Protocol Template for Human Subjects Research without an Investigational Product

Supporting Self-Management of Healthy Behaviors (SMART-HABITS)

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1. Background Information and Rationale

1.1 Introduction

The escalating burden of chronic kidney disease (CKD) and end-stage renal disease (ESRD) is widely acknowledged, and thus kidney disease presents itself not only as a very potent cause of mortality and morbidity but also as a serious economical challenge around the world, which makes it necessary to optimize its management.[1,2] Currently, the management of CKD includes extensive participation in self-management behaviors, including monitoring blood glucose and blood pressure, maintaining physical activity, changing eating patterns, adhering to complicated medication regimens, and avoiding nephrotoxins, in the effort to slow kidney disease progression and reduce adverse outcomes.[3]

However, CKD patients demonstrate high rates of non-adherence to self-management, leading to increasing costs, morbidity and mortality, and overall poor outcomes, which presents a compelling need to better understand how to help this population self-manage the disease.[4] To improve self-management, it is to develop core self-management skills, which include problem-solving, decision making, action planning, goal-setting, seeking social support, and resource utilization, as well as to explore factors related to engagement.[5,6] In other chronic diseases, important influences of engaging in self-management include improved knowledge, self-efficacy (or the confidence in their ability to overcome barriers in order to perform self-management behaviors[7-13]), and social support.[14-19] Individuals with CKD have also identified similar factors as important to them for self-managing.[20]

Therefore, effective self-management support that improves self-efficacy, knowledge, and social support could ultimately improve engagement in self-management behaviors in pre-dialysis CKD, which could then favorably influence the course of the disease.[21] The Institute of Medicine defines self-management support (SMS) as “the systematic provision of education and supportive interventions to increase patients’ skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support”.[22] SMS is recognized as widely effective across numerous chronic conditions, and a meta-analysis of SMS programs found improved clinical outcomes.[23] The benefits of SMS in kidney disease is growing, although most programs have focused on ESRD, which have led to improvements in disease specific and self-care knowledge, health-related quality of life, health service utilization, progression and understanding of CKD, and increased physical activity.[24-33] Participants of SMS programs also report finding them helpful and those who have not yet participated in such a program express interest and willingness to participate, and learn how to self-manage.[34-36]

The use of digital technology to support chronic disease self-management is growing, as advances in technology have made real-time assessments of health behaviors and their influences possible with minimal respondent burden.[29,37] An example of one of these digital solutions is mobile health (mHealth) technology, the use of mobile and wireless devices to enhance health and wellness by extending health interventions and research beyond the reach of traditional clinical care.[38] Recent studies that have examined mHealth tools across various diseases have shown significant improvement in medication adherence, weight management, HbA1c, stress levels, smoking quit rates, and self-efficacy, as well as high level of patient satisfaction, and levels of familiarity with mobile technology.[39-43]

Therefore, mHealth technology offers an attractive and novel tool to support CKD patients integrate self-management into their lives through a SMS program. Specifically, the smartphone is an especially attractive option for SMS and remote monitoring due to their ubiquity, connectivity, computational power, portability, and relatively low cost.[44-46] According to a Pew Research Center Survey conducted in November 2016, 90% of US adults own a cell phone and nearly 77% of all Americans own a smartphone, including 64% among lower income Americans, 74% those aged 50-64 years and 42% of those 65 and older.[47] Smartphones can collect data for purposes such as patient monitoring, reminders, and recommendations, as well as offer additional functionality offered by their built in devices and connection with other devices.

The planned intervention, entitled, Supporting Self-Management of Healthy Behaviors in (SMART-HABITS), aims to provide SMS for CKD patients by providing text messages delivered as motivational reminders and support to encourage blood pressure self-monitoring and physical activity monitoring, and will also provide access to educational resources and opportunities to engage in social support. The SMART-HABITS intervention will undergo feasibility testing in a single group prospective trial within a renal clinic affiliated with the Division of Renal-Electrolyte and Hypertension within the University of Pennsylvania Health System.

1.2 Name and Description of Intervention

Altogether, SMART-HABITS aims to increase self-efficacy, disease-specific knowledge and social support via mHealth through the Way to Health Platform in order for CKD patients to enhance self-management and its core skills. The coupling of mHealth technology and SMS is novel, innovative, and potentially cost-effective. Although various mHealth interventions have been developed across a spectrum of chronic illnesses with promising results[48-53], there have been few such applications to support health behaviors in patients with CKD, of which have primarily focused only on a single component of self-management.[54-56] Expanding on this,, SMART-HABITS encompasses multiple behavior change techniques, and is centered in the Health Belief Model and the Social Cognitive Theory in order to foster behavior change and improve self-management.[18,57-62]

A critical component to the success of any mHealth program is the willingness and ability of the target population to adopt and effectively utilize the technology. The attitudes towards mHealth have been assessed in other chronic diseases[46,63-66], but there has been limited data on those with kidney disease, which has been primarily assessed only in kidney in transplant recipients. Among kidney transplant recipients, interest in receiving CKD education and SMS through mHealth has been confirmed through focus groups, and surveys, and kidney recipient participants of an mHealth intervention were comfortable using mobile phones and being monitored using mobile technology, with many of already owning and using smartphones.[67-69] In order to improve the SMART-HABITS program, it is important to understand and consider patients' opinions and preferences, we plan to perform semi-structured interviews with participants at the end of the study for further refinement of the program.

SMART-HABITS is intended to be delivered outside the clinical encounter and employ accessible technology to empower patients diagnosed with pre-dialysis CKD to manage their condition by enhancing knowledge of CKD through low literacy education materials, support engagement in self-monitoring of blood pressure, increasing participation in physical activity or weight loss through customized task prompts via text message, and promote social support through accountability sponsors and linked to community resources as described in the following sections.

