Project title

"Feasibility and acceptability of a co-designed self-management program for adults with chronic kidney disease"

Sponsor Name: Central Northern Adelaide Renal and Transplantation Service (CNARTS), Central Northern Adelaide Local Health Network (CALHN)

Investigators details:

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Ms Anne Britton
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Role: Anne has extensive experience in change management and quality improvement. She will provide guidance and support with the implementation of nurse-led questionnaires of the project across the service, having oversight of clinical nursing resource allocation to the project.

Dr Richard Le Leu
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Dr Lisa Matricciani
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Dr Shyamsundar Muthuramalingam
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Dr. Muthuramalingam seeks to enhance study design and reporting by incorporating the perspective of lived experiences. Dr. Muthuramalingam will provide strategic guidance on consumer engagement strategies. This includes various aspects such as creating plain language summaries, involving consumers in the recruitment process, refining study designs to be more consumer-friendly, and effectively disseminating research findings.

A/Prof Shilpa Jesudason
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Contribute adding Nephrologist's perspective to this project and promotion of this program within CNARTS nephrologists. Shilpa has extensive experience in research involving chronic kidney disease population such as the Partnering with patients with chronic kidney disease to transform care and outcomes (CRE-PACT) project. Shilpa will also contribute to study design, analysis and reporting of results.

Prof Paul Bennett
Griffith University, Queensland.
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Role: Contribute to study design, analysis, and reporting. Provide mentorship and support to the PI implementing the study. Paul has 20 years' experience in CKD patient research. Expertise in qualitative and nurse-led studies.

Background

Chronic kidney disease (CKD) is a progressive condition associated with reduced quality of life, high mortality, and healthcare costs.(1) The chronicity of this disease necessitates individuals actively self-manage their health care to maximise health outcomes.(2, 3) A person's ability to self-manage their health is, therefore, fundamental in managing CKD and requires individuals to actively engage in minimising the impact of their CKD and slow the progression of the disease.(4)

The term 'patient activation' explicitly identifies the skills, knowledge and confidence that underpin a person's willingness and ability to self-manage their health.(5) The patient activation model proposed by Hibbard in 2004(5, 6) explores (a) patient beliefs about their role in their health; (b) patient knowledge relating to their disease and its complications; (c) patient confidence to follow through health-care recommendations and to identify when medical care is needed; (d) patient skills to maintain required life changes; and (e) the skills to handle health-related complications. Patient activation/engagement has predominantly been assessed using the Patient Activation Measure (PAM-13), a 13-item questionnaire that assesses each domain.(6)

Studies that utilise the PAM-13 suggest highly activated patients are more likely to participate in self-management behaviours, seek out and use health information, have lower levels of unmet needs for medical care and have greater support from health professionals for the self-management of their chronic conditions.(7, 8) In contrast, individuals with lower levels of patient activation are more likely to have a higher number of hospital admissions, longer length of stay in hospitals, more significant health costs, less likely to participate in self-management activities such as blood pressure monitoring and have poorer care experiences compared to those with higher activation level. (9, 10)

Our recent system meta-analysis of the effectiveness of patient activation interventions compared to usual care on health-related behavioural outcomes in adults with CKD found that education alone was insufficient for patients to take an active role in their self-management.(11) This review's findings suggest that when tailored and interactive, patient activation interventions are effective in improving self-management and self-efficacy. We identified the need to develop a prototype patient self-management program co-designed with consumers and clinicians.

Our recent survey of South Australian people with CKD stage 5 not receiving dialysis showed that most (73%) patients had low patient activation levels.(12) Low patient activation levels were associated with more hospital emergency department visits, higher hospital admission rates, more missed renal appointments, and poor medication adherence.(12) Given the current low patient activation levels and lack of a co-designed self-management intervention, we aim to develop and test the feasibility and acceptability of a CKD self-management program using a co-design approach co-led by renal consumers and clinicians.

Aims

This study aims to:

1) Develop a co-designed self-management program for people with stage 5 CKD not receiving dialysis.

