PROTOCOL

A randomized controlled trial protocol testing a decision support intervention for older patients with advanced kidney disease

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Abstract

Aim. To assess the effectiveness of a decision support intervention using a pragmatic single blind Randomized Controlled Trial.

Background. Worldwide the proportion of older people (aged 65 years and over) is rising. This population is known to have a higher prevalence of chronic diseases including chronic kidney disease. The resultant effect of the changing health landscape is seen in the increase in older patients (aged ≥65 years) commencing on dialysis. Emerging evidence suggests that for some older patients dialysis may provide minimal benefit. In a majority of renal units non-dialysis management is offered as an alternative to undertaking dialysis. Research regarding decision-making support that is required to assist this population in choosing between dialysis or non-dialysis management is limited.

Design. A multisite single blinded pragmatic randomized controlled trial is proposed.

Methods. Patients will be recruited from four Queensland public hospitals and randomizd into either the control or intervention group. The decision support intervention is multimodal and includes counselling provided by a trained nurse. The comparator is standard decision-making support. The primary outcomes are decisional regret and decisional conflict. Secondary outcomes are improved knowledge and quality of life. Ethics approval obtained November 2014.

Conclusion. This is one of the first randomized controlled trials assessing a decision support intervention in older people with advance chronic kidney disease. The results may provide guidance for clinicians in future approaches to assist this population in decision-making to ensure reduced decisional regret and decisional conflict.

Keywords: chronic kidney disease, conservative kidney management, decision making, dialysis, non-dialysis management, nurse, randomized controlled trial

Why this study or review is needed?

- Research has shown that decisional regret is high in people undertaking dialysis and withdrawal from dialysis is one of the most common causes of death.
- There are no decision support interventions available that have been designed specifically for the older person with advance kidney disease.
- Limited research is available to determine if decision support interventions for the older person with advance kidney disease will lower decisional regret and decisional conflict.

Introduction

Globally, expenditure on health care is high and predicted to increase further due to the ageing of the population and the advancement of healthcare technologies. This is evidenced by increasing expenditure of 2·6% in the year 2013 and a further rapid increase predicted of approximately 5·3% per year between 2014–2017 (Deloitte 2014). The primary factor contributing to the increasing expenditure on health care is the increase in life span in developed countries and the prevalence of chronic diseases. The worldwide proportion of older people (aged 60 years or over) has risen from 9·2% in 1990-11·7% in 2013 (United Nations 2013). The proportion of older people globally is expected to grow and represent 21% of the world population by 2050 (United Nations 2013). As a consequence of the ageing population, there is a higher prevalence of chronic diseases such as diabetes, hypertension, cardiovascular diseases and chronic kidney disease (CKD) which contribute to increased health expenditure (Eckardt *et al.* 2013, Deloitte 2014).

Chronic diseases are also the most common cause of morbidity and early death (Couser *et al.* 2011). The World Health Organization has identified cardiovascular, cancer, diabetes and chronic respiratory disease as representing a major proportion of the global non-communicable diseases (Couser *et al.* 2011). Chronic kidney disease is regarded as a key determinant in the poor outcomes for those who have cardiovascular, cancer, diabetes or chronic respiratory disease (Couser *et al.* 2011). The presence of chronic kidney disease is known to be related to an eight to tenfold increase in cardiovascular mortality and also increased risk for those with diabetes (Couser *et al.* 2011).

Chronic Kidney Disease is defined as the presence of kidney damage and/or reduced kidney function, for a period greater than 3 months (Chadban *et al.* 2003). The classification of kidney disease has five stages; stage 1 indicates mild kidney disease and stage 5 indicates end stage kidney disease (ESKD). Globally, the number of deaths from CKD has increased by 82% in the last two decades (Radhakrishnan *et al.* 2014). End Stage Kidney Disease (ESKD) is the most severe form of kidney disease, with kidney function working at less than 15 ml/min/1·73 m². The number of patients with ESKD receiving renal replacement therapy worldwide is greater than 1·4 million, with an annual growth rate of 8% (Radhakrishnan *et al.* 2014). In the presence of ESKD, renal replacement therapy (transplant or dialysis) is usually required for survival (Australian Institute of Health and Welfare 2009). Dialysis is an expensive treatment and places a considerable burden on health care. In Australia, for example, the predicted cost of treating all prevalent and incident cases of ESKD between the years of 2009–20 is estimated between $11·3 billion and $12·3 billion (Kidney Health Australia 2010). In the context of an ageing population worldwide, increasing numbers of people with chronic diseases such as CKD and the predicted expenditure on technologies such as dialysis, it is necessary to consider the morbidity and mortality related to this treatment and the rationale for undertaking dialysis in this population.