Within SMART-HABITS' smartphone web-based application, there will be a portal which:

- Provides educational information that incorporates both clinical and lay-experiential CKD knowledge
- Displays personally set goals and real-time progress to goals
- Links to social support

The following sections further describe the components of the program:

1) **Education**: informational content on CKD related health risks, self-management behaviors to slow progression of disease and prevent complications; provide examples of how everyday lifestyle activities can impact CKD.
   - The education section in the web-based application will include the following sections:

General Information about Kidney Disease

1. Kidney Disease and Manage You Kidney disease: https://www.youtube.com/watch?v=M8kbD4mgxFA
2. Detect and Manage Your Kidney Disease: https://www.youtube.com/watch?v=ZhWHpJN3KaY&feature=emb_logo
3. Trustworthy Information about Kidney Disease: https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd
4. High blood pressure and Kidney Disease: https://www.kidneyfund.org/prevention/are-you-at-risk/high-blood-pressure.html
5. Diabetes and Kidney Disease: https://www.kidneyfund.org/prevention/are-you-at-risk/diabetes.html

Tips for Checking your blood pressure at home

1. https://www.youtube.com/watch?v=6oYUYcK57Kc

Tips about Physical Activity

1. Health Benefits of Physical Activity: https://www.nia.nih.gov/health/real-life-benefits-exercise-and-physical-activity
   a. If also have diabetes: https://www.youtube.com/watch?v=z-UfMvBoGVU
2. Daily Physical Activity Goals: https://www.youtube.com/watch?v=xBCgB8EvzYo

3. Examples of exercise and physical activity: https://www.nutrition.gov/topics/exercise-and-fitness/exercise-examples-and-videos

2) **Developing Goals and Action plan:** setting personalized goals for blood pressure self-monitoring and physical activity
   - Patients will complete a patient-generated "action plan" to assist in developing goals to help them initiate changes and achieve success in managing their condition effectively
     - Develop goals for blood pressure control by the end of the study and the level of adherence to blood pressure measurements
     - Develop daily step count goal for physical activity over the study period

3) **Support Adherence and Increase Self-efficacy**:
   - Provide personalized daily and weekly texts to encourage participation and progress towards blood pressure monitoring, physical activity goals
   - For blood pressure readings that are texted to the Way to Health platform,the participant will receive predefined comment on the control of their blood pressure
   - For each daily step count transmission, the participant will also received similar feedback
   - Additionally, if the participant elects to enroll an accountability sponsor, progress will be shared with this individual

4) **Monitoring**:
   - For the participants using the OMRON Connect app, self-monitoring will be captured by electronically recording blood pressure measurements via Bluetooth by participant using a wireless blood pressure device (OMRON 5 series cuff)
     - CKD patients will be asked to self-measure blood pressure using a blood pressure cuff at home at least 3 times per week and then further personalized by goal-setting
   - Remote monitoring of physical activity will be done via a physical activity sensor (Fitbit Inspire 2) that is worn as a watch and link the data to the Fitbit app in order to help patients monitor their own personal progress.

5) **Social Support**: support through kin/sponsor
   - As indicated above in supporting adherence, by sharing feedback and progress with family members, peers or any other identified sponsor/support aims to support adherence.
   - In addition, there will be a link provided to the available social support:
     - Peers Lending Support- free, anonymous phone calls with other CKD patients (http://www.kidney.org/patients/peers/index.cfm)
   - Participants will also be provided with directions to access friends and a community with the FitBit App.
   -

1.3 Relevant Literature and Data

At all stages of CKD is a massively increased risk of CVD and associated events and early death.[70] Hypertension is a leading caused of cardiovascular disease events. Hypertension is an asymptomatic but dangerous condition, which carries risk of catastrophic cardiac, renal and cerebrovascular events. However, commonly, it is inadequately controlled. There is evidence that self-monitoring of blood pressure at home is useful in improving medication adherence, and controlling BP.[71-73] A previous systematic review of randomized controlled trials demonstrated that SBP readings in people undertaking home monitoring was significantly lower than control patients.[74] Further evidence suggests that greater reductions in BP may be achieved by the addition of behavioral support for self-monitoring.[75-77] This may be further facilitated when combined with efficacious lifestyle changes, such as increasing physical activity[78,79], or weight loss. Physical inactivity is also leading risk factor for CVD[80-82] , and it has also been suggested that it contributes to the development of CKD in the general population.[83] However, higher levels of physical activity can lower all-cause mortality[84,85], CAD[80,49586], diabetes[87], lower rate of nephropathy[88] and renal dysfunction[89,90] in diabetic patients, and weight gain[91], and weight loss is associated with cardiovascular health benefits[92,93], reduction in the incidence of diabetes by 50%[94,95], and lowering of systolic blood pressure1.0-2.4 mmHg[96]. Additionally, two studies suggest that weight loss is beneficial for renal function[97,98] but there is insufficient evidence that it affects CKD progression. These findings along with

others provide evidence that reducing multiple risk factors concurrently, rather than targeting single factors, is likely to deliver greater reduction in cardiovascular disease events[99].

Telehealth is being increasingly used to assist patients and healthcare professionals responsible for their care to monitor medication conditions. A variety of delivery methods are available, from web-based methods to telephone touch pads.[100] Increasingly, widespread access to the Internet and mobile phones means that healthcare digital interventions are accessible to the majority of patients and can be used to provide information and support at any time the patient needs it.[101] Ehealth/mHealth can empower patients by providing better access to personalized information and support for active involvement in treatment and self-management. A large meta-analysis found a small but significant positive effect of digital interventions on health-related behaviors[102], while a Cochrane review found evidence that computer-based health interventions for those with chronic health conditions significantly improved knowledge, health behaviors, and clinical outcomes.[103] Therefore, this intervention program has been developed to incorporate previously identified effective intervention components (self-monitoring, and behavioral support).

