Interventions for improving health literacy in people with chronic kidney disease (Review)

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DOI: 10.1002/14651858.CD012026.pub2.

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Interventions for improving health literacy in people with chronic kidney disease

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Editorial group: Cochrane Kidney and Transplant Group.


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ABSTRACT

Background
Low health literacy affects 25% of people with chronic kidney disease (CKD) and is associated with increased morbidity and death. Improving health literacy is a recognised priority, but effective interventions are not clear.

Objectives
This review looked the benefits and harms of interventions for improving health literacy in people with CKD.

Search methods
We searched the Cochrane Kidney and Transplant Register of Studies up to 12 July 2022 through contact with the Information Specialist using search terms relevant to this review. Studies in the Register are identified through searches of CENTRAL, MEDLINE, and EMBASE, conference proceedings, the International Clinical Trials Register (ICTRP) Search Portal and ClinicalTrials.gov. We also searched MEDLINE (OVID) and EMBASE (OVID) for non-randomised studies.

Selection criteria
We included randomised controlled trials (RCTs) and non-randomised studies that assessed interventions aimed at improving health literacy in people with CKD.

Data collection and analysis
Two authors independently assessed studies for eligibility and performed risk of bias analysis. We classified studies as either interventions aimed at improving aspects of health literacy or interventions targeting a population of people with poor health literacy. The interventions were further sub-classified in terms of the type of intervention (educational, self-management training, or educational with self-
management training). Results were expressed as mean difference (MD) or standardised mean difference (SMD) with 95% confidence intervals (CI) for continuous outcomes and risk ratios (RR) with 95% CI for dichotomous outcomes.

Main results

We identified 120 studies (21,149 participants) which aimed to improve health literacy. There were 107 RCTs and 13 non-randomised studies. No studies targeted low literacy populations. For the RCTs, selection bias was low or unclear in 94% of studies, performance bias was high in 86% of studies, detection bias was high in 86% of studies reporting subjective outcomes and low in 93% of studies reporting objective outcomes. Attrition and other biases were low or unclear in 86% and 78% of studies, respectively.

Compared to usual care, low certainty evidence showed educational interventions may increase kidney-related knowledge (14 RCTs, 2632 participants: SMD 0.99, 95% CI 0.69 to 1.32; I² = 94%). Data for self-care, self-efficacy, quality of life (QoL), death, estimated glomerular filtration rate (eGFR) and hospitalisations could not be pooled or was not reported.

Compared to usual care, low-certainty evidence showed self-management interventions may improve self-efficacy (5 RCTs, 417 participants: SMD 0.58, 95% CI 0.13 to 1.03; I² = 74%) and QoL physical component score (3 RCTs, 131 participants: MD 4.02, 95% CI 1.09 to 6.94; I² = 0%). There was moderate-certainty evidence that self-management interventions probably did not slow the decline in eGFR after one year (3 RCTs, 855 participants: MD 1.53 mL/min/1.73 m², 95% CI -1.41 to 4.46; I² = 33%). Data for knowledge, self-care behaviour, death and hospitalisations could not be pooled or was not reported.

Compared to usual care, low-certainty evidence showed educational with self-management interventions may increase knowledge (15 RCTs, 2185 participants: SMD 0.65, 95% CI 0.36 to 0.93; I² = 90%), improve self-care behaviour scores (4 RCTs, 913 participants: SMD 0.91, 95% CI 0.00 to 1.82; I² =97%), self-efficacy (8 RCTs, 687 participants: SMD 0.50, 95% CI 0.10 to 0.89; I² = 82%), improve QoL physical component score (2 RCTs, 2771 participants: MD 2.56, 95% CI 1.73 to 3.38; I² = 0%) and may make little or no difference to slowing the decline of eGFR (4 RCTs, 618 participants: MD 4.28 mL/min/1.73 m², 95% CI -0.03 to 8.85; I² = 43%). Moderate-certainty evidence shows educational with self-management interventions probably decreases the risk of death (any cause) (4 RCTs, 2801 participants: RR 0.73, 95% CI 0.53 to 1.02; I² = 0%). Data for hospitalisation could not be pooled.

Authors’ conclusions

Interventions to improve aspects of health literacy are a very broad category, including educational interventions, self-management interventions and educational with self-management interventions. Overall, this type of health literacy intervention is probably beneficial in this cohort however, due to methodological limitations and high heterogeneity in interventions and outcomes, the evidence is of low certainty.

Plain Language Summary

Health literacy interventions in people with chronic kidney disease

What is the issue?

The long-term management of chronic kidney disease (CKD) requires people with the disease to be involved in their own care because it is a complex chronic disease. Many people who have CKD may not understand how to use health information to best support their decisions about treatment and management. This ability or skill is referred to as health literacy. Improving the health literacy of people with CKD may improve their health outcomes and help them to manage their disease and avoid complications.

What did we do?

We searched the literature for any studies that included an intervention aimed at improving health literacy in people with CKD. The interventions were divided into educational interventions, self-management training interventions, and educational with self-management training interventions.

What did we find?

We found 120 studies enrolling 21,149 patients. Compared to usual care, educational interventions may increase kidney-related knowledge; however, information on self-care, self-efficacy, quality of life (QoL), death, kidney function, and hospitalisations could not be analysed or was not reported. Self-management interventions may improve self-efficacy and one aspect of QoL (physical component score) but probably did not slow the decline in kidney function after one year. Information on knowledge, self-care behaviour, death and hospitalisations could not be analysed or was not reported. Educational with self-management interventions may increase knowledge, improve self-care behaviour scores, self-efficacy, one aspect of QoL (physical component score), and probably decreases the risk of death, but may make little or no difference to slowing the decline in kidney function. Data for hospitalisation could not be analysed.

Conclusions

Interventions to improve aspects of health literacy are a very broad category, including educational interventions, self-management interventions and educational with self-management interventions. Overall, this type of health literacy intervention is probably beneficial to patients with CKD however, due to limitations with the study methods and high variability in the interventions and outcomes make it difficult to give any recommendations.
### Summary of findings 1.  Educational interventions versus usual care for improving health outcomes in people with chronic kidney disease (CKD)

**Educational interventions versus usual care for improving health outcomes in people with CKD**

**Patient or population:** Improving health outcomes in people with CKD  
**Setting:** any setting  
**Intervention:** educational interventions  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No. of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge:</strong> kidney disease-related knowledge</td>
<td>Risk with usual care</td>
<td>Risk with educational interventions</td>
<td>-</td>
<td>2632 (14 RCTs)</td>
<td>⊕⊕⊝⊝</td>
</tr>
<tr>
<td></td>
<td>The SMD was 0.99 higher with education interventions (0.65 higher to 1.32 higher) compared to usual care</td>
<td>-</td>
<td>99 (2 non-RCTs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Self-care behaviour assessed with:</strong> Self-care behaviours for HD scale - 0 to 88 (higher equates to more self-care behaviours)</td>
<td>Risk with usual care</td>
<td>Risk with educational interventions</td>
<td>-</td>
<td>60 (1 non-RCT)</td>
<td>⊕⊕⊕</td>
</tr>
<tr>
<td></td>
<td>The mean self-care behaviour score was 61 with usual care</td>
<td>The self-care behaviour score was 5.8 points higher with educational interventions (5.07 higher to 6.53 higher) compared to usual care</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Self-efficacy</strong></td>
<td>Risk with usual care</td>
<td>Risk with educational interventions</td>
<td>-</td>
<td>579 (2 RCTs)</td>
<td>⊕⊕⊕</td>
</tr>
</tbody>
</table>
### Interventions for improving health literacy in people with chronic kidney disease (Review)

**QoL**
- Physical and psychological domain sections of the WHOQOL-BREF improved in the intervention group compared with control (P < 0.001) (one study)
- Overall KDQoL scores improved in the intervention group compared with control (P < 0.001) (one study)
- No change with educational interventions on the KDQoL or the SF-36 domains (three studies)

**Death**
- Two studies reported a reduction in median survival. One study measured this in years (7.96 versus 5.07, P = 0.053), while the other study, which reported survival in months (11.9 versus 11.2, P < 0.001), also reported more patients died in the control group compared to the intervention group (29 versus 5, P < 0.001)

**eGFR: mL/min/1.73 m²**
- eGFR increased by 0.08 ± 0.14 in the intervention group and decreased by 0.113 ± 0.79 in the control group (P < 0.011)

**Duration of hospital stay**
- One study reported education decreased the time spent in hospital by 8.7 days (13.54 days less to 3.86 days less) compared to control
- One study reported that the provision of educational materials had no effect on the number of hospital readmissions

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*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

**CI:** Confidence interval; **SMD:** Standardised mean difference; **RCT:** Randomised controlled trial; **HD:** Haemodialysis; **QoL:** Quality of life; **WHOQOL-BREF:** Abbreviated World Health Organization Quality of Life questionnaire; **KDQoL:** Kidney disease quality of life questionnaire; **SF-36:** Short form 36 questionnaire; **eGFR:** estimated glomerular filtration rate

**GRADE Working Group grades of evidence**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
- **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
- **Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
- **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

---

1 Downgraded once: unclear risk of bias for randomisation, allocation concealment, and selective reporting
2 Downgraded once: Considerable heterogeneity, possibly due to differences in intervention structure and delivery
## Summary of findings 2. Self-management training versus usual care for improving health outcomes in people with chronic kidney disease (CKD)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No. of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge: kidney disease-related knowledge</td>
<td>The mean knowledge was 97.1 points with usual care. The kidney disease-related knowledge score was 2.1 points higher with self-management training (0.15 higher to 4.05 higher) compared to usual care</td>
<td>-</td>
<td>103 (1 RCT)</td>
<td>★★★★</td>
<td>LOW 1 2 3. Two studies not included in the meta-analysis found increases in knowledge with self-management training group compared with control</td>
</tr>
<tr>
<td>Self-care behaviour</td>
<td>Self-management interventions increased self-reported self-care behaviours in some domains</td>
<td>-</td>
<td>497 (4 RCTs)</td>
<td>★★★★</td>
<td>LOW 3 4 5.</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>The SMD for self-efficacy was 0.58 higher with self-management interventions (0.13 higher to 1.03 higher) compared to usual care</td>
<td>-</td>
<td>417 (5 RCTs)</td>
<td>★★★★</td>
<td>LOW 3 6 7.</td>
</tr>
<tr>
<td>QoL</td>
<td>The mean SF-36 physical component score was 4.02 higher with self-management interventions (1.09 higher to 6.94 higher) compared to usual care.</td>
<td>-</td>
<td>1470 (9 RCTs)</td>
<td>★★★★</td>
<td>LOW 3 8 9.</td>
</tr>
</tbody>
</table>
There was no evidence to suggest self-management interventions improved scores on the KDQoL (effect and burden of kidney disease domains) or the SF-36 (physical functioning, role physical, mental component score, emotional well-being and role emotional domains).

<table>
<thead>
<tr>
<th>Death</th>
<th>There was 1 death during the study period; however, the group assignment was not reported</th>
<th>-</th>
<th>89 (1 RCT)</th>
</tr>
</thead>
</table>

- eGFR: The mean eGFR was 1.53 mL/min/1.73 m² higher with self-management training (1.41 lower to 4.46 higher) compared to usual care

- Hospitalisation: One study reported self-management training participants were hospitalised less (57.3% versus 23.9%) and for shorter time periods than the control group; however, they did not report a difference for the emergency department, outpatients, or home healthcare visits

   One study reported no significant difference in readmission rates between the self-management training and control groups

   Long-term follow-up in one large study found the rate of eGFR decline in the self-management training group was 0.45 mL/min/1.73 m²/year less than the control group (P = 0.01)

   The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

   **CI:** Confidence interval; **SMD:** Standardised mean difference; **RCT:** Randomised controlled trial; **QoL:** Quality of life; **KDQoL:** Kidney disease quality of life questionnaire; **SF-36:** Short form 36 questionnaire; **eGFR:** estimated glomerular filtration rate

   **GRADE Working Group grades of evidence**

   **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

   **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

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   **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

   1 Downgraded once: high rates of loss to follow-up

   2 Downgraded once: small sample size
Summary of findings 3. Educational interventions and self-management training versus usual care for improving health outcomes in people with chronic kidney disease (CKD)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No. of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge: kidney disease-related knowledge</td>
<td>The SMD for kidney disease-related knowledge was 0.65 higher with education plus self-management interventions (0.36 higher to 0.93 higher) compared to usual care/control</td>
<td>-</td>
<td>2185 (15 RCTs)</td>
<td>☮⊗⊗⊗ LOW 1 2</td>
<td>Two non-RCTs reported an increase in knowledge in the intervention group compared to control</td>
</tr>
<tr>
<td>Self-care behaviours: self-report questionnaires (higher is better)</td>
<td>The SMD for self-care behaviours was 0.91 higher with education plus self-management interventions (0.00 lower to 1.82 higher) compared to usual care/control</td>
<td>-</td>
<td>913 (4 RCTs)</td>
<td>☮⊗⊗⊗ LOW 2 3 4</td>
<td>One non-RCT an increase in the self-care practice scale in the intervention group compared to control</td>
</tr>
<tr>
<td>Self-efficacy: self-report questionnaires (higher is better)</td>
<td>The SMD for self-efficacy was 0.50 higher with education plus self-management interventions (0.10 higher to 0.89 higher) compared to usual care/control</td>
<td>-</td>
<td>687 (8 RCTs)</td>
<td>☮⊗⊗⊗ LOW 2 6</td>
<td>Two non-RCTs reported an increase in self-efficacy in the intervention group compared to control</td>
</tr>
</tbody>
</table>
### QoL: SF-12, SF-36, KDQoL

Educational and self-management training interventions did not improve QoL in the majority of studies. However, they may improve the physical component score of the SF-36 measurement tool.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Effect Size</th>
<th>Certainty</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoL</td>
<td>-</td>
<td>LOW</td>
<td>14 RCTs, 129 (2 non-RCTs)</td>
</tr>
</tbody>
</table>

Two non-RCTs found no difference in QoL scores between the intervention and control groups.

### Death

6 per 100 (3 to 6) participants died in the intervention group compared to 4 per 100 in the control group.

**Death**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Effect Size</th>
<th>Certainty</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>RR 0.73 (0.53 to 1.02)</td>
<td>MODERATE</td>
<td>2801 RCTs, 1938 (1 non-RCT)</td>
<td></td>
</tr>
</tbody>
</table>

One non-RCT reported lower death rates in the intervention group when compared with control.

### eGFR: mL/min/1.73 m²

The mean eGFR was 4.28 mL/min/1.73 m² higher with educational and self-management training interventions (0.03 lower to 8.85 higher) compared to usual care/control.

### Hospitalisation

1) Three studies reported no difference in hospitalisation rates between the intervention and control groups.

2) Two studies reported fewer participants were hospitalised in the intervention group when compared with control.

### Death

6 per 100 (3 to 6) participants died in the intervention group compared to 4 per 100 in the control group.

**Death**

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One non-RCT reported lower death rates in the intervention group when compared with control.

### eGFR: mL/min/1.73 m²

The mean eGFR was 4.28 mL/min/1.73 m² higher with educational and self-management training interventions (0.03 lower to 8.85 higher) compared to usual care/control.

### Hospitalisation

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2) Two studies reported fewer participants were hospitalised in the intervention group when compared with control.

**Hospitalisation**

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<th>Certainty</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR 0.73 (0.53 to 1.02)</td>
<td>MODERATE</td>
<td>2801 RCTs, 1938 (1 non-RCT)</td>
<td></td>
</tr>
</tbody>
</table>

Three non-RCTs reported reductions in hospitalisations for the intervention group compared with control.

---

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).*

CI: Confidence interval; SMD: Standardised mean difference; RCT: Randomised controlled trial; QoL: Quality of life; SF-36: Short form 36 questionnaire; eGFR: estimated glomerular filtration rate

**GRADE Working Group grades of evidence**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect
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1 Downgraded once: unclear risk of bias in many domains across studies
2 Downgraded once: high heterogeneity, probably due to differences in interventions, e.g. provision of materials
3 Downgraded once: unblinded outcome assessors
**Background**

**Description of the condition**

Chronic kidney disease (CKD) is a worldwide health problem, with an estimated 10% to 13% of the world's population being affected (Couser 2011; Szczek 2009). CKD is classified into 5 stages; stage 1 and 2 are considered mild, stage 3 and 4 are considered moderate, and stage 5 is referred to as end-stage kidney disease (ESKD). Stages 1 to 4 CKD have been independently associated with diabetes, hypertension, cardiovascular disease, some cancers, increased hospitalisations and acute kidney injury (Hsu 2008). Specifically, there is increased cardiovascular-related death even in very early disease (Hallan 2006). The aims of stage 1 to 4 CKD management include decreasing progression to ESKD and reducing the risk of cardiovascular complications through the management of kidney function and common factors of CKD progression, such as hypertension and diabetes. Effective treatment methods include, but are not limited to, decreasing hypertension and proteinuria, increasing glycaemic control, encouraging weight loss and healthy-living behaviours, smoking cessation, and treatment of other cardiovascular risk factors such as dyslipidaemia (James 2010).

Only a minority of stage 1 to 4 CKD patients go on to develop ESKD. This is partly because of the increased risk of death in earlier stages of kidney disease from other related comorbidities (Go 2004). ESKD can require kidney replacement therapy (KRT) in the form of dialysis or a kidney transplant, or can be managed in a more conservative way, usually in older patients with multiple co-morbidities. ESKD is associated with extremely high death rates, morbidity and a substantially lower quality of life (QoL) (Foley 1998). More than 2 million people worldwide are being kept alive by KRT. However, this is thought to only account for 10% of those who need it (Eggers 2011). The high financial and social cost of ESKD to both individuals and society makes it a significant health priority in the field of non-communicable diseases, and it is considered a death sentence in many low to middle-income countries (De Vecchi 1999).

**Description of the intervention**

The long-term management of CKD requires a high level of patient involvement, both in decision-making and in the implementation of care. For patients to be effective at health decision-making and self-management, they must possess the ability to understand and utilise health information, a skill which is referred to as ‘health literacy’ (Nielsen-Bohlman 2004). The concept of health literacy can be approached in two ways: health literacy can be seen as a risk factor or as an asset. However, these two ideas are not mutually exclusive. Health literacy as a risk factor - the idea that low health literacy is a risk for poorer health outcomes - has been widely investigated. Low health literacy has been associated with an increase in death and poorer overall health status (Berkman 2011). Those with lower general literacy are more likely to have a lower level of knowledge and comprehension regarding health-related issues, have fewer immunisations and health screenings, have more hospitalisations, and are admitted to an emergency department more frequently than those on the other end of the spectrum (Berkman 2011; Dewalt 2004). Some health literacy interventions aim to mitigate the negative effects of low health literacy, improve patients’ literacy, or make it easier for those with low health literacy to understand and access health information. Health literacy can also be viewed as an asset, a skill that can be built through patient education, although this concept requires further solidification. Within this framework, health literacy is seen as an outcome of health education and communication rather than as a factor that may lead to poorer health outcomes. Health literacy interventions that treat health literacy as an asset have a wider variety of aims, including developing self-management abilities, improving patients’ ability to negotiate or navigate within the health system, and improving patients’ ability to understand and implement healthcare information. These interventions are not necessarily aimed at those with low health literacy and could, in theory, help any patient. A more detailed appraisal of these two similar but distinct conceptualisations of health literacy can be found in “The evolving concept of health literacy” (Nutbeam 2008).

Both health literacy, the risk factor, and health literacy, the asset, impact the ability of a patient to competently manage a health problem, especially in the context of chronic disease such as CKD, which has an extremely high level of patient involvement in care. We have treated all interventions that fall under either category as a ‘health literacy intervention’ as the separation of the two types of intervention seems counter-intuitive in this setting.

The evidence about the effectiveness of specific health literacy interventions is still emerging. There is no standardised intervention to date, and there may never be; however, some common design features have been found to improve health literacy (Sheridan 2011):

- Presenting written information in a different way (e.g. giving essential information first)
- Presenting numerical information in a different way (e.g. the highest number is always better)
- Use of icons, symbols and graphs
- Presenting information pitched at a lower literacy level (e.g. that of primary school comprehension)
- Use of video tutorials
- Literacy training for physicians
- Implementing self-management plans.

**How the intervention might work**

There is evidence that health literacy interventions can reduce emergency department visits, hospitalisations, and disease severity in other chronic diseases. Specifically, within CKD, low health literacy has been found to be associated with a higher risk of death (Cavanaugh 2010) and also a lower likelihood of being referred for transplant (Grubbs 2009). Low health literacy was found to be common amongst CKD patients in a systematic review in 2013; however, the studies in this review predominately looked at patients with ESKD (Fraser 2013). Since then, one study has investigated the prevalence of low health literacy, specifically in those with stage 1 to 4 CKD, and found that low health literacy is also common in this subpopulation of patients (Devraj 2015). This study also found a small but significant positive relationship between kidney function (estimated glomerular filtration rate (eGFR)) and health literacy. Due to the link between low health literacy and poorer health outcomes and the indication that it is prevalent in CKD and ESKD patients, it follows that improving the health literacy of these patients could have a positive effect on their health outcomes.

Health literacy interventions are not just about reducing the risk for those with low health literacy but also about improving the health management of any individual. This is most important in
diseases which require a high level of patient involvement, such as CKD. The management of CKD is complex and requires patients to understand the impact of many different factors, including, but not limited to, blood pressure (BP), weight, cholesterol, fluid intake, diet, exercise, medications (both adherence and interactions), as well as how to navigate the health system and interact with many different health care providers. Health literacy interventions aimed at improving an individual’s self-management ability could be incredibly useful in both stage 1 to 4 CKD and ESKD, and this study will investigate both populations.

Why it is important to do this review

Health literacy and how to improve it has been identified as a central research priority by both The National Institute of Diabetes and Digestive and Kidney Diseases in Canada and Kidney Health Australia (Manns 2014; Tong 2015a). It is now well-accepted that a high proportion of patients with CKD do have low health literacy, as measured by an array of health literacy measurement tools (Dageforde 2013; Kutner 2006). Those at higher risk for developing CKD may also be at high risk for having low health literacy because both low health literacy and CKD are disproportionately apparent in those who have low educational status, are from low socioeconomic backgrounds, are from minority groups, and are of older age (Dageforde 2013; Kutner 2006). Research into health literacy interventions thus far has been broad, focusing on all chronic diseases (Sheridan 2011); however, patients with CKD have specific complications and outcomes that should be analysed separately. One example of this is the decrease in cognitive ability seen in CKD patients. CKD is an independent risk factor for the development of cognitive decline (Etgen 2012) and is thought to be related to cognitive impairment both directly, through inflammation, toxins, and dialysis, and indirectly, through related complications such as hypertension and diabetes (Bugnicourt 2013). A review of health literacy interventions specifically targeted to patients with CKD will provide more focused information, as what works in one chronic disease may not work in another. Van Scoyoc 2010 completed a similar review analysing health literacy interventions in patients with diabetes. They highlighted the aspects of the interventions that had an impact on health outcomes, as well as the ones that had no effect, providing information for the future development of health literacy interventions in this population. This review hopes to advance the development of tools to improve healthcare for those with low health literacy in the CKD population.