Background

The high incidence of comorbid diseases in the older population, combined with the rise in the number and age of cases of ESKD receiving renal replacement therapy, has generated discussion around the appropriateness and benefit of dialysis. Worldwide the most common cause of death for a dialysis patient is withdrawal from dialysis (Brown *et al.* 2014). The high incidence of withdrawal as the cause of death for dialysis patients indicates that there is a proportion of people who commence dialysis for whom dialysis becomes untenable, with the most common reason for withdrawal from treatment being psychosocial (McDonald *et al.* 2010). Research has identified that 61% of patients regretted their decision to commence dialysis (Davison 2010). Furthermore, this study found that high proportion of the patients reported that there was no discussion regarding end-of-life care preferences within the last 12 months. The study identified that almost 50% of the patients wanted to have end-of-life care discussion with the nephrologist, however in reality, this occurred for less than 10% of the cases (Davison 2010). This is one of the few studies examining end-of-life care preferences. None the less the findings from Davison's research indicate that it may be important for

patients to have access to information needed to assist in objective and informed decision-making.

Facilitating informed decision-making regarding health treatment options is important when there is no explicit health outcome benefit of one treatment. Decision support interventions have been used when there is no clear advantage in relation to health outcomes and when there are benefits and risks for each option, with the patient values becoming the determining factor in treatment choice. Evidence has demonstrated decision support interventions have facilitated decision-making through improving knowledge regarding the treatment options and their benefits and risks (Stacey *et al*. 2014). In addition, decisional conflict can be lowered in relation to feeling uninformed and unclear regarding their individual values (Stacey *et al*. 2014).

In the setting of chronic kidney disease, there is limited literature on the effectiveness of decision support interventions. A Cochrane systematic review identified two decision support interventions specific to kidney disease, however neither have been formally evaluated (Stacey *et al*. 2014). Other research identified includes a quasi-experimental study which was undertaken using multimedia interactive DVD nurse guided interviews, for patients with ESKD, with the comparator being standard education, in assisting the patient to choose between dialysis modalities (Chiou & Chung 2012). This study achieved statistically significant improvements in knowledge, pre-dialysis uncertainty and decision regret in the intervention group (Chiou & Chung 2012). More recently, a decision support intervention has been developed by Kidney Health Australia called 'My Kidneys – My Choice' (Fortnum *et al*. 2015) which has yet to be thoroughly evaluated against patient related outcomes. The dearth of good quality evidence regarding the use of decision support interventions in chronic kidney disease has prompted the implementation of this research. The study design of a pragmatic single blind multisite randomized controlled trial will enable robust evaluation of the effectiveness of this innovative intervention. The aim of the research was to evaluate an evidence based decision support intervention to assist patients' 70 years and over who have advanced CKD, to choose between dialysis and non-dialysis management.

Intervention development

The decision support intervention to be tested in this research was developed from the Ottawa Decision Support Framework (ODSF). This framework is an evidence-based, mid-range theory developed to guide patients to make health or social decisions (O'Connor *et al*. 2011). The three concepts of ODSF are providing decision support, assessing the patients' needs or determinants of decision and evaluating decision quality and outcomes of decision as illustrated in Figure 1 (O'Connor 2006, O'Connor *et al*. 2011). The framework was developed for health decisions where decisional conflict is high, in particular, for decisions that need to be made when there is a new diagnosis or condition. The decision regarding the choice between dialysis or non-dialysis management has a high level of decisional conflict as evidenced by previous studies identifying a high level of decisional regret and also withdrawal from dialysis as a common cause of death.