- ***Rationale for inclusion of an education component***: There is a low baseline understanding of CKD health risks. Increasing knowledge of CKD is a critical pathway to ensuring that patients can be taught how to integrate self-management activities and participate in care decision and planning.[104] For example, patients need to be taught that maintaining appropriate blood pressure readings[105], blood glucose control and taking their medication as prescribed all work together to protect kidney health[106]. Research has shown that patient understanding of CKD improves self-management and outcomes.[107-110] Conversely, CKD patients who have a poor understanding on their disease process tend to participate less in their health care management.[111] Additionally, CKD patient education programs may improve overall mood and feelings of good health[110] and many patients desire CKD education.[36,112,113]

However, simply providing information is not sufficient for behavior change and people may struggle to integrate this information into their lives.[114] The following components were guided by health behavior theory to further bolster behavior change:

- ***Rationale for inclusion of goal-setting and action planning***:
    - Developing core self-management skills, such as action planning and goal-setting is central to improving adherence to self-management behaviors.[5] A systematic review of SMS programs that used health information technology revealed that goal-setting was among the successful solutions, which also included education, monitoring, and collaboration.[115]
- ***Rationale for inclusion of adherence support***:
    - Follow up prompts have been associated with increased effectiveness.[62] Previous studies have indicated that patients with higher self-efficacy have improved problem solving, open communication, and patients-provider partnership.[11,116-118] Increased self-efficacy has also been shown to be correlated to engagement in self-management behaviors, and improved outcomes (i.e., health status, decreased hospitalizations, improved QOL in dialysis patients).[8,10,11,116,117,119-125]
- ***Rationale for monitoring***:
    - Self-monitoring is a component of effective behavior interventions.[61,126] Other chronic disease studies found that electronic self-documentation of blood sugars and weights, as in diabetes and heart failures, respectively, was shown to be an effective strategy to promote self activation.[127,128]
    - Remote monitoring via mobile phones has been shown to be an effective and sustainable strategy for improving health outcomes, increasing adherence to medical regimens and reducing costs in some chronic illness.[42,44,128-131]
- ***Rationale for inclusion of social support***:
    - As trusted sources of information, family and community members have the potential to help overcome sociocultural barriers and institutional/medical mistrust, which is prevalent among those with a large burden of CKD.[132] In CKD, family, friends, and other social groups provide practical and emotional support and facilitate self-management (e.g., changing dietary patterns, increasing physical activity).[133-136] The Internet has also become a resource for the development of social support systems for those affected by chronic diseases, including kidney disease.[137]
    - The Internet has also become a resource for the development of social support systems for those affected by kidney disease, and an analysis of online discussions revealed patients are actively

discussing CKD on social media.[137,138] CKD patients have reported they desire social support[139] but are unsure of available support and wish that SMS programs included information about local, community-based resources, organizations and support groups.[140]

2. Study Aims and Research Questions

The primary aim is to assess the feasibility of using a smartphone-based behavioral intervention, SMART-HABITS, to support self-management of individuals with pre-dialysis CKD patients.

Research Questions:

- Will patients with CKD adopt SMART-HABITS?
- Will patients with CKD adhere to prompts of the SMART-HABITS intervention?
- Will patients with CKD wear and use wearable remote sensors (i.e. wireless blood pressure cuff and physical activity sensor)?
- How many patients with CKD will drop out throughout the study period?
- Is SMART-HABITS acceptable to patients?
- What are patient views and experiences of using SMART-HABITS?
- Is there any change in blood pressure control throughout the study period?
- How well did participants achieve their step count goals throughout the study period?
- Did SMART-HABITS associate with improved self-efficacy, knowledge, attitudes to mHealth, self-management, or quality of life?

3. Investigational Plan

A cross-over prospective trial of feasibility of a smartphone-based behavioral intervention in a real-life setting.

General Schema of Study Design

Nephrology Practices: PCAM and Presbyterian

Identification of Potential Participants(48-72 weeks):
- Letter of invitation sent by research team after reviewing schedule for follow up visits, followed by phone call
- Study advertisement posters within the practice
- Pre-Screen all eligible patients who respond to invitation or inquire about poster

Conducted remotely through Way to Health: Baseline consultation and enrollment:
- Screening survey: Assess eligibility
- Informed Consent
- self-reported height, weight
- Patients given unique log-in for Way to Health
- Patients provided with instructions with how to use wearable devices (BP cuff and FitBit)
- Provide authorization for data to be shared from wearable devices
- Complete survey questions

Intervention (12 weeks)
- Arm 1 (first 6 weeks): Text message reminders to check BP and text BP readings to research team
    - Tailored text message feedback for transmitted BP readings
- Arm 2 (first 6 weeks): push notification reminders via OMRON Connect app on participant's phone to check BP and BP readings shared via OMRON app
- Start of week 7: Arms cross-over
- All participants:
    - Personal dashboard with access to educational and social support resources
    - Daily text message reminders and feedback for step count data
    - Re-engagement protocol for low participation
    - Weekly feedback on BP monitoring adherence

Outcome assessments (end of 12 weeks)
- Primary outcome assessments of adoption, adherence, and acceptability
- Secondary outcome assessments of effectiveness and reach

3.2 Allocation to Treatment Groups
Participants will be prospectively enrolled and randomized into one of two arms. Randomization will occur after enrollment on the Way to Health Platform utilizing random number generator. Specifically, permuted block randomization will be used for balance between cross-over arms throughout the investigation. The study coordinator will maintain the master list and securely store the randomization files.

3.3 Study Duration, Enrollment and Number of Sites
Recruitment and conduction of the trial is expected to start two years after notice of K23 award (3/1/2021) and be complete by four years after notice of award (4/1/2023). There are two study sites, located at the Renal Clinics affiliated with the Renal, Electrolyte and Hypertension Division in the Perelman Center for Advanced Medicine and in Presbyterian Medical Center.

