saving your selections.

Which IRB

The **Medical IRB** reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The **Nonmedical IRB** reviews research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communications & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs, testing safety or effectiveness of medical devices, or studies that involve invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification;
- by expedited review.

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please go to ORI's "Getting Started" web page.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXPEDITED CERTIFICATION

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements- 21 CFR 812.2(c)

☑ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP [PDF] for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a) If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☑ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☑ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☑ 5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

☑ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☑ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

RESEARCH DESCRIPTION

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Despite major advances in the treatment of HF, the prognosis of patients with HF remains poor and high rehospitalization rates are a major target of researchers and clinicians.1-3 Poor self-management is a major contributor to these negative outcomes.1, 4-8 In fact, poor self-management, particularly nonadherence to a SRD is one of the main predictors of rehospitalization for exacerbation of HF,1-2, 6, 9-11 yet the prevalence of non-adherence to the SRD remains as high as 50%.12-15

A major barrier to adherence is lack of knowledge about how to follow a SRD.12, 15-17 Most educational interventions have focused on improving knowledge by teaching patients specific skills including how to read food labels, how to choose low sodium foods when eating out, and how to modify their usual diet.18-22 The majority of these educational self-management interventions have focused only on patients.21, 23-28 Family members are an overlooked but essential resource for support of patient self- management.29-31 Their lack of knowledge or support in following the SRD can be an important barrier to adherence.17, 32 Their perceived difficulty in managing a separate diet for the patient with HF contributes to feelings of burden.33 However, the same level of sodium recommended for patients with HF is now recommended for all healthy adults to prevent chronic disease,34 making a whole family intervention for restricting sodium in the diet an ideal approach.

Other important barriers to adherence to the SRD are the perceived poor taste of low sodium foods and an appetite for high sodium foods that make dietary changes difficult.12, 15, 17 As people age, their perception of saltiness is diminished, causing an increased preference for high salt (sodium) foods.35-37 Complex physiologic and evolutionary mechanisms operate to maintain preference for foods high in sodium.38 Abrupt and marked reductions in sodium intake can lead to sodium-seeking behaviors; thus changing dietary preferences requires at least 8 weeks to reach a new hedonic state and to reset sodium taste buds.39-40 Thus, an intervention that uses a gradual adaptation strategy should produce the best long-term adherence results.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

The long-term objective of this program of research is to improve outcomes of patients with heart failure (HF) by increasing their adherence to a sodium restricted diet (SRD). The purpose of the proposed randomized, controlled trial is to test the effects of the Family Sodium Watcher Program (Family SWaP), designed to improve both patients' and caregivers' adherence to a SRD. The Family SWaP program is an innovative self-management intervention using a gradual adaptation strategy and an electronic salt monitoring device that allows individuals to monitor and over time reduce sodium content in their food. Given the recommendation that all individuals should consume a SRD, the intervention has the potential for expanded application beyond patients who need to follow a SRD for cardiovascular reasons to everyone consuming a diet high in sodium.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance [PDF] or the UK Research Registry Guidance [PDF]

A two-group, randomized controlled design will be used to determine the effect of Family SWaP on sodium intake of patients with HF and family caregivers (Figure 1). Dyads will be randomly assigned to intervention or usual care group using a stratified randomization strategy after we determine patients' adherence level to SRD at baseline. Because adherence level at the baseline may affect outcomes, stratification is needed to insure similar sample characteristics between Family SWaP and usual care groups. Non-adherence will be defined as a 24-hour urinary sodium excretion greater than 3000 mg. The 3000 mg 24-hour urinary sodium excretion cut point was chosen because it is the upper limit of sodium intake recommended for patients with HF.69, 123-124 The intervention will be delivered to both adherent and non-adherent patients because it has not known whether the intervention delivered to a dyad can maximize their adherence behavior or promote long-term adherence behavior. The intervention will be delivered 16 weeks (6 weekly 45 minutes sessions and 5 bi-weekly 20 minutes sessions).using video conferencing technology via digital device (i.e., ipad). Post-intervention effects will be assessed at 4 and 12 months to identify short- term and long-term post-intervention. We will collect hospitalization information up to 12 months by phone follow up. Dependent variables include adherence to the SRD, symptom distress, knowledge of SRD, perceived control, perceived social support, quality of life, and caregiving burden (caregiver only), symptom distress (patient only), and rehospitalization (patient only). We will also collect 4 variables to evaluate salt taste: salt food preference, sensory density, and diet quality. Qualitative data regarding salt taste preference and family experiences.

