Proposal

Title:

Improving Care for Peritoneal Dialysis Patients with the "CKD-PD" app

Detailed Proposal:

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Principle Investigators

Massachusetts General Hospital, Harvard University
Katharine Morley, MD MPH

Srinagarind Hospital, Khon Kaen University
Sirirat Anutrakulchai MD PhD

Summary

The number of patients in Thailand with end stage renal disease on peritoneal dialysis (PD) is growing rapidly. Thai nephrologists have identified a critical gap in the current management of PD patients: a lack of timely information about fluid (hydration) status. Real time access to this information creates the opportunity for the early treatment of overhydration - the most common cause of complications and hospitalization in this population. Early treatment of overhydration in PD patients can decrease the incidence of complications, improve quality of life, and decrease health care costs.

Our research project aims to improve the monitoring of fluid status in PD patients from a bimonthly, in-clinic review of handwritten log books to a smartphone based app ("CKD-PD") with digitized data. This allows for near real time data visualization, hydration status monitoring, outlier notifications, and more timely treatment interventions for overhydration. Data from home monitoring equipment will be transferred to the CKD-PD app using near field communication (NFC) – a novel, low cost solution for automatic data entry. Hydration metrics are uploaded to the chronic kidney disease database "CKDNET" in the Thai Care Cloud - Thailand's national health database, merging patient collected data with hospital and clinic records.

The objective of our proposed study is to determine if use of the CKD-PD app can improve early treatment of overhydration in PD patients. Aim 1 of our research proposal is to optimize the usability of the CKD-PD app. We will employ user surveys based on the Unified Theory of the Acceptance and Use of Technology model, observations using the "Think Aloud" methodology and % completion of hydration metrics. Using these results, we will conduct a process improvement project with 3 rapid cycles to iteratively improve the CKD-PD app usability. In Aim 2, we will conduct a randomized clinical trial comparing the incidence of clinical interventions for treatment of overhydration. PD patients from Srinagarind Hospital, Khon Kaen Hospital, and Chaiyaphum Hospital nephrology clinics in Northeastern Thailand (N=200) will be randomized into two groups – one using the CKD-PD app, and one receiving usual management. Our primary outcome will be the incidence of clinical intervention to treat overhydration as an intermediate outcome related to our secondary outcomes: complications, hospitalizations, and mortality related to fluid overload. We will measure the effect size of the app usage on these secondary outcomes.

Design

Process improvement (Aim 1)

Interventional randomized control trial (Aim 2)

Populations

Adult patients with chronic kidney disease on peritoneal dialysis

Study site

Srinagarind Hospital, Khon Kaen University, Khon Kaen Thailand (Aim 1)

Srinagarind Hospital, Khon Kaen Hospital, and Chaiyaphum Hospital (Aim 2)

Aims

Our proposed study objective is to answer the question:

Does the use of the CKD-PD app improve early treatment of overhydration in PD patients compared with those receiving usual care?

Aim 1: Optimize the usability of the CKD-PD app and validate hydration metrics collection with NFC

Aim 2: Conduct a randomized controlled trial to determine if using the CKD-PD app improves early treatment of overhydration by comparing the incidence of clinical interventions to treat overhydration in CKD-PD app users and non-users.

Hypothesis: Use of the CKD-PD app will allow for earlier treatment of OH compared to patients not using the app, thereby potentially reducing complications, hospitalizations, and mortality from congestive heart failure, infections, hypertensive emergencies, and major cardiovascular events.

Background and significance

Chronic kidney disease in Thailand

The global prevalence of chronic kidney disease (CKD) is 11-13% [1] and increasing in low and middle-income countries paralleling the rising rates of diabetes and hypertension and lack of access to early CKD treatment [2,3]. The use of peritoneal dialysis (PD) for renal replacement therapy in patients with end-stage renal disease is increasing as many countries, especially in Asia, try to meet the increasing demand with limited resources [4,5,6]. In 2008, Thailand adopted a "PD first" policy in order to offer this benefit in its Universal Health Coverage Scheme [7], resulting in a 9-fold increase in PD patients from 2,760 to 24,244 from 2008 to 2015 [8]. PD is done at home; patients typically perform 4 exchanges of dialysate fluid per day into the peritoneal cavity to remove excess fluid and metabolic waste.

Table 1: Admission of PD Patients Srinagarind Hospital 2016 (N=39 pts)	
Reason	**N (%)**
Volume overload*	21(33)
Peritonitis*	13(20)

Other infections*	9(14)
Exit site infection	4(6)
Major Adverse Cardiac Event*	4(6)
Catheter malfunction	3(5)
Severe Hypertension*	2(3)
Anemia	3(5)
Stroke*	1(2)
Others	4(6)
Total admissions	**77 (100)**
*Overhydration complication	

Peritoneal dialysis and overhydration

Patients on peritoneal dialysis have frequent complications requiring hospitalization. Overhydration (OH), a qualitative description of fluid status, with excess fluid in the extracellular space [9], is one of the most common complications in PD patients. Clinical manifestations of OH include peripheral edema, congestive heart failure, pleural effusions, and hypertension [9]. It is estimated that 50-60% of PD patients are overhydrated, with severe OH producing clinical symptoms in 25% [10,11]. OH is associated with increased morbidity and mortality due to infections including peritonitis [12], and major adverse cardiovascular events such as myocardial infarction, pulmonary edema, stroke, and hypertensive crisis [9]. OH alone, independent of coexisting cardiovascular pathologies, is a risk for increased morbidity and mortality [13]. In 2016, at Srinagarind Hospital, at Khon Kaen University (KKU), Thailand, nearly half of the PD patients were hospitalized at least once, and some were hospitalized 2-4 times. Thirty-nine of the 91 patients (43%) were hospitalized a total of 77 times (some had 2-4 admissions). Sixty-five percent (50/77) of the hospitalizations were OH related (Table 1). The 5-year survival rate for PD patients is 48% [14]. Sixty-five percent of the PD admissions were for OH and related complications, with an average cost of $3,000 USD/admission [14]. Extrapolating this data to a national level, the estimated cost for OH-related admissions in PD patients in Thailand is $37,500,000 USD/year.

CKD and mobile health technology

Early treatment of overhydration can decrease complications and hospitalizations, improve quality of life, and decrease costs for PD patients. OH can be managed with treatments such as diuretics and anti-hypertensive medications, adjustments in dialysis prescriptions, and sodium/fluid restrictions [9,15]. Early detection of OH is possible by monitoring patients' hydration metrics: weight, blood pressure (BP), and ultrafiltration volume (difference between fluid input and output in dialysis). Currently, the critical gap lies in obtaining these hydration metrics in a timely and actionable format. A few studies have shown that smartphone and tele-monitoring programs are feasible and acceptable for patients with CKD [16-19]. Remote monitoring systems for PD patients

have been reported in India [20, 21] and Japan [22]. However, these studies used home visits, conventional mobile phones and computers, and did not include real time visualization of hydration metrics for management of OH. The eNephro RCT, underway in France, investigates the impact of tele-monitoring on clinical outcomes, cost, and quality of life for all CKD patients, but this is a high resource setting with low use of PD [23]. There is no good evidence about the impact of mHealth or remote monitoring on clinical outcomes in PD patients in low and middle-income countries where it is widely used. Our research aims to address this knowledge gap by investigating how mHealth technology can facilitate PD patient data collection and transform it into actionable information for nephrologists. We hope to shift the management paradigm of PD patients from bimonthly assessments to near real-time monitoring and early treatment.