3.3.1 Total Number of Subjects
The study will be limited to 40 patients with CKD and hypertension.

3.3.2 Duration of Study Participation
The intervention will be conducted for each participant over a 12-week period.

3.4 Study Population
Patients with stage 3 or 4 CKD and hypertension seen in the Renal Clinic at PCAM and Presbyterian Medical Center scheduled for a follow up appointment.

3.4.1 Inclusion criteria
The criteria will aim to capture adult patients with hypertension (treated with three or less anti-hypertensive medications) and chronic kidney disease stage 3 or 4 managed in participating nephrology practices that will be aged 18 or over. Eligible patients will also be required to have an iPhone or Android smartphone that they state are willing to carry with them the majority of the time while enrolled in the study, able to comprehend English, , and have the ability to walk. Further inclusion criteria include a mean blood pressure reading of <=180/100 mmHg from historical blood pressure readings in the electronic medical record, and able and willing to provide informed consent

3.4.2 Exclusion criteria
Exclusion criteria included conditions that made participation infeasibility (inability to provide consent or read or speak English); having had MI or stroke within the previous six months, inability to self-monitor (e.g., diagnosis of dementia), inability to walk, already participating in another physical activity study, or stated for any other reason that they did not expect to be able to complete the study. Other exclusion criteria include: vulnerable populations, likely to receive a kidney transplant within 1 month of enrollment into the trial, living in a long-term care or rehabilitation institution, likely to have their care transferred to another facility outside participating clinic areas during the course of the study, planning to travel or live consecutively out of the country for more than one month, participating in another intervention trial, cognitive impairment, mean blood pressure reading of >180/100 mmHg (stage 3 hypertension or greater requiring more urgent intervention than would be available in the study), hypertension not managed by the nephrologist in the clinic, prescribed more than three anti-hypertensive medications (i.e. resistant hypertension), an acute cardiovascular event in last 3 months (as blood pressure and antihypertensive medication may not be stable), and any other reason they do not expect to be able to complete the study.

4. Study Procedures
4.1 Screening and Enrollment Visit
At screening and enrollment (to be conducted remotely using the Way2Health platform), eligibility will be ensured and informed consent will be taken. Upon completion of the informed consent and screening survey questions (Appendix III), the Way2Halth platform will automatically create a unique study ID. Individuals not wanting to take part in the study will be provided with a form to return should they wish to decline to take part in the trial. This will ask for basic demographic information and their reasons for declining, including an option to give a reason if they prefer not to. At study entry all participants will be given a brief training via the PSOM-secure Zoom video-based platform on how to use the Way to Health application after downloading onto their smartphone. Participants will be provided with details regarding how to

contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants' individual Way to Health web portal dashboards throughout the study.

Participants will mailed an OMRON 5 series wireless blood pressure cuff (BP7250) or if preferred by the participant, given the OMRON blood pressure machine at one of the nephrology practices using appropriate social distancing and face coverings. The blood pressure monitor given to each participant will be checked for accuracy. Participants will be directed to a brief training video on how to correctly measure their blood pressure using this device. Participants will also be mailed a physical activity sensor watch (Fitbit Inspire 2) that will monitor their step counts, or if preferred by the participant, they will be given the FitBit at one of the nephrology practices using appropriate social distancing and with face coverings. The participants will be asked to wear the Fitbit every day for the entire 12 weeks. All participants will be asked to authorize the electronic transmission of de-identified data to the study database from the devices during the Way2Health enrollment phase.

Instructions on how to correctly set up both wireless devices will also be mailed and available online as a google doc (see Appendix II).

Participants will be asked to complete baseline questionnaires and report on their sociodemographic characteristics, including age, gender, highest level of education, and race/ethnicity, baseline step counts on their smartphone or on a computer. They will also be asked to fill out an action plan for their BP and daily step count goals. The intervention will commence after these baseline measures have been collected.

At the end of the study, qualitative interviews will be scheduled with willing participants to provide an in-depth understanding of the factors that may facilitate or diminish the acceptability of the intervention and adherence to the implementation. Open-ended inductive questions will be used to elicit user perspectives and experiences of the intervention, allowing participants to freely describe their experiences and views in their own way. Interviews will be audio-recorded, fully transcribed and analyzed thematically.

4.4. Subject Completion/Withdrawal
Participants will be withdrawn from the study if they become no longer eligible to participate (e.g., no longer can walk or self-monitor BP). Participants who choose not to continue with the study will be offered the opportunity to continue self-monitoring only rather than withdrawing completely from the study and asked if they would be willing to be interviewed for additional feedback.

5. Study Evaluation and Measurements

5.1 Screening and monitoring Evaluations and Measurements
A screening mean blood pressure measurement of ≤180/100 mmHg using historical blood pressures documented in the electronic medical record is required for enrollment. Additional measurements include the remote transmission of BP monitoring and daily step counts. Questionnaires listed below will collect patient reported measures.

5.2 Efficacy Evaluations
The efficacy measures in this trial are only secondary or exploratory as the study's purpose is to assess feasibility. The study was not powered to detect efficacy or effectiveness. The evaluations of effectiveness will include questionnaire scores, BP measures and step counts at baseline, 4, 8 and 12 weeks. Questionnaires will be administered at baseline, 4 weeks, 8 weeks, and end of the study (after 12 weeks).

5.3 Feasibility Evaluations
To assess feasibility, we will collect information on participant retention rates, usage of the SMART-HABITS application, transmitted blood pressure and step count data, usability surveys, and conduct semi-structured interviews to assess user-experience.

6. Statistical Considerations
Since this is a feasibility study, there are no true primary endpoints for statistical consideration.

6.1 Primary Endpoints
The RE-AIM framework, which focuses on five dimensions (reach, effectiveness, adoption, implementation and maintenance), considered to be important for behavioral health interventions will guide the evaluation for the primary endpoints of feasibility of the SMART-HABITS program.