OBJECTIVES

This review looked at the benefits and harms of interventions for improving health literacy in patients with CKD.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs), quasi-RCTs (RCTs in which allocation to treatment where allocation to treatment was obtained by alternation, use of alternate medical records, date of birth, or other predictable methods), cluster RCTs, cohort studies and non-randomised studies looking at interventions for improving health literacy in patients with CKD.

Types of interventions

Inclusion criteria

Patients with CKD, defined by abnormalities of kidney structure or function, present for more than three months, with implications for health (KDIGO 2012), with one or more markers of kidney damage:

• Albuminuria (albumin excretion ratio > 30 mg/24 hours; albumin-creatinine ratio > 30 mg/g (> 3 mg/mmol))
• Urine sediment abnormalities
• Electrolyte and other abnormalities due to tubular disorders
• Abnormalities detected by histology
• Structural abnormalities detected by imaging
• History of kidney transplantation
• Decreased GFR: GFR < 60 mL/min/1.73 m² (GFR categories G3a to G5)

Exclusion criteria

• Children (< 18 years) or those under guardianship, proxies (carers)
• Studies with populations including people without CKD, perhaps another chronic disease, will only be included if the data for the CKD patients can be analysed separately.

Types of outcome measures

Primary outcomes

1. Progression of kidney disease (change in GFR, doubling of serum creatinine, progression of CKD stage)
2. Health literacy (improvement on an accepted health literacy measurement tool, knowledge, skills, self-management, involvement with care)

Secondary outcomes

1. Change in QoL on a recognised QoL scale, either general (e.g. QoL, Short Form 36 Question Survey (SF-36)) or disease appropriate (e.g. Kidney Disease Specific Quality of Life Instrument Short Form (KDQoL))
2. Death (including cause-specific deaths, cardiovascular and kidney disease-related death)
3. Hospitalisations, including use of emergency care and length of stay
4. Complications of CKD (hypertension, diabetic control, metabolic bone disease, anaemia)
5. Adverse outcomes of health literacy intervention (depression, decreased self-efficacy)

Search methods for identification of studies

Electronic searches

We searched the Cochrane Kidney and Transplant Register of Studies up to 12 July 2022 through contact with the Information Specialist using search terms relevant to this review. The Register contains studies identified from the following sources:

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL)
2. Weekly searches of MEDLINE OVID SP
3. Searches of kidney and transplant journals and the proceedings and abstracts from major kidney and transplant conferences
4. Searching the current year of EMBASE OVID SP
5. Weekly current awareness alerts for selected kidney and transplant journals

Studies contained in the Register are identified through searches of CENTRAL, MEDLINE, and EMBASE based on the scope of Cochrane Kidney and Transplant. Details of search strategies, as well as a list of hand-searched journals, conference proceedings, and current awareness alerts, are available on the Cochrane Kidney and Transplant website.

We also searched MEDLINE (OVID) and EMBASE (OVID) for non-randomised studies.

See Appendix 1 for search terms used in strategies for this review.

Searching other resources

1. Reference lists of review articles, relevant studies, and clinical practice guidelines.
2. Letters seeking information about unpublished or incomplete studies to investigators known to be involved in previous studies.

Data collection and analysis

Selection of studies

The search strategy described was used to obtain titles and abstracts of studies that may have been relevant to the review. The titles and abstracts were screened independently by two authors, who discarded studies that were not applicable. However, studies and reviews that may have included relevant data or information on studies were retained initially. Two authors independently assessed retrieved abstracts and, if necessary, the full text of these studies to determine which studies satisfied the inclusion criteria. Differences between authors in the screening were reconciled by discussion and, if needed, the inclusion of a third party.

Data extraction and management

Data extraction was carried out independently by two authors using standard data extraction forms. Studies reported in non-English language journals were translated before assessment. Where more than one publication of one study existed, these were grouped together, and the publication with the most complete data was used in the analyses. Where relevant outcomes are only published in earlier versions, these data were used. Any discrepancy between published versions has been highlighted.

Assessment of risk of bias in included studies

The following items were independently assessed by two authors using the risk of bias assessment tool (Higgins 2021) (see Appendix 2).

- Was there adequate sequence generation (selection bias)?
- Was allocation adequately concealed (selection bias)?
- Was knowledge of the allocated interventions adequately prevented during the study?
  - Participants and personnel (performance bias)
  - Outcome assessors (detection bias)
- Complete outcome data adequately addressed (attrition bias)?
- Are reports of the study free of suggestion of selective outcome reporting (reporting bias)?
- Was the study apparently free of other problems that could put it at risk of bias?

For non-randomised studies, the risk of bias was assessed by two authors individually using the ROBINS-I tool (Sterne 2016) (Appendix 3). The key confounders and co-intervention identified by the authors were:

- Age
- Gender
- Socioeconomic status
- Minority group status
- Cognitive impairment
- Health literacy or baseline literacy ability
- Drug interventions

The tool was applied to the following outcomes:

- eGFR
- Knowledge
- Self-care behaviours
- Self-efficacy
- QoL
- Death
- Serum albumin
- Hospitalisations

Measures of treatment effect

For dichotomous outcomes (e.g. death, number of patients progressing to ESKD), results were expressed as risk ratio (RR) with 95% confidence intervals (CI). Where continuous scales of measurement were used to assess the effects of treatment (e.g. health literacy measurement, length of hospital stay), the mean difference (MD) was used, or the standardised mean difference
(SMD) if different scales had been used, and reporting 95% CIs, interpreting the data using Cohen’s rule of thumb (Higgins 2021).

Where meta-analysis was not possible, adverse effects were tabulated and assessed with descriptive techniques, as they were likely to be different for the various interventions used. Where possible, the risk difference with 95% CI was calculated for each adverse effect, either compared to no treatment or to another intervention.

Unit of analysis issues

ClusterRCTs were analysed in one of two ways.

1. Using a statistical analysis that properly accounts for the cluster design. Some examples of these are based on a ‘multi-level model’, a ‘variance components analysis’ or may use ‘generalised estimating equations’ (Higgins 2021)

2. Conduct the analysis treating the sample size as the number of clusters and proceed as if the study were individually randomised, treating the clusters as individuals.

When considering cross-over studies, we used data from the first period as this best represents an RCT with a treatment group and a control group. Once the groups cross over, the control group’s result risks being confounded by exposure to the intervention.

When considering studies with multiple treatment groups, we combined all relevant experimental intervention groups of the study into a single group and combined all relevant control intervention groups into a single group to enable a single pairwise comparison.

Dealing with missing data

Any further information required from the original author was requested by written correspondence (e.g. emailing the corresponding author), and any relevant information obtained in this manner was included in the review. Evaluation of important numerical data such as screened, randomised patients, as well as intention-to-treat, as-treated and per-protocol population, was carefully performed. Attrition rates, for example, drop-outs, losses to follow-up and withdrawals, were investigated. Issues of missing data and imputation methods (for example, last-observation-carried-forward) were critically appraised (Higgins 2021).

Assessment of heterogeneity

Heterogeneity was analysed using a Chi² test on N-1 degrees of freedom, with an alpha of 0.05 used for statistical significance and with the I² test (Higgins 2003). I² values of 25%, 50% and 75% may correspond to low, medium and high levels of heterogeneity.

Assessment of reporting biases

Funnel plots were planned to be used to assess for the potential existence of small study bias (Higgins 2021).

Data synthesis

Data were pooled using the random-effects model, but the fixed-effect model was also used to ensure the robustness of the model chosen and susceptibility to outliers. Where the authors judged that included quasi-RCTs are similar in study design to included RCTs, they were analysed together. Adjusted data from the quasi-RCTs were used before unadjusted data.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis was used to explore possible sources of heterogeneity. Specifically, we were interested in subgroup analyses of stage 1 to 4 CKD and ESKD; however, the way the data was collected in the studies prevented this analysis from being possible. Subgroup analysis of intervention delivery was analysed.

Sensitivity analysis

We performed sensitivity analyses in order to explore the influence of the following factors on effect size.

- Repeating the analysis, excluding unpublished studies
- Repeating the analysis taking account of the risk of bias, as specified
- Repeating the analysis, excluding any very long or large studies to establish how much they dominate the results
- Repeating the analysis excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), delivery medium (paper versus electronic media versus other), stage of kidney disease (mild versus moderate versus ESKD).

Summary of findings and assessment of the certainty of the evidence

We have presented the main results of the review in 'Summary of findings' tables. These tables present key information concerning the certainty of the evidence, the magnitude of the effects of the interventions examined, and the sum of the available data for the main outcomes (Schunemann 2021a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach (GRADE 2008; GRADE 2011). The GRADE approach defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true certainty of a specific interest. The certainty of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, the precision of effect estimates, and the risk of publication bias (Schunemann 2021b). We presented the following outcomes in the 'Summary of findings' tables:

- Knowledge
- Self-care behaviours
- Self-efficacy
- QoL
- Death
- eGFR
- Hospitalisations

Results of the search

We identified 948 reports from the search of electronic databases up to July 2022 (MEDLINE 275, CENTRAL 297, EMBASE 214,
Specialised Register 162), 68 of which were duplicates. After screening 880 titles and abstracts and undertaking full-text review of 324 records, 120 studies (230 reports) were included, and 53 studies (70 reports) were excluded. Three ongoing studies were identified (KTF-TALK 2017; NCT00394576; NCT00782847) and seven studies were completed prior to publication (Gordon 2016; HED-START 2021; KARE 2015; Schaffhausen 2020; TALKS 2015; Waterman 2015; YPT 2014). These 10 studies will be assessed in a future update of this review (Figure 1).

![Study flow diagram](image)

**Figure 1. Study flow diagram.**

**Included studies**

**Study and participant characteristics**

We included 120 studies that involved 21,149 people with CKD; 107 were RCTs, and 13 were non-randomised studies (Aliasgharpour 2012; An 2011; Choi 2012; Hall 2004; Joost 2014; Karamanidou 2008; Kazawa 2015; Nozaki 2005; Rasgon 1993; Slowik 2001; Taghavi 1995; Wang 2011; Wingard 2009). Of those claiming randomisation, 96 had a parallel design, while 11 used cluster randomisation (ESCORTEC 2014; Hed-SMART 2011; Kauric-Klein 2012; Leon 2006; Molaison 2003; Sehgal 2002; Sharp 2005; So 2007; Sullivan 2012; Yamagata 2010). The 13 non-randomised studies all compared an intervention group with a control group, however, their methods varied considerably. Study size was variable and ranged from 10 (Mathers 1999) to 2379 (Yamagata 2010) participants, with a median of 83 and an interquartile range of 98.

Ninety-seven studies exclusively recruited participants with ESKD, and 52 of these recruited people who were on haemodialysis (HD). Some of the HD studies had further recruitment criteria such as serum albumin less than 3.7 g/dL (Leon 2003; Leon 2006), baseline serum phosphate (Clark 2010; Ford 2004; Sullivan 2009), high average BP (Kauric-Klein 2012), fluid restriction adherence issues (Sharp 2005) and problematic pruritus (So 2007). Of the remaining ESKD studies, six included participants on peritoneal dialysis (PD), one included participants on PD or HD, 16 included kidney transplant recipients, 11 included participants awaiting transplant, and nine did not specify. Participants in one PD study also had problematic fluid restriction adherence (Hare 2014), and participants in one transplant study had poor medication adherence (MAGIC 2016).

Three studies explicitly stated that they included participants of any stage (Rodrigue 2011; Ten 2013; Yamagata 2010), and two studies did not define the stage of CKD (Chen 2012; Choi 2012). Seven studies included participants with CKD stages 3 to 5 (Chen 2011; Cooney 2015; MASTERPLAN 2005; Paes-Barreto 2013; TALK 2011; TALK 2011; Wu 2009), and five studies included participants with CKD stages 4 to 5 (Campbell 2008; Fishbane 2017; Manns 2005; Massey 2015; Slowik 2001). Two studies included participants with CKD stages 2 to 4 (Flesher 2011; LANDMARK 3 2013), one study only included participants with CKD stage 3 (BRIGHT 2013), while two
Interventions for improving health literacy in people with chronic kidney disease (Review)

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Health literacy
No studies used a recognised health literacy measurement tool to record health literacy as an outcome.

Knowledge
Forty-three studies reported knowledge as an outcome. The measurement tools used to assess knowledge differed greatly among the studies. They measured knowledge of areas such as kidney disease, nutrition, sun protection, organ transplant, self-management, kidney protection, and phosphorous, or were unspecified. All used continuous outcome measures except Manns 2005, which reported the number of people in each group that had poor knowledge, and Trofe-Clark 2017, which reported the number of participants with fewer questions wrong post-intervention. iChoose 2018 stratified the outcome of knowledge in terms of health literacy scores using the Newest Vital Sign (Weiss 2005).

Behaviour
Behaviour was reported in 14 studies. Most used self-report questionnaires relating to the perceived amount of behaviour within a certain time frame, and no two studies used the same measurement tool. Teng 2013 used the Health Promoting Lifestyle Profile IIC Chinese Version (Walker 1987) to measure changes in health promotion behaviour and self-reported stage of change. Kazawa 2015* reported the percentage of days per month that subjects performed a certain behaviour, while Karavetian 2014 and Molaison 2003 reported the stage of behavioural change as assessed by a research assistant. Two studies used the self-monitoring and insight section of the Health Education Impact Questionnaire (Osborne 2007) to represent a self-management outcome (BRIGHT 2013; Hed-SMART 2011). Liu 2014c measured participants’ willingness to change their behaviour.

Self-efficacy
Twenty studies reported self-efficacy as an outcome. Four used the Strategies Used by People to Promote Health scale (Aliasgharpour 2012; Li 2007; Moattari 2012; Tsay 2004c), one measured the number of participants who lacked self-efficacy in relation to performing their own self-care (Manns 2005), while another used the decisional conflict scale so that a higher score equalled less self-efficacy (Song 2010). The remainder of the studies all used a different self-efficacy scale - some broad, such as the Self-Efficacy Scale of Health Belief in Patients with Chronic Disease, and some narrow, such as the Blood Pressure Control in Haemodialysis Self-Efficacy Scale.

Quality of Life
QoL was measured using a wide range of scales in 30 studies. Nine studies measured QoL using the KDQoL or the KDQoL Instrument Short Form (KDQoL-SF) (Aliasghar 2019; Campbell 2008; Chow 2010; Cooney 2015; Hed-SMART 2011; Leon 2006; Li 2014b; Sehgal 2002; Wong 2010), and nine studies used the Medical Outcomes Study 36-Item Short Form Survey Instrument (MOS SF-36) (ESCORT 2014; Hare 2014; INTENT 2014; Joost 2014*; Rason 1993*; Rodrigue 2011; Sharp 2005; Tsay 2005; Tzvetanov 2014). The World Health Organization Quality of Life BREF (WHO-BREF) instrument was used in two studies (Abraham 2012; Hed-SMART 2011), as was the Medical Outcomes Study 12-Item Short Form (Cooney 2015; Urstad 2012). The remainder of the studies used a range of QoL instruments ranging from those designed for the individual study to other more validated tools. One abstract lacked information about what tool was used to measure QoL (Tsuji-Hayashi 2000). The QoL instruments and overall scores for each study are presented in Appendix 5.

Glomerular filtration rate
Only 13 studies reported GFR as an outcome. Eight compared the average eGFR between the comparison groups in mL/min/1.73 m² (Campbell 2008; Chien 2011e; Choi 2012*; ESCORT 2014; Joost 2014*; Kazawa 2015*; MESMI 2010; Tzvetanov 2014). Four studies measured GFR change over time (MASTERPLAN 2005; Navaneethan 2017; Yamagata 2010; Wu 2009), and one reported the number of participants that improved their GFR as well as the percentage of decline in a one-year period (Flesher 2011).

Albumin
Sixteen studies reported albumin as an outcome. Most reported the mean blood albumin at a specific time point in g/L or g/dL (Baraz 2010; Campbell 2008; Hall 2004*; Hernandez-Morante 2014; Kazawa 2015*; Leon 2006; Lou 2012; Paes-Barreto 2013; Shi 2013; Slowik 2001*; Wingard 2009*; Wu 2009). One study reported the number of people that had an improvement in their blood albumin (Leon 2001), and three studies lacked information about how albumin was measured (Li 2014b; Tsuji-Hayashi 2000; Wong 2010).

Hospitalisations
Outcomes related to hospitalisations were reported in 10 studies. There was great variation in how this outcome was reported. Duration of stay in hospital was reported in three studies (Chisholm-Burns 2013; Wingard 2009*; Wu 2009), while the number of participants admitted to hospital was reported in two studies (Chen 2011e; Wong 2010). Other forms of measurement included the number of admissions (Fisbante 2017; Giacoma 1999; Navaneethan 2017; Jasinski 2018), the rate of hospitalisations (Fisbante 2017; Hall 2004*), and the number of emergency visits (Chisholm-Burns 2013).
Death

Eight studies reported death. Median survival was measured in two studies (Live and Learn 1993; Wu 2009), while the number of people who died within a time frame was reported in six studies (Chen 2011; Cooney 2015; ESCORT 2014; MAGIC 2016; Navaneethan 2017; Wingard 2009†).

Excluded studies

After full-text review, we excluded 53 studies for the following reasons:

- Wrong study design (21 studies)
- Wrong population (9 studies)
- Wrong intervention or control (23 studies).

See Characteristics of excluded studies and Figure 1.

Risk of bias in included studies

RCTs: we summarised the risk of bias for each study in Figure 2 and the risk of bias for all included studies in Figure 3. The included studies were of varying quality, as described below.
Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.
### Figure 2. (Continued)

| Study Title                  | Outcome 1 | Outcome 2 | Outcome 3 | Outcome 4 | Outcome 5 | Outcome 6 | Outcome 7 | Outcome 8 | Outcome 9 | Outcome 10 | Outcome 11 | Outcome 12 | Outcome 13 | Outcome 14 | Outcome 15 | Outcome 16 | Outcome 17 | Outcome 18 | Outcome 19 | Outcome 20 | Outcome 21 | Outcome 22 | Outcome 23 | Outcome 24 | Outcome 25 | Outcome 26 | Outcome 27 | Outcome 28 | Outcome 29 | Outcome 30 | Outcome 31 | Outcome 32 | Outcome 33 | Outcome 34 | Outcome 35 | Outcome 36 | Outcome 37 | Outcome 38 | Outcome 39 | Outcome 40 | Outcome 41 | Outcome 42 | Outcome 43 | Outcome 44 | Outcome 45 | Outcome 46 | Outcome 47 | Outcome 48 | Outcome 49 | Outcome 50 | Outcome 51 | Outcome 52 | Outcome 53 | Outcome 54 | Outcome 55 | |
|-----------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
## Figure 2. (Continued)

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Interventions for improving health literacy in people with chronic kidney disease (Review)
Figure 2. (Continued)

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Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Non-randomised studies: we summarised the risk of bias for the 13 non-randomised studies in Figure 4. The overall risk of bias for a study is calculated using the most significant risk of bias judgement taken from any of the seven domains in the ROBINS-I tool. Detailed information about each domain is located under 'Other potential sources of bias'.
**Figure 4. Risk of bias of non-randomised studies**

<table>
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<tr>
<th>Study ID</th>
<th>Risk of bias assessment of non-randomised studies</th>
<th>Con founding</th>
<th>Selection of participants</th>
<th>Classification of interventions</th>
<th>Deviation from intended intervention</th>
<th>Missing data</th>
<th>Outcome measurements</th>
<th>Selection of reported outcomes</th>
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**Allocation**

**Sequence generation**

We judged 63 RCTs to have used an adequate method for generating the random sequence and 38 studies as unclear as there was insufficient information to ascertain the method used. Six studies were classified as high risk of bias; two described an alternate allocation method (Abraham 2012; de Brito Ashurst 2003), two randomised participants by day and shift of dialysis (Ebrahimi 2016; Hasanzadeh 2011), one randomised based on location (ESCORT 2014), and one study had insufficient information; however, was judged to be at high risk due to the difference in the size of the groups at baseline (Tanner 1998).

**Allocation concealment**

Thirty-three RCTs were found to have sufficient allocation concealment and were judged as low risk of bias, while 66 RCTs had insufficient information and were given an unclear rating. We judged eight studies to have a high risk of bias; four stated they had no allocation concealment (Chisholm-Burns 2013; Hare 2014; KTAH 2012; MASTERPLAN 2005), while the randomisation method used in four studies made allocation concealment impossible (Ebrahimi 2016; ELITE 2013; ESCORT 2014; Hasanzadeh 2011).

**Blinding**

**Blinding of participants and personnel**

The risk of bias was judged to be unclear for 14 studies. Eight studies reported blinding of personnel only (Chisholm-Burns 2013;
Interventions for improving health literacy in people with chronic kidney disease (Review)

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Blinding of outcome assessment

Subjective outcomes

QoL, self-management (if self-reported), self-efficacy, depression and anxiety, adherence (if self-reported) and other more specific

Seventy-eight studies reported subjective outcomes, and 68 were judged to be at high risk of detection bias due to the unblinded nature of the study design. Ten studies were given an unclear rating, either because the outcome assessor was blinded but the participant was not (Barnieh 2011; Devins 2003; Hed-SMART 2011; Saeedi 2014; Tsay 2004c; Tsay 2005) or because there was insufficient information to make a judgement (Liu 2014c; Reedy 1998; Rodriguez 2011; Tsuji-Hayashi 2000).

Twenty-nine studies did not report a subjective outcome and therefore did not receive a risk of bias rating.

Objective outcomes

Knowledge, self-management (if not self-reported), GFR, CKD stage change, health literacy measurement, death, hospitalisations, BP, bloods (creatinine, urea, albumin, HBA1c, markers of bone disease, haemoglobin) and other more specific

Eighty-two studies reported objective outcomes. When judging the risk of bias for objective outcomes, it was assumed that objective outcomes are often not affected by unblinded outcome assessors, and for this reason, 76 studies were given a low risk of detection bias rating. Robinson 2011 was given a high risk of bias for the knowledge outcome because the questionnaire was completed over the phone with unblinded outcome assessors. Five studies received an unclear rating due to the lack of information about how the knowledge questionnaire was delivered (ELITE 2013; Sathivik 2007; So 2006) or because there was insufficient information to make a judgement (Reedy 1998; Trofe-Clark 2017).

Twenty-five studies did not report an objective outcome and therefore did not receive a risk of bias rating.

Incomplete outcome data

Fifty-two studies were judged to be at low risk of attrition bias, and 40 were judged unclear. The main reason for an unclear rating was a lack of information; however, a mixture of not using intention-to-treat analysis, high or unbalanced dropout rates and lack of analysis of drop-outs also contributed. Fifteen studies were judged to have a high risk of attrition bias due to high dropout rates, underpowered data analysis, or reasons for dropout associated with group allocation (Alikari 2019; Barnieh 2011; INTENT 2014; KTAH 2012; Lii 2007; Live and Learn 1993; Mathers 1999; Paes-Barreto 2013; Rodrigue 2007; SMART 2006; Teng 2013; Tsay 2005; Tsuji-Hayashi 2000; Tzvetanov 2014; Yamagata 2010).

Selective reporting

We judged 25 studies to be at low risk of reporting bias, and 74 had unclear risk of bias due to insufficient information or inability to view protocol. Eight studies were judged to be at high risk of bias for not reporting all outcomes described (BALANCEWise-PD 2011; HED-SMART 2011; Karavetian 2014; MASTERPLAN 2005; MESMI 2010; Sehgal 2002), adding outcomes that weren’t described (Giacoma 1999), or a mixture of the two (Hernandez-Morante 2014).