Chronic Kidney Disease- Peritoneal Dialysis app (CKD-PD)

Thai nephrologists identified a critical gap in the ability to monitor hydration status in PD patients in a timely fashion. Currently, they assess PD patients' hydration status every 2 months by reviewing hydration metrics recorded in a handwritten logbook during their clinic visit or, more acutely, when patients decompensate and require urgent contact with PD clinic staff or hospitalization. They brought this issue to the KKU-MIT mHealth Hackathon in January 2017, an intensive 2-day event where multidisciplinary teams collaborate to develop an mHealth solution to a clinical problem. Joined by biostatisticians and software programmers from DAMASAC (Data Management and Statistical Analysis Center) at the KKU Faculty of Public Health, the team developed the CKD-PD app prototype. This initial work was followed by a user design process at Srinagarind Hospital nephrology clinic where patients and PD clinic staff worked with software engineers to improve the app. The app is Android based, with an iOS version in development. It is available for free download, but patients need to be registered for use. There are fields for entry of hydration metrics: weight, blood pressure, ultrafiltration volume (Fig 1). Near field communication (NFC) capability was recently added to the app for use with home scales and BP machines allowing automatic entry of hydration metrics. NFC has been widely used for wireless transfer of small amounts of data such as payments and transit cards [24]. There have been several research healthcare innovations using NFC [24-26], including home monitoring of pediatric populations [27] and in low income countries [28], chosen because of its simplicity and ease of use. It is now an emerging technology in commercial health care markets for home BP monitoring [29] and implantable glucose sensors [30]. CKD-PD with NFC allows patients, including those with limited technology skills, low literacy, or visual impairment to easily enter hydration metrics, by bringing their smartphone within 4 cm of the host NFC sensor. This information is uploaded via WIFI or cellular internet connection to the CKDNET (CKD-Northeast Thailand) database in the Thai Care Cloud, a national health database [31]. The data is graphically displayed on the CKD-PD web application accessible to PD clinic staff, and PD to patients on their smartphone. The key innovative features of the CKD-PD app are: 1) automated data entry for weight, BP and ultrafiltration volumes using NFC, 2) graphical display of

hydration metrics in the CKD-PD app, so patients can monitor their own hydration status 3) access to near real time data and alerts to PD clinic staff about critical abnormalities in patients' hydration metrics, 4) enhanced communication between PD patients and clinic staff, 5) integration of patient collected data from the CKD-PD app with electronic longitudinal health data in the CKDNET database on the Thai Care Cloud. Combining these data types has potential to predict which patients are most likely to need early treatment intervention and serve as a platform for data analytics to improve outcomes.

Aim 1: Optimize the usability of the CKD-PD app and validate hydration metric collection with NFC

Overall study design: This project will involve human subjects research at Srinagarind Hospital for participation in the optimization of the usability of the CKD-PD app, using process improvement methodology. It will involve collecting qualitative data from participant questionnaires and observation, and quantitative data from the CKDNET (Chronic Kidney Disease in NorthEast Thailand) database regarding their use of the CKD-PD app. A multidisciplinary team will review results and make iterative improvements to the CKD-PD based on whether or not the modification is expected to fulfill one or more of the following improvement criteria: 1) ease of use, 2) improved hydration metric monitoring, 3) increased user engagement and benefit, 4) facilitation of patient/provider communication. We have set thresholds after each improvement cycle to define successful optimization (Table 2). We will also compare hydration metrics collected using the CKD-PD app with hydration metrics collected directly by PD staff using usual methods. After completion of the 3 improvement cycles, we will conduct an implementation pilot of the CKD-PD app with a different group of 5 users. They will use the CKD-PD app for 1 week, collecting the same metrics as during the improvement cycles. The goal is to identify training and implementation issues, and assess usability with a different group of users. During the second week, research assistants will visit each participant at home collect hydration metrics, using PD clinic equipment (scales and BP cuffs) and compare with patient collected hydration metrics using CKD-PD app to assess validity of home collected hydration metrics with CKD-PD app.

Subject population and assignment: Our subject population is patients with chronic kidney disease on peritoneal dialysis. Since all PD patients have end stage kidney disease, they have chronic illness. Some patients will have more advanced disease and other co-morbidities such as diabetes and hypertension that are commonly found in this population. We will recruit 10 participants for this study. All 10 participants will complete activities in improvement cycle 1, and then be randomly assigned to 2 equal groups. Group 1 will have 5 patients who will participate in improvement cycles 2 and 3. Group 2 will have 5 patients that will participate in the pilot implementation trial.

Inclusion criteria are

- patients with CKD from any cause on home based peritoneal dialysis
- receive care at the Srinagarind Hospital nephrology clinic, Khon Kaen University
- age ≥18
- access to a smartphone capable of running the CKD-PD app
- willingness to allow research staff in observe using CKD-PD app in home

Exclusion criteria are

- vulnerable populations specified as pregnant women, children, prisoners, institutionalized individuals, refugees.
- inability to participate in home data collection

Recruitment plan: The study population will be recruited from patients at the Srinagarind Hospital Nephrology clinic who are undergoing peritoneal dialysis. Participants will be informed about the possibility of participating in a research study using a smartphone app to help collect information about peritoneal dialysis, which they currently collect using a handwritten log book. They will be provided with written and verbal information about the research study. All questions will be answered. Participation is completely voluntary, and participants can withdraw from the study at will. Inclusion criteria include: 1) on home-based peritoneal dialysis due to end stage renal disease from any cause, 2) age >18. The following exclusion criteria will be used: 1) vulnerable populations such as children, prisoners, pregnant women, patients with cognitive defects, and refugees, 2) unwillingness or inability to provide signed informed consent or participate in the study 3) unwillingness or inability to participate in home observation.

Retention plan: Retention will be maximized by frequent involvement and contact with the research team and PD clinic staff. Patients undergoing peritoneal dialysis already require frequent clinic contact and daily management of their peritoneal dialysis making it less likely that they will "lose interest" or be non-compliant, and more likely to use a labor and time saving app. The research study will take place over 6 months, and most activities will take place as part of their usual clinic and home-based PD care. We also expect that the planned enhancements of the app and opportunity to contribute to their development, thereby making PD easier and safer for them and their family, will help promote retention.

Planned distribution of subjects by sex/gender, race, and ethnicity: We will not select or reject patients based on gender, race or ethnicity. The racial and ethnic composition of the general population, the PD patient population,

and the research study population is nearly exclusively Thai. The study will take place at Srinagarind Hospital located in an area of exclusively Thai ethnicity. We expect nearly equal numbers of male and female enrollment given the nearly equal rates of PD between the sexes. We base this assumption on the reported prevalence of females on PD (50.8%) and males (49.2%) [8].