- 1) Adoption: a) participant retention rate at 4, 8, and 12 weeks, b) Percentage of participants who used SMART-HABITS at any point during the 12 weeks.
- 2) Adherence: a) percentage of self-monitored BP transmissions performed out of the recommended and b) percentage of step count data transmissions out of the recommended.
- 3) Acceptability: a) improvement of the pre- and post-study scores on the attitudes toward mHealth questionnaire, b) satisfactory ratings on the ease of use survey during the study and at the end of the study and, c) interview feedback after the end of the pilot study.

6.2 Secondary Endpoints
The secondary measures of effectiveness will include: a) change in pre-pilot and post-pilot questionnaire scores regarding CKD knowledge, self-efficacy, self-management, eHealth literacy and disease-related quality of life; b) change in baseline BP (as determined by the first BP measure transmitted) compared to mean BP after 4, 8, and 12 weeks, and c) change in mean step count in first week compared to mean step count after 4, 8, and 12 weeks.

An additional endpoint includes an assessment of “Reach”, which will be the number and characteristics of participants enrolled in the study.

6.3 Statistical Methods
We will describe the study population with mean values (standard deviations) or medians and quartiles as appropriate for continuous variables and percentages for categorical variables using STATA software. Specifically, we will report the enrollment rate, the retention rate, and participant ratings on ease of use surveys. We will explore if these characteristics differ by age, gender, and education level with analysis of variance and Pearson’s Chi2-testing. We will report the adoption as the percentage of participant still enrolled in the intervention at 4, 8, and 12 weeks and the percentage of participants who used SMART-HABITS at any point during the 12 weeks of the pilot trial. We will report the percentage of the self-monitored BP transmissions performed out of the recommended and also the percentage of the step count data transmissions out the recommended during the pilot trial.

We will perform an exploratory analysis of the change in 1) pre- and post-trial questionnaire scores, and 2) baseline BP and first week mean step count compared to the mean BP and step counts after 4, 8, and 12 weeks using paired t-tests, recognizing that over time the amount of information will diminish as we anticipate fall out, but also, a longer time for the intervention to have an effect. We will explore the association of baseline questionnaire scores with adoption and adherence with linear regression models adjusted for age, sex, race, and education. These will be exploratory analyses since the study was not powered to detect a statistically significant difference. We hypothesize that higher adherence and adoption will be associated with increased scores on baseline measures of self-efficacy, attitude toward mHealth, and self-management. We will also explore for trends in adherence with generalized linear mixed effects models and if blood pressure control or amount of steps modifies trend in adherence.

6.4 Sample Size and Power
The primary purpose of the pilot trial is to assess for acceptance and feasibility of a patient-centered mHealth self-management support intervention. Therefore, no sample size was formally computed.

7. Study Intervention
7.1 Description
The intervention will utilize the Way to Health platform to provide: a) text message reminders, b) text message tailored feedback in response to transmitted data on blood pressure (in the text message arm) and daily step counts, c) positive affirmation text messages sent throughout the study to encourage behavior participation, d) provide links to educational resources, including a video on demonstrating how to correctly perform blood pressure self-mentoring in the portal, e) provide links to community resources and CKD patient forums within the portal, and the f) option to select a accountability partner to share the participant's reminders and feedback. The intervention was developed using a theory-based, and evidence-based approach.

The Way to Health platform is an automated information technology platform that integrates wireless devices, clinical trial randomization and enrollment processes, messaging (text, e-mail, voice), self-administered surveys, and secure data capture for research purposes.[141,142] Way to Health has been used in prior behavior intervention studies.[143-146]

At enrollment, a questionnaire (see Appendix IV) will be completed by all participants to capture demographics, kidney disease knowledge, ability to manage kidney disease, confidence in managing kidney disease, opinions of and ability to use mobile health technology. At enrollment, participants will complete a patient-generated "action plan" (questions in Appendix IV) in order to set realistic goals and encourage participants to create goals that involve positive action- with the minimum targets. Participants will develop short-term goals to help initiate changes and achieve success.

Participants will be asked to check their BP at least three times per week and then to communicate these BP readings with the research team using text message or with the OMRON Connect app (depending on the phase- please see below), and upon receipt, the participants will then receive tailored feedback.

Participants will be asked to set a daily step goal of at least 3,000 steps per day at the start of the study and transmit their step count information to the research team on a daily basis. By providing a minimum threshold puts more emphasis on encouraging more sedentary individuals to walk more and less emphasis on getting highly active individuals to be more active. Participants will be reminded once a day in the evening to sync their steps with the FitBit app in order to transmit them to the Way to Health platform. Participants will receive daily individual performance feedback on their steps from the previous day. Participants will later be sent messages to see if they would like to increase their daily step goal.

Participants will be instructed how to correctly undertake BP self-monitoring to promote self-efficacy through a demonstration video available on Way to Health. Participants will be asked to rehearse self-monitoring at the initial study visit via a secure video-based platform using Zoom.