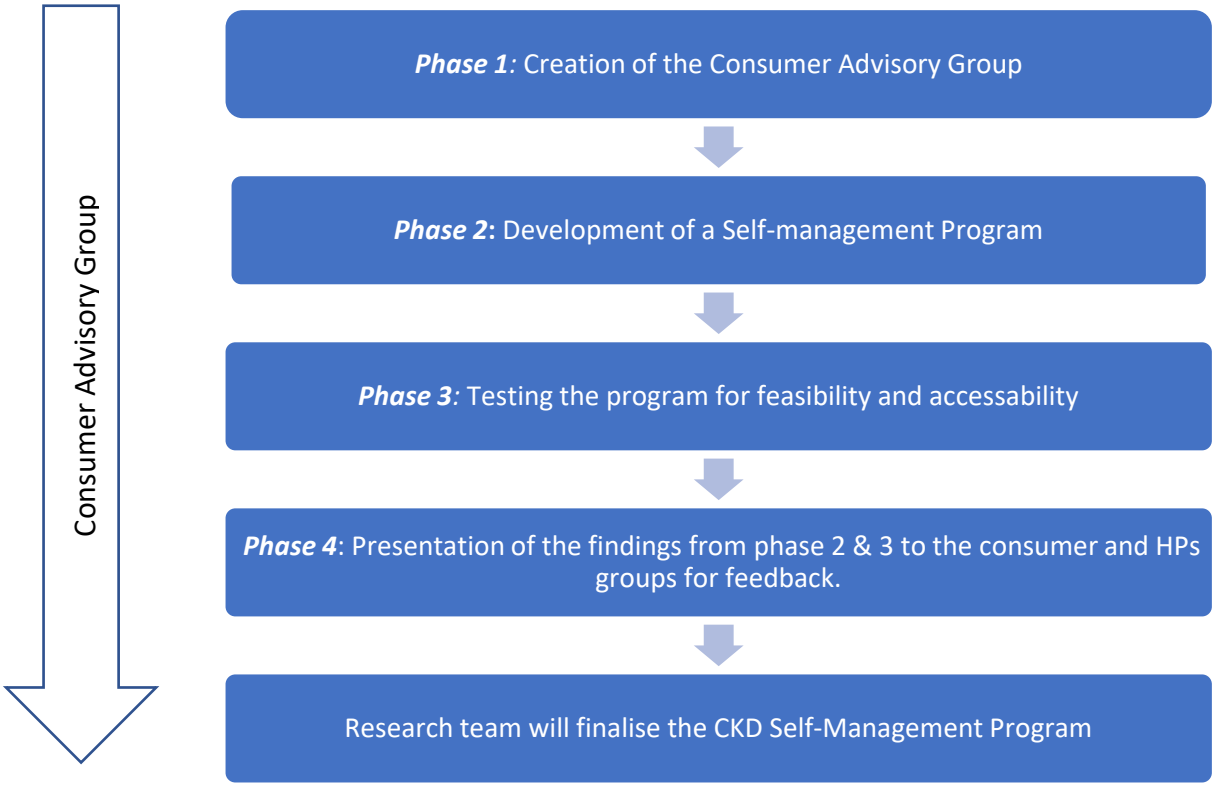
2) Determine the clinical feasibility and acceptability in usual kidney care service of this co-designed self-management program among patients with CKD stage 5 not receiving dialysis.

Methods

The project will use a systematic co-design approach to partner with researchers, consumers, and clinicians. As presented in Figure 1, this project involves four phases.

Phase 1 will consist of creating the Consumer Advisory Group (CAG) to provide strategic input throughout the project.
Phase 2 will involve the development of a self-management program.
Phase 3 will pilot the program and test clinical accessibility and feasibility.
Phase 4 will present the findings and proposed CKD self-management program to the consumer and health professionals (HPs) groups for feedback and further refinement.