Inclusion of children: We will enroll patients 18 years of age or older. The prevalence of PD in patients in Thailand under 18 years of age is <1% [8], therefore making it difficult to include this age group in our study. In addition, the etiologies of chronic kidney disease and co-morbidities are different in children and PD is used less frequently in children compared to hemodialysis.

Collaborating sites: None

Planned research procedures: Our process improvement project has 6 research procedures.

1. *Structured interviews using UTAUT:* We will be collecting quantitative data from 10 participants using a structured interview questionnaire based on The Unified Theory of Acceptance and Use of Technology (UTAUT) model [32] to collect perceptions on user technology acceptance and usability. Each question is scored on a Likert scale and reported as a mean score for each question. We will use these results to assess opportunities to improve usability, facilitate user adoption and incentives to maintain use.
2. *Observation using CKD-PD in clinic:* Research assistants will introduce the CKD-PD app to 10 participants in the PD clinic, demonstrating its use and current features. This is will be following by observing participants use CKD-PD for the first time. During this observation, research assistants will follow an observation guide, which lists key tasks and features: 1). opening and accessing screens on CKD-PD app 2). using NFC to enter hydration metrics, 3). viewing hydration metrics, 4). identifying abnormal hydration metrics and follow up actions, 5). communication features to contact PD clinic staff, 6) user incentives (e.g. LINE stickers). Users will also be prompted to "Think Aloud" as they go through each step to collect information about how they use the CKD-PD and identify steps which need to be improved through training or design modifications. They will also be asked what they "like and dislike" about each task and feature, and rate each feature as: 1= good, 2= neutral, 3= not good. Observation data will be collected by research assistants using handwritten notes and digital recorders.
3. *Observation using CKD-PD in participant homes:* Research assistants will observe 5 users in their home (Group 1) while they set up and use the CKD-PD app for the first time, and again after subsequent CKD-PD app revisions. They will use the same observation guide and process used during the in-clinic

observation, specifically looking for new issues arising in the home environment. They will ask what they "like and dislike" about each task and feature, and rate each feature as: 1= good, 2= neutral, 3= not good. Observation data will be collected by research assistant using handwritten notes.

4. *Collection of quantitative data regarding hydration parameters and data entry completion metrics from patients using the CKD-PD app:* We will collect quantitative data regarding the completion of hydration metric data using the CKD-PD app. This information is uploaded to the CKDNET database in the Thai Care Cloud, which is linked to patient identifiable data.
5. *Collection of PD clinic contacts:* Information will be collected for each contact between the PD clinic staff and the participant. We will collect time and date, method of contact, who made the contact, reason for contact, outcome of contact. This will be collected in an electronic study log in the PD clinic.
6. *Validation of hydration metrics*: During the second week of the implementation pilot, PD clinic staff will conduct a home visit for the 5 participants (Group 2). They will collect hydration metrics directly and compare with the results collected by the participant using CKD-PD. If there is a discrepancy, PD staff will review the hydration metric collection with the participant and check the equipment. After correcting any issues, they will conduct a repeat visit and repeat the process.

Table 2: Summary of Process Improvement Project to Optimize Usability of the CKD-PD app

	Improvement Cycle #1 1 month (N=10)	**Improvement Cycle #2** 1 month (N=5, Group 1)	**Improvement Cycle #3** 1 month (N=5, Group 1)
Step 1: Collect data			
Objective	- Introduce CKD-PD app	- Test revised app for 1 week	-Test revised app again 1 week
Method	- Structured interviews - In-clinic observation	- "Think Aloud" in home testing	- "Think Aloud" in home testing
Metrics	- Score on UTAUT structured interview - Observation summary	- Average feature rating - % completion of data entry - # & type of clinic contacts	- Average feature rating - % completion of data entry - # & type of clinic contacts

Step 2: Identify improvement opportunities, determine app modifications, and training needs with team			
Step 3: Revise CKD-PD app and re-test			
Optimization goal	Collect baseline rating of features	- Average feature rating <2.5 ->70% data fields complete	-Average feature rating <1.5 ->90% data fields complete
Deliverable	- Revised app - User training needs	- Revised app - Draft user training materials	- Final app revision - Final training guide & video

Potential risks to participants All results will contain patient identifiable data. We believe this study will have low risk to participants with regard to physical, psychological, social, cultural or legal aspects. Potential risks exist due to loss of privacy and concern about change or access to PD care have been specifically identified. Technological problems may expose users to risk through failures of notification of the PD care team or patient of outlier results, misunderstood expectations, or unintended consequences. Strategies to mitigate these risks are discussed below. Alternative strategies available to participants are the option to decline or withdraw from the project at any time.

Protection Against Risks

Informed Consent and Assent

Trained research staff will obtain informed consent from all participants. Dr. Sirirat Anutrakulchai and Dr. Wilaiphorn Thinkhamrop will oversee this process, including training of research staff and answering any questions from staff or participants as needed. The informed consent form and process will be approved by the Khon Kaen University Ethics Committee and the Partners Health Care/Massachusetts General Hospital Institutional Review Board. All participants will be informed that their participation is voluntary and does not in any way impact access to treatment or other resources for care, and they can drop out of the study at any time for any reason. Signed copies of the informed consent will be kept with study records, and given to the participant.

Planned strategies to minimize potential risks:

We will include the following general protections:

1. De-identify and summarize results from questionnaires, observations, interviews, and the CKD-PD database when possible prior to sharing this information with the CKD-PD app process improvement team.
2. Confirm all study staff successfully completed CITI ethics training
3. Provide all written materials and descriptions of study activities in local language (Thai) at an appropriate literacy level.
4. The CKD-PD app and validation of application from phase I study will be reported to the Khon Kaen University Ethics Committee before apply to participants in phase II study.

We will obtain IRB approval for this proposed research through the Khon Kaen University Ethics Committee and the Partners Health Care/Massachusetts General Hospital Institutional Review Board. We will not begin enrollment until this has been secured.

We have identified these potential risks and have developed plans for mitigation.

1. *Loss of confidentiality and or privacy due to loss of data or hardware:* Privacy and confidentiality loss may occur due to data breaches, physical loss or theft of computers, or carelessness of study personnel. We will minimize these threats by using password enabled and encrypted computers, de-identified data where possible, and research ethics training for study participants. The CKDNET and Thai Care Cloud has data safety features built in to its foundational structure including firewalls, encryption, and robust access restrictions.
2. *Loss of confidentiality and or privacy during home visit:* We have identified additional potential privacy risk by conducting in-home user evaluations. Participants will also give specific consent for this activity during enrollment.
3. *Concern about impact on PD clinic access and care:* Participants will be assured participation does not impact their ability to receive the same access and care in the PD clinic as non-participants.