- Phase 1 (weeks 1-6):
  - After consenting to participate in the study, participants will be randomized to start with Texting (Arm 1) or the OMRON Connect App (Arm 2) to communicate BP readings.
  - Each arm will receive specific instructions pertinent to the specific phase tasks - available as a google document and will also be mailed at the beginning of the study (Appendix II).
  - Participants randomized to the texting arm in Phase 1 will receive automated text message reminders to check their BP on a personalized basis (minimum of three days per which) as participants will choose which days and times to receive these reminders at the beginning of the study. Participants will then transmit the BP readings with text message to the secure Way to Health server. If a blood pressure reading is not received within 3 hours, another reminder will be sent. Automated text message feedback will be sent after the BP reading is recorded with a tailored message regarding any further required actions based upon the BP readings obtained. Any participant with a single systolic blood pressure reading >200mmHg or two consecutive systolic blood pressure readings >180 mmHg or diastolic blood pressure readings >110 mmHg will be contacted immediately by an MD (Dr. Schrauben) for assessment (including evaluation for symptoms of hypertensive emergency) and referral to the emergency department, if indicated. Please see full text message algorithm (Appendix VII).
  - Participants randomized in Phase 1 to the OMRON Connect App arm will complete the same survey questions as those in the Texting Arm. Participants using the OMRON connect app will also receive reminder messages on a similar frequency as the texting arm and will also be customized the partiicpant's schedule as they can choose which days and times to receive push notification reminders delivered by the OMRON connect app. Upon receipt of the BP reading, participants will receive similar BP feedback (Appendix VII).
- Phase 2 (weeks 7-12):
  - At the conclusion of week 6, individuals will "crossover" to the opposite study arm and will continue in the study for an additional 6 weeks using the opposite technology to communicate their BP readings.

Motivating and positive affirmation messages will be sent to participants on a weekly basis (Appendix VII). After 4 weeks,

and 8 weeks of the intervention, a usability survey (Appendix V) will be sent out to assess the ease of use of SMART-HABITS. Automated messages will be sent at key milestones to promote adherence to study procedures. Weekly feedback will be sent the morning after the end of the week. Daily feedback on performance from the prior day will be sent each morning.

Within SMART-HABITS' smartphone web-based application, there will be a portal which provides:

- Educational information that incorporates both clinical and lay-experiential CKD knowledge: Educational resources will present the health-related benefits of self-monitoring, reducing blood pressure, and increasing physical activity. Positive expectations will be outlined by ways that use self-monitoring BP and increasing physical activity may reduce the chances of experiencing negative health consequences.
- Graphical displays of personally set goals and real-time progress to goals
- Web links to social support

Throughout the study, if participants are identified to have low engagement with the intervention, identified through remote monitoring and defined as no BP readings for >1 week or no step counts in 4 days, they will undergo a re-engagement protocol. The re-engagement protocol includes the research team contacting participants with text messages to re-engage them and if after two attempts, the participant continues to not be engaged, they will be called and interviewed over the phone to provide more granular information to assess real-time barriers.

8. Safety Management

There will only be direct contact with human subjects if they are given the wearable devices in person but this would only be done so in a socially distanced fashion (at least 6 feet apart) and with appropriate face coverings. There will be an intervention delivered by health information technology to help encourage healthy behaviors. The potential risk posed by study participation remains minimal, as the intervention is simply text reminders and collection of data from self-monitoring of blood pressure and physical activity via remote devices. According to the Food and Drug Administration (FDA) guidance, the Way to Health research platform, Fitbit and OMRON blood pressure machine wearable devices would be considered general wellness products since they meet the following two factors: (1) intended use that relates to maintaining or encouraging a general safety of health or a healthy activity or an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic disease or conditions (e.g, weight management, blood pressure management, physical fitness, self-esteem), and (2) present a low risk to the safety of users and other persons since the mHealth technology and wearable device are not invasive, are not implants, and do not involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are applied (e.g., lasers or radiation exposure). General wellness products may include software programs and other products that are commonly, though not exclusively, available from retail establishments. A mobile application or wearable device that solely monitors and records physical activity or blood pressure might present a risk of inaccuracy, but the technology does not pose a risk to the safety of users and others persons if specific regulatory controls are not applied. Additionally, a mobile technology that reminds users of measures to reduce a medical condition or increase health does not pose a risk to the safety of users and others persons if specific regulatory controls are applied. Since we have access to participants smartphones, there is potential loss of confidentiality. Additionally, the risks posed by blood pressure monitoring, and participating in general wellness, such as increasing physical activity poses no greater risk than if not participating in study or usual care. Additionally, the health behavior interventions delivered through Way to Health have been shown to be safe.

Additionally, this study will include the following data and safety monitoring plan.

Purpose: The data and safety-monitoring plan is written to ensure the safety of participants and verify the validity and integrity of the data. This monitoring plan details the source data verification of intervention, safety parameters, and the frequency of monitoring and regulatory document review.
Risk of Study: The study incurs minimal risk because the Way to Health research platform has proven to be safe in multiple prior behavioral health intervention studies, the technology and devices used in the feasibility trial are considered by the FDA to be general wellness products, and the real risk is to confidentiality.

Responsible Parties of Monitoring
1. Principal investigator: The PI will regularly monitor the data in collaboration with the research team.

The PI will also be responsible for ensuring all source documentation exists for the data and all corrections are done according to the principles of Good Clinical Practice.
2. IRB: periodic review by the University of Pennsylvania's IRB.
3. Research Assistant (RA): during the course of the study, safety and data quality monitoring will be performed on an ongoing basis by the RA, in addition to the PI. The RA will be responsible for monitoring all data collected.
Ongoing Monitoring Meeting: monitoring days will be conducted periodically throughout the study; beginning no later than 2 weeks after the first participant is enrolled. Subsequent monitoring meetings will be every four weeks.
Assessing Adverse Events: Monitoring for adverse events will be conducted by the PI, Dr. Schrauben, and the RA. Participants will be asked an open-ended question via Way to Health to assess if participants are experiencing any medical concerns related to their participation in the study.
Reporting Events: Any side effects of notable medical concerns will be reported to the PI to determine a course of action. Any adverse effect will be reviewed by Dr. Schrauben and Dr. Feldman (primary mentor). After removal of identification information, all serious adverse events will be reported to the University of Pennsylvania IRB and the funding agency within 24 hours. All adverse events will be recorded and a summary table reviewed by the IRB annually.
Data, Safety, and Monitoring Report: The PI will provide a summary of the DSM report on an annual basis as part of the progress report. The DSM report will include the expected versus actual recruitment rates, retention rates, any quality assurance and regulatory issues that occurring during the past year, summary of adverse events, and any actions or changes with respect to the protocol. Copies of each report and documentation of IRB notation and receipt will be kept in the PI's study file.