Figure 1 - Study Flow



This study will be guided by the co-design principles in healthcare at CNARTS, as advocated by the NSW Agency for Clinical Innovation (ACI)(13) and the Central Adelaide Local Health Network (CALHN) Consumer, Carer and Community Engagement framework(14). Co-design is a dynamic and inclusive approach that brings

together consumers, carers, families, and HPs to actively participate in improving healthcare services. The fundamental principle underlying co-design is the establishment of:

1. Equal Partnership and Valued Insights to ensure that the invaluable voices and insights of all stakeholders are not only heard but also genuinely valued and integrated into the design and implementation of healthcare services.
2. Patient-centred care is essential for ethical healthcare practices, ensuring our efforts improve outcomes for everyone receiving care at CNARTS.
3. The real-time feedback mechanism enables HPs to listen actively to consumers, providing an immediate avenue for addressing concerns and making necessary improvements.
4. Diversity and Inclusivity: recognizing that equitable care extends to all individuals, regardless of their backgrounds or geographical locations.

Phase 1

The aim of *phase 1* is to create the CAG, inviting community representatives from different backgrounds and demographic locations acting in an advisory capacity to provide a strategic direction throughout this project. This group will act as the CKD lived experience voice in developing the CKD self-management program.

Population:

Five consumer representatives will be required to be part of the CAG. Eligible individuals are those who are aged ≥18 and diagnosed with CKD (any stage). We will exclude people under 18, those with no kidney condition, those unable to speak English and those who provide written consent to participate in this study.

Recruitment and informed consent:

Established renal consumer representatives from the CNARTS Clinical Research Group, CALHN Carer and Community Engagement and the Better Evidence and Transplantation in Chronic Kidney Disease (BEAT-CKD) Consumer Advisory Board (who have previously consented to be contacted for consumer related activities) will be invited via email that will include the flyer of this project (attachment 1) or they will be approached over the phone by the principal investigator (PI) (LL). The different Consumer and Community Engagement groups mentioned above have already been contacted and they will provide a list of renal consumer representatives with their contact details.

Individuals who express interest in participating by responding to the invitation via email or over the phone will be approached by the PI (LL), who will provide them with the participant information sheet to review with directions for enrolling in the project (reply to email and attach a signed consent form) and finalise the enrolment process. We aim to recruit five individuals to be part of this CAG. Consumers who attend the meeting will receive refreshments and will be reimbursed for time as per the SA Health reimbursement policy (time parking fees, parking/travel/childcare). Video-link will be offered to those participants unable to attend in person.

One consumer representative from the CAG will be invited to co-facilitate the focus groups (*phase 2* of this project) with a researcher to deliver a presentation. This co-design lead or facilitator will guide and coordinate the collaborative efforts of all stakeholders involved in the project, ultimately contributing to a more patient-centred, responsive, and ethically grounded healthcare system at CNARTS.

Method:

Five group meetings involving five people living with chronic kidney disease to be part of the CAG and two research team members will be conducted. This group will act in an advisory capacity to provide a strategic direction throughout this project. The meetings will be audio-recorded. Each meeting will be 120 minutes long and will be held at the Royal Adelaide Hospital; a video link will be offered to attend the meeting for those consumers unable to attend in person.

Phase 2:

The aim of *phase 2* is to collect and analyse qualitative information from consumers and HPs required to develop a codesigned CKD Self-Management Program for people with stage 5 CKD not receiving dialysis. This phase will consist in three focus group discussions including consumers and HPs to design the program.

Population:

Six CNARTS HPs and 15 consumers above 18 years of age at any stage of their CKD who are receiving care at CNARTS will be invited to participate in the design process of this self-management program. We will exclude people under 18, those with no kidney condition, those unable to speak English and those who provide written consent to participate in this study.

Recruitment and informed consent:

Health professionals (HPs)' group: Renal clinicians (doctors, nurses, renal allied health professionals and pharmacists) working at CNARTS will receive an email from the PI (LL) with information about this study inviting them to take part. Individuals who express interest in participating will receive a participant information sheet to review with directions for how to enrol in the project (reply to email and attach a signed consent form) and will be approached by the principal investigator (PI) to finalise the enrolment. We aim to recruit six renal clinicians. CNARTS has approximately 60 HPs working in this field with this cohort of patients.