Plan for medical intervention

In the event of unexpected/unplanned need for medical intervention, participants will be instructed to contact the PD clinic. Since all of the participants are currently patients managed in this clinic, they will be able to provide any necessary medical intervention in the clinic or through the emergency room which is the same access as study non-participants. During the in-home process improvement cycle and pilot implementation, it is possible that patients will have abnormal hydration metrics. The PD clinic staff will be monitoring this information during these trials and will provide clinical care as needed based on current standards of care. Participants will be provided with information to contact the PD clinic if needed.

Vulnerable Subjects

Our study does not involve special vulnerable populations such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals.

Potential Benefits of the Proposed Research to Research Participants and Others

The objective of research is to improve the usability of the CKD-PD app for PD patients. The benefit of this research to participants is that the CKD-PD will be easier to use, incorporate features that bring benefit to PD patients, and potentially improve their health. Participants will also have the opportunity to contribute their ideas and experiences to this process, thereby helping the research staff understand the needs of PD patients Another benefit project is that patients can learn how and why they are valuable partners in research about mHealth technologies and how they can support the management of chronic diseases. Given the minimal risk involved in this study, the anticipated benefits presented are reasonable

Importance of the Knowledge to be Gained

The knowledge gained from this research is important for several reasons. First, optimizing the practical utility of this app in a real-world setting is essential before further research is conducted. Testing the various functionalities of the app such as the accuracy of PD metric collection, communication enhancements, patient self-monitoring, and monitoring of the outlier alert system are needed to make the app fulfill its potential. Understanding the limitations and unintended consequences of this technology is also of great value. We also hope to demonstrate how process improvement methodologies can be used in the development of mHealth interventions. If successful, we believe rapid-cycle process improvement methodologies can be an important tool to expedite and enhance the development of effective mHealth interventions.

Aim 2: Conduct a randomized controlled trial to determine if using the CKD-PD app improves early treatment of overhydration by comparing the incidence of clinical interventions to treat overhydration in CKD-PD app users and non-users.

Overview: We will conduct a randomized controlled trial (RCT) that will evaluate whether **use of the CKD-PD app improves early treatment of OH by comparing the incidence of clinical interventions to treat OH in CKD-PD app users and non-users.** Participants recruited from the PD clinics at Srinagarind Hospital, Khon Kaen Hospital, and Chaiyaphum Hospital will be randomized into two equal groups, one using the CKD-PD app ("app" group, N=100), and one receiving usual management ("no-app" group, N=100). Each group will collect

the same hydration metrics - blood pressure (BP), weight, and ultrafiltrate volumes - using home monitoring equipment (BP cuff, body weight scale, and hanging scale). The no-app group will manually enter the information into their "PD logbook"- the handwritten paper booklet which is usual care. In contrast, the app group will automatically collect and enter the same information into the CKD-PD app using NFC technology on their smart phone. It will be displayed in the CKD-PD app for the patient and uploaded to the CKDNET database in the Thai Care Cloud; it then can be view on the CKD-PD web application by the PD clinic staff. Patients will monitor their hydration status on a graphical display on their smartphone. PD clinic staff will be notified daily about "action required" alerts on the web application. For example, systolic BP greater than 140 mmHg, diastolic BP greater than 90 mmHg, weight gain greater than 3% based on dry weight, or ultrafiltrate volume < 500 milliliters will trigger a response from the PD clinic. Nephrologists will make clinical interventions to treat OH according to standard practice in Thailand, which include BP and diuretic medication adjustments, change in diet or fluid intake, dialysis prescription adjustments or referral for urgent clinical evaluation. Clinical interventions can occur at unscheduled patient contact (e.g. patient call) or scheduled patient contact (routine clinic visit) Our primary outcome measure will be the incidence of clinical interventions for OH, both routine and urgent, in 1 year from enrollment. Secondary outcome measures include OH related complications, hospitalizations and deaths, and will be collected from PD clinic and hospital records, and the CKDNET database.

Setting and study population: The study will be conducted at the PD clinics at Srinagarind Hospital (N=100) the academic referral hospital affiliated with Khon K aen University, Khon Kaen Hospital (N=50) the government referral hospital for Khon Kaen province, and Chaiyaphum Hospital (N=50), the government referral hospital for the neighboring Chaiyaphum province in northeast Thailand. We will recruit 200 patients with end-stage renal disease on PD from KKH to achieve a total sample size of 160.

Inclusion criteria are

- patients with CKD from any cause on home based peritoneal dialysis
- age ≥18
- access to a smartphone capable of running the CKD-PD app
- ability of the patient or surrogate to demonstrate successful use of the CKD-PD app

Exclusion criteria are

- vulnerable populations
- unwillingness to sign consent or participate in the study.

Recruitment plan: The study population will be recruited from patients at the nephrology clinic at each of the participating hospitals who are undergoing peritoneal dialysis. Participants will be recruited over a 3-month period

at scheduled PD clinic appointments. This is feasible since all patients are seen within a 2-month interval. Accrual will be monitored by Thai study staff by recording enrolled participants in the electronic study log and a list of patients from KKH who declined enrollment or were excluded. Participants will be informed about the possibility of participating in a research study using a smartphone app to help collect information about the peritoneal dialysis, which they currently collect using a handwritten log book. They will be provided with written and verbal information about the research. All questions will be answered. Participation is completely voluntary, and participants can withdraw from the study at will.

Retention plan: Retention will be maximized by frequent involvement and contact with the research team and PD clinic staff. Patients undergoing peritoneal dialysis already require frequent clinic contact and they have a long-standing relationship with the MDs and RNs in the nephrology clinic. Compliance with PD clinic appointments is estimated at over 90%; participants who miss their scheduled appointments will be contacted by PD clinic and rescheduled.

Planned distribution of subjects by sex/gender, race, and ethnicity: We will not select or reject patients based on gender, race or ethnicity. The racial and ethnic composition of the general population, the PD patient population, and the research study population is nearly exclusively Thai. The study will take in place at Khon Kaen province , located in an area of nearly exclusively Thai ethnicity. We expect nearly equal numbers of male and female enrollment given the nearly equal rates of PD between the sexes. We base this assumption on the reported prevalence of females on PD (50.8%) and males (49.2%) [8].

Inclusion of children: We will enroll patients 18 years of age or older. The prevalence of PD in patients in Thailand under 18 years of age is <1% [8], therefore making it difficult to include this age group in our study. In addition, the etiologies of chronic kidney disease and co-morbidities are different in children and PD is used less frequently in children compared to hemodialysis.

Collaborating sites: None

Statistical Design and Power: We determined our sample size by using the difference in incidence rates between two Poisson means with 25% precision. Data collected from Srinagarind Hospital indicate the intervention rate for OH, based on current practice of patients contacting the PD clinic staff with symptoms or concerns of OH outside of scheduled appointments, to be 4 times/week in 91 patients or a mean intervention rate of 2.3 times/patient-year. Assuming a two-fold increase in the mean event rate for patients using the CKD-PD app or

4.6 times/patient-year in the CKD-PD app group, the desired sample size is 80 patients for each group, using a two-sided, large-samples z-test of the Poisson event-rate difference at a significance level of 0.05. Allowing for a 10% dropout rate, we will recruit a total of 200 patients (100 in each group). Our assumption that use of CKD-PD app will result in a twofold increase in the incidence of clinical interventions is based on our preliminary experience with the 42 patients currently using the CKD-PD app. In those 42 patients, especially those with unstable fluid and blood pressure control, the app frequently identifies outlier measurements resulting in intervention opportunities which are not possible in the no-app control group.