Other potential sources of bias

We judged 39 studies to be at low risk for other potential biases due to their transparent reporting and following of protocol. Twenty-five were given a high risk of bias rating for a wide variety of reasons outlined in the Characteristics of included studies section. The remaining 43 studies were given an unclear risk of bias, mostly due to insufficient information.

Non-randomised studies

See Figure 4

Overall risk of bias

We did not find any studies to have a low overall risk of bias because none were judged low in the confounding domain. Only Hall 2004* was given a moderate risk of bias for all outcomes reported, and five studies scored a moderate overall rating for objective outcomes and a serious overall rating for subjective measures (Choi 2012*; Joost 2014*; Karamanidou 2008*; Wang 2011*; Wingard 2009*). Five studies were judged to be at overall serious risk of bias due to a serious rating in at least one domain - usually confounding, selection of participants, or measurement of outcomes (Aliashgharpour 2012*; An 2011*; Nozaki 2005*; Rasgon 1993*; Slowik 2001*). Kazawa 2015* was given a serious rating for most outcomes but a critical rating for outcome 5: percentage of days self-care behaviour was performed. Taghavi 1995* did not provide enough information for an overall judgement.

Bias due to confounding

We judged nine studies to be at moderate risk of bias due to confounding as the majority allocated group based on the day of the week or dialysis shift and sufficiently analysed the possible inherent differences between groups (Aliashgharpour 2012*; Choi 2012*; Hall 2004*; Joost 2014*; Karamanidou 2008*; Nozaki 2005*; Rasgon 1993*; Wang 2011*; Wingard 2009*). Three studies were given a serious risk of bias due to their allocation methods, lack of formal analysis, or obvious differences between groups at baseline (An 2011*; Kazawa 2015*; Slowik 2001*). Taghavi 1995* did not provide enough information.

Bias in selection of participants into the study

Five studies did not present enough information to be given a risk of bias judgement in relation to the selection of participants (Hall 2004*; Kazawa 2015*; Taghavi 1995*; Wang 2011*; Wingard 2009*). Four studies were judged to be at low risk of bias (Choi 2012*; Joost 2014*; Karamanidou 2008*; Slowik 2001*), and four studies were judged to be at serious risk of bias (Aliashgharpour 2012*; An 2011*; Nozaki 2005*; Rasgon 1993*).
Bias in classification of interventions

Twelve studies were judged to have a low risk of bias due to the classification of outcomes, and one study did not present enough data for a judgement (Rasgon 1993*).

Bias due to departure from intended interventions

Ten studies did not present enough information for the authors to make a risk of bias judgement in relation to departures from intended interventions. Two studies were given a low risk of bias assessment (Karamanidou 2008*; Kazawa 2015*), and one was given a serious risk of bias due to possible problems with implementation fidelity (Rasgon 1993*).

Bias due to missing data

We judged one study to be at serious risk of bias due to missing data because the dropout reasons between groups were different (Kazawa 2015*). Two studies were judged to be at low risk of bias (Choi 2012*; Nozaki 2005*), and four were judged to be at moderate risk of bias (Aliasgharpour 2012*; An 2011*; Joost 2014*; Rasgon 1993*). Six studies did not present not enough information to make a judgement (Hall 2004*; Karamanidou 2008*; Slowik 2001*; Taghavi 1995*; Wang 2011*; Wingard 2009*).

Bias in measurement of outcomes

We judged the risk of bias for most outcomes to be low or moderate as they were either objective or assessed by blinded personnel. Seven studies reported subjective outcomes assessed either by un-blinded participants or un-blinded personnel and were given a serious risk of bias judgement (Choi 2012*; Joost 2014*; Karamanidou 2008*; Kazawa 2015*; Rasgon 1993*; Wang 2011*; Wingard 2009*). Self-care behaviour in Kazawa 2015* was the only outcome given a critical rating as it relied on un-blinded participants to self-report the percentage of days they completed an action.

Bias in selection of the reported result

Two studies were given a serious risk of bias judgement in the selective reporting domain for reporting the same outcome in different ways (Rasgon 1993*) or failing to separate two streams within the intervention group (Slowik 2001*). Two studies were judged to be low risk of bias (Choi 2012*; Hall 2004*), seven were judged to be moderate (Aliasgharpour 2012*; An 2011*; Joost 2014*; Karamanidou 2008*; Kazawa 2015*; Nozaki 2005*; Wingard 2009*), and two studies did not provide enough information (Taghavi 1995*; Wang 2011*).

Effects of interventions

See: Summary of findings 1 Educational interventions versus usual care for improving health outcomes in people with chronic kidney disease (CKD); Summary of findings 2 Self-management training versus usual care for improving health outcomes in people with chronic kidney disease (CKD); Summary of findings 3 Educational interventions and self-management training versus usual care for improving health outcomes in people with chronic kidney disease (CKD)

Educational Interventions

See Summary of findings 1.

Knowledge

Nineteen RCTs reported knowledge, and 14 were included in our meta-analyses. There was low-certainty evidence that educational interventions may improve knowledge when compared to standard care (Analysis 1.1 (14 studies, 2632 participants): SMD 0.99, 95% CI 0.69 to 1.32; I² = 94%). There was very high heterogeneity in this analysis, most likely due to the different structure and content of the educational interventions, as well as the different tools used to measure knowledge.

Two studies reported educational interventions significantly improved knowledge compared to control post-intervention (Chen 2012g; Giacoma 1999). The remaining two studies did not compare an intervention to a control group; rather, they found that knowledge significantly increased in the intervention group when compared to baseline (Reedy 1998; Sathvik 2007). Sathvik 2007 reported no improvement in the control group, while Reedy 1998 did not report the control group findings. Trofe-Clark 2017 reported improvement in knowledge post-educational intervention for both the intervention and control groups; however, the data was not quantified.

Two non-randomised studies reported knowledge. Karamanidou 2008* reported no difference between the intervention and control groups’ scores on the knowledge test at one month; however, at four months, there was a significant group effect in favour of the intervention group (F = 9.05, df = 1, 24, P < 0.01). Wang 2011* reported self-care knowledge significantly improved in the intervention group compared to the control group (F = 218.816, P < 0.000).

Mode of delivery

The test for subgroup differences suggests there was a significant subgroup effect in relation to the mode of delivery (Chi² = 12.01, df = 3, P = 0.0007, I² = 57%). Individual Analysis 1.1.2 (8 studies, 862 participants): SMD 0.73, 95% CI 0.39 to 1.07; I² = 90%), group Analysis 1.1.3 (3 studies, 272 participants): SMD 2.30, 95% CI 0.56 to 4.05; I² = 97%) and combined individual and group education interventions improved knowledge when compared to standard care (Analysis 1.1.4 (1 study, 80 participants): SMD 1.34, 95% CI 0.85 to 1.83). Provision of educational materials did not improve knowledge when compared to usual care (Analysis 1.1.5 (2 studies, 287 participants): SMD 0.37, 95% CI -0.03 to 1.77; I² = 82%). The majority of the subgroups contain a small number of studies, and there is high unexplained heterogeneity between the trials within each subgroup. This may limit comparison by mode of delivery.

Self-care behaviour

One non-randomised study reported a self-care behavioural outcome. There was low-certainty evidence that the provision of educational materials may improve participants’ scores on the Self-Care Behaviours for HD scale (Wang 2011*), a self-reported self-management questionnaire (Analysis 1.2.1 (1 study, 60 participants): MD 5.80, 95% CI 5.07 to 6.53).

Self-efficacy

Self-efficacy was reported in two RCTs which could not be meta-analysed. They reported no difference in self-efficacy between the educational intervention group and the usual care group (ELITE 2013; Massey 2015).
Self-efficacy was reported in two non-randomised studies. Karamanidou 2008 reported no difference in self-efficacy between the intervention and controls group at one month; however, at four months, self-efficacy improved in the intervention group (F = 5.2, df = 1, 24, P < 0.05). Wang 2011 reported that feelings of powerlessness decreased in the intervention compared to usual care (P < 0.000).

Quality of life

QoL was reported in five RCTs. Three used the KDQoL tool (Chow 2010; Ebrahim 2016; Sehgal 2002), Abraham 2012 used the WHOQoL-BREF tool, and Alikari 2019 used the Greek version of the kidney disease questionnaire. No two studies reported data for the same domain, so results could not be pooled, and due to heterogeneity and high risk of bias, the evidence for this outcome was downgraded to very low certainty. Sehgal 2002 did not report any data which could be analysed. Ebrahim 2016 reported the mean overall score for all of the domains of the KDQoL tool was higher in the intervention group than in the control group (P < 0.001). Chow 2010 reported educational interventions did not improve the effect of kidney disease, the burden of kidney disease, physical functioning, physical, emotional well-being, or emotional domains of the KDQoL scale when compared to usual care (Analysis 1.3). Abraham 2012 reported educational interventions improved the physical (Analysis 1.3.3 (1 study, 50 participants): MD 4.38, 95% CI 2.87 to 5.89) and psychological (Analysis 1.3.6 (1 study, 50 participants): MD 5.44, 95% CI 3.82 to 7.06) domain sections of the WHO-BREF; however, this study had a small sample size and was rated high risk of bias for randomisation methods.

Death

Two RCTs reported death; however, we were unable to include them in our meta-analysis (Appendix 6). A 20-year follow-up of Live and Learn 1993 found that participants who received an educational intervention survived significantly longer than those who did not (7.96 versus 5.07, P = 0.053). Similarly, Wu 2009 found a significant increase in median survival 12 months post-intervention (11.2 months versus 11.9 months). Wu 2009 also found more participants died in the control group than in the intervention group at one year (29 versus 5). Due to the inability to combine data, the small number of studies and the risk of bias analysis, the certainty of the evidence was downgraded to very low.

eGFR

Wu 2009 reported that in a 12-month period, the rate of change of eGFR was better in participants who underwent an individual educational intervention (0.08 ± 0.139 mL/min/month) than those who underwent usual care (0.113 ± 0.786 mL/min/month) (P < 0.011). This evidence was judged to be low certainty due to the inability to pool data, small number of studies, and the unclear risk of bias.

Hospitalisations

Two studies reported hospitalisations; in Wu 2009, the average time spent in hospital was decreased by 8.7 days in the intervention group compared to the control group (P < 0.001) (Analysis 1.4). Giacoma 1999 reported that the provision of educational materials had no effect on the number of hospital readmissions. Due to the inability to pool data and the small number of studies, the certainty of the evidence was downgraded to moderate.

Serum albumin

Two studies reported serum albumin. Due to high heterogeneity (I² = 97%, different intervention structures and content), these studies were not pooled. Wu 2009 reported higher serum albumin in the individual intervention group compared to the control (Analysis 1.5.1 (573 participants): MD 0.40 g/dL, 95% CI 0.32 to 0.48), while Shi 2013 reported no difference for individual/group intervention versus control (Analysis 1.5.2 (80 participants): MD -0.03 g/dL, 95% CI -0.16 to 0.10).

Self-management interventions

See Summary of findings 2.

Knowledge

Three RCTs reported knowledge as an outcome; however, none could be included in our meta-analysis. Teng 2013 reported that an individually delivered self-management intervention had no effect on kidney protection knowledge in the intervention group when compared with the control group. Deimling 1984 reported that there were gains in knowledge for both the participants in the self-management intervention and those in the control group; however, they did not include enough data for the difference between the groups to be formally analysed. Liu 2014c reported that a self-management intervention improved an individual’s knowledge in seven domains when compared to a control group; however, these data were stratified, and no overall measurement was analysed. Due to the inability to pool data, the small number of studies, and the risk of bias judgements, the certainty of the evidence was downgraded to low.

Self-care behaviour

Four RCTs reported behavioural outcomes; however, none could be included in our meta-analysis due to differences in measurement tools. All four studies reported increases in some of the domains measured (see Appendix 7).

Self-efficacy

Five RCTs reported self-efficacy, and all were included in our meta-analysis. There was low-certainty evidence that self-management interventions may improve self-efficacy when compared to usual care (Analysis 2.1 (5 studies, 417 participants): SMD 0.58, 95% CI 0.13 to 1.03; I² = 74%). There was moderate heterogeneity in this analysis, likely due to the differences in intervention structure and content, as well as the self-efficacy tools used.

The subgroup analysis for the mode of delivery was not undertaken as all subgroups contained just one study, and therefore there was only a limited amount of data for this analysis.

Quality of life

Nine RCTs reported QoL (Appendix 5). Two did not present any data (Hed-SMART 2011; MASTERPLAN 2005), and the data from Korniewicz 1994 could not be pooled due to stratification between the three groups. Four studies used the SF-36 tool; however, Tzvetanov 2014 could not be included in the meta-analysis as the data were only presented in graph form. Liu 2014c used the KDQoL measurement tool, as did Campbell 2008, alongside the SF-36. The remaining two studies used lesser-known measurement tools. There was low-certainty evidence that self-management interventions may improve the physical component
score (Analysis 2.2.3 (3 studies, 131 participants): MD 4.02, 95% CI 1.09 to 6.94; $I^2 = 0\%$), but do not improve any other domain of the SF-36 when compared to usual care (Analysis 2.2).

**Death**

MAGIC 2016 reported one death during the study period; however, the group assignment was not reported.

**eGFR**

Three RCTs reported GFR, and all were meta-analysed. There was moderate-certainty evidence that self-management interventions probably did not slow the decline in GFR after one year when compared to control (Analysis 2.3 (3 studies, 855 participants): MD 1.53 mL/min/1.73 m$^2$, 95% CI -1.41 to 4.46; $I^2 = 33\%$). Two studies had small sample sizes, wide CIs, and did not control for baseline variables; however, were not thought to influence this result as their combined weight was only 0.8%.

Long-term follow-up of MASTERPLAN 2005 reported a small but significant difference in the rate of decline of eGFR between the intervention group (1.26 mL/min/1.73 m$^2$/year) and the control group (1.71 mL/min/1.73 m$^2$/year) (median follow-up 5.7 years, $P = 0.01$).

**Hospitalisation**

Hospital admissions and emergency department visits were reported in two RCTs. Chisholm-Burns 2013 reported self-management training participants were hospitalised less (57.3% versus 23.9%) and for shorter time periods (Analysis 2.4 (1 study, 150 participants): MD -0.26 days, 95% CI -0.49 to -0.03) than those in the control group; however, they did not find an effect on emergency department visits, outpatients visits, or home healthcare visits. Li 2014b reported no significant difference in readmission rates between the intervention and control group participants; however, the data were not reported. Due to the inability to pool data, the certainty of the evidence was downgraded to low.

**Serum albumin**

Three RCTs reported serum albumin, and two were included in our meta-analysis. There was low-certainty evidence that self-management interventions may or may not increase serum albumin levels when compared to usual care (Analysis 2.5 (2 studies, 130 participants): MD 0.14 g/dL, 95% CI -0.15 to 0.43; $I^2 = 63\%$). There is moderate heterogeneity in this analysis, likely due to the differences in intervention type and structure. Supporting this, Li 2014b reported that there was no significant difference in serum albumin between the two groups; however, the data were not reported.

**Educational with self-management interventions**

See Summary of findings 3

**Knowledge**

Sixteen RCTs reported knowledge, and 14 of these were included in our meta-analysis. Although no two RCTs used the same tools, all were self-reported questionnaires aimed at measuring the individual’s knowledge of a specific topic or kidney disease as a wider subject. Kirchhoff 2010 reported the results from surrogate/patient pairs, and the data for the patients could not be analysed separately. There was low-certainty evidence that educational with self-management interventions may increase knowledge when compared to usual care (Analysis 3.1 (15 studies, 2124 participants): SMD 0.67, 95% CI 0.37 to 0.97; $I^2 = 91\%$). There was high heterogeneity in this analysis, likely due to the differences in intervention structure and content and tools used to measure knowledge.

Two non-randomised studies (Choi 2012*; Taghavi 1995*) reported that an individually-delivered educational with self-management intervention increased knowledge when compared to the control group ($P < 0.001$, $P < 0.001$, respectively).

**Mode of delivery**

The test for subgroup difference suggests that there is a significant subgroup effect in relation to mode of delivery ($Chi^2 = 12.06$, df = 3, $P = 0.007$, $I^2 = 75.1\%$). Individual (Analysis 3.1.1 (6 studies, 802 participants): SMD 0.33, 95% CI 0.04 to 0.62; $I^2 = 72\%$), group (Analysis 3.1.2 (2 studies, 478 participants): SMD 1.13, 95% CI 0.70 to 1.56; $I^2 = 76\%$), and individual and group interventions all increases knowledge when compared to usual care (Analysis 3.1.3 (2 studies, 130 participants): SMD 1.19, 95% CI 0.54 to 1.85; $I^2 = 62\%$). It is unclear if the provision of materials increases knowledge when compared to usual care (Analysis 3.1.4 (4 studies, 714 participants): SMD 0.67, 95% CI -0.12 to 1.46; $I^2 = 95\%$). There is high unexplained heterogeneity between the trials within each subgroup. Most of the subgroups contain only a small number of RCTs.

**Self-care behaviour**

Six RCTs measured the perceived amount of self-care behaviour using a self-reported questionnaire. Of these, two could not be included in our meta-analysis due to insufficient information (Flesher 2011) and stratification of data (Liu 2016d). There was low-certainty evidence that educational with self-management interventions may improve scores on self-care questionnaires when compared with usual care (Analysis 3.2 (4 studies, 913 participants): SMD 0.91, 95% CI 0.00 to 1.82; $I^2 = 97\%$). Liu 2016d reported a significant increase in self-reported self-care behaviours across seven domains. There was high heterogeneity in this analysis, likely due to the differences in intervention structure and content and the differences between the tools to measure behavioural outcomes.

Robinson 2011 reported that participants who underwent an educational with self-management intervention were more likely to check their skin for skin cancer than the control group (Analysis 3.3 (1 study, 75 participants): RR 4.14, 95% CI 2.22 to 7.72).

Two non-randomised studies reported self-care behaviours. Choi 2012* reported educational with self-management increased scores on the self-care practice scale over time compared to the control group ($P = 0.001$), while there was insufficient data reported by Kazawa 2015* for analysis.

The results are summarised in Appendix 8.

**Self-efficacy**

Nine RCTs reported self-efficacy as an outcome, and eight were included in our meta-analysis. Manns 2005 was not included in the analysis as this study reported the number of people who reported low self-efficacy in training or self-care. There was low-certainty evidence that educational with self-management interventions
may improve self-efficacy compared to usual care (Analysis 3.4 (8 studies, 687 participants): SMD 0.50, 95% CI 0.10 to 0.89; $I^2 = 82\%$).

Two non-randomised studies reported self-efficacy. Aliasghehpour 2012* reported self-efficacy was higher in participants who underwent an educational with self-management intervention compared to usual care ($P < 0.001$). Kazawa 2015* reported self-efficacy improved for the intervention group at six months but returned to baseline level at 24 months, and in the control group, there was no significant improvement at any time point.

**Mode of delivery**

The test for subgroup differences for the RCTs showed no subgroup effect in relation to mode of delivery ($Chi^2 = 0.79, df = 2, P = 0.67$, $I^2 = 0\%$). Individual (Analysis 3.4.1 (2 studies, 126 participants): SMD 0.27, 95% CI 0.03 to 0.51; $I^2 = 0\%$) and group interventions (Analysis 3.4.2 (3 studies, 252 participants): SMD 0.38, 95% CI 0.12 to 0.64; $I^2 = 0\%$) improved self-efficacy compared to usual care. It is unclear if the provision of materials increases self-efficacy when compared to usual care (Analysis 3.4.3 (2 studies, 176 participants): SMD 0.97, 95% CI -1.04 to 2.98; $I^2 = 97\%$). There was unexplained high heterogeneity between the trials in the provision of material subgroup.

**Quality of Life**

Fourteen RCTs reported QoL (Appendix 5). A version of the SF-12 or SF-36 was used in nine studies, while three studies used the KDQOL questionnaire. ESCORT 2014 reported no significant difference in any of the domains of the SF-36, and Leon 2006 reported no difference in the KDQOL scale. Neither study reported data to accompany their findings. Two studies did not report any QoL data. Mathers 1999 reported there was no effect of the intervention on the psychosocial adjustment to illness scale, while the abstract by Tsuji-Hayashi 2000 reported an improvement in the intervention group; however, it is not known what QoL measurement tool was used. The remaining three studies all used different measurement tools (Song 2010; Raisifar 2014; BRIGHT 2013). There was low-certainty evidence that educational with self-management interventions may improve the physical component score of the SF-36 QoL measurement tool (Analysis 3.5.3 (3 studies, 2771 participants): MD 2.56, 95% CI 1.73 to 3.38; $I^2 = 0\%$) but there was no evidence to suggest they improved the other domains of interest.

Two non-randomised studies reported no difference in the QoL scores between the intervention and control groups (Joost 2014*; Kazawa 2015*) (Appendix 5).

**Death**

Four RCTs reported death. Moderate-certainty evidence shows educational with self-management interventions probably decreases death (any cause) compared to usual care (Analysis 3.6 (4 studies, 2801 participants): RR 0.73, 95% CI 0.53 to 1.02; $I^2 = 0\%$).

One non-randomised study reported lower death rates for participants who underwent an educational with self-management program compared to usual care ($P < 0.001$) (Wingard 2009*).

**eGFR**

Seven RCTs reported eGFR. Four compared the eGFR of the intervention group with the control group and were included in the meta-analysis. There was low-certainty evidence that educational and self-management interventions may make little or no difference in slowing the decline of eGFR when compared to usual care (Analysis 3.7 (4 studies, 618 participants): MD 4.28 mL/min/1.73 m$^2$, 95% CI -0.03 to 8.85; $I^2 = 43\%$). There was moderate heterogeneity in this analysis, likely due to the differences in intervention delivery and structure. Flesher 2011, Navaneethan 2017 and Yamagata 2010 measured the rate of eGFR decline and found no evidence to support education and self-management interventions; however, Flesher 2011 did not formally analyse the data due to low participation rates.

Three non-RTCs reported eGFR; two reported educational with self-management training interventions did not increase eGFR compared to usual care (Joost 2014*; Choi 2012*). Kazawa 2015* did not find a difference in eGFR between the intervention and control groups but did report a worsening of eGFR over a 24-month period in the control group which was not seen in the intervention group.

**Hospitalisation**

Five RCTs reported hospitalisations; however, none were included in the meta-analysis. Three studies reported no difference in hospitalisation rates between the intervention and control groups (Jasinski 2018; Navaneethan 2017; Wong 2010). Chen 2011e stated that fewer participants were hospitalised in the intervention group when compared with the control ($P < 0.05$). Fishbane 2017 reported hospitalisation rates were lower in the intervention group compared with the control ($P = 0.04$). Due to the inability to pool data and the high risk of bias, the certainty of the evidence was downgraded to low.

Three non-randomised studies reported hospitalisations. Hall 2004* reported the average number of hospitalisations/patient-month was less for participants who underwent an educational with self-management intervention when compared to usual care ($P = 0.08$). Taghavi 1995* reported intervention participants spent fewer days in hospital ($P < 0.001$), and Wingard 2009* reported a reduction in the mean hospitalisation days/patient-year for the intervention group ($P = 0.001$).