The ODSF has been used to guide the development of over 30 distinct patient decision support interventions. Numerous randomized controlled trials have been undertaken to evaluate decision support interventions covering topics such as: women after menopause (O'Connor *et al*. 1998b), pregnancy in older women (Drake *et al*. 1999), breast cancer (Goel *et al*. 2001) and non-valvular atrial fibrillation (Man-Son-Hing *et al*. 1999). The ODSF provided guidance for development of the decision support intervention to be used in this study (hereafter referred to as OPTIONS). The development of the OPTIONS intervention assimilated the decision-making process as defined by the ODSF incorporating the three concepts described above. The determinants of decisions are elements that influence decisions such as inadequate knowledge, personal values, unrealistic expectation of the health care, perceptions of others and personal resources to make a decision (O'connor *et al*. 1998a). When these are inadequate a poor decision – relative to the individual's personal values – is often made. In contrast, a good decision from the individual's perspective, may lead to poor clinical outcome but can result in a high level of satisfaction, congruence between values and choice and a low level of uncertainty (O'connor *et al*. 1998a).

The study

Aim

The aim of the study was to examine the effectiveness of OPTIONS for older people considering the choice between dialysis and non-dialysis management when they have reached ESKD. Hence the following null hypotheses will be tested: For patients with ESKD who are ≥70 years and receiving the decision support intervention there will be no differences in:
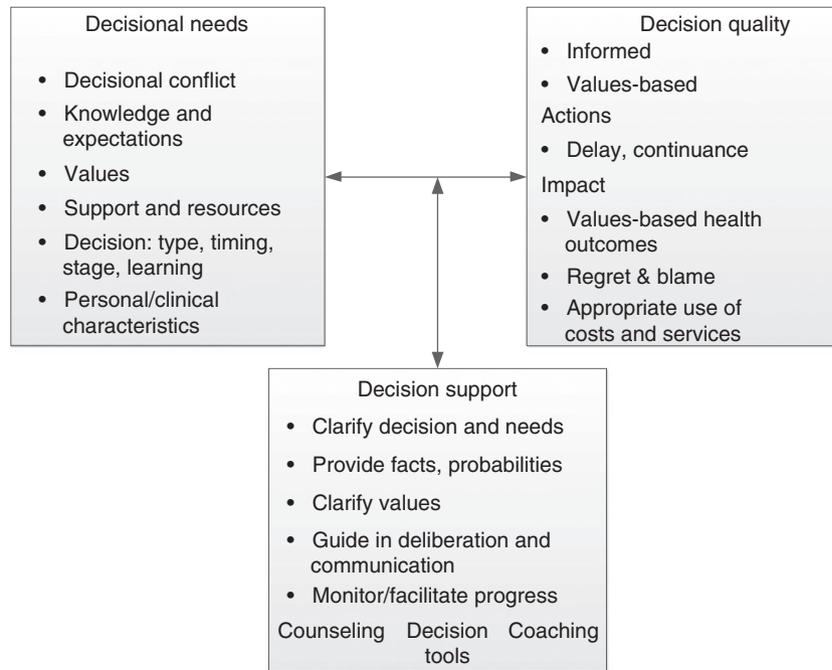
Figure 1 Ottawa decision support framework.

Primary outcomes of:

1 Decisional regret score
2 Decision conflict score

Secondary outcomes of:

3 Knowledge score
4 Quality of life

Study design and methods

The study design is a pragmatic randomized controlled trial (RCT) measuring the effectiveness of the OPTIONS tool in supporting the patient and their family in making a choice between dialysis and non-dialysis management for ESKD. The research is part of Author one's doctoral studies. The methodological complexities of development, delivery and evaluation of the intervention, relate to the nature of the clinical situation, whereby participants are undertaking value-sensitive health decisions in everyday situations. The decisions to be made are complex and often have no clear 'best choice' for everyone, either because the outcomes are uncertain or due to the fact that the decision involves trade-offs between advantages and disadvantages of receiving treatment (Wennberg 2002). The pragmatic RCT design allows for evaluation of a complex intervention (Hotopf 2002). A complex intervention can be defined as having multiple interacting components and a non-linear casual pathway