Baseline variables of the CKD-PD app and no-app groups will be described by summary statistics. Percent distribution will be presented for all categorical variables. Mean with its standard deviation and median (Minimum: Maximum) will be presented for continuous variables. The primary outcome will be assessed by comparing the difference between the CKD-PD app group (intervention) and the no-app group (control), in incident rate (or Poisson count) of intervention for OH. A linear mixed model with an identity link and a Poisson distribution will be performed. By this modeling, the incidence rate difference and its 95% confidence interval will be estimated to answer the primary research question. Estimations will be adjusted for effects of important covariates that are imbalanced at baseline. Effect size will be calculated for secondary outcomes. All analyses will be performed using STATA version 14 (StataCorp, College Station, TX), using a significance level of 0.05. All statistical tests will be two-sided.

Randomization

Participants (Srinagarind N=100, Khon Kaen N=50, Chaiyaphum N=50) will be randomized into two equal groups at each site, one using the CKD-PD app (app group, N=50/25/25), and one receiving usual management (no-app group, N=50/25/25), using 4-block computer randomization in STATA. They will be assigned a PD clinic visit day based on their randomization allocation to reduce contamination or cross talk between the 2 study groups.

Delivery of intervention

Definition of study intervention:

Our study intervention is defined as the CKD-PD app, home hydration metric measurement equipment, and the monitoring of the uploaded hydration metrics to the CKDNET database.

Collection of hydration metrics: After enrollment, participants in both groups will undergo training on how to collect daily hydration metrics: body weight, blood pressure, and dialysate inflow and outflow volumes for each cycle. The app group will receive training on how to enter hydration metrics using NFC on the CKD-PD app, in

addition to training on how to use other features on the CKD-PD app including self-monitoring of hydration metrics and in-app communication with PD staff. The no-app group will receive instructions on how to record the same information in their paper PD log book as well as information about how to contact the clinic by phone. Research staff will also make a home visit for app-group participants at the start of data collection to confirm correct equipment set up and use.

Clinical interventions: In both the app and no-app groups, clinical interventions for OH can occur at either an unscheduled patient contact (e.g. phone call, clinic visit, or emergency visit) or at a scheduled clinic visit. In the app group, clinical interventions can also occur when an action required notification occurs, and the PD clinic staff contacts the patients and determines that a change in treatment is indicated to manage the OH. This occurs when a patient is flagged as an outlier (action required) because one or more of the hydration metrics is outside of the established acceptable range (see paragraph directly below). The PD clinic staff, after reviewing the patient's hydration metrics, will initiate contact with the patient, to review hydration metrics and patient symptoms. If the PD nurse confirms abnormal hydration metrics (action required) or clinical symptoms consistent with OH, the case will then be referred to the nephrologist to review the information and determine the need for a clinical intervention. Nephrologists will make clinical interventions according to standard practice in Thailand, summarized as guidelines and provided to nephrologists and PD clinic staff for reference at the beginning of the study. An episode of clinical intervention is defined as treatment intervention for abnormal hydration metrics or clinical symptoms of OH with 1 or more changes in patient management: change in medications, dialysis prescription, fluid or salt restriction, or urgent clinic/hospital visit. A contact that results in no change in management is not considered a clinical intervention for OH.

Monitoring CKD-PD smartphone and web applications: We will set 3 categories to be used by PD clinic staff when monitoring hydration metrics on the CKD - PD web application: normal, monitor, and action required. Based on criteria specified by KKU nephrologists, deviations in weight of >3% from baseline dry weight, BP>140/90, and ultrafiltration volume of <500 ml will be used as baseline parameters for triggering an outlier alert for action required, indicating that the patient's hydration metrics need to be reviewed. We will also set critical values for hydration metrics, which require patient to go directly to the emergency department. We expect that some patients will require different parameters for triggering an outlier alert. In order to address this issue, a study nephrologist will provide normal and action required values for weight, blood pressure, and ultrafiltration volumes for each patient, at the time of enrollment after reviewing previous values from their PD logbook. During the study, the patient's nephrologist will have the option to modify the notification parameters. Hydration metric values between normal and action required will be categorized as monitor status.

PD clinic staff nurses will receive a list of patients with action required alerts once a day. They will review the hydration metrics and contact the patient(s), ask about symptoms, and have the nephrologist review the data and case to determine need for clinical intervention.

PD patients will also have the ability to self-monitor using the visual display of hydration metrics on the CKD-PD app. Planned features to simplify patients understanding of their fluid status include color coded zones corresponding to the normal (green), monitor (yellow), and action required (red) categories. During training, patients will be instructed to contact the PD clinic if one or more of the hydration metrics indicate action required.

Planned research procedures: Our project has 5 research procedures, all of which will collect private, identifiable patient information.

1. *Monitoring for abnormal hydration metrics by PD clinic staff:* PD clinic staff will review the CKD-PD web application daily for outlier alerts. Outliers are determined based on the hydration metric parameters set by the nephrologist at enrollment. See 4.2.a.3 below.
2. *Clinical intervention for overhydration:* Change in medical treatment in response to OH detected by clinical symptoms or hydration metrics. Interventions may include a change in medications to treat OH such as anti-hypertensives or diuretics, dialysis prescription, dietary sodium/fluid restriction, referral for evaluation in clinic, or hospitalization. This information will be collected in the electronic PD clinic study log at the time of the clinical intervention.
3. *Unscheduled clinic contacts:* When patients in either group make an unscheduled contact with the PD clinic this will be recorded in the PD clinic electronic study log. Unscheduled clinic contact can also occur in the "app" group when PD clinic staff contact a patient in response to abnormal hydration metrics. Unscheduled contacts include any phone call, text, social media, or web app message, and unscheduled visit to the PD clinic or emergency department. The information collected included patient name/MR#, reason for contact, mode of contact, who initiated contact, date and time of day, and action taken. Unscheduled clinical interventions will be recorded at the time of the event.
4. *Scheduled clinic contacts:* Patients in both groups will have regularly scheduled clinic visits, typically bimonthly. Clinical interventions for OH made during this visit will be recorded in the electronic PD clinic study log. A medical record review will also occur at each visit to collect any other hospitalizations, complications, or clinical interventions that may have occurred in the interim.
5. *CKDNET database review:* In order to ensure all events have been captured, we will review the CKDNET database, which has all inpatient and outpatient visits, on a bimonthly basis.

Data collection overview

Data elements for analysis of covariates at enrollment: These will include: age, sex, educational level, cause of CKD, eGFR, co-morbidities (e.g. diabetes, hypertension, albumin level), previous hospitalizations for OH, smoking status, distance from clinic, months on PD, months of CKD-PD usage, and app user type (patient or surrogate). The source will be medical records and patient interview at time of enrollment.