Attachments

Attach Type	File Name
StudyDesign	Figure and Table 1 Study Design.docx

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

A total of 300 patient-caregiver dyads (i.e., 600 individuals; see sample size justification in data analysis section) will be randomized into intervention and usual care groups.
Eligible patients will have (1) have a diagnosis of chronic heart failure with either preserved or non- preserved ejection fraction (2) be able to speak and write English, (3) have a phone in home and (4) without cognitive impairment of dementia and Alzheimer. Patients will be excluded I they have a co- existing terminal illness, or have a dietary prescription at odds with following a 2-3 gram sodium diet (e.g., clinician does not support use of a SRD). Patients without dedicated caregivers are excluded in this study. Improving outcomes of patients without caregivers are important to study, but it is not appropriate to include them in this study. After this study demonstrate effect of gradual adaptation strategy, it will be important to test the effect on patients without caregivers by providing support from nurses. A family member is eligible if he/she is: (1) a primary caregiver identified by a patient; (2) the spouse, committed partner, or family member living with the HF patient; (3) able to speak and understand English; (4) without cognitive impairment of dementia and Alzheimer. Despite the fact that HF is equally distributed between the genders, the representation of women in many studies of HF has been low. We plan to enroll 50% female patients. The population of HF patients at the University of Kentucky Medical Center (UKMC) is sufficient and approximately 50% are women, so we do not anticipate difficulty in obtaining an adequate sample of women and men with HF for this study. Based on our dyadic study, we expected at least 10% more female caregivers than male caregivers. This is consistent with the common observation that more females take on the caregiver role than males. Based on national estimates and University of Kentucky Chandler Hospital (UKCH) discharge data, planned enrollment in this study is 80% Caucasian and 20% African American.

Attachments

Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will

meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research [PDF].

HF patients will be referred to this project by physicians and nurse practitioners from multiple recruitment pools: Cardiology at the Linda and Jack Gill Heart Institute, University of Kentucky Chandler Medical Center, Good Samaritan and the Chandler Medical Center Hospitals and associated University of Kentucky Clinics and Baptist Health Lexington Hospital and outpatient clinics.

In the UK facilities, a trained nurse research assistant who has background of cardiovascular nursing will screen participants f or eligibility by reviewing medical charts. A trained nurse researcher will screen patients' eligibility before patients arrive by reviewing medical chart at their appointment time. Then, the UK CON nurse will contact the patient via phone and using the approved script will tell them briefly about the study and request to meet them at their appointment time to further discuss the study.
When the eligible dyads are willing to participate in the study, they will sign the approved consent after they receive information on the study contents.

In the Baptist Health Lexington locations, the healthcare providers caring for cardiovascular patients will review the medical record for eligibility an then refer eligible patients to the recruiter who is a UK research assistant.

We will also gather hospitalization/event/survival data using a form we designed for this purpose. We will have the nurse recruiters/liaisons at St. Claire and Baptist Health Lexington hospital systems gather this data, complete our form and send it to us using secure email.

The CCTS EDT will provide a list of patients that meet the enclosed inclusion/exclusion criteria; as well as, basic demographics (full name, medical record number, sex, race, date of birth) and attending/primary physician name and service.