**Serum albumin**

Serum albumin was reported in four RCTs, two were included in our meta-analysis. There was low-certainty evidence that educational with self-management interventions may make little or no difference to serum albumin when compared to usual care (Analysis 3.8 (2 studies, 140 participants): MD 0.04, 95% CI 0.21 to 0.28; $I^2 = 85\%$). Leon 2001 reported that participants in the intervention group were more likely to have a moderate (0.25 g/dL to 0.49 g/dL) or large (> 0.50 g/dL) improvement in their serum albumin than those in the control group ($P < 0.001$ Analysis 3.9). Tsuji-Hayashi 2000 reported no difference between intervention and control in terms of serum albumin; however, this was only a conference abstract, and no data were included for analysis.

Serum albumin was reported in four non-randomised studies. Sliwok 2001* and Wingard 2009* reported participants in the intervention group had higher mean serum albumin than those in the control group; however, the absolute difference in both studies was relatively small. Conversely, Kazawa 2015* and Hall
Improving outcomes for low health literacy populations

Three RCTs used health literacy as a covariate, and all analysed the outcome of knowledge.

iChoose 2018 reported a clinical decision aid improved knowledge about kidney transplantation for all intervention participants compared to control ($P < 0.001$). However, a subgroup analysis found that this effect was only significant for those with high ($P < 0.001$) or medium ($P = 0.04$) health literacy and was not found in those with low health literacy ($P = 0.26$).

Robinson 2014a reported an electronic interactive sun protection program improved knowledge of skin cancer and sunscreen use for all intervention participants when compared to the control ($P < 0.4$). The increase in knowledge was larger for those with inadequate health literacy than for those with adequate health literacy ($P < 0.05$).

In the abstract by Trofe-Clark 2017, kidney transplant recipients either underwent an educational intervention, an educational intervention with a medication list, or usual care. They were also assessed for cognitive impairment and health literacy. It was reported that all groups improved their knowledge and that cognitive impairment and health literacy were not a barrier to this; however, the data was not formally analysed.

DISCUSSION

Summary of main results

Of 120 included studies with 21,149 participants, predominantly people with ESKD, 97 studies included outcomes of interest. The study size was variable ranging from 10 to 2379 participants, and over half had fewer than 100 participants. Just six studies focused exclusively on people with mild to moderate kidney disease, reflecting a well-known disparity in the research, which is skewed towards more advanced CKD. The interventions and comparators were varied, but all focused on improving health literacy. We found no studies targeting a population with poor health literacy.

Those studies that aimed at improving health literacy were further sub-classified in terms of the type of intervention (educational, self-management training, or educational with self-management training), and then subgroup analyses were performed in relation to mode of delivery (individual, group, individual/group, provision of materials). Subgroup analysis using the level of kidney disease could not be completed due to the data from the studies not being stratified in this way. Within these classifications, there were still considerable differences in the type and delivery of the intervention, as well as the outcome measures. Due to this and the frequent high or unclear risk of bias judgements, the quality of the evidence from the RCTs was mostly low or very low.

Results from the RCTs included:

- Educational interventions and self-management training interventions may improve self-care behaviours; however, educational with self-management training interventions had no effect.
- Self-management training interventions and educational with self-management training interventions improved self-efficacy; however, educational interventions did not, suggesting that the self-management training aspect of these interventions is a key component for improving self-efficacy.
- Self-management training interventions and educational with self-management training interventions probably had no effect on eGFR over time.
- Educational with self-management interventions probably decrease death, and educational interventions may improve median survival.
- Although the data could not be pooled, all three interventions had a positive effect on health service-related outcomes.
- All eight educational and self-management training interventions either decreased hospitalisation rates or length of stay in hospital.
- Similarly, the QoL measurement tools varied greatly from study to study, limiting the amount of data that could be pooled.

No studies specifically targeted a low health literacy population; however, three RCTs included a health literacy measurement tool in their analysis. One study found a clinical decision aid improved knowledge for people with high or moderate health literacy more than those with low health literacy. Conversely, one study found an interactive sun protection program improved knowledge more for those with low health literacy. A third study did not formally analyse the data but stated that there was no difference in knowledge between those with high or low health literacy. It was not possible to draw conclusions about interventions specifically for people with CKD who have low health literacy, and this paucity of data highlights the need for more focused research in this vulnerable population.

Overall completeness and applicability of evidence

The broad scope of this review and the Cochrane methodology means that it presents a comprehensive mapping and summary of what is known about a wide variety of health literacy interventions across the CKD spectrum.

Quality of the evidence

We assessed the quality of study evidence using the risk of bias domains within the Cochrane tool for RCTs, and the ROBINS-I for non-randomised studies, together with GRADE methodology. There was considerable variability in interventions and outcome reporting. Data synthesis proved difficult due to non-standardised outcomes, measurement tools, or time frames. An example was the outcomes related to hospitalisation: although reported frequently, the data was rarely able to be combined. This, paired with the inability to blind participants, resulted in most of the evidence in this review being downgraded to low or very low certainty.

Potential biases in the review process

We strove to access unpublished data as well as that identified in our comprehensive search. We contacted many study authors for additional information to inform our risk of bias assessment and received data for 14 studies (Abraham 2012; Campbell...
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2008; Ford 2004; Hall 2004; Hasanzadeh 2011; Hed-SMART 2011; Karamanidou 2008; KTAH 2012; MASTERPLAN 2005; Robinson 2011; Taghavi 1995; Wong 2010; Yamagata 2010). We also contacted study authors to obtain additional outcome data when required and received information for five studies (ELITE 2013; Hed-SMART 2011; Leon 2006; Robinson 2011; Teng 2013).

Our decision about how to consider the definition of health literacy in this review was pragmatic. The studies we identified and their interventions could have been grouped in multiple ways. Our approach aimed to summarise studies in a way that supported the implementation of the results. However, we acknowledge that other approaches may be equally valid. The use of the TIDieR intervention table (Hoffman 2014), although helpful as an overview, did not assist in the interpretation of the summary findings (Appendix 4).

Agreements and disagreements with other studies or reviews

This study separated health literacy interventions into those that aimed to improve aspects of health literacy and those aimed at a low health literacy population. This is not a novel concept - viewing health literacy as a risk factor or an asset has been described in the literature previously (Nutbeam 2008; Nutbeam 2018). One study investigating health literacy interventions in people with HIV used a similar approach; however, they used specific outcomes in their inclusion criteria while, in line with Cochrane methods, our review did not exclude studies on the basis of the outcomes they reported (Perazzo 2017).

There are no previous systematic reviews investigating interventions aimed at individuals with low health literacy in CKD. Two recent systematic reviews have investigated educational interventions in people with kidney disease. Mason 2016 only included RCTs, while Lopez-Vargas 2016 excluded studies that exclusively recruited patients people with ESKD. Both these reviews found, as we did, that evidence for educational interventions in CKD is of low certainty and difficult to formally summarise due to the high heterogeneity of interventions, outcomes, and outcome measurement. In these two reviews, there was also a lack of data in the mild and moderate CKD populations. These reviews also concluded that educational interventions may improve knowledge, self-management, death, QoL, and some clinical outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

Interventions to improve aspects of health literacy are very broad and include educational interventions, self-management interventions and educational with self-management interventions. Overall, this type of health literacy intervention is probably beneficial in this cohort however, due to methodological limitations and high heterogeneity in interventions and outcomes, the evidence is of low certainty.

Interventions for individuals with low health literacy are increasing in number and complexity (Sheridan 2011) and are now being applied in many different chronic disease populations, such as diabetes (Van Scoyoc 2010), cardiovascular disease (Lee 2012), and HIV (Perazzo 2017). Many health literacy screening tools have been validated in the CKD community, and they continue to become shorter and easier to use. Whether the use of health literacy screening tools could improve patient outcomes by targeting interventions to this high-risk population remains unclear (Jain 2016). Our review highlights the paucity of data and the overall lack of research into interventions aimed at people with low health literacy and CKD.

Implications for research

This review highlights the need for the following:

- Centralised agreed-upon outcome measures and tools for CKD. The concept of widely accepted outcome measures is central to the Standardised Outcomes in Nephrology initiative (SONG), which is in the process of developing a set of validated and feasible outcome measures for core outcomes for people with CKD (Manera 2017; Tong 2015a; Tong 2015b; Tong 2017). Although the amount of data collected was large, the variation in outcome measurement tools greatly limited the ability to make overall conclusions.
- Adequately powered future studies of high methodological quality to improve the certainty of the overall data and analysis.

Only three studies included a validated health literacy tool despite there being many health literacy tools currently in use, many of which have been used in a CKD population already (Jain 2016). Future studies in this area should include a health literacy measurement tool to:

- Define a population for inclusion;
- As a subgroup analysis for the data;
- Or as a stand-alone outcome.

Future studies could focus on one of two things:

1. Investigate whether these interventions are more beneficial for those with low health literacy;
2. Analyse whether these interventions improve scores on a health literacy measurement tool. The question remains whether health literacy interventions should be implemented for all people with CKD or in a more targeted population.

ACKNOWLEDGEMENTS

The authors are grateful to the following peer reviewers for their time and comments: Dr Kelly Lambert (University of Wollongong, Australia); Dr Elisabeth Hodson (Centre for Kidney Research, The Children’s Hospital at Westmead, Australia)
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Interventions for improving health literacy in people with chronic kidney disease (Review)

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Wright Nunes 2013  (published data only)

Yamagata 2010a  (published data only)

References to studies awaiting assessment

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HED-START 2021  (published data only)

KARE 2015  (published data only)


Schaffhausen 2020  (published data only)

TALKS 2015  (published data only)


Waterman 2015  (published data only)


Waterman A, Peipert J, McSorley AM, Goalby C, Peace L. At-home transplant education increases black and low-income dialysis patients’ transplant knowledge, attitudes, informed decision-making, and pursuit: An explore transplant @ home


Waterman AD, Peipert JD, Beaumont JL. Efficacy of at-home transplant education on transplant knowledge and pursuit in low-income and black dialysis patients with varying educational characteristics [abstract no: 422.7]. *Transplantation* 2018;102(7 Suppl 1):S195-6. [EMBASE: 623701490]


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De Vecchi AF, Dratwa M, Wiedemann ME. Healthcare systems and end-stage renal disease (ESRD) therapies—an international review: costs and reimbursement/funding of ESRD therapies. *Nephrology Dialysis Transplantation* 1999;14 Suppl 6:31-41. [MEDLINE: 10528710]

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Interventions for improving health literacy in people with chronic kidney disease (Review)

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**Nutbeam 2018**

**Osborne 2007**

**Perazzo 2017**

**Schünemann 2021a**

**Schünemann 2021b**

**Sheridan 2011**

**Sterne 2016**

**Szczecz 2009**

**Tong 2015a**

**Tong 2015b**

**Tong 2017**

**Van Scoyoc 2010**

**Walker 1987**
**Weiss 2005**

**References to other published versions of this review**
Campbell 2016

* Indicates the major publication for the study

**Characteristics of studies**
Characteristics of included studies [ordered by study ID]

**Abraham 2012**

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel RCT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Setting: single centre (Nephrology Dept of tertiary care hospital)</td>
</tr>
<tr>
<td></td>
<td>Country: India</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: ESKD on HD</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: Under the age of 18; not interested in counselling; withdrawn from dialysis; severe illness; psychoses; infection with HIV; pregnant; lactating; &lt; 3 months on HD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number: intervention group (25), control group (25)</td>
</tr>
<tr>
<td>Mean age ± SD (years): intervention group (49.72 ± 13.2); control group (51.5 ± 11.6)</td>
</tr>
<tr>
<td>Sex (M/F): intervention group (73%/27%), control group (67%/33%)</td>
</tr>
<tr>
<td>Stage of CKD: ESKD on HD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of kidney failure, socioeconomic status, and co-morbidities seem to be quite evenly distributed between the groups</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Type of intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Individual versus control</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient counselling given in relation to diet, exercise, lifestyle modification and the importance of regular dialysis and ongoing follow-up</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
</tr>
</thead>
</table>
Abraham 2012 (Continued)

- Usual care with no patient counselling

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WHO-BREF</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conflict of interest</td>
</tr>
<tr>
<td>• Not reported</td>
</tr>
<tr>
<td>Funding source</td>
</tr>
<tr>
<td>• Not reported</td>
</tr>
<tr>
<td>Other information</td>
</tr>
<tr>
<td>• Received email from Dr Abraham: Participants were randomised by alternate allocation method; this was an individual intervention</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Emailed author: participants were randomised by alternate allocation method</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>This study was not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Blinding would not have been possible; QoL is a subjective outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>There was no reporting of attrition or loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Report included all expected outcomes; did not view protocol</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Participants excluded from the study that were not interested in counselling</td>
</tr>
</tbody>
</table>

### Afrasiabifar 2013

### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
</tr>
<tr>
<td>• Parallel RCT</td>
</tr>
<tr>
<td>Duration of study</td>
</tr>
<tr>
<td>• 1 year (all patients referred to dialysis unit in 2010)</td>
</tr>
</tbody>
</table>
### Afrasiabifar 2013 (Continued)

**Duration of follow-up**
- 8 weeks

**Participants**

**General information**
- **Setting**: single centre; dialysis ward
- **Country**: Iran
- **Inclusion criteria**: ESKD on HD for at least 3 months
- **Exclusion criteria**: < 3 months on HD; < 18 years and > 75 years; undergoing kidney transplant; unwilling to participate, migrating from the place of research; psychiatric disorders or handicaps; no reading or writing literacy; been in a similar study in the past

**Baseline characteristics**
- **Number**: intervention group (31); control group (28)
- **Mean age ± SD (years)**: intervention group (48.03 ± 13.79); control group (46.86 ± 14.36)
- **Sex (M/F)**: intervention group (16/15); control group (15/13)
- **Stage of CKD**: ESKD on HD

**Other information**
- No significant difference found between the two group demographics

**Interventions**

**Intervention type**
- Education: individual versus control

**Intervention group**
- Education before and during dialysis and if a patient needed expert consultation, they were referred to a specialist
- The education plan contained information about kidney function, diagnosis, treatment, complications and self-care information
- The plan was held for 8, 1-hour sessions over 8 weeks. At the end of the plan, they were given an educational booklet containing the main points of self-care for HD patients

**Control group**
- Usual care with no education plan

**Outcomes**

**Adaptation**
- RAM (Roys adaptation model): four modes: physiological, self-concept, role function, interdependence

**Notes**

**Conflict of interest**
- "none declared"

**Funding source**
- "none declared"

**Other information**
- Emailed author about additional information about randomisation method; no response to date

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>

Interventions for improving health literacy in people with chronic kidney disease (Review)

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### Afrasiabifar 2013 (Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear</td>
<td>Quote: &quot;selected using convenience sampling but randomly divided into 2 groups of test and control&quot;. Comment: unclear how randomisation was done.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear</td>
<td>No mention of whether nursing staff who administer education were part of the research team, and no mention of whether allocation was concealed to the research team.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>This was not described as a single or double-blind trial and unlikely to be possible to blind participants or personnel involved in conducting education session.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self-report questionnaire - not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>No loss to follow-up reported, but it was reported 59 patients (all that were eligible) completed the study with no significant differences reported between the 2 groups.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All outcome measures were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>There may have been some bias in allocation to test or control group depending on patients usual compliance, however as there was no significant difference in pre-test scores, this may have a low impact on results of this study.</td>
</tr>
</tbody>
</table>

### Aliasgharpour 2012*

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Parallel cohort study</td>
</tr>
</tbody>
</table>

#### Duration of study

| Study duration                              | May to June 2010                                  |

#### Duration of follow-up

| Follow-up duration                           | 2 weeks                                           |

#### Participants

<table>
<thead>
<tr>
<th>General Information</th>
<th>Setting: multicentre (2 sites)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Country: Iran</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: 18 to 65 years; ability to speak the Persian or Turkish language; receiving HD for at least one year; having the physical ability to perform self-care activities; having 3 x self-efficacy 4-hour HD sessions/week; no history of known mental disorder, congestive heart failure, or hepatic cirrhosis</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: any incidence of acute emergencies during HD; any disturbance in the process of education; people who did not want to participate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th></th>
</tr>
</thead>
</table>
### Aliashgarpour 2012* (Continued)

- **Number**: intervention group (32); control group (31)
- **Mean age ± SD (years)**: intervention group (52.09 ± 11.31); control group (47.06 ± 15.84)
- **Sex (M/F)**: intervention group (17/15); control group (19/12)
- **Stage of CKD**: ESKD on HD

### Other information

- No significant difference between the groups in age, gender, marital status, education, habitancy, urinary output

### Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>Intervention group</th>
</tr>
</thead>
</table>
| **Education: self-efficacy** | Educational materials focused on four components of self efficacy  
  a. Performance attainment  
  b. Vicarious experience  
  c. Verbal persuasion  
  d. Physiological feedback  
  Educated in small groups (2 or 3 patients in each group) using the face-to-face lecture method. Delivered half an hour before and during HD in 6 subsequent sessions. Four groups of 3 people and 10 groups of 2 people. Patients also were provided with a booklet containing a summary of the lecture and related pictures |
| **Control group** | No education |

### Outcomes

<table>
<thead>
<tr>
<th>Mean body weight gain</th>
<th>Proposed benefit</th>
</tr>
</thead>
</table>
| **Self-efficacy** | Proposed benefit  
  **SUPPH questionnaire**  
  Four sub-scales: adaptation, stress management, decision making, enjoying life |

### Notes

- **Conflict of interest**
  - "No conflict of interest has been declared by the authors"

- **Funding source**
  - Not reported

- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| **Non-RCT overall judgement** | Unclear risk | **Outcomes**  
  1. Mean body weight gain: proposed benefit  
  2. Self-efficacy: proposed benefit |
**Aliasgharpour 2012** (Continued)

**Bias due to confounding**
Moderate: Allocation based on hospital could confound

**Bias in selection of participants into the study**
Serious: Start of follow-up and start of intervention do not coincide

**Bias in classification of interventions**
Low

**Bias due to deviations from intended interventions**
Insufficient information

**Bias due to missing data**
Moderate: Missing participants with insufficient reasons reported

**Bias in measurement of outcomes**
O1. NI
O2. Moderate: Not clear who completed interview for SE

**Bias in selection of the reported result**
Moderate: Did not view protocol but overall followed the plan outlined

**Overall risk of bias judgement**
Serious: All outcomes judged at serious risk of bias in at least one domain

---

**Alikari 2019**

**Study characteristics**

**Methods**

**Study design**
- Parallel RCT; stratification test was performed based on the demographic and clinical features

**Duration of study**
- August 2017 to December 2017

**Duration of follow-up**
- Not reported

**Participants**

**General information**
- **Setting:** single centre; HD unit
- **Country:** Greece
- **Inclusion criteria:** HD program 3 times/week for at least 6 months; 18 to 65 years; ability to write, read and understand the Greek language; ability to read and sign the consent; time and space-oriented
- **Exclusion criteria:** cognitive and psychological disorders; eye or hearing problems; limited self-care

**Baseline characteristics**
- **Number:** intervention group (25); control group (25)
- **Mean age ± SD [years]:** intervention group (51.2 ± 11.5); control group (49.8 ± 8.5)
### Interventions

- **Sex (M/F):** intervention group (15/10); control group (15/10)
- **Stage of CKD:** ESKD on HD

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational intervention versus control</td>
<td>One-time face-to-face educational intervention lasting 45 minutes and provision of a booklet</td>
<td>Provision of a booklet: Dialysis. Answers to common questions</td>
</tr>
</tbody>
</table>

### Outcomes

- **Knowledge**
  - Kidney Disease Questionnaire (Greek)
- **Adherence**
  - GR-Simplified Medication Adherence Questionnaire-HD (Greek)
- **QoL**
  - Missoula VITAS Quality of Life Index-15

### Notes

- **Conflict of interest**
  - No conflict of interest reported by the authors
- **Funding source**
  - Not reported
- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information about the randomisation process, which included a stratification test for demographic and clinical features</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Due to nature of intervention participants and personnel could not be blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Due to nature of intervention participants and personnel could not be blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcomes should not be affected by blinding of outcome assessors</td>
</tr>
</tbody>
</table>
Alikari 2019 (Continued)

|Incomplete outcome data (attrition bias)| High risk | High rate of loss to follow-up 28% |
|Selective reporting (reporting bias)| Low risk | No evidence of selective reporting |
|Other bias| Low risk | No other bias could be identified |

An 2011*

**Study characteristics**

**Methods**

**Study design**
- Pre-test/post-test and parallel RCT

**Duration of study**
- 6 weeks

**Duration of follow-up**
- 6 weeks

**Participants**

**General information**
- **Setting**: multicentre (2 sites, HD units)
- **Country**: Korea
- **Inclusion criteria**: aged 60 to 70 years; HD 3 times/week for more than 1 year; patients in the e-mail group had to meet the additional requirement of having a valid e-mail address and checking their e-mail messages every day using their computer
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (21); control group (19)
- **Mean age ± SD (years)**: intervention group (62.59 ± 2.06); control group (63.7 ± 2.42)
- **Sex (M/F)**: intervention group (10/9); control group (12/9)
- **Stage of CKD**: ESKD on HD

**Other information**
- No significant differences between the 2 groups: age, sex, male, female, education, religion, living with a spouse, employed, monthly income

**Interventions**

**Intervention type**
- Education: provision of materials versus usual care

**Intervention group**
- E-mail education: 12 sessions; the material of each session was e-mailed twice a week for 6 weeks, focused on fluid balance, sodium balance and hyperkalaemia and managing this. Medications, eating out and desirable menu

**Control group**
An 2011* (Continued)

- Routine care

Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Bloods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Compliance (potassium and phosphate)</td>
</tr>
<tr>
<td></td>
<td>Weight gain</td>
</tr>
<tr>
<td></td>
<td>Compliance (IDWG)</td>
</tr>
<tr>
<td></td>
<td>Stress</td>
</tr>
<tr>
<td></td>
<td>Stress instrument developed by Kim JH 1995, reference 13 in this article</td>
</tr>
<tr>
<td></td>
<td>Cortisol, adrenaline and noradrenaline levels</td>
</tr>
</tbody>
</table>

Notes

- **Conflict of interest**
  - Not reported

- **Funding source**
  - Supported financially by a research grant from Cheongju University

- **Other information**
  - Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td>Outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Stress score</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. IDWG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Bloods: serum cortisol, epinephrine, norepinephrine, potassium, phosphorus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias due to confounding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: Didn't adjust for confounders; hospital, SES and education and the effect these could have on outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias in selection of participants into the study</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: Selection into the study was related to intervention and outcome; start of follow-up and start of intervention do not coincide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias in classification of interventions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias due to deviations from intended interventions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NI: Possibility that intervention patients did not read emails and they didn't check this in any way</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias due to missing data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate: Outcome data reasonably complete, but didn't give a reason for one intervention participant for missing too many HD sessions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias in measurement of outcomes</td>
</tr>
</tbody>
</table>
### Study characteristics

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- 6 months (May to October 2012)

**Duration of follow-up**
- 4 weeks

#### Participants

**General information**
- **Setting**: multicentre (2 sites; HD units)
- **Country**: Iran
- **Inclusion criteria**
  - Patient: 18 to 65 years; undergoing HD 3 times/week, history of chest pain or symptoms of headache, nausea or vomiting during the 2 weeks before the intervention; no cardiovascular, GI and cerebral vascular diseases and not using cardiac, anti-headache, anti-nausea and anti-vomiting medications, and lack of uremia phase
  - Active family member: the main person with the highest participation in treatment issues and spending more time with the patient (according to the patient’s opinion), being literate
- **Exclusion criteria**: kidney transplant candidate or faced with changes in food and pharmaceutical diets by the physician

**Baseline characteristics**
- **Number**: intervention group (30); control group (30)
- **Mean age ± SD [years]**: intervention group (48.16 ± 9.21); control group (47.41 ± 10.31)
- **Sex (M/F)**: intervention group (15/15); control group (11/19)
- **Stage of CKD**: ESKD on HD

**Other information**
- Similar demographic variables of occupation, income rate, residential place, education level. Marital status and lifestyle differed, which were not associated with compliance based on the independent t-test
Interventions

**Intervention type**

- Education: group versus individual

**Intervention group**

- Individual face-to-face education in regard to the patient's training needs in 3 areas of diet, exercise program and medication diet on the patient's bed
  - In the family-centred group, in addition to the patient, 1 active member of the family attended the training session
  - In the patient-oriented group, the education was provided only to the patients individually

**Control group**

- Usual care

Outcomes

**Complications of dialysis**

- Chest pain, headache, nausea, vomiting

Notes

**Conflict of interest**

- Not reported

**Funding source**

- "This paper was a result of a research project enacted by Nursing and Midwifery Care Research Center of Tehran University of Medical Sciences, No. 91-01-99-17037."

