The Health Integrated, Nutrition and Kidney-Wellness (THINK-Well) Program- Phase 2

Funding Sponsor: AHA Career Development Award

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PRINCIPAL INVESTIGATOR SIGNATURE

Study Sponsor: AHA Career Development Award

Study Title: The Health Integrated, Nutrition and Kidney-Wellness (THINK-Well) Program (Phase 2)

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I, the Investigator, acknowledge that I have read and understood this protocol. I agree to conduct and supervise the educational study according to all applicable regulations for protecting the rights, safety, and welfare of the subjects under my care. I will adhere to the study requirements as presented in the protocol and agree to start the study only after IRB approval is obtained or this activity is deemed exempt. I will maintain accurate, complete, and current records relating to my participation in the study, consistent with good scientific and ethical practices.

Name: Dr. Linda-Marie Lavenburg

Institution: University of Pittsburgh

Signature: 

ABBREVIATIONS

AHA	American Health Association
CKD	Chronic Kidney Disease
COM-B	Capability, Opportunity, Motivation-Behavior model
CVD	Cardiovascular Disease
EHR	Electronic Health Record
eGFR	Estimated Glomerular Filtration Rate
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
KDOQI	Kidney Disease Outcome and Qualify Initiative
PHI	Protected Health Information
UPMC	University of Pittsburgh Medical Center

STUDY SUMMARY

Title	The Health Integrated, Nutrition and Kidney-Wellness Program (Phase 2)
Short Title	THINK-Well Program (Phase 2)
Description/Objectives	We will conduct a 12-week, two-arm 2:1 randomized controlled pilot feasibility study of THINK-Well intervention compared to enhanced usual care in patients with non-dialysis CKD
Primary Outcome	Primary outcome is feasibility (i.e., recruitment, retention, and satisfaction).
Secondary Outcome	Secondary outcomes include change in Life's Essential 8 score, diet intake, self-efficacy, activation, quality of life, change in anthropometric measures, change in body composition (e.g., fat mass, muscle mass, % fat, % muscle mass).
Study Population	45 Adult (age ≥ 18 years) patients of UPMC Kidney Clinic and the presence of non-dialysis CKD.
Study Site	UPMC Clinics
Intervention	THINK-Well Program- In-person and virtual educational workshop series
Study Duration	18 months

BACKGROUND AND SIGNIFICANCE

An estimated 1 in 7 US adults have chronic kidney disease (CKD) and the prevalence is projected to increase, due in large part to obesity, hypertension, diabetes and aging.[1,2] Patients with CKD have high cardiovascular disease (CVD) morbidity and mortality.[1,3] Due to the intricate interplay between CKD and CVD, the American Heart Association (AHA) proposed a new cardiovascular-kidney-metabolic phenotype and released a Presidential Advisory calling for holistic and equitable approaches to manage CKD, CVD and metabolic risk factors.[3,4] Health goals set by the AHA's Life's Essential 8 for cardiovascular health align well the National Kidney Foundation's Kidney Disease Outcome and Quality Initiative (KDOQI) guidelines for optimal CKD management, especially for nutrition and physical activity.[5] However, despite Medical Nutrition Therapy for CKD being a Medicare benefit since 2002, 9 out of 10 patients with CKD do not receive nutrition counseling until they start dialysis.[6] Furthermore, available CKD management programs typically do not unify the complex dietary needs of competing comorbidities, or offer support to overcome barriers to diet, physical activity, behavior change, or address social needs such as food insecurity, reported by 1 in 4 adults with CKD.

Comprehensive lifestyle intervention programs offer a promising approach to unify health promoting behavior change for multimorbid conditions, like CKD and CVD. Lifestyle intervention programs that encourage balanced eating to promote weight management, and physical activity, are a first line intervention therapy recommended for diabetes and CVD prevention.[7-10] Lifestyle intervention programs, such as the Diabetes Prevention Program, are now reimbursable through Medicare.[8,11,12] However, CKD lifestyle intervention programs are not yet widely available.[13-15] Medical Nutrition Therapy is a covered benefit for CKD, but estimates suggest only one in ten patients receive this benefit, likely due to several reasons including lack of awareness, referral, and/or scarcity of Medical Nutrition Therapy providers.[10,15] Thus, an equitable diet-focused lifestyle intervention rooted in behavior change theory may provide an effective and personalized approach to CKD and CVD risk reduction meanwhile, also addressing complex dietary needs of competing comorbidities and providing support to overcome barriers to food access or behavior change, such as food insecurity.[16] AHA's Life's Essential 8[3] (**Table 1**) is a measure of cardiovascular health and aligns well with CKD management guidelines (i.e., KDOQI)[17] and thus can serve as an important educational tool for goal setting in a diet-focused CKD lifestyle intervention program.[18]

OBJECTIVES

The goal of the current proposal is to pilot test THINK-Well Program, which will offer practical, culturally aware guidance on affordable and sustainable strategies to nutrition optimization, which may potentiate improvements in other kidney and cardiovascular health behaviors (e.g., physical activity).