9. Study Administration

9.1 Treatment Assignment Methods

All participants in the study will be assigned to the interventions but in a different order (first 6 weeks or second 6 weeks of the study) since this is a cross-over design.

9.2 Data Collection and Management

Questionnaires will be completed electronically through the Way to Health Platform on the SMART-HABITS app on a participant's smartphone or on a computer at enrollment (Appendix IV) and at the end of study (Appendix VI). Questionnaires include:

1. Measure of CKD Knowledge: Kidney Knowledge Survey (KiKS)[147]
2. Measure of e-health literacy: eHealth Literacy scale (eHEALS)- an eight-item measure of eHealth literacy developed to measure individuals' combined knowledge and perceived skills at finding, evaluating, and applying electronic health information to health problems.[148]
3. Measure of chronic disease self-efficacy: Self-efficacy for Managing Chronic Disease Scale (SEMCDS)- 6 item scale.[149]
4. Self-management in Chronic Disease: Partners in health scale[150,151]
5. Kidney Disease Quality of Life (KDQOL-36)[152], consists of five subscales:
    - 1- Physical component summary (12 items about general health, activity limits, ability to accomplish desired tasks)
    - 2 -Mental component summary (12 items depression and anxiety, energy level, and social activities)
    - 3- Burden of kidney disease (4 items on how much kidney disease interferes with daily life, takes up time, causes frustration, or makes the respondent feel like a burden)
    - 4- Symptoms and problems (12 items about how much respondent bothered by CKD related symptoms)
    - 5- Effects of Kidney Disease on Daily life (7 items about much how respondent bothered by fluid limits, diet restrictions, ability to work around the house or travel, feeling dependent on doctors or other medical staff, stress or worries, sex life and personal appearance).

Several questions from the Attitudes toward mHealth and remote monitoring (10 item questionnaire).[69]

Data collected from participants' smartphone using Fitbit app and OMRON Connect ap, including survey and questionnaire responses and will be sent electronically to the Way to Health research platform and stored on a secure data server. This system is hosted onsite at the University of Pennsylvania with a level of security identical to that used for the clinical data of patients within the University of Pennsylvania Health System.

We will use Federal Information Processing Standards (FIPS) to assure secure, HIPAA-compliant data control and management to minimize risks by using rigorous data security protocols to protect subject confidentiality and comply with all federal and HIPAA requirements. Databases will be password protected, further restricting access to only study personnel. Interview transcript data will be labeled with a unique ID number, which will be linked in a separate password protected file, to demographic data. Study information will not be included in any medical records.

All study computers will sit behind the University's firewall protection and in locked offices. Further, our computers are continually scanned for vulnerability and to insure that no personal identifying information is found in appropriate places. All analyses will be conducted on de-identified data on secure computers. Lastly, using network firewall technologies, the database administrator will prevent the three major sources of data security problems: unauthorized internal access to data, external access to data, and malicious intent to destroy data and systems. Controlled user access will ensure that only appropriate and authorized personnel are able to view, access, and modify study data.

9.3 Confidentiality and Privacy

The risk of loss of confidentiality is paramount since we will have access to the participant's phone number but extensive efforts will be made to ensure that participants' confidentiality is maintained. To assure that participant confidentiality is preserved, individual identifiers (such as name) are stored in a single password protected system that is accessible only to research staff. Each participant will be assigned a unique study identification number and will never be tracked through the study by name, social security number, medical record number, and no other patient identifier other than mobile phone number. The study ID number will be used on all data collection instruments. A log of participant names, participant ID numbers, and pertinent registration information (e.g. emergency contact information) will be maintained in a locked area. Only de-identified data will be stored securely on servers.

All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project and is where the Way to Health web portal is based. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by University of Pennsylvania system managers. We believe this multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. In addition, risk of loss of confidentiality will be minimized by storing signed informed consent forms in locked file cabinets in locked offices accessible only to trained study staff. Each subject will be assigned a unique identifier without identifying information, and data will be entered into an electronic database using only the unique identifier. Only trained study staff will have access to the code that links the unique identifier to the subject's identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania.

The study team will work to uphold the privacy of the participants in several ways. First, any communications made among study staff regarding participants will use ID numbers only and never include names or other personal information. Second, all paper copies of participant data will be kept in locked files. Third, in all data sets, we will use ID numbers only.

A separate list of linking names with ID numbers will be accessible by the research team that is kept separate from data collected for the pilot study in a password-protected file on a password protected computer in a locked office. Whether in person or by phone, the research team will ensure that no persons who are not authorized by study participants to share personal health information are in the room when discussing informed consent (Appendix I) or during data collection at the initial study visit or at the end of study interviews.

Dr. Schrauben and a research assistant will conduct the end-of-study interviews and will have formal training by the Mixed Methods Research Laboratory at the University of Pennsylvania. The training will include proper methods for handling sensitive issues that arise during the interviews (note that the interviews themselves are not intended to include sensitive issues but because of their open-ended nature this possibility must be considered). Data from the interviews will be transcribed using a HIPAA-compliant service and verbatim transcriptions will be provided to the study team void of any personal identifiers and thus, only anonymous data will be used for all analyses.

9.4 Regularity and Ethical Considerations

Dr. Schrauben will be responsible for carrying out registering the clinical trial and submitting summary results to ClinicalTrials.gov for public posting. Dr. Schrauben will also be responsible for registering the trial in ClinicalTrials.gov no later than 21 calendar days after the enrollment of the first participant and submitting results information no later than one year after the trial's completion date. In addition, informed consent documents will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

There are no ethical considerations of the recruitment or intervention that are anticipated at this time.