(Medical Research Council 2000). OPTIONS conforms to the features of a complex intervention in that there is interaction between the individual with ESKD, their family and the health professional delivering the intervention. The individual's response to OPTIONS is unpredictable with the opportunity of several differing outcomes. The elements of the study that are characteristic of a pragmatic design include specific features of the patient and comparison group, broad inclusion criteria, potential for clinician variance in the delivery of OPTIONS and specific outcomes. To address some threats to bias, this study design includes control strategies for blinding at the points of randomization, data collection and outcome analysis. These design elements contribute to the study's internal and external validity. The CONSORT flow diagram in Figure 2 summarizes the study design.

Participants

The study population is all adult patients ≥70 years of age with an estimated glomerular filtration rate of ≤20 ml/min/ 1·73 m^2 who are attending specialist nephrology services (renal clinics) and who have been diagnosed with chronic kidney disease by a nephrologist. The exclusion criteria is: non-English speaking, those who are declared medically incompetent to make healthcare decisions, those who are eligible to receive a kidney transplant or those who have already made a decision regarding treatment. This is an Australian study which will be conducted at four public
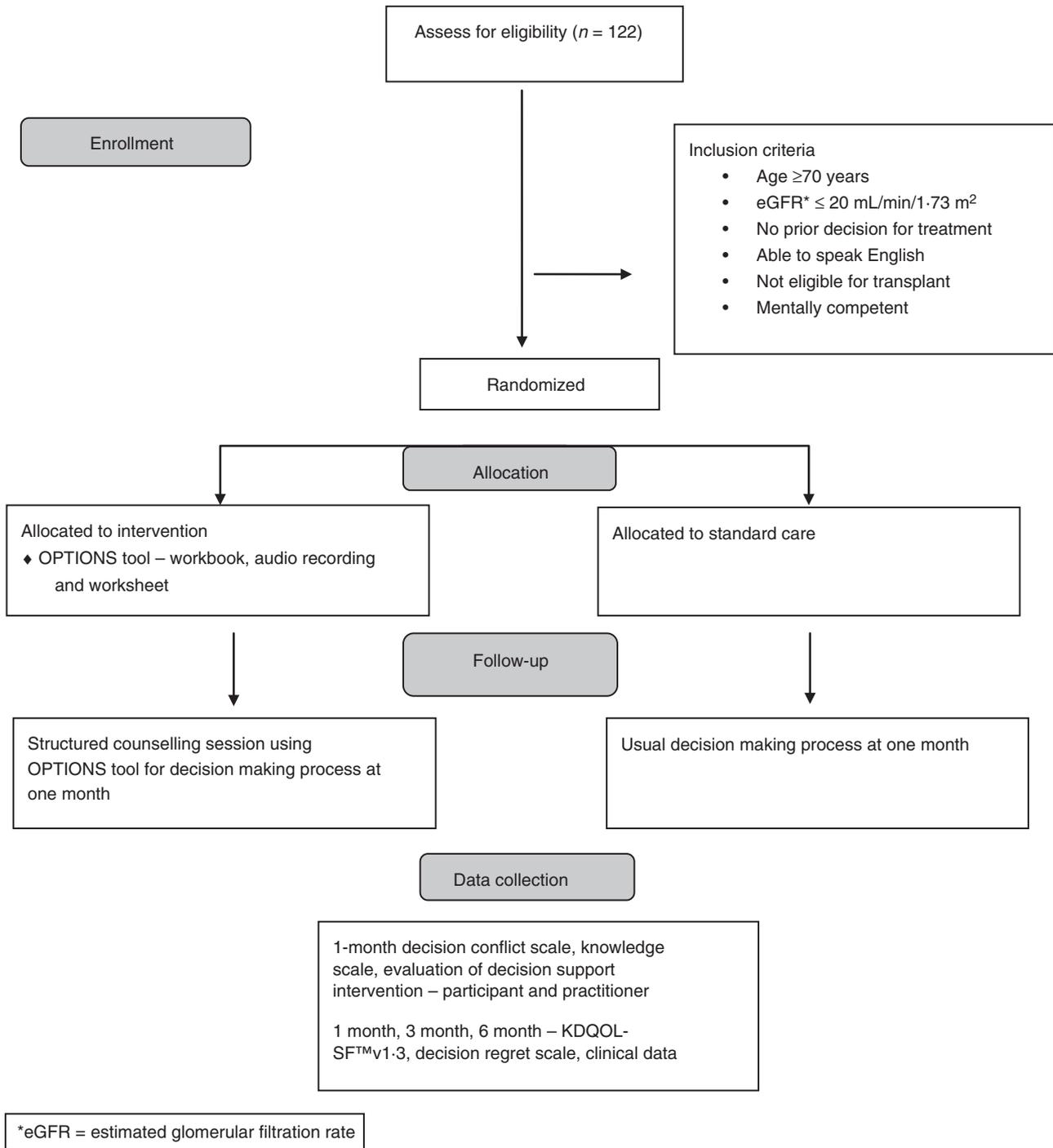
Figure 2 CONSORT summary diagram showing flow of participants at each stage of the study.