Primary outcomes: (**Table 1**)

- Feasibility (i.e., recruitment, retention, and satisfaction).

Secondary outcomes:

- Change in Life's Essential 8 score, diet intake, self-efficacy, activation, quality of life, change in anthropometric measures, change in body composition (e.g., fat mass, muscle mass, % fat, % muscle mass.

Table 1. Primary Outcomes	**Benchmarks**
Feasibility	
Recruitment # patients screened # eligible patients / # patients screened # patients enrolled / number of eligible patients x 100 (per month)	>40% of eligible patients provide informed consent, and complete baseline assessments
Retention Monthly dropout rate and reason for dropout # patients who complete post-questionnaires / Number of patients enrolled x 100	>70% retention of participants at 12 weeks
Satisfaction Patient and provider satisfaction reported using client satisfaction questionnaires	>80% satisfaction on survey
Secondary Outcomes	
Mediterranean Eating Pattern for Americans tool[20], Life's Essential 8 score[21], Hunger vital sign[22], Chronic Disease Self-Efficacy[23,24], Patient Activation Measure-13[25], and Kidney Disease Quality of Life-36[26], Change in anthropometric measures (e.g., weight, body mass index, waist to hip ratio), Change in fat mass, muscle mass, percent body fat, and percent muscle mass	

STUDY DESIGN

We will conduct a 12-week two-arm 2:1 randomized pilot feasibility study of THINK-Well intervention compared to enhanced usual care. We will recruit patients with non-dialysis CKD from the UPMC Clinics.

PARTICIPANTS

45 Adult (age ≥ 18 years) patients with non-dialysis CKD defined by lab values (eGFR ≤ 60 ml/min/1.73m^2).

INTERVENTION

THINK-Well Program is a workshop series of seven alternating virtual and in-person group activities led by a trained interventionist every two weeks aimed to promote capability, opportunity and motivation to change kidney health promoting behavior. Group activities will include education, goal setting, peer support, cooking classes, physical activity coaching, and provision of functional retention items (such as food vouchers, cooking supplies, etc.). We will also provide a one-time opt-out 1:1 dietitian counseling to facilitate goal attainment and personalized meal planning.

THINK-Well intervention components described in **Table 2** were developed using:

a) A conceptual framework often used to design behavior change interventions.[27,28] We used the Capability, Opportunity, Motivation- Behavior (COM-B) model, a behavior change theory embodied in the Behavior Change Wheel, to ensure program components fulfill behavior change functions.[29] The COM-B model theorizes that behavior is the result of an interaction between three components: capability, opportunity, and motivation.

b) Human centered design approach. Patient recruitment, engagement and retention are major barriers to impacting patients, especially in populations with socioeconomic disadvantages. To overcome these

challenges, we used a human centered design approach to incorporate lived experiences and input from a Community Partner Advisory Panel to design THINK-Well intervention and solve challenges.

c) Community Partnerships. THINK-Well intervention was developed with a Community Partner Advisory Panel including patients, nephrologists, a Women, Infants, and Children Director, Giant Eagle Grocery, a public health and lifestyle intervention expert, local National Kidney Foundation executive director, and a Health Plan representative.

COMPARATOR

The comparator arm will be enhanced usual care. Standard of care for people with kidney disease is an optional 30–60-minute one-time educational session with a nurse educator during which topics such as kidney disease stages, nutrition, physical activity, medications to avoid, and renal replacement therapy are discussed. The comparator group will receive two group virtual educational sessions delivered by a trained educator. Educational topics will include Nutrition and Kidney Disease, Dining out with confidence, and will direct participants to the websites, such as National Kidney Foundation, American Kidney Fund, and American Heart Association to find more nutrition guidance.

