Quality of life, decision-making, costs and the impact on carers in people managed without dialysis: A study protocol

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PACKS
PAlliative care in Chronic Kidney Disease Study

- Funding - National Institute for Health Research
- Amount - £512,000
- Post Doctoral Fellowship in UK
- Three years – full time
Aim of study

- Measure and describe longitudinally, over 12 months, QOL, satisfaction with decision-making, costs, cognition, frailty and performance in patients with advanced chronic kidney disease managed without dialysis.
- Impact on carers will also be studied.
Background

- Number of people living with end-stage kidney disease (ESKD) has increased
  - Diabetes (Coresh et al. 2007)
- Older people
  - Increasing prevalence of co-morbidities (Ashby et al. 2005)
  - High mortality - median of five life years remaining for a 70-year old (Ansell et al. 2009)
- For some dialysis may be of little benefit
- Provision of treatment for ESKD consumes approx 2% of annual National Health Service budget (Steencamp et al. 2010)
## Stages of renal disease & treatment options

### Table 10. Stages of Chronic Kidney Disease

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>GFR (mL/min/1.73 m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage with normal or ↑ GFR</td>
<td>≥90</td>
</tr>
<tr>
<td>2</td>
<td>Kidney damage with mild ↓ GFR</td>
<td>60–89</td>
</tr>
<tr>
<td>3</td>
<td>Moderate ↓ GFR</td>
<td>30–59</td>
</tr>
<tr>
<td>4</td>
<td>Severe ↓ GFR</td>
<td>15–29</td>
</tr>
<tr>
<td>5</td>
<td>Kidney failure</td>
<td>&lt;15 (or dialysis)</td>
</tr>
</tbody>
</table>

Chronic kidney disease is defined as either kidney damage or GFR <60 mL/min/1.73 m² for ≥3 months. Kidney damage is defined as pathologic abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies.

KDOQI CKD classification 2000
Renal Replacement Therapy
Why opt not to dialyse

- Travel times
- PD too difficult
- Transplant not possible
- Arduous
- Surgical procedures
- Burden
- Feel too old (Noble 2009)
Primary and secondary outcomes

**Primary Outcome:** Quality of life of patients at 3 months from baseline measured using the EQ-5D-5L visual analogue scale.

**Secondary outcomes:**
- Changes in QOL and symptoms (including anxiety and depression)
- Changes in cognition, frailty and performance
- Understanding of the decision making process that precedes referral to CKM
- Patient satisfaction with decision-making

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Secondary outcomes (cont)

- Associated health and social care costs of patients receiving CKM
- Changes in QOL for carers
- Care related costs to carers of patients
- Calculation of the number(%) of deaths at 3, 6, 9 and 12 months and time to death
Recruitment & sample

- Recruited from renal clinics over 7 sites
- Patients – 112
- Carers – up to 112
- Renal physicians/CNS - 15-20
  - Qualitative interviews
Inclusion criteria patients:

- Stage 5 chronic kidney disease
- A confirmed decision for conservative management, i.e. management without dialysis or other renal replacement therapy. The decision for conservative kidney management will be confirmed with the nephrologist responsible for each patient.
- Aged over 18 years.
- Able to speak English
Inclusion criteria carers:

- Primary carer for patient with stage 5 chronic kidney disease who has made a confirmed decision for conservative kidney management as agreed with clinicians.
- Aged over 18 years.
- Patient has agreed that the carer can be approached to participate.
- Able to speak English
Inclusion criteria – renal physicians/CNS

- Experience of managing clinical consultations of patients with stage 5 chronic kidney disease who opt for conservative kidney management
- Employed in the renal specialty
Data collection tools - Patient

3-monthly
Kidney Disease QOL-36™ Survey
EQ-5D-5L
POS-S Renal

6monthly
Decisional Conflict Scale

Ongoing
Patient Service Use Log
## Decisional Conflict Scale

1. I knew which options were available to me.
2. I knew the benefits of each option.
3. I knew the risks and side effects of each option.
4. I was clear about which benefits mattered most to me.
5. I was clear about which risks and side effects mattered most to me.
6. I was clear about which was more important to me (the benefits or the risks and side effects).
7. I had enough support from others to make a choice.
8. I was choosing without pressure from others.
9. I had enough advice to make a choice.
10. I was clear about the best choice for me.
11. I felt sure about what to choose.
12. This decision was easy for me to make.
13. I felt I made an informed choice.
14. My decision shows what is important to me.
15. I expect to stick with my decision.
16. I am satisfied with my decision.
### POS-S RENAL – PATIENT COMPLETION

Below is a list of symptoms, which you may or may not have experienced. Please put a tick in the box to show how you feel each of these symptoms has affected you and how you have been feeling over the past week.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Severely</th>
<th>Overwhelmingly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Shortness of breath</td>
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<td></td>
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<tr>
<td>Weakness or lack of energy</td>
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<tr>
<td>Nausea (feeling like you are going to be sick)</td>
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<tr>
<td>Vomiting (being sick)</td>
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<td></td>
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<tr>
<td>Poor appetite</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Constipation</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Mouth problems</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Drowsiness</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Poor mobility</td>
<td></td>
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<tr>
<td>Itching</td>
<td></td>
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<tr>
<td>Difficulty sleeping</td>
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<tr>
<td>Restless legs or difficulty keeping legs still</td>
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<tr>
<td>Feeling anxious</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Feeling depressed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Changes in skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
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</tr>
</tbody>
</table>