Clinical interventions used: We will record the type of clinical intervention, patient symptom/hydration metric abnormality, whether it was occurred from a scheduled or unscheduled communication, and ordering clinician. This information will be recorded in an electronic study log at time of PD clinic visit, or time of communication to patients.

Outcome measures: Our primary outcome measure will be the incidence of clinical interventions for OH in 1 year from enrollment. Secondary outcome measures include OH-related complications

Drop out/Lost to follow up: The number of patients who drop out, are lost to follow up or died during the study period will be collected. This information will be collected from chart reviews and PD clinic communications and recorded in the electronic clinic study log.

PD clinic/patient communications: We will also collect data about communications between PD clinic staff patients or their surrogates by logging phone calls and messaging app contacts. This information will include who initiated the call, whether or not is resulted in a clinical intervention, the type of clinical issue, and mode of communication. This information will be recorded in the PD clinic electronic study.

Potential risks to participants: This study poses low risk to participants with regard to physical, psychological, social, cultural or legal aspects as both groups receive the same standard of care as currently provided to PD patients at the study site nephrology clinics, including routine clinic appointments, medications, dialysis prescriptions, dietary recommendations, educational and other community support networks, and urgent services e.g. phone contact to PD clinic, unscheduled clinic visits, and emergency care. We have identified some potential specific risks including data breaches, lost or malicious hacking of computers, loss of privacy, concern about change or access to PD care, over or under identification of overhydration, failure to detect life threatening outlier data points in a timely fashion, technology failure, communication failures and errors, and unintended consequences of using a new technology. Strategies to mitigate these risks are discussed below. Alternative strategies available to participants are the option to decline or withdraw from the research at any time.

Informed Consent and Assent

Informed consent: Trained research staff will obtain informed consent from all participants. Dr. Sirirat Anutrakulchai and Dr. Wilaiphorn Thinkhamrop will oversee this process, including training of research staff and answering any questions from staff or participants as needed. The informed consent form and process will be approved by the Khon Kaen University Ethics Committee and the Partners Health Care/Massachusetts General Hospital Institutional Review Board. All participants will be informed that their participation is voluntary and does not in any way impact access to treatment or other resources for care, and they can drop out of the study at any time for any reason at all including no reason. Signed copies of the informed consent will be kept with study records, and a copy will be given to the participant.

Planned strategies to minimize potential risks: We will include the following general protections:

1. De-identify and summarize results from study logs and medical records prior to analysis when feasible.
2. Confirm all study staff successfully completed CITI ethics training.
3. Provide all written materials and descriptions of study activities in local language (Thai) at an appropriate literacy level.
4. We will obtain IRB approval for this proposed research through the Khon Kaen University Ethics Committee and the Partners Health Care/Massachusetts General Hospital Institutional Review Board. We will not begin enrollment until this has been secured.
5. We will use password protected, encrypted computers.
6. Access to study data will be limited to research team members

We have identified these specific potential risks to patient and surrogate participants and have developed plans for mitigation.

1. *Concern that access to PD staff and urgent services will change because of research.* We will assure all participants that patients in both groups will have the same access to PD clinic staff for questions or concerns, same as in current practice.
2. *CKD-PD app may not identify overhydration as anticipated.* We will advise patients that they still need to keep all the usual scheduled PD clinic appointments, so participants receive the current standard of care.
3. *We anticipate that CKD-PD app users will receive increased number of clinical interventions as a result of increased monitoring.* We believe this result will improve effectiveness and quality of care, however there is always inherent risk in any clinical intervention even if the benefits are determined to outweigh them. All clinical decisions will be made by the same providers already caring for the patients, according to the usual standard of care. Study clinicians will receive training for interpreting CKD-PD app data

which includes a summary of the local standard of practice, assessing the whole clinical picture, and looking at data trends rather than single isolated readings.

4. *CKD-PD app users may introduce new source of potential error by incorrect data entry.* Patient or surrogate will be given training in proper data entry techniques and observed in their homes to make sure they can use app correctly.
5. *Failure of technology (loss of network connection, malfunction of smart phone) could result in unanticipated delay or loss of data for CKD-PD app users.* We will provide participants in the CKD-PD app group with directions on how to respond to failure of technology. This includes resuming use of the PD logbook and how to notify study staff in the event of technology failure or question on correct use of CKD-PD. This inadvertent data loss is similar to a lost log book in the control group.
6. *CKD-PD app users are at risk for potential unexpected or unintended consequences of introducing a new process or technology.* Study staff will be monitoring the use of CKD-PD, looking for potential issues or problems that were unexpected or unanticipated throughout the study including mismatched expectations among MDs, RNs, and patients.
7. *Loss of confidentiality and or privacy due to loss of data or hardware.* Privacy and confidentiality loss may occur due to data breaches, physical loss or theft of computers, or carelessness of study personnel. We will minimize these threats by using password enabled and encrypted computers, de-identified data where possible, and research ethics training for study participants. The CKDNET and Thai Care Cloud has data safety features built in to its foundational structure including firewalls, encryption, and access restrictions.
8. *Failure to react to life threatening data elements in a timely fashion.* Patients will be informed that the PD clinic will only check PD metrics once a day and be available for calls from patients according the usual practice. We will advise patients that if they detect PD metrics in the action required range or have any concerning symptoms, and are unable to contact the PD clinic, they should proceed as standard practice for PD patients or go to the emergency department.

Plan for medical intervention

In the event of unexpected need for medical intervention, patients will be instructed to contact the PD clinic or emergency room depending on the circumstances. Since all of the participants are currently patients managed in this clinic and in this tertiary care hospital, they will be able to provide any necessary medical intervention. Patients and family members will receive information on how to obtain emergency care during off hours for clinical concerns and critical values of hydration metrics e.g. BP >200/120, BP< 80/40 during the enrollment, in accordance to the usual practice at the PD clinic.

Vulnerable Subjects

Our study does not involve special vulnerable populations such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals.

Potential Benefits of the Proposed Research to Research Participants and Others

The objective of this research is to improve early treatment of OH thereby decreasing complications and hospitalizations. If our hypothesis is true, this is a potential benefit to CKD-PD app users. It will also support further efforts to develop and scale up use of CKD-PD app thereby benefiting many more individuals. Patients benefit from accurate and timely monitoring of hydration status as it increases opportunity for meaningful and early intervention. The CKD-PD app also aims to improve patient engagement in self-management of PD by providing a graphical display of PD monitoring metrics similar to a dashboard with trends and current status displays. Patients and their surrogates can gain insight about their own health status and learn how they can work more efficiently with the PD care team to manage their PD and hydration status. Given the minimal risk involved in this study, the anticipated benefits presented are reasonable.