**Other information**

- Emailed author about additional information about randomisation; no response to date

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>No mention of blinding and it is unlikely that participants or personnel could have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Participants self-reported outcomes (complications)</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>No mention of any loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes reported on (however, some had more information provided than others)</td>
</tr>
</tbody>
</table>
Other bias | Low risk | There may have been some contamination between groups with patients and family discussing the education sessions

**BALANCEWise-HD 2013**

*Study characteristics*

**Methods**

**Study design**
- Parallel RCT

**Duration of study**
- 16 weeks (September 2009 to September 2012)

**Duration of follow-up**
- 16 weeks

**Participants**

**General information**
- **Setting:** multicentre (17 sites in total from 3 dialysis chains)
- **Country:** USA
- **Inclusion criteria:** > 18 years who had been undergoing intermittent in-centre HD for at least 3 months (to permit initial nutritional stabilization)
- **Exclusion criteria:** could not read, write, or speak English; could not see the PDA or use a stylus to make selections from the PDA screen; had overt dementia; planned to move out of the area or change dialysis centres within the next 16 weeks; scheduled for a living donor transplant within the study period; deemed by dialysis centre staff to have a life expectancy < 12 months; were institutionalised

**Baseline characteristics**
- **Number:** intervention group (93); control group (85)
- **Median age, IQR (years):** intervention group (62, 53 to 71) 60, 50 to 69; control group ()
- **Sex (M/F):** intervention group (57/36); control group (44/41)
- **Stage of CKD:** ESKD on HD

**Other information**
- Median Kt/V differed between the groups, with attention control group participants being better dialysed. Otherwise, no significant differences found between the groups at baseline in terms of race, gender, marital status, income, employment, aetiology of ESKD, age, duration of ESKD, education, BMI, weight, albumin

**Interventions**

**Intervention type**
- Self-management: individual versus control (both groups got education) provided with PDA

**Intervention group**
- Social cognitive theory-based behavioural counselling was delivered to intervention group participants via one-to-one, face-to-face meetings with a study dietitian during HD treatments
- Counselling was delivered twice/week during the first 8 weeks, weekly in weeks 9 to 12, and every other week during weeks 13 to 16
- The counselling was focused on building a sense of self-efficacy regarding adherence to the HD diet. Participants in the intervention group were also engaged in technology-based self-monitoring

**Control group**
• Did not receive extra counselling

Co-interventions

• During HD appointments, a study dietitian delivered 6 computer dietary educational modules to participants.
  a. Overview of the HD diet
  b. Sodium and fluid restrictions
  c. Strategies for maintaining adequate calorie intake
  d. Strategies for maintaining adequate protein intake
  e. Phosphorus restrictions
  f. Potassium restrictions
  • This assured comparability regarding participant knowledge in both groups and also provided some attention to the control group

Outcomes

Weight gain

Nutrition

• PDA sodium intake; number of meals recorded into PDA

Adherence

• Number of meals recorded

Perceived difficulties

Notes

Conflict of interest

• "The authors declare that they have no relevant financial interests"

Funding source

• "The work of this article was supported by the following National Institutes of Health (NIH) grants: NINR/R01-NR010135, NINR/NIDDK/NHLBI/NIA-K24-NR012226, NIA/R01-AG02717, NIA/P30-AG024827 & NIA/K07-AG033174. The NIH played no role in study design; collection, analysis, and interpretation of data; writing the report; or the decision to submit the report for publication"

Other information

• Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Participants were randomised using a permuted block algorithm developed by the study statistician</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>There was no blinding</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-reported sodium intake and perceived difficulties</td>
</tr>
<tr>
<td>Study characteristics</td>
<td></td>
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<tr>
<td>------------------------</td>
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<tr>
<td><strong>Methods</strong></td>
<td></td>
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<tr>
<td><strong>Study design</strong></td>
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<tr>
<td>- Parallel RCT</td>
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<tr>
<td><strong>Duration of study</strong></td>
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<td>- 16 weeks</td>
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<td><strong>Duration of follow-up</strong></td>
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<tr>
<td><strong>Participants</strong></td>
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<tr>
<td><strong>General information</strong></td>
<td></td>
<td></td>
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<tr>
<td>- <strong>Setting</strong>: multicentre (3 centres)</td>
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<tr>
<td>- <strong>Country</strong>: USA</td>
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<td>- <strong>Inclusion criteria</strong>: &gt; 18 years who had been undergoing intermittent in-centre HD for at least 3 months (to permit initial nutritional stabilization)</td>
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<tr>
<td><strong>Baseline characteristics</strong></td>
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<tr>
<td>- <strong>Number</strong>: intervention group (13); control group (13)</td>
<td></td>
<td></td>
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<tr>
<td>- <strong>Mean age ± SD (years)</strong>: intervention group (51.7 ± 19.8); control group (not reported)</td>
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<tr>
<td>- <strong>Sex (M/F)</strong>: intervention group (7/6); control group (not reported)</td>
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<tr>
<td>- <strong>Stage of CKD</strong>: ESKD on PD</td>
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<tr>
<td><strong>Interventions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Self-management: one-on-one versus control (with provision of dietary monitoring device)</td>
<td></td>
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<tr>
<td><strong>Intervention group</strong></td>
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</tbody>
</table>
The counselling was focused on building a sense of self-efficacy regarding adherence to the HD diet. Participants in the intervention group were also engaged in technology-based self-monitoring.

Control group

- Did not receive extra counselling

Co-interventions

- During scheduled HD appointments, a study dietitian delivered 6 computer dietary educational modules to participants
- These modules included
  a. Overview of the PD diet
  b. Sodium and fluid restrictions
  c. Strategies for maintaining adequate calorie intake
  d. Strategies for maintaining adequate protein intake
  e. Phosphorus restrictions
  f. Potassium restrictions
- This assure comparability regarding participant knowledge of different aspects of the standard HD dietary regimen. And to provide some attention to the control group

Outcomes

- PDA self-monitoring
  - How many meals they entered

Notes

Conflict of interest

- Not reported

Funding source

- "The work in this article was supported by the following grants: Paul Teschan Research Foundation, NIH/NIDDK/DK-R21DK067181, NIH/NCRR/CTSA-UL1-RR024153, and NIH/NCRR/GCRC-M01-RR00056"

Other information

- Not requested

Risk of bias

<table>
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<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>There was no blinding</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Number of meals recorded - objective outcome does not matter there was no blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Loss to follow-up substantial as small sample size to begin with. Did not use ITT</td>
</tr>
</tbody>
</table>
Selective reporting (reporting bias) | High risk | The primary outcomes were not reported
Other bias | Unclear risk | Small sample size; age less than normal age for patients with CKD

**Baraz 2010**

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - 2007

- **Duration of follow-up**
  - 2 months

**Participants**

- **General information**
  - **Setting**: multicentre (3 sites)
  - **Country**: Iran
  - **Inclusion criteria**: > 18 years; receiving HD routinely 3 times/week; HD for at least 6 months; living in a home setting; not received any educational intervention in the past
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - **Number**: intervention group 1 (32); intervention group 2 (31)
  - **Mean age ± SD**: 34.85 ± 9.51 years
  - **Sex (M/F)**: 33/30
  - **Stage of CKD**: ESKD on HD

- **Other information**
  - Missing data about demographics between groups, only overall demographics available

**Interventions**

- **Intervention type**
  - Education: oral versus video

- **Intervention group 1 (oral)**
  - 30-minute group education sessions where a nurse performed a didactic teaching intervention with questions at the end and a workbook to take home

- **Intervention group 2 (video)**
  - Invited to watch a 30-minute film while they were having dialysis

- **Other information**
The 2 educational interventions had similar content and covered general knowledge about ESKD and dietary management for HD, identification of restricted/non-restricted food, fluid restrictions, reasons for compliance and possible consequences of non-compliance.

### Outcomes

<table>
<thead>
<tr>
<th>Bloods: compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine, Na, K, Ca, PO4, uric acid, BUN, albumin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight gain: compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDWG</td>
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</tbody>
</table>

### Notes

**Conflict of interest**

- "No conflict of interest has been declared by the authors."

**Funding source**

- "This research received a grant from Tarbiat Modarres University (no grant number supplied)."

**Other information**

- Emailed author about additional information with no response to date (missing data - difference in demographics between groups; ages and sex within specific group; allocation concealment)

### Risk of bias

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “They were allocated into two groups at random. The random allocation was performed using computer-generated random numbers from 0 to 99. For an equal allocation to the two groups, we took odd numbers to indicate group 1 (oral education) and even numbers to indicate group 2 (video education).”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Computer-generated random numbers</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants could see who watched video on dialysis and nurse administering education was principal researcher. No blinding in this study</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>No blinding of outcomes but as it is blood reading (and weight gain) not thought to be a problem</td>
</tr>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>6% to 8% loss to follow-up in both groups</td>
</tr>
<tr>
<td>All outcomes</td>
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</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcome measures reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>May have been some contamination between patients</td>
</tr>
</tbody>
</table>
Study characteristics

Methods

**Study design**
- Parallel RCT

**Duration of study**
- 1 July 2007 to 24 September 2009

**Duration of follow-up**
- 2 weeks

Participants

**General information**
- **Setting**: single centre
- **Country**: Canada
- **Inclusion criteria**: after initial visit considered medically able to continue transplant workup process, signed informed consent
- **Exclusion criteria**: cognitive dysfunction, < 18 years; not English speaking; already identified a living donor

**Baseline characteristics**
- **Number**: intervention group (49); control group (50)
- **Age (years)**: intervention group (19 to 40 (1), 41 to 60 (24), > 60 (24)); control group (19 to 40 (10), 41 to 60 (24), > 60 (16))
- **Sex (M/F)**: intervention group (35/14); control group (33/17)
- **Stage of CKD**: ESKD - assessed for transplant

**Other information**
- Demographic results appear similar across groups in marital status, education, employment, diabetes, hypertension, cardiovascular disease, dialysis length and type, and attitude and availability of acceptance of kidney from a close friend

Interventions

**Intervention type**
- Education: combination

**Intervention group**
- Took part in a structured education session and written education materials in the mail. The written materials provided information of advantages of living donor transplantation and information on living donors and came about 2 weeks after the education session. The second component occurred 2 weeks after receiving the written materials was a 2 hours small group interactive session involving 3 to 5 patients, family members, transplant nephrologist and a recipient and a donor. Problem-based learning in small groups

**Control group**
- Usual care, no additional education

Outcomes

**Transplant live kidney contact**
- Contact by a potential living donor

Notes

**Conflict of interest**
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| Random sequence generation (selection bias) | Low risk           | Quote: “Randomization was done by using a computer-generated sequence in blocks of 6.”  
Comment: patients randomised correctly                                                   |
| Allocation concealment (selection bias)   | Low risk           | Quote: "Patients were randomly assigned to the education interventions or standard of care in a one-to-one ratio using a central phone-in system to conceal allocation."  
Comment: allocation adequately concealed                                                   |
| Blinding of participants and personnel (performance bias) | High risk          | Quote: "Given the nature of the intervention, neither the investigators, nurse educators or patients were blinded" - no blinding  
Unable to blind participants – as done in clinics less likely to be influenced by other participants data collector was blinded to the allocation |
| Blinding of outcome assessment (detection bias) Subjective outcomes | Unclear risk       | Outcome assessor for primary outcome was blinded to treatment group. Secondary outcome was ranking of treatment preference by unblinded participants |
| Incomplete outcome data (attrition bias) All outcomes | High risk          | Quote: "one patient received a deceased donor kidney transplant after randomisation but before the intervention and was therefore excluded from the study. Of the 49 patients randomised to the education session, 37 attended the sessions. One patient in the standard of care group and 3 patients in the education sessions intervention did not complete either the baseline or the follow up questionnaire and were therefore excluded from analysis of the secondary outcome."  
Comment: Dropouts and incomplete data were treated with an ITT analysis. About the same amount (30 for education and 39 for control), completed both the first and second questionnaires. Study was underpowered to start with - they did not get enough participants, and dropout rates were high - 30% |
| Selective reporting (reporting bias)      | Unclear risk       | Outcome measures are reported                                                                       |
| Other bias                                | Low risk           | No evidence of other bias                                                                            |
### Study characteristics

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- 6 months (recruitment April to November 2012)

**Duration of follow-up**
- 6 months

#### Participants

**General information**
- **Setting**: multicentre (24 general practices)
- **Country**: UK
- **Inclusion criteria**: stage 3a and 3b CKD
- **Exclusion criteria**: unable to communicate in English, had reduced capacity to provide informed consent or were in receipt of palliative care

**Baseline characteristics**
- **Number**: intervention group (215); control group (221)
- **Mean age ± SD (years)**: intervention group (72.4 ± 9.2); control group (71.8 ± 9.0)
- **Sex (M/F)**: intervention group (90/125); control group (91/130)
- **Stage of CKD**: stage 3 CKD

**Other information**
- Minimisation method used to balance groups in terms of age, smoking status and evidence of other vascular disease - degrees of randomisation still in this method. No formal analysis of differences between groups but on observations groups seem to be similar in terms of age, ethnicity, CKD stage, co-morbidities, self-report CKD and blood pressure control. Could be some differences between groups in terms of education with slightly more higher educated individuals in the intervention group, also more people with no qualifications in this group, and slight more trade or professionals in the control group.

#### Interventions

**Intervention type**
- Education, other: provision of materials and phone support versus control

**Intervention group**
- Provision of a kidney information guidebook; a booklet and interactive website that tailored access to community resources; and telephone-guided help from a lay health worker

**Control group**
- Sent the kidney information guidebook and the PLANS booklet with links to the website at the end of the trial period

#### Outcomes

**Self-management**
- HEIQ - Health Education Impact Questionnaire: Positive and active engagement in life: ‘The Positive and Active Engagement in Life’ domain was the main outcome. Also the other five domains - (social integration and support, skill and technique acquisition, emotional well being, self-monitoring and insight, and health service navigation)

**QoL**
• EuroQoL EQ-5D index, four physical and psychological well-being health education outcome measures taken from the Medical Outcomes Study (general health, social role/limitation, energy/vitality and psychological well being)

BP

• Controlled versus poorly controlled

Anxiety and depression

• Anxiety sub-scale from the Hospital Anxiety and Depression Scale (HADS-A), and as a measure of CKD-specific anxiety the Emotional Response item from the Brief Illness Perception Questionnaire (BIPQ) in relation to the patient’s CKD

UCLA Loneliness Scale

Social capital service use

• Frequency of contact with primary care services and hospital outpatient services

Levels of Illness

• Practical everyday and emotional work done by social network members

Cost-effectiveness

• Summary of Diabetes Self Care Activities Measure (SDSCA)

Notes

Conflict of interest

• "The authors have declared that no competing interests exist"

Funding source

• "The study was conducted as part of the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. The views expressed in this article are those of the authors and not necessarily those of the NHS, NIHR or the Department of Health. No funding bodies had any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript"

Other information

• Areas for practice recruitment were chosen because they served some of the most deprived populations of the UK: 20.4% of participants lived in the 20% most deprived local areas in England

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| Random sequence generation (selection bias) | Low risk | Quote: “Participant was allocated to receive either the intervention or usual care (1:1) via a minimisation algorithm.”  
Quote: “The minimisation procedure ensured that within each practice, as each subsequent patient was recruited the two trial arms remained well-balanced on three key prognostic factors (age, smoking status and evidence of other vascular disease). The method also includes a degree of random allocation to avoid complete determination.”  
Comment: adequate randomisation performed |
| Allocation concealment (selection bias) | Low risk | Quote: “An independent clinical trials unit was contacted by telephone”  
Comment: allocation sufficiently concealed |
## BRIGHT 2013 (Continued)

| Blinding of participants and personnel (performance bias) All outcomes | High risk | Quote: "an unblinded trial"
Comment: participants could not be blinded. unclear whether researchers blinded - as questionnaires administered by post |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Health education impact questionnaire and QoL are self report questionnaires from unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>BP is an objective measurement</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>14.3% lost to follow-up in a reasonably large sample, no mention about whether these participants differed in demographics</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All stated outcome measures were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Quote: &quot;Areas for practice recruitment were chosen because they served some of the most deprived populations of the UK: 20.4% of participants lived in the 20% most deprived local areas in England.&quot;</td>
</tr>
</tbody>
</table>

## Campbell 2008

### Study characteristics

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- 12 weeks

**Duration of follow-up**
- Not reported

#### Participants

**General information**
- **Setting**: single centre (pre-dialysis clinic)
- **Country**: Australia
- **Inclusion criteria**: ≥ 18 years, eGFR < 30 mL/min/1.73 m² (0.50 mL/s/1.73 m²), CKD, not previously seen by a dietitian for stage 4 CKD, absence of communication or intellectual impairment inhibiting their ability to undertake the intervention, absence of malnutrition from a cause other than CKD, and not expected to require KRT within 6 months
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (31); control group (29)
- **Mean age ± SD (years)**: intervention group (71 ± 12.3); control group (68.5 ± 12)
- **Sex (M/F)**: intervention group (14/9); control group (15/9)
- **Stage of CKD**: stage IV and V pre-dialysis CKD

### Other information

*Interventions for improving health literacy in people with chronic kidney disease (Review)*

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
**Interventions**

**Intervention type**
- Self-management

**Intervention group**
- Initial individual consultation with a dietitian, just one for the whole study group, then follow-up phone calls fortnightly for the first month and monthly thereafter. The intervention used self-management principles (goal setting, menu planning, label reading and identification of foods containing protein, sodium etc, depending on requirements) and was individualised to each participant, depending on their level of kidney function, existing symptoms of kidney disease and co-morbidities.

**Control group**
- Received generic nutrition information containing an overview of nutrition advice for CKD and co-morbidity management. No individualised advice or monitoring was provided.

**Outcomes**

**QoL**
- KDQoL-SF with a kidney disease specific module as well as general

**Nutritional status**
- Patient-Generated Subjective Global Assessment (PG-SGA)

**Notes**

**Conflict of interest**
- Not reported

**Funding source**
- "This study was funded in part by a Royal Brisbane and Women's Hospital Foundation Seeding grant, Queensland University of Technology Postgraduate Research Award (PhD scholarship), and an Institute of Health and Biomedical Innovation Research Scholarship."