The attending/primary physician will be contacted by the Investigator study coordinator to approach the patient to obtain permission for the PI/study coordinator to contact them. No cold calls/ contact will be made directly with the patient without obtaining permission through their attending physician. A card will be supplied to the patient from the attending/primary physician so the patient can complete contact information for the Investigator. Once permission has been granted by the patient, the Investigator study coordinator will contact the patient for recruitment into the study.

The CCTS EDT will provide a list of patients that meet the enclosed inclusion/exclusion criteria; as well as, basic demographics (full name, medical record number, sex, race, date of birth) and attending/primary physician name and service to the CCTS Participant Recruitment Coordinator.
The attending/primary physician will be contacted by the Participant Recruitment Coordinator o approach the patient to obtain permission for the PI/study coordinator to contact them. A draft letter regarding the study recruitment will be supplied to the attending/primary physician for approval prior to mailing to patients. No cold calls/ contact will be made directly with the patient without obtaining permission through their attending/primary physician. Once permission has been granted by the attending/primary physician, the CCTS Participant Recruitment Coordinator will contact the patient for recruitment into the study via mailings.

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Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language.

We will also advertise via the CCTS using CCTS wall mounts, social media venues, Participate in Research, Current Studies, CenterWatch, and CISCRP websites, Research Match, Articles, Newspapers, Paid Facebook boost.

Attachments

Attach Type	File Name
Advertising	flyer updated new logo.pdf
Advertising	flyer updated new logo APPROVED.pdf
Advertising	UK Phone Script.pdf

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

The primary PI or research assistants who are certified CITI will explain study requirements to individuals and obtain informed, written consents from the individuals and arrange a home visit if the individual agrees to participate. During the informed consent process, the PI or research nurse will fully explain all procedures and answer all questions.

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

After eligible patient-caregiver dyads sign the consent forms, they will participant in this study. Baseline data will be collected during a home visit. At the baseline assessment, they will fill out questionnaires using the RedCap system and collect 24-hour urine specimens. Urine containers, collection devices (urinals for men and toilet "hats" for women) and written instructions will be provided. The research assistant will interview participants to obtain demographic characteristics and to confirm their comorbidities. Information about demographics and comorbidities will be obtained using a structured questionnaire in interview. A research assistant and the dyads will set up the starting day of urine collection within 3 days of completion of questionnaires and pick up dyad's urine specimens in the dyad's home and deliver University of Kentucky Chandler Hospital Laboratory to determine 24-hour urinary sodium excretion level. Additional data collection for qualitative data, and diet quality will be also collected by home visiting. The medical chart will be reviewed to confirm only patients' comorbidities. After patients are categorized as adherent or non- adherent using 3000mg urine sodium cut point, the dyads will be randomly assigned to the Family SWaP intervention or usual care group using stratified randomization. Caregivers' adherence level at baseline will not be used in randomization but will be used to compare adherence at follow up. Dyads in the Family SWaP intervention will participate in a 16-week intervention delivered by the interventionist. The usual care patients will receive the standard medical and nursing care for HF patients provided at the clinics from which they were recruited. The usual care dyads will participate in the same data collection procedures as dyads in the intervention group. Follow-up data collection will be conducted 4 and 12 months after the intervention group completes the 16 week intervention to evaluate short and long term effects. At each follow-up, patient-caregiver dyads will complete the same questionnaires as baseline. Self-report of all hospitalization events will be collected from patients/family caregiver via monthly phone calls and a hospitalization logbook kept by the dyad for 12months. The medical record and administrative database will be queried to confirm rehospitalizations by the research nurse who will be blinded to the study group assignment. Data from the optional recorded interviews will be transcribed by a HIPAA compliant third party transcription service (REV).