Importance of the Knowledge to be Gained

The knowledge gained from this research is important for several reasons. First, determining whether or not using the CKD-PD app can result in earlier treatment for OH is important before scaling up the intervention to a larger population. Second, the information gained from this research is important preliminary information in order to conduct the research of greatest interest – whether or not use of the CKD-PD app can reduce complications and hospitalizations and decrease mortality for PD patients. If proven successful, this can meaningfully impact the lives of thousands of PD patients and potentially reduce costs. Third, this research will also provide information about whether or not PD patients can successfully self-monitor their hydration status, which is valuable knowledge affecting further implementation of the CKD-PD app to a larger population. Fourth, it will also provide the opportunity to link patient collected mobile health data with hospital and clinic records to provide a rich multi-modal database for predictive analytics. Considering these benefits to individual participants and other PD patients, the risks are reasonable

Monitoring and Quality Assurance

Our project measures the impact of the CKD-app on managing OH. Our intervention is the use of the app, not a specific medication or treatment and all participants will receive the same clinical interventions based on the same usual standard of practice. Therefore, we feel there is low risk to patients as the care and treatment of patients is

standardized- the difference is the timeliness of the interventions. Because our research will introduce a technology that can impact the frequency of clinical interventions and the quality of data used to manage patients, we have outlined several ways to reduce or manage the potential risks. In addition, we will take the following steps to ensure safety.

1. Develop guidelines for PD clinic staff regarding the process of monitoring and response to the daily outlier alerts generated by the CKD-PD web application, and communications from patients or surrogates. These guidelines will provide details on the daily review of hydration metric alerts for "action required", action steps to be taken (e.g. contact patient, review with nephrologist), recording in study log.
2. Provide a summary of guidelines for managing OH in the study site nephrology clinics based on Thai standards of care to serve as a reference and promote consistency of clinical interventions nephrologists and PD nurses.
3. Develop a process for case review by study investigators (nephrologists) for unexpected complications or hospitalizations, and unexpected increase /decrease in clinical interventions for OH.
4. Dr. Sirirat Anutrakulchai and Dr. Wilaiphorn Thinkhamrop will be primarily responsible for oversight of the research activities and data collected at Srinagarind Hospital, Khon Kaen Hospital and Chaiyaphum Hospital. The consortium steering committee comprised of Drs. Katharine Morley, Sirirat Anutrakulchai, Michael Morley, and Wilaiphorn Thinkhamrop will also serve as a data safety monitoring committee and will monitor data during collection for safety signals such as increased complications or mortality in either study groups or other indications of potential concerns. They will be in frequent contact throughout the study via email, video calls, in addition to scheduled site visits. All serious adverse events will be reported to the Srinagarind Hospital/Khon Kaen University Ethics Review Committee and Partners/MGH IRB according to their requirements. Data collection and study activities will be suspended until appropriate precautions have been taken to address or avoid repeat safety concerns
5. We will register with clinicaltrials.gov.

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Information and Consent for Research Study Volunteer

Research project name: Experimental study comparing use of CKD-PD mobile app in patients undergoing peritoneal dialysis with those not using the CKD-PD app to detect excess fluid accumulation

Principle researcher: Associate Professor Dr. Sirirat Anutrakulchai (Thailand)

Principle researcher: Katharine Morley, MD MPH (USA)

Funding source: National Institutes of Health (NIH)

Introduction

Thailand has many patients with end stage renal disease that require peritoneal dialysis to clear waste products and excess fluid from their body because their kidneys do not function properly. Patients on peritoneal dialysis have to collect information every day including blood pressure, body weight and the amount of fluid removed during dialysis. This information helps the kidney doctor make sure patients have good fluid balance. It is important to maintain good fluid balance to reduce complications that can occur in peritoneal dialysis patients, such as high blood pressure, accumulation of fluid on the lungs, infections, heart attack, and strokes. These complications can result in hospitalizations, decreased quality of life, and sometimes death.

A team from Khon Kaen University including kidney specialists, computer engineers and public health researchers developed a mobile phone application to help peritoneal dialysis patients collect information that is needed by the kidney doctors to help make sure that they maintain good fluid balance. It is called the “CKD-PD app”. Peritoneal dialysis patients can use it to collect blood pressure, body weight and the amount of fluid removed during dialysis. This information is sent the kidney clinic where it can be checked by the kidney doctors and nurses. The app will also allow patients to monitor their own fluid status. The goal is to find patients who are accumulating too much fluid sooner so the kidney doctors can make adjustments in their treatment earlier, and hopefully decrease complications, improve quality of life for patients, and decrease health care costs.

This research project intends to study how the CKD-PD app with basic home monitoring equipment can improve care for peritoneal dialysis patients through earlier detection of excess fluid accumulation. The research will evaluate if of CKD-PD app with home monitoring equipment allows nephrologists to make changes in medications, dialysis and diet. It will also collect information to see if complications related to too much fluid retention are decreased.

Research objective: To compare the number of treatments for fluid accumulation (changes to medication, dialysis prescription and diet) in patients using the CKD-PD app with home monitoring equipment with patients not using the CKD-PD app.

Participation in your research project is voluntary.
You are invited to participate in this research study about using the CKD-PD app to improve early detection of excess fluid accumulation in peritoneal dialysis patients compared with patients not using the app. Before you agree to participate in the research project, you need to know the risks and benefits of participating in the research, so you can make an informed decision. This process is called "consent to participate in research studies".

You will be given consent documents in order to provide you with information about participating in the research. They will explain why you might want to join the research, what happens during the research, and the risks and benefits of participating in the research. Please read this information carefully. If you have any questions, you may consult with one of the research staff, your doctor, or any other person you want. After learning about the details of the research, you will be asked to sign this consent document to confirm your participation in the research. It is your choice whether or not you want to participate. Your decision does not change the medical care you receive now or in the future. You can agree to take part in the research now and change your mind at any time and drop out later. You do not need to provide a reason if you chose not to participate or to drop out.

The purpose of this research
You are invited to participate in this research because you are receiving treatment for kidney disease with peritoneal dialysis, and you or your caretaker can use the CKD-PD app on your mobile phone. This research will compare the number of treatments for fluid accumulation (changes to medication, dialysis prescription and diet) in patients using the CKD-PD app with home monitoring equipment with patients not using the CKD-PD app. It will also compare the number of complications and hospitalizations in each group. A total of 200 patients on peritoneal dialysis from Srinagarind Hospital, Khon Kaen Hospital and Chaiyaphum Hospital will participate. They will be randomly assigned to 2 groups with 100 patients in each group. One group will use the CKD-PD app and home monitoring equipment and the other group will not use the app. The group not using the app will follow the usual process of performing peritoneal dialysis and record their information about blood pressure, body weight and amount of dialysis fluid removed in a notebook.

What you will do if you participate in this research
If you decide to participate in this research and sign the consent form, you will be assigned to the group using the CKD-PD app or the group not using the CKD-PD app. The process of assigning you to a group is done randomly. You will have an equal chance (50%) of being assigned to either group. If you are assigned to the app user group, you will be asked to install the CKD-PD app on your mobile phone and participate in training on how to use the app and the equipment. If you are assigned to the group not using the CKD-PD app, you will not do anything different that the usual way you collect information about blood pressure, body weight and amount of dialysis fluid removed and record it in your notebook.
Participants in both groups will be asked to come to the kidney clinic every 2 months over 1 year. Your appointment with the kidney clinic doctor and/or nurse will be the same as usual. You will be asked to spend about 10 extra minutes in the clinic to speak with the research staff.