**Other information**
- Received email from author with QoL raw data

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Patients were randomised to receive either individual counselling with fortnightly telephone follow-up, or standard care (written material only), allocated via a computer-generated number sequence&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Allocated via a computer-generated number sequence, which was concealed to the recruiting officer&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Blinding of both participants and personnel (e.g. dietitian) would not have been possible</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Subjective outcomes with self report questionnaires</td>
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</table>
### Campbell 2008 (Continued)

<table>
<thead>
<tr>
<th>Incomplete outcome data (attrition bias) All outcomes</th>
<th>Low risk</th>
<th>Nine lost to follow-up. No voluntary drop out after week 0. When formally assessed no differences between those that dropped out and treatment groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Both nutritional status and QoL are reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence of other bias</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Study design
- **Parallel RCT**

#### Duration of study
- 1 April 2004 to 31 November 2004

#### Duration of follow-up
- Not reported

#### General information
- **Setting**: single centre
- **Country**: China
- **Inclusion criteria**: not reported
- **Exclusion criteria**: significant cognitive impairment and thus did not understand the food contents during the training course

#### Baseline characteristics
- **Number**: intervention group (35); control group (35)
- **Mean age ± SD (years)**: intervention group (57.57 ± 14.17); control group (52.86 ± 14.86)
- **Sex (M/F)**: intervention group (18/17); control group (15/20)
- **Stage of CKD**: ESKD, just started PD

#### Other information
- There were no significant differences in gender, age, education, or prevalence of diabetes between the two groups

#### Intervention type
- Self-management: one-on-one versus control

#### Intervention group
- Individualised menu suggestions based on their food preferences and education on how to exchange the foods at equivalent amounts according to the exchange list as well as traditional patient education

#### Control group
- Traditional patient education

#### Outcomes
- Nutrition
- Dietary protein intake from self-reported food diary

**Notes**

- **Conflict of interest**
  - Not reported

- **Funding source**
  - Not reported

- **Other information**
  - Emailed asking about allocation concealment

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “all patients were then randomly assigned to 1 of 2 groups using random numbers.”</td>
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<td>Allocation concealment (selection bias)</td>
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<td>Insufficient information to permit judgement</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Both participants and personnel could not have been blinded</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self-report food diary completed by unblinded participants</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Does not seem to be any loss to follow-up or missing data</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Outcome measures were not explicitly stated so unsure if there is missing data</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Patients could have shared the additional menu plans with each other, however as PD is conducted at home this may be less likely in this group</td>
</tr>
</tbody>
</table>

### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - January to December 2008

- **Duration of follow-up**
  - 12 months
**Chen 2011e (Continued)**

### Participants

**General information**
- **Setting**: single centre (outpatients clinic)
- **Country**: Taiwan
- **Inclusion criteria**: incidental CKD (stages III to V); 18 to 80 years; ability to communicate verbally and orally in Taiwanese and Mandarin
- **Exclusion criteria**: cardiovascular disease (coronary artery disease, myocardial ischaemia, cerebrovascular disease or peripheral artery disease) in the last 3 months; infections requiring admission in the previous 3 months; uncontrolled hypertension; serum albumin level of < 2.5 g/dL; unwillingness to participate in the trial

**Baseline characteristics**
- **Number**: intervention group (27); control group (27)
- **Mean age ± SD (years)**: intervention group (67.93 ± 12.87); control group (68.85 ± 14.65)
- **Sex (M/F)**: intervention group (15/12); control group (15/12)
- **Stage of CKD**: stage III to V

**Other information**
- There was no significant difference between groups for variables such as age, gender, marital status, education level, diabetes, hypertension, initial kidney function and CKD stage

### Interventions

**Intervention type**
- Self-management and education: group and one-on-one versus control

**Intervention group**
- Self-management support group: health information, patient education, telephone-based support and the aid of a support group.
- The health information and education included lectures delivered by a case-management nurse focused on kidney health, nutrition, lifestyle, nephrotoxin avoidance, dietary principles and pharmacological regimens
- Patient education consisted of monthly one-on-one meetings on CKD self-management
- Telephone-based support was a weekly telephone call
- The support group took place twice a month; 5 to 10 CKD patients were present at each meeting. Each stage had different information

**Control group**
- Non-SMS patients received customary care from a nephrologist

### Outcomes

**Progression of kidney disease**
- Absolute eGFR alteration, eGFR decrease of up to 50%, ESKD demanding KRT

**Death (any cause)**
- Number of hospitalisations

### Notes

**Conflict of interest**
- "None declared"

**Funding source**
- "Chang Gung Memorial Hospital provided grant support (CMRPG260323) to this study"

**Other information**
Risk of bias

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<thead>
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<th>Bias</th>
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<th>Support for judgement</th>
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<td>Quote: &quot;Sent to a center research nurse who randomized patients into SMS and non-SMS group at a 1:1 ratio by using a random table.&quot;</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
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<td>No mention of whether randomisation was concealed</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither participants or personnel were blinded &quot;open labelled&quot;</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>All outcomes were objective so blinding not thought to affect outcome</td>
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<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;All patients were followed up for at least 1 year after randomization.&quot; No loss to follow-up</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcome data reported</td>
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<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
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</tbody>
</table>

Chen 2011e (Continued)

- Emailed about whether treatment nurse was blinded to allocation

Chen 2012g

Study characteristics

Methods

**Study design**
- Parallel RCT

**Duration of study**
- Not reported

**Duration of follow-up**
- Not reported

Participants

**General information**
- **Setting:** multicentre (6 sites)
- **Country:** China
- **Inclusion criteria:** not reported
- **Exclusion criteria:** not reported

**Baseline characteristics**
- **Number:** 200 (numbers per group not reported)
- **Mean age ± SD (years):** not reported
- **Sex (M/F):** not reported
**Interventions for improving health literacy in people with chronic kidney disease (Review)**

**Chen 2012g** (Continued)

- **Stage of CKD:** not reported

<table>
<thead>
<tr>
<th>Interventions</th>
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</thead>
<tbody>
<tr>
<td><strong>Intervention type</strong></td>
<td></td>
</tr>
<tr>
<td>Education: individual versus control</td>
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</table>

<table>
<thead>
<tr>
<th>Intervention group</th>
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<tbody>
<tr>
<td>Face-to-face education on dietary protein exchange, as well as attention in follow-up is conducted by dietitians</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Control group</th>
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<tbody>
<tr>
<td>Regular face-to-face counselling as well as attention in follow-up is conducted by dietitians</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of diet protein</td>
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</tr>
<tr>
<td>Compliance with dietary protein exchange</td>
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</table>

<table>
<thead>
<tr>
<th>Notes</th>
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<tr>
<td><strong>Conflict of interest</strong></td>
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<table>
<thead>
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<thead>
<tr>
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<th>Authors' judgement</th>
<th>Support for judgement</th>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>&quot;Randomly divided&quot; No mention of how randomisation undertaken</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Blinding of both participants and personnel would not have been possible</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcome assessors were not blinded however knowledge is thought to be an objective outcome</td>
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<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Small loss to follow-up 10%. No analysis of this subset of the population</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other risk of bias</td>
</tr>
</tbody>
</table>
### Study characteristics

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- February 1997 to January 1999

**Duration of follow-up**
- 12 months

#### Participants

**General information**
- **Setting**: The Medical College of Georgia (MCG) Hospital and Clinics
- **Country**: USA
- **Inclusion criteria**: 18 to 60 years; at least 1 kidney transplant; received follow-up care at MCG for at least 1-year post-transplantation, prescribed the same immunosuppressant medication for at least 1-year post-transplantation; received their immunosuppressant medications from the MCG Outpatient Pharmacy for the entire first-year post-transplantation
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (12); control group (12)
- **Mean age ± SD**: 49.2 ± 10.2 years
- **Sex (M/F)**: 18/6
- **Stage of CKD**: ESKD, have received transplant

#### Interventions

**Intervention type**
- Self-management: individual versus control

**Intervention group**
- Monthly medication reviews and counselling by pharmacist focused on the importance of medication compliance.

**Control group**
- Routine care

#### Outcomes

**Compliance**
- Refill records and serum concentration of immunosuppressive agent

#### Notes

**Conflict of interest**
- Not reported

**Funding source**
- This research was supported by a grant from the Carlos and Marguerite Mason Trust Fund

**Other information**
- Not requested

### Risk of bias

---

**Chisholm 2001**

Interventions for improving health literacy in people with chronic kidney disease (Review)  
Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Chisholm 2001 (Continued)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information about how blinding was completed</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Could not of been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcomes were objective, number of refills and amount of drug in the blood</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>No comparison on baseline characteristics between groups</td>
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</table>

### Chisholm-Burns 2013

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Parallel RCT</td>
</tr>
</tbody>
</table>

**Duration of study**

- 1 year

**Duration of follow-up**

- 1 year

#### Participants

**General information**

- **Setting**: multicentre (Avella Specialty Pharmacies based in southwest USA)
- **Country**: USA
- **Inclusion criteria**: at least 21 years; at least 1 year post-transplant to allow for stabilization of the prescribed immunosuppressant therapy regimen; receive an immunosuppressant regimen that contains oral TAC or CSA; obtain their immunosuppressant therapy from Avella for at least 1 year prior to study enrolment and during the study period
- **Exclusion criteria**: not reported

**Baseline characteristics**
Chisholm-Burns 2013 (Continued)

- **Number**: intervention group (76); control group (74)
- **Mean age ± SD (years)**: intervention group (52.78 ± 13.55); control group (51.32 ± 13.69)
- **Sex (M/F)**: intervention group (43/33); control group (41/33)
- **Stage of CKD**: ESKD 1-year post kidney transplantation

**Other information**

- There were no significant differences between the groups at baseline based on characteristics such as age, education, employment, ethnicity, immunosuppressant therapy, marital status, Medicare status, race or type of transplant

**Interventions**

**Intervention type**

- Self-management: individual versus control

**Intervention group**

- Participants met with the study pharmacist in person or by telephone and signed an immunosuppressant therapy adherence contract. Contract reviewed 3, 6 and 9 months post enrolment and progress towards goals discussed.
- Things discussed and negotiated: motivation, barriers, social support, tools and strategies, possible consequences.
- Standard pharmacy care as below.

**Control group**

- Standard pharmacy care: mail or telephone reminders of monthly medication refills and adherence-focused educational pamphlets and a pillbox.

**Outcomes**

All outcomes are objective

- Pharmacy refill records, days in hospital, emergency department visits, outpatient visits and home healthcare visits.

**Notes**

**Conflict of interest**

- "The authors of this manuscript have no conflicts of interest to disclose"

**Funding source**

- "This publication was made possible by grant number 7R01DK081347-04 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIDDK. The study is registered with ClinicalTrials.gov (ClinicalTrials.gov identifier NCT01739803)."

**Other information**

- Not requested

**Risk of bias**

<table>
<thead>
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<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;randomized participants by computerized random number sequence (generated by a biostatistician) to the intervention or control group (1:1 allocation) using a stratified block sampling approach&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>The study participants, coordinator and investigators were not blinded to allocation</td>
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</table>

Interventions for improving health literacy in people with chronic kidney disease (Review)
**Chisholm-Burns 2013 (Continued)**

<table>
<thead>
<tr>
<th>Blinding of participants and personnel (performance bias)</th>
<th>Unclear risk</th>
<th>Pharmacy technician who refill records for data collection was blinded. Study clinical pharmacist who performed intervention was blinded to control group participants.</th>
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<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
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<td>Incomplete outcome data (attrition bias)</td>
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<td>Reasons and numbers for drop out between groups was similar; ITT analysis performed.</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Did not review protocol.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No risk of other bias identified.</td>
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</table>

**Cho 2013a**

**Study characteristics**

**Methods**

**Study design**
- Parallel RCT

**Duration of study**
- November 2007 to January 2008

**Duration of follow-up**
- 4 weeks

**Participants**

**General information**
- **Setting:** single centre
- **Country:** South Korea
- **Inclusion criteria:** ≥ 20 years; receiving dialysis 2 or 3 times/week for at least 3 months; ability to read and communicate in Korean; understood the purpose of the study; and willingness to participate with consent
- **Exclusion criteria:** switching from HD to PD or receiving transplantation during the research period; requiring clinical treatment for physical or mental complications; participating in another intervention

**Baseline characteristics**
- **Number:** intervention group (21); control group (22)
- **Mean age ± SD (years):** intervention group (56.52 ± 12.5); control group (64.23 ±12.19)
- **Sex (M/F):** intervention group (15/6); control group (9/13)
- **Stage of CKD:** ESKD on dialysis

**Other information**
- There was a significant difference found between the two groups in age (P = 0.047) and gender (P = 0.044)
- The other demographic characteristics were not different between groups - marital status, education, religion, occupation, monthly income, frequency of HD, duration of HD, type of HD
Interventions

**Intervention type**
- Self-management versus control

**Intervention group**
- The health contract intervention was used once/week for 4 weeks. Each session lasted between 30 and 60 minutes
- A week prior to each session, participants were provided with and requested to complete a self-care log, which covered fistula management, BP and body weight measurement, exercise, and a dietary intake diary

**Control group**
- Routine care: checking the self-care behaviours of the participants monthly and informing them of the results

Outcomes

**Bloods**
- Serum phosphorus, serum potassium

**Weight gain**
- Mean weight gain

**Self-management**
- Self-care behaviour was measured using an inventory developed by Song 2000 - included activities important for maintaining or improving their health such as fistula management, measurement of BP and body weight, diet, medication, exercise and rest, physical problem management, and social adjustment by themselves

Notes

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Emailed author about allocation concealment

**Risk of bias**

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<thead>
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<th>Support for judgement</th>
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<td>Low risk</td>
<td>Adequate randomisation using a random numbers table</td>
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<td>Insufficient information to permit judgement</td>
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<td>Blinding of participants and personnel (performance bias) All outcomes</td>
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<td>Because of the nature of the intervention participants and personnel were not blinded</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>The researcher was blinded however this is a self care self report questionnaire and the participants were not blinded</td>
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### Cho 2013a (Continued)

<table>
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<tr>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Low risk</th>
<th>Objective outcomes are thought not to be influenced by blinding, although the research assistant completing the outcomes measures was blinded to allocation group</th>
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<td>Low risk</td>
<td>Only one participant was excluded. Does not seem to be any other loss of data</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Did not view protocol</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Gender and age were significantly different between groups</td>
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</table>

### Choi 2012*

**Study characteristics**

**Methods**

- **Study design**
  - Pre-test/post-test design with control group

- **Duration of study**
  - Control group: May 2011 to August 2011
  - Intervention group: September 2011 to March 2012

- **Duration of follow-up**
  - 8 weeks

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: South Korea
  - **Inclusion criteria**: outpatients diagnosed as CKD; hadn’t started KRT; ≥ 20 years; understood the study process and were able to communicate
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - **Number**: intervention group (31); control group (30)
  - **Mean age ± SD (years)**: intervention group (53.93 ± 13.47); control group (58.33 ± 12.54)
  - **Sex (M/F)**: intervention group (21/10); control group (21/9)
  - **Stage of CKD**: stage not defined

- **Other information**
  - No statistical difference between groups at pre-test in terms of gender, age, sex, education, religion, marital status, job, income, type of caregiver, experience of similar education, knowledge, self-care practices, or physiological index

**Interventions**

- **Intervention type**
  - Self-management and education: group and individual versus control

- **Intervention group**
  - Small group face-to-face education and individualized consultation
Pre-program session to identify individual characteristics, face-to-face education, individualised consultation time each session, and re-enforcement education one week later

**Control group**

- No extra education. Was completed first to avoid contamination

### Outcomes

**Progression of kidney disease**

- GFR

**Bloods**

- Indicators of kidney function: urea, creatinine, sodium, potassium, calcium, phosphate, Hb

**Knowledge**

- Knowledge of CKD scale: 20-item CKD knowledge instrument

**Self-management**

- Self-care practice scale for CKD

### Notes

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Not requested

### Risk of bias

<table>
<thead>
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<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Self-care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. BUN/creatinine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Sodium/potassium</td>
</tr>
<tr>
<td></td>
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<td>5. Calcium/phosphate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Hb</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. GFR</td>
</tr>
</tbody>
</table>

**Bias due to confounding**

Moderate: Although some things were controlled for between groups there is still always going to be an un-measurable risk of bias when the two groups undertake a study at different times

**Bias in selection of participants into the study**

Low

**Bias in classification of interventions**

Low

**Bias due to deviations from intended interventions**

Low
Choi 2012* (Continued)

NI: Can't judge fidelity of implementation based on given information

Bias due to missing data
Low

Bias in measurement of outcomes
O1. Moderate
O2. Serious: self-care is subjective
O3-O7. Low: objective measure, no mention of blinding but not important as objective measures

Bias in selection of the reported result
Low

Overall risk of bias judgement
Serious: O2 (self-care)
Moderate: O1/O3-O7 (knowledge and kidney physiology)

Chow 2010

Study characteristics

Methods

Study design
- Parallel RCT with a pre-test and post-test

Duration of study
- Undertaken in 2005

Duration of follow-up
- 12 weeks

Participants

General information
- Setting: multicentre (2 local regional hospitals)
- Country: Hong Kong
- Inclusion criteria: access to a telephone after discharge
- Exclusion criteria: intermittent PD or HD and those with planned admissions for special treatment procedures; Tenckhoff catheters in situ < 3 months

Baseline characteristics
- Number: intervention group (50); control group (50)
- Mean age ± SD (years): intervention group (59.4 ± 13.97); control group (54.5 ± 12.8)
- Sex (M/F): intervention group (28/15); control group (24/18)
- Stage of CKD: on PD

Interventions

Intervention type
- Educational: individual versus usual care

Intervention group
Comprehensive discharge planning protocol including participation of patients and family members in discussions about the plan, assessment of social, physical, cognitive and emotional needs, and an individualised educational program

6-week nurse-initiated telephone follow-up program

Control group

Routine discharge care: standard information and a telephone hotline service, a set of self-help printed materials and an appointment reminder. Control and study group participants received the same routine care during hospitalisation as other patients in the unit

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>KDQoL-SF</td>
</tr>
</tbody>
</table>

Notes

Conflict of interest

"No conflict of interest has been declared by the authors"

Funding source

"The source of funding of this project was Research Grants Council of Hong Kong (PolyU S435/05H)"

Other information

Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Fifty sets of computer-generated random numbers were used, and patients who fitted the criteria were randomized to the study or control group.” Computer generated randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants were not blinded because of nature of intervention. Nurses conducted education and follow-up phone calls and were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Quote: &quot;Data collection was through face-to-face interview.” Self report questionnaire collected through face-to-face interview neither patient nor interviewer were blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>There was a dropout reducing the sample size from 123 to 100; the required size for significant effect was 90 The dropout after randomisation seems similar between the groups</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Non-generalisable sample population</td>
</tr>
</tbody>
</table>
### Study characteristics

#### Methods

**Study design**  
- Parallel RCT

**Duration of study**  
- Not reported

**Duration of follow-up**  
- 7 months

#### Participants

**General information**  
- **Setting**: not reported  
- **Country**: USA

**Inclusion criteria**: serum phosphorus levels of ≥ 6.5 for ≥ 3 consecutive months

**Exclusion criteria**: not reported

**Baseline characteristics**  
- **Number**: intervention group (6); control group (6)
- **Mean age ± SD (years)**: not reported
- **Sex (M/F)**: not reported
- **Stage of CKD**: ESKD on dialysis

#### Interventions

**Intervention type**  
- Self-management: individual versus control

**Intervention group**  
- Met with the study physician monthly for 3 months with a review of food diaries, binder use and compliance, proper diet choices and descriptions of potential vascular complications (in addition to the standard dietician visit)

**Control group**  
- Met with the dietician monthly with a review of labs and diet

**Co-interventions**  
- Both groups were also seen monthly by their nephrologists

#### Outcomes

**Bloods**  
- PO₄, Ca x PO₄ product

#### Notes

**Conflict of interest**  
- Not reported

**Funding source**  
- Not reported

**Other information**  
- Abstract-only publication
### Clark 2010 (Continued)

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
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<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Unclear whether personnel were blinded. Participants could not of been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Probably not blinded but objective outcome measures</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information; does not seem to be any dropouts but a very small sample size</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Unclear</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>No mention of whether control and intervention were significantly different. Small sample size. Was the intensive study physician trained in nutrition education?</td>
</tr>
</tbody>
</table>

#### Cooney 2015

#### Study characteristics

**Methods**

*Study design*
- Parallel RCT

*Duration of study*
- 1 February 2010 to 31 January 2011

*Duration of follow-up*
- Not reported

**Participants**

*General information*
- Setting: multicentre (13 community-based veterans affairs outpatient clinics)
- Country: USA
- Inclusion criteria: moderate to severe CKD defined by a most recent eGFR < 45 mL/min/1.73 m²; GFR < 60 mL/min/1.73 m² between 90 days and 2 years prior to the index GFR to ensure the presence of CKD; at least one primary care visit in the year prior to study initiation
- Exclusion criteria: ESKD, were ever referred for hospice care; > 85 years or < 18 years

*Baseline characteristics*
- Number
Cochrane Database of Systematic Reviews

Interventions for improving health literacy in people with chronic kidney disease (Review)

Cooney 2015 (Continued)

- Information from the registry: intervention group (1070); control group (1129)
- Additional survey (QoL): intervention group (194); control group (95)
  - Mean age (years): intervention group (75.6); control group (75.7)
  - Sex (M/F): intervention group (1054/16); control group (1106/23)
  - Stage of CKD: moderate to severe CKD

Other information
- Patients did not seem to differ significantly between groups in terms of age, gender, race, comorbidities, diabetes, hypertension, CAD, heart failure, systolic BP, eGFR, proteinuria, class of antihypertensives, adherence, QoL.

Interventions

 Intervention type
- Education and self-management training: individual versus control

 Intervention group
- Delivery system which involved engaging pharmacists to interact with patients and collaborate electronically with primary care physicians; self-management support in the form of a handout about CKD and a CKD registry

 Control group
- Usual care

Outcomes

Progression of kidney disease
- Incidence of ESKD

Bloods
- PTH, PO4 and UACR, number of antihypertensives prescribed, treatment with ACE/ARB, phosphorus binders, vitamin D, sodium bicarbonate, medication adherence, percentage of subjects seen by nephrology

Health literacy

QoL
- HRQoL(SF-12) KDQoL short form
- Death (any cause)

BP
- Systolic BP, percentage of patients at goal BP

Adherence
- Medication adherence using the MMAS, acceptability of the intervention

Notes

Conflict of interest
- "The authors declare that they have no competing interests."

Funding source
- "The study was funded in part by the Cleveland VA Medical Research & Education Foundation. Additional support was provided through a Career Development Award K23DK087919 (P.E.D.) from the National Institute of Diabetes and Digestive and Kidney Diseases."

Other information
### Cooney 2015 (Continued)

- Not requested

**Risk of bias**

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<td>Low risk</td>
<td>Quote: “a blinded computer generated randomization list and a 1:1 ratio.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>&quot;Blinded&quot; randomisation</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not able to be blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Subjective outcomes completed by non blinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>The study was not blinded but this is not thought to affect objective outcomes</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>All participants were analysed by ITT. In the control group only 42 lost to follow-up because they did not see a VA during the study period. In the intervention group this number was 23. In the intervention group, 552 did not receive the intervention because of: death, seen but no opt-out letter sent, declined phone call, unable to reach after three phone calls. Similar loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All specified outcome data was reported on</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Only 518 patients in the intervention group received intervention so this may have diluted the benefits, as those who did not get intervention were included in the ITT. No standardised methods for measuring BP, limited ability for the pharmacist to intervene, only 23% were seen by Nephrologists, therefore medication doses would not have been changed</td>
</tr>
</tbody>
</table>

### Cummings 1981

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• RCT; pre-test/post-test</td>
</tr>
</tbody>
</table>

**Duration of study**

- Not reported

**Duration of follow-up**

- 3 months
Cummings 1981 (Continued)

- **Setting**: multicentre (2 outpatient dialysis clinics)
- **Country**: USA
- **Inclusion criteria**: no physical or mental disability; 18 to 80 years; receiving dialysis > 3 months
- **Exclusion criteria**: not reported

**Baseline characteristics**

- **Number**: intervention group 1 (24); intervention group 2 (19); intervention group 3 (28); control group (25)
- **Mean age**: 54.8 years
- **Sex**: 54% males
- **Stage of CKD**: not reported

**Other information**

- No difference was found in characteristics between clinics. A significant difference between groups was found for weight gain \(F(1,92) = 5.24, P < 0.05\); a non-statistical difference was found for patients' average SPL. Also, patients in the weekly telephone contact group were less compliant than patients in the other experimental groups. No difference was found for sociodemographics, medical history, and belief variables

### Interventions

**Intervention type**

- Self-management

**Intervention group 1**

- Individual behavioural contract
  - a. Identifying a behaviour or set of behaviours to be targeted for change in the contract
  - b. Working out a timetable for the specified behaviours and how this can be achieved, along with finding out reward system
  - c. Completing a formal written contract
  - d. Recording progress with rewards as per the contract

**Intervention group 2**

- Behavioural contract with a family member or friend: as above but with a third person selected by the patient included

**Intervention group 3**

- Weekly telephone contacts
  - a. Asking patient what problem they may be having with adherence
  - b. Providing education and information about potential negative health consequences of not adhering to therapy and suggestions for better compliance
  - c. Verbal support to patients for maintaining proper adherence

**Patients were contacted once a week for 6 weeks**

**Control group**

- Routine medical care, which included coming into the clinic for dialysis treatments 2 or 3 times/week and provision of information about their blood levels and weight gains between treatments
- If a patient was experiencing difficulty complying with the treatment regimen a nurse or a dietician would counsel the patient as per usual care

### Outcomes

**Dietary compliance**

- Potassium levels, fluid limit adherence

**Health beliefs**
Cummings 1981 (Continued)

- Perceived susceptibility to noncompliance complications, beliefs about benefits of the diet, barriers related to diet and fluid intake

<table>
<thead>
<tr>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conflict of interest</strong></td>
</tr>
<tr>
<td>Not reported</td>
</tr>
<tr>
<td><strong>Funding source</strong></td>
</tr>
<tr>
<td>Not reported</td>
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<tr>
<td><strong>Other information</strong></td>
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<tr>
<td>Not requested</td>
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</table>

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;Within clinics, patients were randomly assigned to either an intervention program or a control group.&quot; Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Blinding not possible in this setting for either participants or personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Subjective self report questionnaires filled out by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Blinding not thought to affect objective outcomes</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Analysis of drop outs showed attrition, potassium, weight gains and belief scores did not differ significantly; did not use ITT</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Unclear whether results are generalisable</td>
</tr>
</tbody>
</table>

**Study characteristics**

**Methods**

**Study design**

- Parallel RCT

**Duration of study**
**de Araujo 2010 (Continued)**

- Not reported

### Duration of follow-up
- 90 days

## Participants

### General information
- **Setting:** multicentre (2 sites)
- **Country:** Brazil
- **Inclusion criteria:** undergoing HD > 3 months; ≥ 18 years; serum phosphorus 6.0 mg/dL; at least 4 years of formal education
- **Exclusion criteria:** amaurotic patients or with severe secondary hyperparathyroidism (PTH > 1000 pg/mL)

### Baseline characteristics
- **Number:** intervention group (16); control group (17)
- **Age (years):** intervention group (18 to 38 (4); 39 to 59 (5); 60 to 80 (7)); control group (18 to 35 (2); 39 to 59 (11); 60 to 80 (4))
- **Sex (M/F):** intervention group (10/6); control group (8/11)
- **Stage of CKD:** ESKD on HD

### Other information
- No formal analysis of differences between groups was undertaken. From the table, there may be more patients in the intervention group that are functionally literate than in the control group - it is not known whether this difference was significant. Age, gender, time in dialysis and underlying disease states seems to be fairly equal between groups.