9.5 Recruitment Strategy

We will recruit adult patients with chronic kidney disease stages 3 or 4 that also have diagnosed hypertension for the pilot study from Renal Clinics within the Department of Medicine at the Perelman School of Medicine for both genders and all races and ethnicities. We are targeting CKD stage 3 and 4 and hypertension since we believe that at these stages, a behavioral intervention could have a greater influence on the trajectory of blood pressure control and CKD complications. Additionally, patients with later stages of CKD reported they wished they had understood the importance of self-management earlier.

As a faculty member of the Division of Renal-Electrolyte and Hypertension within the Department of Medicine, the PI (Dr. Schrauben) will have access to patients that are seen in the Division-affiliated clinics located within the Perelman Center for Advanced Medicine (PCAM) and at Penn Presbyterian Medical Center. We will aim to recruit up to 40 patients with stage 3 or 4 CKD and hypertension over an 18-24 month period, which conservatively is 1-2 recruited patients per month. Since there are approximately 88 patients with stage 3 CKD and concomitant hypertension seen monthly in the Renal Clinic at PCAM, we do not anticipate difficulty enrolling participants during the study period since our conservative recruitment rate translates to approximately 2% per month.

If recruitment is slower than expected, recruitment will be expanded to include an additional Division-affiliated Renal clinics (located at Radnor), and if it continues to lag, we will expand eligibility criteria to stage 2 and 5 CKD. In the event of lost to follow up, we will be able to contact participants via text message, and implement a re-engagement protocol, but if we observe 20% loss to follow up, we will enroll more patients.

Recruitment will focus on patients scheduled for follow-up appointments in two nephrology clinics associated with the Renal Division within the Department of Medicine at the Perelman School of Medicine. Patients identified from review of the list of scheduled follow up appointments in the Renal Clinics who also have the diagnoses of CKD stage 3 or 4 and hypertension will be identified for potential eligibility for the study. After reviewing the schedule of follow up appointments in the renal clinic, the research team (i.e., Dr. Schrauben or a research assistant (TBD)) will first contact the nephrologist of the scheduled patient for potential eligibility. Then, a letter of invitation will be sent by the research team followed by a phone call. During the recruitment phone call, research personnel will review the inclusion and exclusion criteria, introduce the study rationale and procedures and try to answer any questions. In addition, there will be study advertisements posted within the clinic (for when in-person visits occur more regularly). With those who respond to the invitation or inquire about the posters, the interested individuals will be directed by the research team to the Way2Health enrollment site for further screening for eligibility using a screening survey. If the interested individuals have any remaining concerns or questions,

they will be asked to contact the research team for further discussion. During the online enrollment process, informed consent will also be obtained.

Patients eligible for the study will have blood pressure readings of less than SBP 180 mmHg and diastolic 110 mmHg in the previous 12 months. We will attempt to avoid commencing the intervention during time periods of extreme outdoor temperatures to prevent seasonal effects of physical activity participation.

At the conclusion of the pilot study, we will perform purposive sampling of the study participants to ensure there is representation of participants with high and low engagement in the mHealth intervention to ensure maximum variation to assess user experience (n=5-10).

Any subject facing materials, including by not limited to, recruitment letters, flyers, and text message templates, will be provided for IRB review prior to use.

8.6 Informed Consent
All research personnel associated with the study will have completed the CITI-Protection of Human Subjects Research Training as well as HIPAA Compliance Training.

The process of informed consent will be carried out using the Way 2 Health online platform. During this process, individuals who have been deemed eligible will be informed of all aspects of the study so they can make an informed decision. Participants will then confirm their willingness to participate in the research study by electronically signing the informed consent form. Informed consent will be collected along with a HIPAA authorization form that will provide consent for study participation, which will entail downloading the Way to Health application onto each participants' individual smartphone, device authorization for the OMRON Connect app, OMRON blood pressure monitor, Fitbit and Fitbit app, along with agreeing to monitor BP and wear Fitbit for the entirety of the study, text message BP readings during the text-message phase, syncing the wearable devices with apps during the appropriate study periods, receiving intermittent text messages from the study team, and completing questionnaires at the beginning, at 4-weeks, at 8-weeks and at the end of the study period. Patients will be informed of the potential risk of loss of confidentiality and the measures in place to protect against it. The application and devices will not record any personal or sensitivity information or require access to other information in the participant’s phone (e.g., contacts, location, etc.).

All subjects will provide informed consent to participate in our study, including: access to their smartphone through Way to Health technology, access to wearable devices, transmission of data from remote sensors to the study database, sending surveys and messages to their phones, for a semi-structured interviews to be conducted at a later point in the study, and potentially including an individual to share reminder and progress messages. Participants will be told that they do not have to answer any questions if they do not wish and can drop out of the study at any time without affecting their medical care or the cost of their care. They will be told that they may or may not benefit directly from the study and that all information will be kept strictly confidential, except as required by law. Please see Appendix I for informed consent.

9.7 Payment to Subjects
Participants will be given a $25 gift card for compensation of their participation at two separate time points (at 6 weeks and at conclusion of study). For participants that agree to and participant in an end-of-study interview, they will also receive another $25 gift card. The participants will not be required to return the blood pressure cuff or the activity monitor and are encouraged to keep them for use after the study completion.

9. Publication

We anticipate that the results generated by this study will result in publications in peer-reviewed journals and these published results will include detailed methods to describe subject selection should other investigators wish to use the data generated for future research related to self-management in chronic kidney disease. In conducting this study, we will develop a unique dataset derived from the data collected through interviews and the feasibility trial. In the future, if valuable additional analyses of the data are proposed, we will take every effort to ensure that analyses are completed efficiently and to the highest standards. We will only share de-identified data for research purposes, and will require 1) Institutional Review Board approval, 2) appropriate measures to ensure security of the data, and 3) commitment to

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