Any other symptoms: □ □ □ □ □

**NAME:**

**PATIENT NUMBER:**
Data collection tools - Carer

3-monthly
EQ-5D-5L
EQ-5D-5L by proxy
Carer questionnaire

6monthly
Decisional Conflict Scale

Data collection tools – Renal Physician/CNS
One exploratory qualitative interview with PI
Data collection tools – performance, frailty, cognition

3-monthly over 12 months

- Changes in cognition - 6 Item Cognitive Impairment Test (6CIT)
- Changes in frailty status - 9-point Clinical Frailty Scale
- Changes in Performance using the Palliative Performance Scale (PPS)
**Palliative Performance Scale (PPSv2)**

**version 2**

<table>
<thead>
<tr>
<th>PPS Level</th>
<th>Ambulation</th>
<th>Activity &amp; Evidence of Disease</th>
<th>Self-Care</th>
<th>Intake</th>
<th>Conscious Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>Full</td>
<td>Normal activity &amp; work No evidence of disease</td>
<td>Full</td>
<td>Normal</td>
<td>Full</td>
</tr>
<tr>
<td>90%</td>
<td>Full</td>
<td>Normal activity &amp; work Some evidence of disease</td>
<td>Full</td>
<td>Normal</td>
<td>Full</td>
</tr>
<tr>
<td>80%</td>
<td>Full</td>
<td>Normal activity with Effort Some evidence of disease</td>
<td>Full</td>
<td>Normal or reduced</td>
<td>Full</td>
</tr>
<tr>
<td>70%</td>
<td>Reduced</td>
<td>Unable Normal Job/Work Significant disease</td>
<td>Full</td>
<td>Normal or reduced</td>
<td>Full</td>
</tr>
<tr>
<td>60%</td>
<td>Reduced</td>
<td>Unable hobbyhouse work Significant disease</td>
<td>Occasional assistance necessary</td>
<td>Normal or reduced</td>
<td>Full or Confusion</td>
</tr>
<tr>
<td>50%</td>
<td>Mainly Sit/Lie</td>
<td>Unable to do any work Extensive disease</td>
<td>Considerable assistance required</td>
<td>Normal or reduced</td>
<td>Full or Confusion</td>
</tr>
<tr>
<td>40%</td>
<td>Mainly in Bed</td>
<td>Unable to do most activity Extensive disease</td>
<td>Mainly assistance</td>
<td>Normal or reduced</td>
<td>Full or Drowsy +/- Confusion</td>
</tr>
<tr>
<td>30%</td>
<td>Totally Bed Bound</td>
<td>Unable to do any activity Extensive disease</td>
<td>Total Care</td>
<td>Normal or reduced</td>
<td>Full or Drowsy +/- Confusion</td>
</tr>
<tr>
<td>20%</td>
<td>Totally Bed Bound</td>
<td>Unable to do any activity Extensive disease</td>
<td>Total Care</td>
<td>Minimal to sip</td>
<td>Full or Drowsy +/- Confusion</td>
</tr>
<tr>
<td>10%</td>
<td>Totally Bed Bound</td>
<td>Unable to do any activity Extensive disease</td>
<td>Total Care</td>
<td>Mouth care only</td>
<td>Full or Drowsy +/- Confusion</td>
</tr>
<tr>
<td>0%</td>
<td>Death</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Instructions for Use of PPS (see also definition of terms)**

1. PPS scores are determined by reading horizontally at each level to find a best fit for the patient which is then
EQ-5D-5L

- Standardised instrument for use as a measure of health outcome.
- Valid instrument for the measurement of health status in renal patients.
- New 5 level version, EQ-5D-5L
- Consists of a descriptive system and a visual analogue scale.
- EQ-5D-5L will be self-completed by the patients
- Completed for the patient by the carer. Inter-rater agreement can then be assessed.

(Herdman et al 2011)
EQ-5D-5L

Under each heading, please tick the box that best describes how you feel today.

**MOBILITY**
- No problems
- Slight problems
- Moderate problems
- Severe problems
- Extreme problems

**SELF-CARE**
- No problems
- Slight problems
- Moderate problems
- Severe problems
- Extreme problems

**USUAL ACTIVITIES**
- No problems
- Slight problems
- Moderate problems
- Severe problems
- Extreme problems

**PAIN/DISCOMFORT**
- No problem
- Slight pain
- Moderate pain
- Severe pain
- Extreme pain

**ANXIETY/DEPRESSION**
- Not anxious or depressed
- Slightly anxious or depressed
- Moderately anxious or depressed
- Severely anxious or depressed
- Extremely anxious or depressed

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Improving Your Health and Wellbeing
We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = [ ]
Development of study

- Ethics application and protocol development
- Working with Clinical Trials Unit
- Site visits to develop protocol
- Advisory Team meeting
- Return next year!
Thank you for your attention

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References