health renal departments in Queensland. These departments vary in the complexity of care provided. Despite the difference in service capabilities and complexity of care all renal departments have formalized CKD management and education strategies for patients with advanced chronic kidney disease.

Sample size

Calculation of sample size was informed by a review of the literature to identify research using decision support interventions that assist CKD patients to make treatment choices. A study conducted in Taiwan (Chiou & Chung 2012) measured the effectiveness of a multimedia education format to

assist patients with CKD to make a treatment choice. Several measures were used, with the variable 'decision regret' achieving a statistically significant difference between the experimental group and the control (Chiou & Chung 2012). The outcome variable of 'decision regret' was considered for effect size. The calculations were based on 90% power and a type1 error rate (two-tailed) of 5%. The effect size was calculated to detect a 15% change in the outcome. Based on this, the minimum sample size required is 122 patients in total allowing for 20% loss to follow up. The study will require a minimum of 61 patients in each study arm.

Randomization and recruitment

Randomization will occur once the eligibility of the patient is confirmed, consent provided and baseline data has been collected. The allocation of the patient to either intervention or standard care will occur through a computer generated program using block randomization.

Sequence generation

The randomization process, in this pragmatic randomized controlled trial, has been developed to eliminate bias. Block randomization ensures there is a balance in the number of patients allocated to intervention or control (Efird 2011). A block size of four will be used. This allocation process provides six possible ways of equally assigning participants to a block sequence and is more appropriate for smaller sample sizes which may occur at some sites. To maintain effect of randomization and reduce bias the block sizes are not revealed to the Clinical Research Assistant (CRA) who is managing treatment mode allocation. To counteract this predictability the lead researcher is the only individual aware of the block size and has no involvement in recruitment, consent or allocation.

Allocation concealment mechanism

The random allocation sequence has been generated using a computer generated block randomization list (Sealed Envelope Ltd. 2015). The lead researcher then placed the code generated into sequentially numbered envelopes. The lead researcher is blinded to the group that is identified by the code.

Before recruitment begins the CRA at each site will ascertain the code for group allocation, by contacting the associate investigator. This communication between the CRA and associate investigator occurs only once for each site prior to the commencement of recruitment. The CRA will obtain a sealed envelope (which are sequentially ordered and contain the computer generated allocation code) and then assign the participant to their allocated group. The CRA will then use the relevant code, to identify the treatment allocation

for that participant in all of the documentation. This code system will ensure concealment of the group identity for the outcome research assistant (ORA) who will collect data at time points of 1-, 3- and 6 months and the lead researcher who will conduct the data analysis.

Implementation

Those participants that have been randomized to receive the intervention will be provided with a booklet, audio recording and personal worksheet by the CRA.

Blinding

Due to the nature of the intervention it was not possible to blind the CRA, participants or the renal nurses. However, to minimize bias, the ORA (responsible for collection of outcome data) and the lead researcher (responsible for data analysis) were blinded to group allocation.