Attachments

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

Questionnaires were attached as individual files

Attachments

Attach Type	File Name
DataCollection	Clinical Characteristics ALL revised 1_29_2015.doc
DataCollection	Memorial Symptom patient baseline FINAL 02_10_15.docx
DataCollection	Patient- Baseline Part1 FINAL revised 03-10-2016.doc
DataCollection	Patient CC II FINAL revised 1_29_2015.doc
DataCollection	Patient- demographic 1_15_2015.doc
DataCollection	Family_Caregiver Q part1 revised 07_25_2016.doc
DataCollection	Family Caregiver Q part2 revised 02_11_2015.doc

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

The UK College of Nursing is the location of the PI and research staffs. Full computer resources and telephone are available as well as locked file cabinets for storage of study related materials in the College of Nursing. The CCTS Biomedical Informatics Core manages the Enterprise Data Trust (EDT) which houses the clinical/claims data stored in the data warehouse within the Institute for Outcomes & Policy (IPOP). This project will utilize the EDT to obtain clinical/claims data associated with the inclusion/exclusion criteria provided in the study.

Obtaining a patient List for Study Recruitment
The CCTS Biomedical Informatics Core manages the Enterprise Data Trust (EDT) which houses the clinical/claims data stored in the data warehouse within the Institute for Outcomes & Policy (IPOP). This project will utilize the EDT to obtain clinical/claims data associated with the inclusion/exclusion criteria provided in the study.

Mailing recruitment letters on behalf of the Investigator
The Center for Clinical and Translational Science (CCTS) Participant Recruitment Core manages the Investigator/Researcher approval process for drafting recruitment letters from the primary physician for initial contact of eligible patients generated from the EDT.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Protection against breach of confidentiality is provided by training all individuals involved in the research process about the necessity for complete confidentiality, housing all data collected in locked file cabinets in an access-restricted area, and by use of password protected computers and secure servers. Genetic data will be accessible only to study personel. Potential risks of the study are related to questionnaire administration. Participants may experience some anxiety or psychological distress when completing questionnaires. In our experience, less than 3% of patients report this effect and when they do it is relatively transient. The acquisition of urine specimen poses no known risks. There is a slight risk for emotional upset as the qualitative questions will focus on family

dynamics and differences regarding low sodium diet.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

Only individuals trained in the research procedures will perform them, and all standard procedures will be followed. Patients identified with major depression (PHQ-9 score greater than 10 or an affirmative response to suicidal ideation) will be assessed by our on staff psychiatric nurse practitioner for emergency needs and referred for treatment after consultation with their primary care provider regarding referral preferences.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

Individuals in intervention program may have a benefit of improving their symptom distress and outcomes by adhering to sodium restricted diet. There are no other immediate benefits to individuals in control group. The knowledge gained in this study will provide vital information about the best way to improve patient self-management behaviors, especially adherence to sodium restricted diet

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

This study offers participants will be assigned randomly into the family Swap intervention group or attention usual care group. Other alternative would be not to participate.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

Demographic data, clinical characteristic information, and psychological and quality of life information will be obtained from brief interview of participants, medical record review using structured questionnaires. Adherence to diet will be assessed using 24-hour urine specimen. The 24-hour urinary sodium level will be determined at the University of Kentucky Medical Laboratory. Diet quality will be assessed using a structured online questionnaire. Qualitative data will be obtained through a structured questionnaire. Demographic data, lab results, history, other study related records and questionnaire responses will be kept confidential and de-identified for data purposes. A secure master list of names and research subject numbers will be kept in a password protected electronic file in a locked research office with access limited to research staffs who are listed in the study personnel list.

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable,

describe procedures for sharing data/specimens with entities not affiliated with UK.