## Interventions

### Intervention type
- Education: individual versus control

### Intervention group
- Attended a course instructing participants to avoid food rich in PO$_4$, the correct use of binders, the importance of serum levels of Ca, PO$_4$, Ca x PO$_4$ product, PTH, and manifestations of bone diseases; there were 6 x 30-minute meetings immediately before HD sessions

### Control group
- Attended a course addressing vascular access, types of catheters and arteriovenous grafts; there were 6 x 30-minute meetings immediately before HD sessions

## Outcomes

### Bloods
- Ca, PO$_4$, Ca x PO$_4$ product; PTH

### Knowledge
- Zero questions concerning vascular access and 10 concerning the metabolism of Ca and PO$_4$

### KT/V

## Notes

### Conflict of interest
- Not reported

### Funding source
- Not reported
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No mention of how groups were randomised</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>No mention, but there would have been an opportunity for patients to discuss and share information while on dialysis. So likely high risk. No mention of whether those giving education were part of the research team and those giving education could not have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>No blinding of participants or personnel but as the outcomes were subjective this was not thought to impact result. No mention of how knowledge was assessed (e.g. written versus verbal, who administered the test)</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>No mention of whether the 8 participants were all from one group. As the groups are fairly even at completion may be able to infer loss to follow-up was even in both groups</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>No indication of any bias in reporting. No reporting of urea or creatinine in outcome data however this is not likely to have a big impact on outcomes</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>In terms of the knowledge outcome the control group pretest knowledge was higher (80.1) than the intervention group pre test knowledge (71.2)</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Methods

- **Study design**
  - Parallel RCT and pre-test/post-test

- **Duration of study**
  - July to September 2001

- **Duration of follow-up**
  - 3 months

#### Participants

- **General information**
  - **Setting**: single centre
  - **Country**: UK
  - **Inclusion criteria**: > 18 years; clinically stable; at least 1 phosphate value > 1.7 mmol during a 3-month period
  - **Exclusion criteria**: unable to read English; cannot prepare their own food

#### Baseline characteristics
Interventions for improving health literacy in people with chronic kidney disease (Review)

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

de Brito Ashurst 2003 (Continued)

- Number: intervention group (29); control group (29)
- Mean age, range (years): intervention group (54.2, 22 to 77); control group (53, 23 to 88)
- Sex (M/F): intervention group (10/19); control group (16/13)
- Stage of CKD: ESKD on HD

Other information
- The groups were broadly balanced in terms of patient age, sex, ethnic group, and renal diagnosis

Interventions

Intervention type
- Education: individual using education tool

Intervention group
- One 40-minute session using an educational tool with a dietitian focused on knowledge of phosphate balance in dialysis patients. Individualised advice on diet, medication compliance, and lifestyle. The education package “A Patient’s Guide to Keeping Healthy: Managing Your Phosphate” comprised a booklet, a medication record chart, and a refrigerator magnet

Control group
- Usual care

Outcomes

Bloods
- PO₄, Ca, Ca x PO₄ product

Notes

Conflict of interest
- Not reported

Funding source
- "We thank Genzyme, Inc, for the supply of the education tool. The company had no other part in the design, conduct, or reporting of the trial"

Other information
- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Quote: &quot;They were randomized by random alternate allocation to either the intervention or the control group.&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information. Probably not done because alternate allocation pattern can be worked out</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Quote: &quot;The hemodialysis dietitian did not know which dialysis patients were participating in the study.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Renal dietitian giving advice was blinded to which group the participants were in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The blinding of the other personnel was judged not to affect the outcome</td>
</tr>
</tbody>
</table>
**de Brito Ashurst 2003 (Continued)**

<table>
<thead>
<tr>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Low risk</th>
<th>Not blinded but reviewers do not think this will affect outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Patients who died or underwent transplantation after the intervention were included in all analyses.&quot;</td>
</tr>
</tbody>
</table>
| All outcomes                                  |          | Quote: "One patient died after randomization but before the intervention had taken place, and another moved from our unit to another before the intervention; both of these patients were in the control group, and their data were removed from the study."
|                                              |          | Quote: "Reasons for not obtaining results were patient death (2 patients), patient transplantation (1 patient), and administrative (1 patient)."
|                                              |          | Missing data explained (although does not say which group they were in). Reasons do not seem to be related to intervention |
| Selective reporting (reporting bias)          | Low risk | No reporting of urea or creatinine in outcome data however this is not likely to have a big impact on outcomes |
| Other bias                                    | Unclear risk | May have been some contamination between patients sharing information from the education session. Authors noted wide variation in outcomes within both groups and therefore improved levels due to another factor - e.g. seasonal variation |

**Deimling 1984**

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - 10 weeks

- **Duration of follow-up**
  - 10 weeks

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
  - **Inclusion criteria**: >30 days of dialysis; recipient of routine phosphorus education; free of severe acute illness, recipient of phosphate binder therapy; able to speak and understand English
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - **Number**: intervention group 1 (12); intervention group 2 (13); control group (12)
  - **Mean age (years)**: intervention group (42); intervention group 2 (50); control group (55)
  - **Sex (M/F)**: intervention group (6/6); intervention group 2 (6/7); control group (7/5)
  - **Stage of CKD**: ESKD on HD

- **Other information**
### Interventions

**Intervention type**
- Self-management: provision of materials and individual versus control

**Intervention group 1**
- Phosphorous education: viewed slide/tape program, which was a cartoon outlining standard information about managing your phosphorous

**Intervention group 2**
- Contingency contracting: verbal and/or written agreement for mutually deciding behaviour change after viewing the tape

**Control group**
- No intervention

### Outcomes

**Bloods**
- PO4

**Knowledge**
- Phosphorus knowledge

### Notes

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Not requested

### Risk of bias

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<th>Support for judgement</th>
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</thead>
<tbody>
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<td>Claims &quot;random distribution&quot; but not enough information about how this was done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Patients could not of been blinded.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quote: “all staff informed about study... patient charts and dialysis logs marked signifying phosphorus counselling and contingency contracting would be done by research nurse”</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Bloods and knowledge thought to be objective outcomes not affected by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Two participants dropped in group 3, no mention of other drop-outs</td>
</tr>
</tbody>
</table>
### Deimling 1984 (Continued)

All outcomes

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Low risk</th>
<th>All stated outcomes reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Small sample populations, no mention of whether representative, short follow-up</td>
</tr>
</tbody>
</table>

Quote: "wide fluctuations in serum PO$_4$ and therefore 3 values did not provide enough data to offset fluctuations"

### Devins 2003

**Study characteristics**

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- August 1996 to April 1998

**Duration of follow-up**
- 18 months

#### Participants

**General information**
- **Setting**: multicentre (15 sites)
- **Country**: Canada
- **Inclusion criteria**: chronic renal insufficiency advancing to progressive kidney failure; SCr ≤ 3.4 mg/dL; deemed highly likely by the attending nephrologist to require KRT within 6 to 18 months: ≥ 18 years; able to communicate in English or French.
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (149); control group (148)
- **Mean age (years)**: intervention group (60.1); control group (57.2)
- **Sex (M/F)**: intervention group (78/71); control group (101/47)
- **Stage of CKD**: progressive and expected to require KRT within 6 to 18 months

**Other information**
- There was a significant difference between the groups in relation to sex. All other between-group demographics were similar, including English language, age, income, working for pay, where they lived, creatinine, Hb, albumin, self-rated health, ESKD, uraemic symptoms, diabetes

#### Interventions

**Intervention type**
- Education

**Intervention group**
- A 90-minute interactive, personalised educational intervention delivered by a health educator. Group also received a booklet and supportive telephone calls once on a 3-week bases

**Control group**
• Usual care entailed differing elements across centres

Outcomes

Progression of kidney disease
• Time to dialysis therapy measured in months

Knowledge
• Kidney disease questionnaire expanded to cover the predialysis interval

Anxiety and depression
• Depression and anxiety were represented by the Center for Epidemiologic Studies Depression scale 31-33 and the State-Trait Anxiety Inventory
• Perceived social support was assessed using the Social Support Questionnaire

Notes

Conflict of interest
• Not reported

Funding source
• “Supported in part by research grant no. 6606-5345-403 from the National Health Research and Development Program (G.M.D. and Y.M.B., co-principal investigators); Ortho-Biotech Inc (Y.M.B. and G.M.D., co-principal investigators); and a Senior Investigator Award from Canadian Institutes of Health Research (G.M.D.).”

Other information
• Allocation concealment requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Participants subsequently were randomly assigned to the PPI or usual-care groups by using random number tables.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: “We did not use any concealment methods although we did keep the referring nephrologists blind to their patients’ group membership in the experiment.” - Email from author</td>
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<td>Blinding of participants and personnel (performance bias) All outcomes</td>
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<td>Quote: “Attending nephrologists and other treatment personnel were kept blind to each patient’s group membership within the experiment” but patients unable to be blinded</td>
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<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>Unclear risk</td>
<td>Outcome assessors were blinded but participants were not</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcome assessors were blinded also objective outcome of time to dialysis</td>
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<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: “At the conclusion of the experiment: (1) 89 patients (59.7%) assigned to PPI had started dialysis therapy compared with 106 usual-care patients (71.6%); (2) 19 PPI patients (12.8%) and 11 usual-care patients (7.4%) had died before starting dialysis therapy; (3) 3 PPI patients (2.0%) and 7 usual-care patients (4.7%) had undergone transplantation as their first mode of RRT (i.e., before starting dialysis therapy); (4) 7 PPI patients (4.7%) and 6 usual-care pa-</td>
</tr>
</tbody>
</table>
 DeVins 2003 (Continued)

Patients (4.1%) were lost to follow-up, withdrew from the study, or were transferred to another treatment facility; and (5) 31 PPI patients (20.8%) and 18 usual-care patients (12.2%) were still awaiting the initiation of RRT.

Selective reporting (reporting bias)  Low risk
All outcomes stated were reported

Other bias  Low risk
No risk of other bias identified

Ebrahim 2016

Study characteristics

Methods

Study design
• Quasi-RCT (randomised by day of the week)

Duration of study
• 16 weeks

Duration of follow-up
• 4 weeks

Participants

General information
• Setting: single centre
• Country: Iran
• Inclusion criteria: > 18 years; no evidence psycho-emotional problems and no psychotropic medications; literate; have telephone access at home
• Exclusion criteria: not reported

Baseline characteristics
• Number: intervention group (48); control group (51)
• Mean age ± SD (years): intervention group (51.6 ± 11.9); control group (50.3 ± 10.1)
• Sex (M/F): intervention group (31/17); control group (30/21)
• Stage of CKD: ESKD on HD

Other information
• No significant difference was found in baseline demographic comparison between groups

Interventions

Intervention type
• Educational intervention: group versus control

Intervention group
• 30 to 40-minute face-to-face education session followed by 10 to 15 minutes to answer questions. Twice a week for 12 weeks

Control group
• Usual care

Outcomes

Knowledge
Ebrahim 2016 (Continued)

- Dietary questionnaire created for this study
- QoL
- KDQoL

Notes

**Conflict of interest**
- "Authors declare that they have no conflict of interest"

**Funding source**
- "This study was sponsored by the Vice Chancellor for research at Shahroud University of Medical Sciences (research grant no. 9116)"

**Other information**
- Not requested

### Risk of bias

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<th>Bias</th>
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<th>Support for judgement</th>
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<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Randomisation was based on day of the week for dialysis</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Unable to conceal allocation with this randomisation method</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Due to the nature of the intervention the participants could not be blinded</td>
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<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self report questionnaire by unblinded participants</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcomes should not be affected by blinding of outcome assessors</td>
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<td>Incomplete outcome data (attrition bias) All outcomes</td>
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<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
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### ELITE 2013

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel, cluster RCT</td>
</tr>
</tbody>
</table>
Duration of study
• December 2010 to June 2012

Duration of follow-up
• 1 week

Participants
General information
• Setting: single centre
• Country: USA
• Inclusion criteria: initial kidney transplant evaluation at Saint Barnabas Medical Center; ≥ 18 years; able to provide informed consent; speak, hear, and understand English.
• Exclusion criteria: neurocognitive disability that would prevent participants from understanding the study or completing the questionnaires; inability to speak, hear, and understand English; visual impairment and inability to complete self-administered questionnaires; self-described unwillingness or inability to complete phone questionnaires

Baseline characteristics
• Number: intervention group (249); control group (250)
• Mean age ± SD (years): intervention group (53.8 ± 12.5); control group (53.6 ± 12.8)
• Sex (M/F): intervention group (171/178); control group (155/95)
• Stage of CKD: transplant candidates

Interventions
Intervention type
• Educational intervention: individual versus usual care

Intervention group
• Intensive education: a 20-minute educational video about LDKT and met for 15 minutes with a transplant educator to discuss LDKT

Control group
• Usual care

Co-interventions
• Both groups received standard transplant education

Outcomes
Knowledge
• Knowledge of LDKT at 1 week after transplant, measured using a 20-point scale

Readiness to accept a LDKT
• Readiness to ask a friend/family member to donate and confidence that they could receive a LDKT

Notes
Conflict of interest
• “The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.”

Funding source
• “The project described was supported by grant R39-OT15059 from the Division of Transplantation, Health Resources and Services Administration, US Department of Health and Human Services.”

Other information
## Risk of bias

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<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer generated randomisation</td>
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<td>Allocation concealment not possible</td>
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<td>Participants and personnel were not blinded</td>
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<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
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<td>Readiness to accept transplant, self efficacy and decisional balance are all subjective measures and the study was not blinded</td>
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<td>Unclear risk</td>
<td>Knowledge is an objective outcome. Outcome assessors were not blinded</td>
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<td>Other bias</td>
<td>Low risk</td>
<td>Study appears free of other biases</td>
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</table>

## ESCORT 2014

### Study characteristics

#### Methods

- **Study design**
  - Cluster RCT

- **Duration of study**
  - 2 years

- **Duration of follow-up**
  - 24 months

#### Participants

- **General information**
  - **Setting**: multicentre (by district)
  - **Country**: Thailand
  - **Inclusion criteria**: aged 18 to 70 years; diabetes and/or hypertension; eGFR 15 to 59 mL/min/1.73 m² estimated twice, 3 months apart
• Exclusion criteria: unstable/advanced cardiovascular diseases; obstructive uropathy; HIV infection; pregnancy; BMI < 18 or > 40 kg/m²; untreated malignancy; UPCR > 3.5 g/g; active urinary sediments

Baseline characteristics

• Number: intervention group (234); control group (208)
• Mean age ± SD (years): intervention group (62.3 ± 6.4); control group (62.4 ± 7.9)
• Sex (M/F): intervention group (64/170); control group (56/152)
• Stage of CKD: stage 3 to 4

Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational and self-management intervention: group versus usual care</td>
</tr>
</tbody>
</table>

Intervention group

• Integrated CKD care program delivered in a group, including a demonstration of optimal diets, medication and exercise

Control group

• Standard care

Outcomes

<table>
<thead>
<tr>
<th>Progression to ESKD</th>
</tr>
</thead>
<tbody>
<tr>
<td>eGFR, SCr</td>
</tr>
<tr>
<td>QoL</td>
</tr>
<tr>
<td>Thai SF-36</td>
</tr>
</tbody>
</table>

Death

Cardiovascular events

Notes

Conflict of interest

• "The authors declare that they have no competing interests."

Funding source

• "This study was supported by research grants of ISN-Global Outreach Clinical Research & Prevention Program (Grant Number #07-004), Ministry of Public Health (Thailand), Bhumirajanagarindra Kidney Institute Foundation, The Medical Association of Thailand and The Government Pharmaceutical Organization of Thailand"

Other information

• Not requested

Risk of bias

<table>
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<th>Support for judgement</th>
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<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Cluster randomisation by district</td>
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<td>Allocation concealment (selection bias)</td>
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</tr>
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<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Study characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Parallel RCT</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Duration of study</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 2009</td>
<td></td>
<td></td>
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<tr>
<td><strong>Duration of follow-up</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 month after last education session</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>General information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Setting: single centre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Country: Iran</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inclusion criteria: patients with kidney failure being treated with HD whose anxiety or depression score was eight or greater according to HADS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Exclusion criteria: experiencing new stressful events during the time of study based on the Holmes-Rahe list of stressful life events; any change in dialysis schedule; starting any other psychiatric treatment during the study; known history of previous psychiatric disorder; having a new stressor during previous 6 months except for those related to kidney disease; failure to attend in all educational sessions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Baseline characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Number: intervention group (27); control group (28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mean age ± SD (years): intervention group (49.14 ± 14.52); control group (52.29 ± 15.58)</td>
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<td></td>
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<tr>
<td>• Sex (M/F): intervention group (13/14); control group (14/14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Stage of CKD: ESKD on dialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention type</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Education and self-management: group versus control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Espahbodi 2015 (Continued)

Intervention group
• Three x 1-hour group educational sessions pre-dialysis with a nephrologist and a psychiatrist focused on anatomy, pathophysiology, causes of kidney failure, variety of treatments with advantages and disadvantages of each, education of dialysis mechanism, necessary care for dialysis patients, problem-solving skills, stress management, adaptive response in humans and muscle relaxation

Control group
• Normal care

Outcomes
Anxiety and depression
• HAD questionnaire

Notes
Conflict of interest
• "None declared"

Funding source
• "We would like to thank Mazandaran University of Medical Sciences for financial support."

Other information
• Emailed author about additional information on randomisation method with no response to date

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;The patients were divided into two groups by a random allocation after being somewhat matched according to intervening factors such as age, gender, marital status, education level, duration of dialysis and number of dialysis per week.&quot; Insufficient information about randomisation process</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self report subjective questionnaire completed by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;Two patients were excluded from the dialysis group with psycho education. This happened due to a change in dialysis schedules. Besides, one patient was excluded from this group because of having a new stressor during the study. Similarly, in control group (the dialysis group without psycho education) two patients were excluded, one due to changes in dialysis schedule and another due to having a new stressor. Therefore, this study was followed by 27 patients in the dialysis group with psycho education and 28 patients in the control group. Similar drop outs between groups for similar reasons.&quot;</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
</tbody>
</table>
Espahbodi 2015

Study characteristics

Methods

Study design
- Parallel RCT

Duration of study
- Enrolment September 2013 to August 2014

Duration of follow-up
- 2 years

Participants

General information
- Setting: multicentre (3 nephrology offices)
- Country: USA
- Inclusion criteria: > 18 years with 2 consecutive eGFR of 0 to 30 mL/min/1.73 m²
- Exclusion criteria: significant cognitive impairment

Baseline characteristics
- Number: intervention group (61); control group (65)
- Mean age ± SD (years): intervention group (66.2 ± 15.8); control group (64.5 ± 15.5)
- Sex (M/F): intervention group (37/24); control group (40/25)
- Stage of CKD: stage 4/5

Other information
- There were no significant differences in baseline characteristics between groups

Interventions

Intervention type
- Education and self-management

Intervention group
- Patient-centred education on CKD, which is health literate, self-management support, and treatment options, was provided to participants and their caregivers in their homes. Motivational interviewing was used to improve comprehension and communication
- Other elements included dietary education, medication reconciliation and a home safety assessment.
- The use of an automated weight recording service and the provision of a weighing scale

Control group
- Usual care by their nephrologist

Co-interventions
- Nurses were given electronic updates of patients' progress

Outcomes

Hospitalisation rate/patient/year

Percentage of home dialysis therapy starts, type of access
**Fishbane 2017** (Continued)

**Notes**

- **Conflict of interest**
  - “The authors declare that they have no relevant financial interests.”

- **Funding source**
  - "None"

- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<tbody>
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<td>Quote: &quot;Patients were randomly assigned using a computer-generated schedule to receive either the Healthy Transitions intervention or usual care (control) in a 1:1 ratio&quot;</td>
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<td>High risk</td>
<td>Participants and personnel were not blinded</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcomes not thought to be impacted by blinding</td>
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<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Analyses were performed using the ITT principle, modified</td>
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<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All prespecified outcomes accounted for</td>
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<tr>
<td>Other bias</td>
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<td>No risk of other bias identified</td>
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</table>

**Flesher 2011**

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th><strong>Study design</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel RCT</td>
</tr>
</tbody>
</table>

- **Duration of study**
  - 12 months

- **Duration of follow-up**
  - 12 months
Flesher 2011 (Continued)

Participants

General information
- Setting: recruitment was multicentre, and eligible patients were referred to 1 centre
- Country: Canada
- Inclusion criteria: eGFR 20 to 60 mL/min for > 3 months; presence of urinary protein; > 19 years; hypertension or taking at least 1 antihypertensive medication; physician approval to exercise
- Exclusion criteria: not reported

Baseline characteristics
- Number: intervention group (23); control group (17)
- Mean age ± SD (years): intervention group (63.4 ± 12.1); control group (not reported)
- Sex (M/F): intervention group (14/9); control group (not reported)
- Stage of CKD: eGFR 20 to 60 mL/min for > 3 months

Interventions

Intervention type
- Education and self-management: group versus control

Intervention group
- Standard nutritional care (as below)
- Group CKD nutrition class: CKD cooking classes with a dietitian and cook educator, CKD cookbook and a 12-week exercise program led by a Certified Exercise Physiologist (CEP) and Nurse. The cooking classes were offered over 4 weeks for 2 hours a session and one shopping outing

Control group
- Standard nutritional care: dietary counselling on protein, sodium, and individualised changes for potassium/phosphate

Outcomes

Bloods
- Cholesterol, sodium

Self-management questionnaire

BP

Physical Activity Readiness Questionnaire

Anthropometrics and musculoskeletal fitness measures

Resting measures of cardiovascular health

6-minute submaximal walk test

Notes

Conflict of interest
- Not reported

Funding source
- "The only financial support for this study came from $1500 grant from the Vancouver Coastal Health Professional Research Award 2008."