Intervention

This is a two arm study with equal allocation randomization for the participants to receive either treatment or control. The treatment is – OPTIONS and control – the standard method of assisting decision-making that is currently provided to CKD patients. In both groups the education given to the participants regarding treatment options will not differ, they may be given a variety of booklets and audio-visual material and also may be invited to attend group education sessions. The differentiating feature between both groups is the OPTIONS intervention which has been designed specifically to assist with complex decision-making.

Treatment

The components of OPTIONS include a workbook, audio recording, personal worksheet and consultation with a trained renal nurse.

Workbook and audio recording

OPTIONS has been developed by the authors using best available evidence regarding patient outcomes, informed by a systematic review (Brown *et al.* 2014). In addition further published evidence regarding morbidity of dialysis patients (McDonald 2012), symptom prevalence, hospital admissions, quality of life and functional performance has also been incorporated into OPTIONS (Joly *et al.* 2003, Murtagh *et al.* 2007a,b, 2011, Carson *et al.* 2009, Kurella Tamura *et al.* 2009, McDonald 2012, Seow *et al.* 2013).

The illustrated workbook consists of pictorial icons and bullet points to help participants in the intervention group to understand the information presented. The workbook includes instructions on how to use the decision support

intervention, learning objectives, definition of ESKD, symptom identification, key points discussed, advantages and disadvantages of dialysis, advantages and disadvantages of non-dialysis management, summary of choices, steps on how to make a choice regarding treatment, two hypothetical scenarios outlining decision-making process, what to do if unable to make a decision, sources of further reading or support groups and references. The text of the workbook has been analysed for readability using FK grade-level function available on the Microsoft Word 2003 Document program using Windows XP. The use of audio recording and workbook is designed for comprehension at education level of Year/Grade 8 which is consistent with the ODSF requirements. The workbook meets the International Patient Decision Aids Standards (IDPAS) (Edwards & Elwyn 2009).

Worksheet

The worksheet will be filled out by the patient after listening to the audio recording and reviewing the workbook. The worksheet is designed to support the patient in summarizing their personal values and is a discussion point for the consultation with the trained renal nurse.

Clinical consultation

The renal nurse undertaking the consultation with patient in the intervention group will have undergone training to support people to make decisions about their health. The training involves completion of the Ottawa Decision Support Tutorial (O'Connor *et al.* 2011). In this tutorial they are required to describe concepts of decision support, identify complex decisions, explain how to assess patients' decisional needs, tailor decision support and explain how to use decision support interventions (O'Connor *et al.* 2011). The renal nurse will assess the participants' understanding of the treatment options and if an explicit decision is made this will be documented in the patient's hospital records.

Control

Standard care in the form of decision support and information presented to each individual patient may vary across sites and is dependent on the clinical expertise of the renal nurse. At all study sites there are formalized clinics for patients with advanced CKD. In these clinics, the patients are provided with assistance to make treatment choices. The clinicians providing the standard decision support will differ from those delivering the intervention.

Outcomes

Primary outcome variables and measures. The primary outcomes have been chosen based on the Ottawa Decision

Support Framework. The premise of this study is decisional regret and decisional conflict will be lower using OPTIONS. The 'decision regret scale' (Brehaut *et al.* 2003) will measure distress or remorse after a (health care) decision. The scale demonstrated strong correlation with decision satisfaction, decisional conflict and quality of life (O'Connor 2003). This scale involves five questions and is quick and easy to complete. Repeated measurements will occur at 1 month (T1), 3 months (T2) and 6 months (T3) following consultation with renal nurse. The scoring and interpretation of the scale will follow the framework outlined by the Ottawa Hospital and Health Research Institute (OHHRI). The validity of this scale has an alpha coefficient between 0·81-0·92.