Consumer group: Eligible individuals with stage 5 CKD not receiving dialysis and their carers receiving care at CNARTS will be invited to participate chronologically until the target number of 15 is met. Flyers advertising the study (attachment 2) will be distributed by the PI (LL) and distributed in renal outpatients' clinics. Treating clinicians will invite participants from the outpatient clinic; verbal information about the study will be provided, and if they accept to participate, the PI (LL) will approach them with the patient information sheet (PIS) and a consent form to sign.

Method:

For *phase 2*, three qualitative focus group discussions (120-minute duration) will be conducted; each focus group will include five consumers, two health professionals, and two research investigators (researchers will take notes and record the sessions). A codesign facilitator will lead each focus group. Questions for discussion will aim for the group to develop a prototype codesigned self-management program. Some pointed questions (Interview Guide (IG)) (attachment 5) addressing the aims of this project will be presented in a PowerPoint presentation that will be developed in phase 1 to open direct discussion with the groups; questions arising will

be reviewed and evaluated among the whole group to formulate indicative research priority questions. The CAG and researchers will develop the IG to guide the development of further questions for the focus groups. Some potential questions to include in the IG are attached to this protocol (attachment 5). The focus group will provide an understanding of the current CKD clinic, what works well/what does not, challenges faced and ideas for changing implementation aspects. The qualitative focus group discussions will also aid in designing the current and the proposed CKD self-management program to be delivered. The overall desired outcome is to co-design a self-management program to improve the knowledge, skills and confidence of people with CKD in managing their health (termed patient activation and measured with PAM-13) and consequent self-management behaviour.

The focus group discussions will be conducted in a room at the Royal Adelaide Hospital; a video link will be offered to those participants unable to attend in person. Consumers who attend the focus group discussions will receive refreshments and will be reimbursed for time as per the SA Health reimbursement policy (time parking fees, parking/travel/childcare).

Data collection:

All focus group discussions will be audio-recorded and transcribed verbatim, de-identified, and undergo content and thematic analyses (described below). All data will be de-identified before being analysed.

Data analysis:

The analysis and reporting of the focus group results will be undertaken and coordinated by research team members (LL, PB, SM also consumer representative) and a system analyst (TBD). Analysis will be undertaken by following the six stages of thematic analysis as outlined by Braun & Clarke(15): familiarisation of data, initial code generation, searching for preliminary themes, refining themes, defining and naming themes, and producing a final report. Thematic analysis from the discussions will be used to assess the shared and contrasting perspectives of the consumer and health professional groups to develop the CKD self-management program. When the analysis is completed, the results will be discussed with the CAG to finalise the interpretation before we move to *phase 3* of this study.

Phase 3:

The aim of *phase 3* is to determine the clinical feasibility and acceptability of this co-designed CKD self-management program in the kidney care service.

The proposed CKD Self-Management Program (Fig 2) was modified from the focus group discussion with consumers and HPs from *phase 1 and 2*, and it will be piloted/tested in phase 3 for feasibility and acceptability. The research team has co-developed alongside renal consumers a 12-week codesigned self-management program that Nephrology Nurse Practitioners will lead. This program will be delivered face-to-face in outpatient renal clinics (weeks 1 and 12), followed by educational activities and setting patients' goals over the phone (weeks 3 and 6). Participants will be given a choice of digital (utilising the Personify Care platform) or paper format (My Kidney Health workbook) to complete the educational activities; the content (digital and paper format) was developed in phases 1 and 2 and will have the same content. In week 9, we plan to organise a

group meeting with participants, members from the CAG and renal health professionals to discuss practical ways of making health choices and simple scenarios that might help participants become more independent in self-managing their health. The Self-Management Program's flowsheet and the "My Kidney Health workbook" are attached (attachments 9 and 10, respectively).