> *NIH-funded genomic research*: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

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All data used throughout the project will be kept in password-protected files on College of Nursing secure server and in locked file cabinets the College of Nursing Center. All data in paper format will be kept for 6 years after study closure and destroyed by shredding papers including questionnaires. In the recruitment process, we will destroy the collected information by shredding the screening log. However, we will not destroy the information that is stored in the computer because we will use this information to avoid duplicating recruitment for other research projects. Trained research nurses who received certificate of CITI will access the medical records and store the information in the locked cabinet in the office with a door lock. The collected information also will be stored in the computer to track recruitment. Only research team members who have a password will access to the computer. Participants' confidentiality will be preserved by coding each participant data sheet with unique subject number, and storing the subject-code number key in a locked file cabinet in the College of Nursing RICH office at 2201 Regency Dr. Suite 403, with access limited to research staffs who are listed in the study personal list. All study personal in this study will complete human research protection training before implementing any research procedures.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

There is no monetary incentive to compensate for their time during 12 months. However, each dyad (patients and their family caregiver dyad) who participant in this study will receive an iPad per family at the beginning of the study. If any one of the dyad members withdraws the study before three assessments complete, we consider patient-caregiver dyad as a unit of the study will end the study and they should return the iPad that will be given during the study. When two dyad members complete all three assessments during 12 months study, the dyad will keep the iPad. Free data plan will be provided for only dyads that don't have home Wi-Fi access during the study (12 months).

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There will be no additional costs to the participants and no personal travel costs to the research site.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your

DSMP, click here for additional guidance for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review.

We have developed a detailed Data Safety Monitoring Plan that includes the following elements.
a. Periodic Review: The Principle Investigator (PI) will hold weekly staff meetings for the first month of enrollment then bi-weekly thereafter. The staff meeting will include the PI, co- investigators, project director, nurses in charge of recruitment and the intervention, and the data manager. The meeting will include evaluation of all research procedures, fidelity to protocol, discussion of newly enrolled participants, and review of status of all formally enrolled participants including all adverse events. Adverse events will be reviewed to determine if changes in the protocol are indicated. Participant demographics to date, recruitment progress, and difficulties encountered during enrollment, an update on data entry, and any other issues or concerns that have arisen since the last research team meeting will also be discussed.
b. Adverse Events: The educational intervention study is minimal risk. We do not anticipate moderate, severe, life-threatening or fatal AEs. Regardless, adverse events will be defined in accordance with Federal Regulation 21CFR §56.108(b)(1) and 45 CFR 46.103(b)(5). Adverse events that are unexpected and related to the study will be promptly reported to the University Institutional Review Board (IRB). The Data and Safety Monitoring Plan for the proposed project incorporates the policies on human subject data and safety monitoring specified by the University of Kentucky IRB.
c. Plan for Safety Review: A methodical review of all procedures will be an integral part of each research team meeting. Review will include discussion of protocol to ensure adherence, discussion of procedures to insure confidentiality is maintained and that data are collected with minimal risk for violations of confidentiality. A meeting involving the PI, co- investigators, and research nurses will be called if an unexpected adverse event occurs.
d. Plan for Data Quality: The research design, methods and procedures will be reviewed by all members of the research team during staff meetings. Meetings with PI and data manager will be conducted every 3 months to verify accuracy of data entry, identify missing data, and run preliminary analyses of demographic, to verify enrollment targets, and outcomes. Data entry errors will be corrected and plans will be developed to address any systematic problems related to data entry and integrity.
e. Reporting Mechanisms: Reporting for this study will include an annual report to the various IRBs, regulatory and sponsoring agencies at a minimum, with appropriate updates and reports in the event of an adverse event(s).

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

All participants will be provided with the contact information for the PI, other research nurse, and the IRB. The consent will include information on how to contact the UK ORI and the PI to discuss the research and/or to handle complaints. Participants will be encouraged verbally and in writing through the informed consent document.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first**.)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

Consent to Participate in a Research Study
Effects of Family Sodium Watcher Program on Outcomes in Heart Failure Patient-Family Caregiver Dyads (Patients)

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about effects of the Family Sodium Watcher Program (Family SWaP), designed to improve both patients' and caregivers' adherence to a sodium restricted diet. You are being invited to take part in this research study because your primary care provider has diagnosed you as having heart failure. If you volunteer to take part in this study, you will be one of about 300 people with heart failure to do so. A total of 300 people will participate in the study.

WHO IS DOING THE STUDY?