The 'decision conflict scale' (O'Connor 2010) has been developed by OHHRI to measure both decision conflict and uncertainty. The scale has been designed to capture decisional conflict with sub scores of uncertainty, feeling informed, values clarity and supported in decision-making. Numerous variations of this scale have been developed to be used in either the clinical or research setting. The scale chosen is a 10 item, three response category where 3 = no, 2 = unsure and 1 = yes (O'Connor 2010). This scale has been developed with a response format found most useful for those with limited reading or response skills. This scale is the second most tested version of the Decision Conflict Scale available from the OHHRI. This scale will be used to measure decisional conflict at 1 month (T1) following consultation with renal nurse. The score will be calculated and used to indicate level of decisional conflict and uncertainty. This will be a once only measurement (T1) unless the patient has been unable to make a decision then a repeated measure will be collected at the 3-month time point (T2). The scale has been validated for low literacy populations in Canada, USA and Chile with alpha coefficient score of 0·86 when tested with English speaking women considering breast cancer options.

Secondary outcome variables and measures. The secondary outcome variables are improved knowledge and quality of life.

Improved knowledge of options and the benefits and harms of these options is measured by administration of a knowledge questionnaire (O'Connor 2004). This questionnaire has been shown to capture the level of understanding the patient has regarding treatment options, possible benefits and harms of the treatment options and the individuals risk perceptions. This style of questionnaire has been used for patients with clinical conditions such as Atrial Fibrillation, Hormone Replacement Therapy, Lung Cancer and Osteoporosis. The knowledge questionnaire has been adapted for this study to assess participants' knowledge of

risks perceptions of dialysis. The measurement of knowledge the patient has achieved, will only occur at after the 1-month consultation (T1). The method for scoring and interpretation of data from this scale has been provided by the OHHRI and will be used as advised. The content validity of the knowledge questionnaire is established by a panel to ensure the questionnaire taps understanding of key concepts. Content of this decision support intervention is based on scientific evidence.

Quality of life will be measured using the KDQOL-SF™v1·3survey (Hawthorne *et al.* 2007). This is a well-validated tool in kidney disease which has demonstrated high internal consistency in all domains. Quality of Life score will be collected at 1-month (T1), 3-month (T2) and 6-month (T3) time points.

Additional measurements

Assessment of the utility of OPTIONS in preparing the patient to communicate with the renal nurse and make healthcare related decisions will provide additional feedback to the researchers as to the effectiveness of the decision support intervention.

Preparation for decision making scale (O'Connor & Graham 1995) – is designed to assess both the participant's and renal nurses perception of how useful OPTIONS was in preparing them to communicate with the renal nurse and make a healthcare related decision (O'Connor & Graham 1995). This questionnaire will be completed by the participant and the renal nurse at the 1-month time point (T1). The alpha coefficient ranges from 0·92-0·96 and reliability was 0·94.

Study procedure

Following ethics and local governance approval, patients who meet inclusion criteria will be approached by the clinical research assistant (CRA). The CRA will explain the study to these patients using comprehensive ethics committee-approved documents and patients will be given opportunity to ask questions and receive further information. This process is to ensure participants are fully informed of the possible burden of appointments and data collection on their time and to enhance retention and reduce loss to follow up.

Once written consent has been obtained by the CRA, they will then collect baseline clinical and demographic variables from the participant as outlined in Table 1. Participants are then randomly allocated to either intervention or control group as described earlier. They are given follow up appointments via a letter to assist with regular attendance at the clinic with the renal nurses.

At the 1-month time point, the participant randomized to receive the intervention, returns with the booklet and worksheet completed. The renal nurse will then work through these with the participant to ensure they understand the content and that they have identified their personal values in the worksheet. Should the situation arise where the participant has not yet read the booklet or completed the worksheet then the renal nurse will work through it with them during the appointment.

Additional clinical data and primary and secondary outcome data are collected at time points of 1 month (T1), 3 months (T2) and 6 months (T3). The CONSORT flow chart of the study protocol is shown in Figure 2.

Data analysis

Data analysis for this study will be conducted on an intention-to-treat basis. Descriptive statistics will be used to summarize patient characteristics. For continuous measures, the differences between intervention and control group will use *t*-tests and Mann–Whitney *U*-test depending on distributions and appropriateness of test. Analysis of the sub scores

Table 1 Clinical and demographic variables.