Enrollment process

The enrollment process will be done before you are assigned to be in the CKD-PD app user group, and the usual care (no app) group. One of the research assistants will do the following steps in the enrollment process.

- Review the consent form, answer any questions and then ask you to sign the consent.
- Confirm that your smartphone or smartphone of you caregiver can run the CKD-PD app.
- Collect basic information about you such as age and gender
- Review your medical history and health habits such as use of alcohol and smoking
- Perform a complete physical examination, including skin, eyes, ears, lungs, heart, abdomen, limbs and nervous system
- Measure height, weight, body temperature, body surface area, blood pressure and heart rate.
- Review all medications you are taking, including medications that you take without a doctor's prescription

Training after enrollment

Participants in each group will attend an educational session. If you are assigned to the CKD-PD app user group, you will either receive training on how to use the CKD-PD app and home monitoring equipment. If you are assigned to the non-app user group, you will receive a review of recording information in your notebook.

Follow up appointments

You will have a follow up appointment at the kidney clinic once every 2 months, just like you normally do. During this appointment the research staff will meet with you about the app or your notebook.

Termination of resear

During the research you will continue to receive treatment with peritoneal dialysis as prescribed by your doctor. Your treatment will continue as long as you benefit from it and you tolerate it. If you develop too many side effects, become pregnant, no longer benefit from the treatment or are no longer able to tolerate the treatment, you can discuss terminating treatment with your doctor. If you no longer continue peritoneal dialysis, the research team will discuss stopping use of the CKD-PD app. If your disease worsens while you are participating in the research and your doctor has evidence to believe that you will receive clinical benefits from continuing to use the app, you will be advised of this information.

Withdrawing consent and exiting the research study

You can decide to stop participating in the research at any time, without providing a reason. You can withdraw your consent to participate in the research project at any time, including asking the research staff to no longer contact you or contacting you at the clinic. You can withdraw your consent to allow research staff to analyze any of the data already collected.
If you want to stop participating in the research, you will receive an appointment to meet with the research team about stopping the research. After discontinuing use of the app, you should resume treatment plan prescribed by your doctor. If you are in the CKD-PD app group, you will

be asked to resume using the notebook to record your peritoneal dialysis information. Your medical care will not be affected by leaving the research study.

Risk and discomfort that may occur

Using the app or your notebook to record your blood pressure, body weight and the amount of dialysis fluid removed while doing peritoneal dialysis does not cause any risk or discomfort. The only discomfort you may experience is the pressure of the arm cuff which causes pressure on your arm when inflated. These are measurement that you are already taking because you are on peritoneal dialysis. You can record your blood pressure, body weight and the amount of dialysis fluid removed in the app yourself or with the help of your caregiver.

Benefits of participating in research projects

You will receive your usual medical care during the study. You may not benefit directly from participating in this study. The information from this research study may help you and /or other chronic kidney disease patients who are treated with peritoneal dialysis. The information from your participation in the study will help to determine if the CKD-PD app can help decrease too much fluid accumulation in patients on peritoneal dialysis.

Compensation for participating in this research

If you agree to volunteer for this research study, the research will be performed when you visit the kidney clinic for your usual appointment. You also may be asked to come to the kidney clinic for additional visits if needed.

Compensation for injury cases resulting from research

If you become ill or injured as a result of participating in this study, the research staff will help you obtain medical care at your hospital. This care will be provided according to established medical standards.

Confidentiality and permission to collect, use and disclose personal medical information

Your personal identifying information, such as name and birthday, will be protected during this study. Research staff, including doctors and nurses, and clinical research organizations such as the US Food and Drug Administration and European Medical Office Inspectors that have been authorized to see this information have received research ethics and confidentiality training. The personal information collected during this study includes information from your medical records. which is necessary to ensure the accuracy and reliability of the research. The research staff may contact your doctor, in order to collect additional medical information history.

During this study your name will be replaced by a unique code to identify you. The data obtained from you during the research will be linked with this code. The research team may disclose your information to other groups or individuals working with the research team. Anyone receiving this information is required to work within the scope of this consent, as determined by the Ethics Review Committee.

This clinical research project is being done by a collaboration of medical researchers. In the future, rights to the information collected in this research may be forwarded to new sponsors or other agencies. This may include the code to the personal identifying and medical information. The identification code and research data collected from you in this research study will be integrated into the secure electronic research system of the research team of physicians These systems are managed and monitored by a team of physicians. You have the right to check your medical information in the records. You have the right to request changes in the medical information if you believe it is incorrect. However, please note that access to medical information may be restricted during the study if necessary, to maintain the integrity of the research. You will have access to medical information stored by the researchers when the research study ends.

Who you should contact if you have questions or concerns

- If you have questions about research, please contact
  Prof. Dr. Sirirat Anutrakulchai, Srinagarind Hospital Kidney Clinic, Department of Medicine. Faculty of Medicine Khon Kaen University Phone number 043 - 36x - xxx (in office hours) or 0xx - xxx - xxxx (outside office hours)

- If you have questions about your rights as a research volunteer, please contact
  Office of the Human Research Ethics Committee, Khon Kaen University (Sub-Branch)
  Room 5317, 3rd Floor, Vejjajakarn Building, Faculty of Medicine, Khon Kaen University,
  Tel. 08 - 9714 - 1913 number within 67133 - 4

Volunteer consent for the research project

I (Mr., Mrs., Ms.) …. …… .. …… ..…. Last name ……. ……. Age ……. year At home number ……. …… .. group…. …… .. district ……. …… district …… ..... Province .... have received an explanation from .... (Name of contributor) about volunteering in a medical research project to study how the CKD-PD app with basic home monitoring equipment can improve care for peritoneal dialysis patients through earlier detection of excess fluid accumulation. The research will evaluate if of CKD-PD app with home monitoring equipment allows nephrologists to make changes in medications, dialysis and diet. It will also collect information to see if complications related to too much fluid retention are decreased.

I have read this document or have had the contents of this document explained to me. I understand the purpose of this research and what will happen to me in this study. I consent to participate in this study independently. According to the details given to me in this document I will receive a copy of this document as signed below. I agree to contact the doctor or clinic staff if I experience any problems or side effects during the research study.

By signing this consent document I am allowed the research staff to use, access and share my personal medical information as specified in the topic "Confidentiality and the permission to collect, use, and disclose personal medical information" .This consent document is valid under the law, unless I revoke my consent.

Note:
(1) The medical practitioner must not be a volunteer applicant. But can provide information / explanation
(2) In the event that the volunteer is unable to read or Read / sign, use the following finger stamp

I cannot read, but the researcher has presented the text in this consent form to me orally in my own language that I can understand. I therefore stamped my right finger in this consent form with willingness.

Name and Signature of the person who explained consent

_____

Witness name and signature

_____
(The witness must not be a doctor or researcher)

Right hand stamped date / month / year _____