Digital Patient Pathways is a Personify Care mobile platform used by Local Health Networks across SA Health to exchange information with patients about their care.(16) Personify Care provide a unique opportunity for researchers, to capture patient-reported data at scale to support research activities and evaluate population-level models of care. The Personify Care platform consists of two end-user components: 1) Clinical Dashboard used by clinicians to configure clinical pathways, detect patients risks early, record early interventions and review patient progress; and 2) Patient Checklist used by patients to follow their personalised pathway.(16)

Population:

We will invite people with CKD stage 5 from the inclusion criteria detailed below (Table 1).

Table 1: Inclusion/exclusion criteria

CKD stage 5 ~20 patients across CNARTS sites	
Inclusion	**Exclusion**
• Age >18 years • English speaking • CKD stage 5 (eGFR ≤ 15 ml/min/1.73 m2) • Attending outpatient setting • Receiving care by the kidney care team in CNARTS. • Willing and able to give informed consent and comply with the study protocol	• Unable to give written consent. • Inability or unwillingness to complete patient self-management program (e.g., due to literacy, vision impairment, cognitive deficits) • Significant disease or disorder that, in the opinion of the patient's own renal clinician, may either put the participation at risk because of participation in the study or may influence the result of the study of the participant's ability to participate in the study • Already receiving dialysis • Following conservative renal management. • Acute kidney injury

Recruitment and informed consent:

Participants under the care of CNARTS Nurse Practitioners (NPs) will be invited to be part of this study. The NPs will approach the eligible participants (see Box 1 inclusion/exclusion criteria) in person and inform them about the project. If the patient is interested in participating, the PI (LL) will contact them and allow them to ask questions related to the research. They will be issued a participant information sheet to review and provide consent for their details to be passed on to the research team so they can be contacted to further discuss participation in the study. Participants will be advised that participation is voluntary and that their decision will not affect their current or future care by the treating renal team.

Study Population

Approximately 350 patients with CKD stage 5 are not receiving dialysis currently attending those sites, and an average of 20 new referrals per month. Sample size: n=40 patients will be recruited, allowing for drop-out of around 50% (mortality, commencement of dialysis, hospital admission, decline continuity of the study) to give a target amount of n=20 (feasible number of patients at CNARTS to recruit).

Feasibility and acceptability measures:

The primary outcome measures are the feasibility and acceptability of the self-management program that has not been designed yet. Feasibility and acceptability will be assessed as follows: (1) Eligibility – defined as the number of participants meeting eligibility criteria out of the total number of people attending the clinics; (2) recruitment—defined as the number of consenting participants as a proportion of those eligible; (2) retention—defined as the number of participants remaining in the trial as a proportion of those enrolled; and (3) acceptability—defined as participants' satisfaction with the program regarding seven items: finding information, intervention setting, program facilitator, setting and acting on attainable goals, self-monitoring, renal clinics attendance and phone calls. Each item will have five answer options, from 1 (“very little”) to 5 (“quite a lot”). Total scores will be obtained by summing the item responses, with higher scores indicating greater acceptance of the program. Acceptability will be also evaluated at the end of the study by asking the participants the following open-ended question: “Would you please share with us your experience and suggestion of this program?” (attachment 6).

The secondary outcome measure is the change in patient activation level of the population measured with the PAM-13 at baseline and after completion of the self-management program.

Data Instrument – PAM-13

To measure change in patient activation, the PAM-13 questionnaire will be assessed (attachment 7).(5) The 13-point PAM-13 (3) is a validated 13-questionnaire scored against a Guttman scale (1 = disagree strongly, 2 = disagree, 3 = agree, 4 = agree strongly and 5 = not applicable). The scores for this tool are then converted from the continuous Rasch item response theory logit scale to an overall activation score between 0–100 by Insignia Health. Scores are transformed to a scale from 0 to 100: Level 1 (0.0–47.0) low activation suggesting that the person does not yet understand their role in healthcare; Level 2 (47.1–55.1) indicating that the person does not yet have the knowledge and confidence to take action; Level 3 (55.2–72.4) indicating that the person is beginning to engage in positive health behaviours; Level 4 (72.5–100) indicating that the person is proactive and engaged in recommended health behaviours.