Table 2. THINK-Well Intervention

Week	Activity (Proposed facility if in-person)	In-person or Virtual	Retention item*
1	Welcome and Overview / Goal setting (at Phipps Teaching Kitchen)	In-person	Swag bag with Cooking Supplies
2	Education: Diet Approaches for Heart-Kidney-Metabolic Health / Goal Progress	Virtual (Zoom)	Food Voucher
4	Activity: Cooking with Salt alternatives (Location to be determined)	In-person	Food Voucher
6	Education: Reading labels and portion control/ Goal Progress	Virtual (Zoom)	Food Voucher
8	Activity: Physical activity and self-monitoring and Goal Progress (Location to be determined)	In-person	Stress ball
10	Education: Dining out and Eating with a budget/ Goal Progress	Virtual (Zoom)	Food Voucher
12	Activity: Cooking Class /Goal Progress/ Graduation (at Phipps Teaching Kitchen)	In-person	T-shirt

Sessions led by a trained health coach. Reminder text message sent 24-and 48 hours prior to Activity
Opt-out virtual 1:1 dietitian counseling to facilitate goal attainment and personalized meal planning
* Retention items are proposed and subject to change

STUDY PROCEDURES AND ASSESSMENTS

DURATION

Phase 2 of THINK-Well is anticipated to have an 18-month implementation period

FIDELITY

The research team will obtain required regulatory approvals and leadership and carry out the study procedures. Fidelity checks will be conducted throughout various time intervals by auditing.

DATA COLLECTION AND MEASURES

Sociodemographic and clinical data (including medications, vital signs, weight, lab values such as urine albumin to creatinine ratio and serum creatinine) will be collected at baseline and end of intervention. Body composition and anthropometric measurements will be collected at baseline and end of intervention +/- 2 weeks. Primary and secondary outcomes data will be collected at baseline and after 12-weeks of intervention. Data will be collected in-person or by phone through patient interviews by trained research staff and supplemented with data from electronic record.

DATA ANALYSIS PLAN

We will perform descriptive statistical analyses of baseline characteristics, primary and secondary outcomes. Point estimates and confidence intervals will be calculated for feasibility parameters. We believe that successfully recruiting >40% of eligible patients (e.g., 9 patients per month) will demonstrate the capacity to recruit for a future trial. This study is not powered to establish the efficacy of THINK-Well Program on clinical (secondary) outcomes. However, we will administer questionnaires to determine feasibility of collecting these data.

HUMAN SUBJECTS

Risks to Subjects

The risks of the proposed study are exposure to food allergies at cooking classes and through food boxes. However, we will collect a list of food allergies before cooking classes and food box distribution. Minor musculoskeletal pain may also result despite performing physical activity within individual limitations. Risks include the slight risk that their confidentiality may be breached. Data containing personal health information will be password protected behind a firewall with access limited to essential study personnel. All data for analysis will be de-identified.

Benefits to participating in the pilot THINK-Well Program may include better understanding of nutrition for kidney and heart health, improved control of blood pressure, blood sugar, and cholesterol, and greater access to health and nutrition resources compared to usual care.

Protections against Risks

The study will be approved by the University of Pittsburgh Institutional Review Board (IRB). All study personnel led by the PI are clinically competent and current on all trainings including HIPAA compliance certification and responsible conduct of research.

Confidentiality

This study will be conducted in compliance with all applicable rules and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Only the minimum data necessary for the study will be obtained. Any data stored electronically will be stored on University of Pittsburgh and UPMC secure password protected computers on secure servers in departmental offices. All paper forms with PHI will be stored in closed cabinets in closed rooms. Only the principal investigator and the research team involved in the study will have access to the data.

Risk-Benefit Ratio

There is minimal risk for participants. The benefits of pilot trial participation include greater understanding of kidney disease and the interrelationship of nutrition with heart-kidney-metabolic health. Participants may also experience greater awareness and access to health resources available outside of the THINK-Well Program. As a result, this leads to the potential of future benefit to patients.

Importance of Knowledge to be Gained

We hypothesize that addressing food accessibility, affordability, behavior change, and education will increase recruitment, retention and satisfaction, meanwhile achieving short-term changes in healthy eating behavior and potentiating change in other health behaviors.

REGULATORY, ETHICAL AND OVERSIGHT CONSIDERATIONS

The Investigators will be responsible for ensuring that the study is conducted in compliance with the protocol and all applicable rules and regulations. This educational study will be conducted in full accordance with all applicable Institutional Research Policies and Procedures and all applicable Federal and state laws and regulations, including 45 CFR 46 and the HIPAA Privacy Rule. It is the Investigator's responsibility to perform the study in accordance with the protocol and all applicable rules and regulations. Any instance of non-compliance will be documented and reported in accordance with the University of Pittsburgh IRB Policies and Procedures and federal requirements.

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