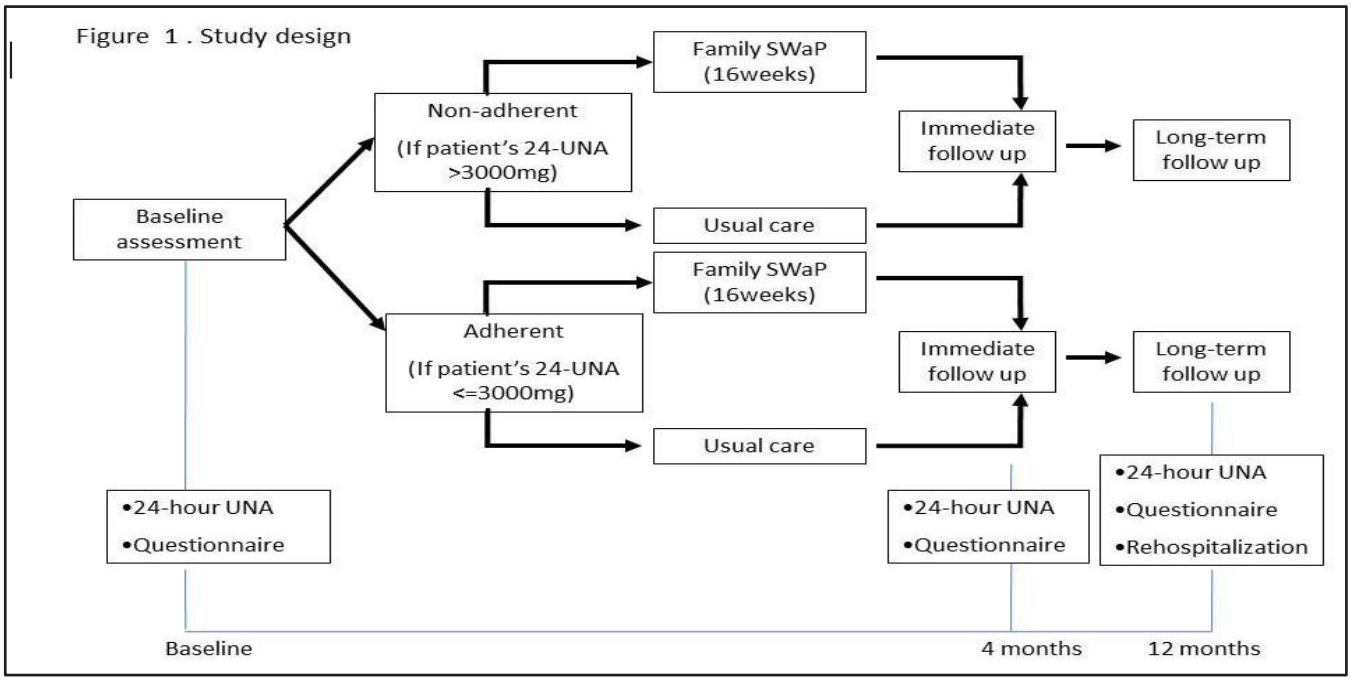
The person in charge of this study is Misook L. Chung, PhD, RN, (PI) of the University Of Kentucky, College Of Nursing. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research is to gather information on whether the self-management program of step-by-step, progressive adaptation to the sodium restricted diet using an electronic sodium monitoring device improves adherence to a sodium restricted diet and decreases symptom distress in HF patients.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted in your home. On the first day you will be asked to collect a 24-hour urine specimen and fill out a series of questionnaires. Completing the questionnaires will take approximately 30 to 40 minutes. You will be assigned randomly by the investigator to either the education group or no education group. The education group will be invited to participate in 6 weekly education sessions (45 minutes) followed by 5 bi-weekly sessions (15- 20 minutes) at your home using video conferencing technology via digital device (i.e., iPad). The education session will be led by a cardiac nurse. You will be asked to collect 24-hour urine specimen and complete the same series of questionnaires at -4 and 12 months follow up. Completing questionnaires for the 2nd and 3rd follow up will take approximately 20 to 30 minutes. The total amount of time you will be asked to volunteer for this study is 90 to 120 minutes per person for completion of the questionnaires. If you are in education group, you will be asked to volunteer for 345 to 370 minutes (approximately 6 hours) of sessions.