Data collection

Change in PAM-13, feasibility, and acceptability will be added to the SA Health-based REDCap. All data will be de-identified before being analysed.

Data Analysis:

The feasibility and acceptability of the CKD self-management program will be examined descriptively by presenting summary statistics for each of the feasibility criteria listed in Table 2. Quantitative data will consist of

descriptive measures as detailed and presented as means and averages or medians and interquartile ranges (IQR) as relevant.

Phase 4

The aim of *phase 4* is to combine the learning from the previous phases into the newly co-designed CKD self-management program.

In this phase, consumer representatives, HPs and researchers will be reunited to discuss the results obtained from previous phases and obtain guidance on the scope and content of the program and the most appropriate delivery format. This meeting will last 120 min and will be held at the Royal Adelaide Hospital.

Program materials used in *phase 3* will be discussed with the CAG, and feedback will be elicited; a description of the program's scope, content and delivery will be outlined.

The research team will meet with the CAG to finalise the CKD self-management program.

Confidentiality, data storage and security

All data collected will be stored as per the standards contained in the Australian Code for Responsible Conduct of Research (17) and the National Standard on Ethical Conduct in Human Research(18). Each study participant will be allocated a code on study entry and stored in a separate spreadsheet from the data collection spreadsheet and will be stored on SA Health server and password protected. Participant data will be collected into CALHN RedCap database which is only accessible on SA Health server and is password protected which can only be accessed using a HAD account and only accessed from SA Health computer. In RedCap data will de-identified and participants will be assigned their allocated code; they will be re-identifiable only by this project investigators to allow collection of follow-up data. Audio-recording will be stored on SA Health password protected computer. Only the project investigators will have access to the information, Data and audio-recordings will be kept for five years and then destroyed by the PI.

Personify Care is ISO27001:2022 certified, the highest level of certification available for assuring global information security and meets Australia's strict privacy and security standards.(16) Personify Care has gained this certification for all aspects of the organisation, including data centres, the digital pathway platform, and company operations. To protect personal and health information, Personify Care adopts a number of best-practice security measures. A licence will be granted to the PI who will have access to the user information. (16)

Publication

This is a CALHN project, a manuscript will be prepared for submission to a nephrology related journal. The manuscript will be made available to participants. All participants will be emailed or posted the manuscript. Results of the study defined as a cohort will be made available to participants. Results of the study defined as a cohort will be made available to the CNARTS Clinical Research Group as well as treating dialysis staff. The principal investigator (PI) will also utilize the outcomes as part of her PhD thesis.

Furthermore, presentations will occur at research meetings involving the treating clinical team as well as domestic and/or international conferences.

Ethical considerations

Benefits of the study

This study is designed to better identify the care needs of individuals with advanced CKD to increase engagement in the self-management of their chronic conditions. This study aims to identify some of the needs of CKD patients to increase their activation level to optimize self-management of their CKD and be better prepared to initiate dialysis. With the implementation of this self-management program, the intention is to improve the quality of the service provided to renal patients and increase the share-making decisions of health care decisions between consumers and clinicians.

Risks

There are no foreseeable risks to participants as a result of participating in the studies.

Protocol Deviations

Protocol deviations will be reported to the reviewing ethics committee as soon as practicable following the investigators becoming aware of the deviation.

Attachments

1. Flyer for the consumer advisory group (phase 1)
2. Flyer for focus group (phase 2)
3. Consumer Information Sheet and Consent Form (phase 1)
4. Consumer Information Sheet and Consent Form (phase 2)
5. Interview Guide
6. Feasibility and acceptability- Excel spreadsheet
7. Patient Activation Measure -13 (PAM-13)
8. Consumer Information Sheet and Consent Form (phase 3)
9. Self-Management Program flowsheet
10. My Kidney Health workbook

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