	Baseline	1 month(T1)	3 months (T2)	6 months (T3)
Sex	X			
Age	X			
Number of people living with participant	X			
Employment status (pensioner/self-funded retiree/working)	X			
Stage of Kidney Disease (eGFR and Creatinine)	X	X	X	X
Comorbidities – Ischaemic heart disease, diabetes, peripheral vascular disease	X			
Australian Karnofsky Performance Scale (Jha *et al.*, 2013)	X	X	X	X
Body Mass Index	X	X	X	X
Hospital Days		X	X	X
Alive/Deceased		X	X	X

of Decision Conflict Scale will also be undertaken if differences in decision conflict score are noted. As both groups will have large numbers (greater than 50) the 95% confidence interval will be calculated for the differences in mean outcome, between the intervention group and the standard group. The confidence intervals for median values would also be undertaken where required. For categorical measures, the chi-square statistics will be applied.

A stepwise logistic regression procedure will be performed if there is a need to adjust for confounding. Baseline factors which may contribute to confounding are socio-economic status (pensioner/self-funded/employed) and participant location. An α level of 0·5 will be used to indicate statistical significance. Cox regression and log rank test methods will be used to estimate and compare survival. An intra-Cluster Correlation *post hoc* analysis will be undertaken to demonstrate that clustering is insignificant.

Ethical considerations

This research will be undertaken according to the National Statement of Ethical Conduct in Human Research (2014) produced by the National Health and Medical Research Council of Australia (National Health and Medical Research Council 2007). Approval has been obtained from the Health Board Research Ethics Committee (HREC/14/QRBW/425) and University Ethics Committee (QUT 1400000937) in November 2015 with site specific agreement obtained from the research governance office at each health service.

Confidentiality of all participants' details will be protected. Patient data will also be de-identified with coding sheet stored at each site. Participants will receive detailed information regarding the study and be invited to participate through a written consenting process. Clinical care will not be impacted should the participant not wish to be involved in the study or should they wish to withdrawal from the study. All data analysed will be de-identified and stored securely for 15 years and then destroyed as per University data management policy. All the data will be collated and there is no intention of analysing individual data or reporting these results to specific participants. The primary investigator and associate investigators are the only individuals who will have access to the final trial dataset and this agreement is outlined in the ethics submission.

Rigour

The study design of a pragmatic RCT will enable evaluation of the decision support intervention through reduction in intrinsic methodological issues that occur when undertaking clinical research in an 'uncontrolled environment'. Creating a combination of explanatory and pragmatic elements helps to ensure both internal and external validity by using a mixture of both methodologies and therefore achieving validity in the research outcomes. This is a major strength of this research design and is relevant to testing complex interventions.

Discussion

There is a paucity of research evaluating the use of decision support interventions to assist older patients with advanced CKD in making treatment choices. The use of a robust study design and evidence based decision support intervention guided by a strong theoretical framework will help to provide further knowledge regarding decisional conflict and decisional regret in the setting of advanced CKD. Research staff will be recruited at each of these sites to ensure appropriate blinding, with renal nurses either delivering the intervention or control to prevent contamination. Agreement and support by all clinical staff in the renal departments at these sites will ensure the maximal number of participants recruited. This pragmatic RCT will be the first study to develop and validate a decision support intervention specifically designed for the aged with advanced CKD to assist them in making a choice between dialysis and non-dialysis management.

Limitations

Despite the efforts to reduce bias, contamination between groups is a potential limitation. This may be as a result of the close environment where the renal nurses' work. When initiation of the study occurs and during site visits the renal nurse delivering OPTIONS is made cognisant of the importance not to discuss this content with the renal nurse providing standard care. In addition observer bias may occur if the ORA become aware of which group the patients have been allocated to. All efforts have been made to ensure this does not occur, including a section in the patient consent form encouraging them not to reveal to the ORA which group they have been allocated. The requirement for such a large sample size in a potentially frail and vulnerable population may prove difficult within the timeframe. The restricted time frame may also fail to capture the phenomenon of the intervention as there is an expectation for the participants to make a decision regarding treatment choice one month after receiving the information and in one specific counselling session.

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Conflict of interest

The authors declare they have no conflict of interest.

Author contributions

Contribution by all authors towards the drafting, critically revising its intellectual content and finalizing the content has occurred. Responsibility for content has been taken by all authors.

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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