WHAT WILL YOU BE ASKED TO DO?

You will be asked to collect a 24-hour urine specimen using collecting hats or urinals and complete a variety of questionnaires 3 times at the first assessment, 4 and 12 months follow up. You may also be asked to participate in an interview that will gather your opinions on the challenges your family has faced regarding low sodium diet. You will be assigned to either the education group or no education group. You will be asked to attend a total of 16 weeks education sessions if you are assigned to the education group. You will get monthly calls to collect hospitalization events for 12 months. You may decline to answer any questions at any time if they make you feel uncomfortable. The questions will cover your symptom distress, eating habits, emotional symptoms, perceived control, quality of life, past medical history, and medications. We will also review your medical records to confirm your medical history and medications.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you do not have heart failure. You will be excluded from this study if you have had a recent stroke or heart attack (within 3 months), co-existing terminal illness, myocarditis, or major psychiatric disorder other than depression.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no known risks associated with filling out these questionnaires. However, you may feel stressed or bothered by the demands placed upon you by answering some of the questions on the study questionnaires. You do not have to answer questions if they cause you undue discomfort. There is a slight risk for emotional upset as the qualitative questions will focus on family dynamics and differences regarding low sodium diet.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have experienced a positive feeling for contributing to knowledge about their condition that may help others. The participants in the education sessions may receive potential benefit of learning self-management techniques and strategies to decrease dietary sodium intake.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any medical or other benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs for you to participate in this study. None of the procedures will be billed to you, or your insurance company, Medicare, or Medicaid. We will pay your urine specimen lab work. We will provide you with the digital device (i.e., an iPad per a family) for the duration of the study (12 months). If a dyad (patient and caregiver) prefers the option of us collecting data and delivering supplies in the office or clinic rather than their home, we will offer payment of $20.00 for travel and time.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. Officials from the University of Kentucky and/or Baptist Health Lexington may look at a copy of pertinent portions of records that identify you. We will have our nurse r ecruiters at Baptist Health Lexington gather data on hospitalization/events/survival on you during your participation in the study. We use a specific form for this. Once the form is completed, the nurse recruiters at Baptist Health Lexington Hospital will send it to us via secure email.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. However, if you and/or your family member decide to stop taking part of the study, you and your family will be asked to return the digital device (i.e., iPad).

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is done during the study, you should call Misook L. Chung at 859-323-8024 immediately. It is important for you to understand that the University of Kentucky and/or Baptist Health Lexington will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. That cost will be your responsibility. Also, the University of Kentucky and/or Baptist Health Lexington will not pay for any wages you may lose if you are harmed by this study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

There is no cost associated with personal transportation to the University of Kentucky and/or Baptist Health Lexington. This study invites you and your ill family member to participate together. Only one iPad will be given to you and your ill family member as a family unit. If you withdraw from the study before the three assessments have been completed, your family participation in the study has ended and you family are asked to return the iPad that was given to your family at the beginning of the study. If you and your ill family member complete the three assessments (baseline, 4- months, and 12 months follow up), your family will be allowed to keep the iPad.

WHAT IF YOU HAVE QUESTIONS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, Dr. Misook L. Chung at 859-323-8024. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a copy of this consent form to take with you.

WHAT ELSE DO YOU NEED TO KNOW?

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study. The National Institutes of Health is providing financial support and/or material for this study.

_____ _____

Signature of person (patient) agreeing to take part in the study Date

_____

Printed name of person (patient) agreeing to take part in the study

_____ _____

Name of person providing information to subject Date

_____

Signature of Investigator