Other information
- Not requested

Risk of bias
### Flesher 2011 (Continued)

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<td>Insufficient information to permit judgement</td>
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<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Patients could not have been blinded. Health professionals providing exercise and cooking class could not have been blinded, unclear whether these were also study personnel</td>
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<td>Subjective self report on self-management by unblinded participants</td>
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</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Two participants in the control group and 3 from the experimental group did not complete the study. One experimental participant died during the research project for an unrelated health reason Small drop out seems even between groups</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Quote: &quot;A recommended sample size of 102 was made with a statistician before starting the study. However, despite extensive attempts, only 45 subjects were recruited who met inclusion criteria and who were willing to participate in our program.&quot; Did not have a large enough sample size however corrections were made Quote: &quot;The total probability or P-value was calculated to be.028 for all 5 endpoints, indicating statistical significance despite the smaller sample size&quot;</td>
</tr>
</tbody>
</table>

### Ford 2004

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
<th>Duration of study</th>
<th>Duration of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel RCT; pre-test/post-test</td>
<td>6 months</td>
<td>6 months</td>
</tr>
</tbody>
</table>
Ford 2004 (Continued)

Participants

General information
- Setting: multicentre (3 sites)
- Country: USA
- Inclusion criteria: mean phosphorous > mg/dL over a 3-month period
- Exclusion criteria: hearing-impaired; nursing home patients; sight-impaired; not mentally competent to answer questions

Baseline characteristics
- Number: intervention group (31); control group (31)
- Mean age ± SD (years): intervention group (18 to 35 (3), 36 to 50 (7), 51 to 75 (17), 75+ (5)); control group (18 to 35 (3), 36 to 50 (3), 51 to 75 (21), 75+ (4))
- Sex (M/F): intervention group (11/21); control group (13/18)
- Stage of CKD: ESKD on HD with high phosphorous

Other information
- No significant differences were found between the groups in demographic variables such as serum albumin, appetite, weight or laboratory values. There was a significant difference in the knowledge level of the two groups. The average pretest score of the intervention group was 59.7% ± 18% correct versus 50.3% ± 18% in the control group (P > 0.05)

Interventions

Intervention type
- Education

Intervention group
- 20 to 30 minutes of additional diet education each month focused on phosphorus control. Educational tools included posters, handouts, puzzles, and a tailored phosphorus tracking tool. The patients monitored their phosphorus levels with the tracking tool

Control group
- Routine care, including a review of the monthly laboratory report by the dietitian without additional patient education materials

Outcomes

Bloods
- Calcium, phosphorus, PTH, Ca x PO₄ product levels

Knowledge of phosphorus
- Test developed by researchers for this trial

Notes

Conflict of interest
- Not reported

Funding source
- Not reported

Other information
- Email from authors: personnel were not blinded; no more information about dropouts

Risk of bias

Bias
Authors’ judgement | Support for judgement
--- | --- | ---

Interventions for improving health literacy in people with chronic kidney disease (Review)
Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
Random sequence generation (selection bias)       Low risk
Quote: "The subjects were randomly assigned to an experimental or a control group using a random numbers table."

Allocation concealment (selection bias)          Low risk
Quote: "Each patient was assigned a case study number to ensure confidentiality, and all signed consent forms indicating their agreement to participate."

Blinding of participants and personnel (performance bias)
All outcomes                                    High risk
Dietitian not blinded and gave the knowledge test verbally and therefore may have influenced answers
Participants not blinded

Blinding of outcome assessment (detection bias)
Objective outcomes                              Low risk
Not blinded however outcomes thought to be objective measures

Incomplete outcome data (attrition bias)
All outcomes                                     Low risk
Quote: "total of 63 patients completed the 6-month study. Those who did not complete the study included 1 patient who received a kidney transplant, 3 who relocated to other dialysis centers, and 3 who died. Of the 63 patients who completed the study, 32 were in the intervention group and 31 were in the control group."
Similar completion rates in both groups with small drop out rate

Selective reporting (reporting bias)             Low risk
All stated outcome measures were reported

Other bias                                       High risk
Knowledge levels significantly lower in control group at baseline

Forni 2012

Study characteristics

Methods

Study design
- Parallel RCT

Duration of study
- January 2010 to April 2012

Duration of follow-up
- 9 months

Participants

General information
- Setting: multicentre (9 sites)
- Country: Switzerland
- Inclusion criteria: daily dose of cinacalcet > 30 mg for at least one month; iPTH values in or above target range
- Exclusion criteria: intolerance to cinacalcet; previous or planned parathyroidectomy; hypocalcaemia; inability to understand the protocol; mental diseases; short-life expectancy (< 6 months)

Baseline characteristics
- Number: intervention group (24); control group (26)
- Mean age ± SD (years): intervention group (61.3 ± 9.8); control group (59.1 ± 15.6)
- Sex (M/F): intervention group (13/9); control group (15/4)
### Stage of CKD: ESKD on dialysis

### Other information
- Baseline characteristics were comparable with regard to age, sex, dialysis time, biologic parameters, and prescription of drugs except for a higher paricalcitol dose in the treatment group at baseline \( (P < 0.05) \)

### Interventions

#### Intervention type
- Self-management: individual versus control

#### Intervention group
- Integrated care: semi-structured motivational interviews every 2 months to discuss medication adherence. MEMS graphical report allowed the direct visualization of date and hour of the box openings. Barriers to adherence and strategies to overcome these discussed resulting in the formation of a tailored adherence plan

#### Control group
- Usual care: no adherence data were available throughout the study

### Outcomes

#### Adherence
- Dose of cinacalcet taken
- PTH levels

### Notes

#### Conflict of interest
- "The authors report that they have no other relevant financial interests"

#### Funding source
- "A research grant has been obtained from Amgen"

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “A central randomization system was used, assigning participants within centers in blocks of four.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information but probably done because used a centralised randomisation system</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Not blinded but the personnel prescribing drugs were not the same as those assessing the data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High risk of contamination between groups as same physician treated both groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>All outcomes are objective. Study was not blinded but this was not thought to affect outcome</td>
</tr>
</tbody>
</table>
### Forni 2012 (Continued)

<table>
<thead>
<tr>
<th>Incomplete outcome data (attrition bias)</th>
<th>Unclear risk</th>
<th>All outcomes</th>
</tr>
</thead>
</table>
| **Quote:** "Out of the 50 patients initially enrolled and included in the study null = 24 in the IC group, null = 26 in the UC group, five patients in the IC group and four in the UC group did not complete the study period, for several reasons: kidney transplantation null = 2), death null = 1), incident neoplastic disease null = 2), cinacalcet-related de novo gastrointestinal side effects null = 1), and violation of the predefined exclusion criteria of previous or planned parathyroidectomy for suspected tertiary hyperparathyroidism null = 3). Only patients who completed the six-month study period were considered in the final analysis."
| Small loss of follow-up with similar reasons between group however did not use ITT analysis |

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>Insufficient information to permit judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other bias</strong></td>
<td>Unclear risk</td>
<td>Small sample size therefore not generalisable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Biochemistry measured locally, therefore may have residual variance in laboratory parameters</td>
</tr>
</tbody>
</table>

### Giacoma 1999

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT; pre-test/post-test
- **Duration of study**
  - March 1994 to March 1996
- **Duration of follow-up**
  - Not reported

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
  - **Inclusion criteria**: not reported
  - **Exclusion criteria**: unable to read English, did not have primary responsibility for their own care management after discharge
- **Baseline characteristics**
  - **Number**: 59 (numbers per group not reported)
  - **Mean age ± SD**: 41.1 ± 13.7 years
  - **Sex (males)**: 57/6%
- **Other information**
  - Limited information about the size of groups, specific demographics and comparison between groups

**Interventions**

- **Intervention type**
  - Educational intervention: provision of materials versus usual care
**Intervention group**
- Standard discharge teaching in combination with discharge video of two parts: 1. reviewed transplant medication 2. discussed general post-discharge care activities

**Control group**
- Standard discharge teaching: use of teaching checklist and review of a discharge book

**Outcomes**
- Knowledge of organ transplant test developed in the study
- Readmission to hospital

**Notes**
- **Conflict of interest**
  - Not reported
- **Funding source**
  - Not reported
- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomly picked envelope by participants</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Envelopes were sealed</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Impossible to blind person giving intervention. Participants could not have been blinded - as would know if received video</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Knowledge and readmission to hospital are objective outcomes therefore blinding not thought to affect outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>No mention of specifically how many in each group or how many lost to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>All outcomes stated in the paper were reported. Added outcomes that were not found at start of paper</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Used an non-validated knowledge test; small sample size</td>
</tr>
</tbody>
</table>

**Giacoma 1999 (Continued)**

**Study characteristics**

**Methods**

**Study design**
Hall 2004* (Continued)

- Longitudinal prospective quasi-experimental design study

**Duration of study**
- 2 years

**Duration of follow-up**
- Not reported

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Setting: multicentre (18 PD sites)</td>
</tr>
<tr>
<td></td>
<td>Country: USA</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: new to PD training</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: non-English speaking; legally blind without sighted caregiver; nursing home residents</td>
</tr>
</tbody>
</table>

**Baseline characteristics**
- Number: intervention group (246); control group (374)
- Mean age ± SD (years): intervention group (53.9 ± 15.1); control group (53.6 ± 29.0)
- Sex (M/F): intervention group (113/133); control group (113/133)
- Stage of CKD: ESKD using PD at home

**Other information**
- There were significantly more females in the treatment group than the control group. There was no difference between groups in terms of ethnicity, diabetes or age

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Educational and self-management intervention: individual versus usual care</td>
</tr>
</tbody>
</table>

**Intervention group**
- Adult learning theory-based teaching on PD

**Control group**
- Non-standardised conventional teaching on PD

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Bloods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transferrin saturation, albumin, calcium, ferritin, Hb, PTH, Kt/V</td>
</tr>
</tbody>
</table>

**Weight gain**
- Fluid balance: weight, BP, absence of oedema, dyspnœa, crackles, dizziness, orthostatics

**Adherence**
- Rated by nurses on a 5-point scale

**Occurrence of infection**
- Time to first infection and number of infections/month/patient

**Hospitalisations**

<table>
<thead>
<tr>
<th>Notes</th>
<th>Conflict of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not reported</td>
</tr>
</tbody>
</table>

*Interventions for improving health literacy in people with chronic kidney disease (Review)*
Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Reduced training time to train patients to use PD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Decreased infections</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Longer retention on PD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Improved fluid balance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Improved compliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Decreased hospitalizations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Improved outcomes in relation to anaemia, adequacy, osteodystrophy and nutrition</td>
</tr>
</tbody>
</table>

**Bias due to confounding**

Moderate: The large sample size and the inclusion of many sites located around many areas indicates to me they did all they could to decrease bias due to confounding. Study seems sound for a non-randomised study with regard to this domain but cannot be considered comparable to a well-performed randomised trial

**Bias in selection of participants into the study**

NI: Recruitment process not detailed

**Bias in classification of interventions**

Low

**Bias due to deviations from intended interventions**

NI: cannot judge fidelity of implementation based on given information

**Bias due to missing data**

NI: Limited information about dropouts or planned data collection or planned analyses

**Bias in measurement of outcomes**

NI: not enough information to make a judgement from any of the outcomes

**Bias in selection of the reported result**

Low

**Overall risk of bias judgement**

Moderate: All outcomes judged at moderate risk of bias in at least one domain
## Study characteristics

### Methods

<table>
<thead>
<tr>
<th>Study design</th>
<th>Parallel RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of study</strong></td>
<td>Recruited December 2011</td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
<td>21 weeks</td>
</tr>
</tbody>
</table>

### Participants

<table>
<thead>
<tr>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Setting</strong>: single centre</td>
</tr>
<tr>
<td><strong>Country</strong>: UK</td>
</tr>
<tr>
<td><strong>Inclusion criteria</strong>: PD patients identified as non-adherent to fluid restrictions; receiving PD (CAPD and APD) for ≥ 3 months; ≥ 18 years; willing to participate in a group intervention; able to speak and/or read English</td>
</tr>
<tr>
<td><strong>Exclusion criteria</strong>: Cognitive impairment; receiving psychological treatment/intervention; significant vision or hearing impairment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong>: intervention group (8); control group (7)</td>
</tr>
<tr>
<td><strong>Mean age ± SD (years)</strong>: intervention group (60 ± 14.1); control group (60.1 ± 12.2)</td>
</tr>
<tr>
<td><strong>Sex (M/F)</strong>: intervention group (8/0); control group (6/1)</td>
</tr>
<tr>
<td><strong>Stage of CKD</strong>: ESKD on PD identified as non-adherent to fluid restrictions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Differences between groups at baseline in terms of demographics were not formally analysed and do not seem to differ too much however very small sample size, so hard to judge</td>
</tr>
</tbody>
</table>

### Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education: liquid intake program versus control</td>
</tr>
</tbody>
</table>

#### Intervention group

| Liquid intake program delivered in group format 6-8 people for 1-hour sessions once/week for 4 weeks. Used CBT techniques - educational, cognitive and behavioural - to assist self-management of fluid. Also provided with structured manual including record sheets, goal setting sheets and daily planners for fluid intake and relaxation CD |

<table>
<thead>
<tr>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not reported</td>
</tr>
</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid overload using the 3 outcomes; weight, BP and visible oedema</td>
</tr>
<tr>
<td>QoL</td>
</tr>
<tr>
<td>HADS and SF-36</td>
</tr>
<tr>
<td>BP</td>
</tr>
<tr>
<td>Health beliefs or attributions relating to fluid adherence (VAS)</td>
</tr>
</tbody>
</table>
Conflict of interest

• “The authors declare no conflicts of interest”

Funding source

• “This research was supported by the Renal Service at the Royal Wolverhampton NHS Trust”

Other information

• Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Randomized into the IG or CG by simply drawing numbers out of a bag; allocated to each group in a sequential order.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Does not seem to be any allocation concealment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Quote: “There was no form of blinding in this study; due to the active nature of group attendance and participation, this could not be concealed.”</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Study was not blinded so subjective outcomes could be at risk of bias</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Objective outcomes thought not to be affected by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Quote: “An intention-to-treat analysis was used for any participants lost to follow-up. In the current study, there were no missing data for those who were retained in the study.”</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Intervention group different with respect to less anxiety and more confidence with fluid control at baseline; small sample size (n = 15)</td>
</tr>
</tbody>
</table>

Hasanzadeh 2011

Study characteristics

Methods

Study design

• Parallel RCT

Duration of study

• Not reported

Duration of follow-up
Participants

- General information
  - Setting: single centre
  - Country: Iran
  - Inclusion criteria: 18 to 65 years; able to read and write; no cognitive, hearing, and/or visual disorders, HD > 6 months < 8 years 2 to 3 times/week for 3-4 hours; no previous formal education about diet
  - Exclusion criteria: not reported

Baseline characteristics

- Number: intervention group 1 (38); intervention group 2 (37)
- Mean age ± SD (years): intervention group 1 (50.8 ± 10.7); intervention group 2 (48.7 ± 12.5)
- Sex (M/F): intervention group 1 (19/19); intervention group 2 (26/11)
- Stage of CKD: ESKD on HD

Other information

- There were no significant differences between the groups at baseline in terms of age, sex, marital status, education, career, monthly income, insurance type, smoking, number of dialysis sessions, durations of HD

Interventions

- Intervention type
  - Education: face-to-face versus video-based

  Intervention group 1 (face-to-face)
  - Two 30 to 45-minute sessions were run with a 1-week gap during the dialysis

  Intervention group 2 (video)
  - Tape with 2 different episodes was broadcasted with a 1-week gap also during dialysis

Outcomes

- Attitudes about fluid and diet adherence

Notes

- Conflict of interest
  - Not reported

- Funding source
  - Not reported

- Other information
  - Received email from Professor Moonaghi with additional demographic material

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Randomised according to day and shift of HD</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Not done due to randomisation method above</td>
</tr>
</tbody>
</table>

Hasanzadeh 2011 (Continued)
### Hasanzadeh 2011 (Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants could not be blinded and personnel were probably not</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self report questionnaire about attitudes towards fluid and diet adherence Subjective measure participants were not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement; no mention of loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Different educations provided by different mediums</td>
</tr>
</tbody>
</table>

Quote: “In face to face group, two 30-45 min sessions were run with 1 week gap during the dialysis. In the other group a tape with 2 totally different episodes were broadcasted with a 1 week gap also during dialysis”

### Hed-SMART 2011

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Parallel, cluster RCT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
<th>3 years, 9 months intervention</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Duration of follow-up</th>
<th>2 months post-intervention</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Setting: multicentre (14 dialysis centres)</td>
</tr>
<tr>
<td></td>
<td>Country: Singapore</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: HD for at least 6 months; ≥ 21 years; willing to attend all sessions of the self-management programme</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: unable to give informed consent; unable to understand spoken English and/or Mandarin, Malay, or Tamil dialects to allow effective communication with the intervention facilitator(s) and/or Research assistants; diagnosis of functional psychosis or organic brain disorder; impaired cognition; major visual or hearing impairments, or other sensory or motor impairments that may prohibit completion of the scheduled assessments; unable to participate in a group program (e.g. house-bound); limited life expectancy due to co-morbid illness such as malignancy</td>
</tr>
<tr>
<td></td>
<td>Baseline characteristics</td>
</tr>
<tr>
<td></td>
<td>Number: intervention group (101); control group (134)</td>
</tr>
<tr>
<td></td>
<td>Mean age ± SD (years): intervention group (53.1 ± 10.5); control group (53.9 ± 10.4)</td>
</tr>
<tr>
<td></td>
<td>Sex (M/F): intervention group (54/47); control group (83/51)</td>
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<tr>
<td></td>
<td>Stage of CKD: ESKD on HD</td>
</tr>
</tbody>
</table>
## Interventions

### Intervention type
- HED-SMART self-management intervention versus usual care

### Intervention group
- Group-based intervention consisted of 3 x 90-minute sessions 2 weeks apart facilitated by 2 healthcare professionals (medical social worker, renal nurse, renal dietician and/or psychologist). Telephone follow-up 2 months post-intervention to assess progress made in relation to goals set. Patients will be contacted by telephone 2 months post-intervention by one of the group facilitators (either psychologist, nurse or social worker) to assess the progress they are making with their goals. Booster session also provided 3 months post-intervention.

### Control group
- Usual care

## Outcomes

### Progression of kidney disease
- ESRD-SI

### Bloods
- Serum phosphate and Ca x PO4 product, serum potassium

### Weight gain
- IDWG

### Health literacy
- Health Education Impact Questionnaire

### QoL
- KDQoL-SF kidney disease short form, WHOQoL-BREF

### Self-efficacy
- Dialysis-specific Self-Efficacy Scale, Self-efficacy for managing chronic disease scale

### BP

### Adherence
- Renal Adherence Attitudes Questionnaire, Renal Adherence Behaviour Questionnaire; beliefs about medication, MARS, 6 other items developed for the study about adherence and qualitative sub-study

### Anxiety and depression
- HADS

## Notes

### Conflict of interest
- "The authors declare that they have no other relevant financial interests"

### Funding source
- "The study was funded by the NKF Singapore Research Fund (NKFRC2008/07/24) and Ministry of Education-NUS Academic Research Fund (FY2007-FRC5-006). Dr Griva received research funding from NKF Singapore."

### Other information
- Not requested
### Hed-SMART 2011 (Continued)

**Risk of bias**

<table>
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<td>Participants were not blinded which may affect self report questionnaires</td>
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### Hernandez-Morante 2014

**Study characteristics**

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**Duration of study**

- January to May 2012

**Duration of follow-up**

- 4 months

**Participants**

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<tr>
<td>• Setting: single centre</td>
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<td>• Country: Canada</td>
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<tr>
<td>• Inclusion criteria: ≥ 18 years, receiving HD therapy &gt; 6 months; stable haemodynamic condition</td>
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<tr>
<td>• Exclusion criteria: transferred to another unit of HD, following any renal drug therapy that would interfere with plasma metabolite concentrations during the study period; poor cognitive impairment or a psychiatric disorder; active inflammatory or infectious disease; pregnant; hospitalised during the study period</td>
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</tbody>
</table>
Baseline characteristics

- Number: intervention group (60); control group (60)
- Mean age ± SE (years): intervention group (71 ± 1); control group (72 ± 2)
- Sex (M/F): not reported
- Stage of CKD: ESKD on HD

Other information

- Baseline characteristics between groups were significantly different in total serum protein (higher in oral supplement group) and creatinine (higher in oral supplement group). Other demographics such as age, weight, BMI, time of kidney insufficiency, time of HD and other more detailed blood were similar between groups

Interventions

Intervention type

- Education versus food supplement

Intervention group

- Nutritional education program: 12 sessions, weekly for the first 2 months and fortnightly for the next 2 months. Group therapy with 2 to 3 participants, topics included nutrition requirements and recommended foods, daily food delivery, and cooking

Control group

- Oral supplement: Nepro, a lactose-free formula that is designed for ESKD patients 3 days/week for 4 months

Outcomes

Progression of kidney disease

- GFR

Bloods

- Protein, creatinine, potassium, calcium, sodium, phosphorus, ferritin, Hb, glucose, lipid levels, CRP

Notes

Conflict of interest

- "A. S.-V. is a member of the private Fresenius Medical Care Clinic. The other authors have no conflict of interest to declare"

Funding source

- "This work was partially supported by a PMAFI-PI-04/11 grant from the Catholic University of Murcia"

Other information

- Not requested

Risk of bias

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<td>Quote: &quot;Randomization was performed through a computer-generated number sequence&quot;</td>
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<td>Allocation concealment</td>
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<td>Quote: &quot;Randomization was performed through a computer-generated number sequence that was concealed from the researchers until after baseline assessment&quot;</td>
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**Hernandez-Morante 2014 (Continued)**

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<th>Bias Type</th>
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| Blinding of participants and personnel (performance bias)  | High | Participants: not blinded because of nature of intervention  
Personnel: unblinded after baseline assessments          |
| Blinding of outcome assessment (detection bias)             | Low  | Study was not blinded but all outcomes are objective measures so blinding not though to affect outcome |
| Incomplete outcome data (attrition bias)                   | Low  | Quote: "To verify that dropout from the study was not related to initial nutrition knowledge or biochemical parameters, a t test analysis comparing patients who completed the study and those who did not was performed; however, no significant difference between both groups in any of the parameters analyzed was observed" |
| Selective reporting (reporting bias)                       | High | There is missing biochemical data which was stated to be outcome measures and other measures reported which were not originally stated as outcome measures |
| Other bias                                                  | Low  | There may have been some contamination between groups sharing information                                                               |

**HOUSE CALLS 2012**

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - 2-years post-randomisation

- **Duration of follow-up**
  - Monthly until 2-year end-point

**Participants**

- **General information**
  - **Setting:** home or in-centre
  - **Country:** USA
  - **Inclusion criteria:** self-identification as black race; ≥ 21 years; approved for placement on the kidney transplantation waiting list; resides ≤ 2.5 hours driving time from the transplant centre
  - **Exclusion criteria:** required multiorgan transplantation; did not speak English; active substance abuse; cognitive or psychiatric disorders significant enough to interfere with study requirements

- **Baseline characteristics**
  - **Number:** intervention group 1 (54); intervention group 2 (49); intervention group 3 (49)
  - **Mean age ± SD (years):** intervention group 1 (50.9 ± 12.4); intervention group 2 (51.8 ± 12.3); intervention group 3 (51.4 ± 2.5)
  - **Sex (M/F):** intervention group 1 (31/23); intervention group 2 (27/22); intervention group 3 (29/20)
  - **Stage of CKD:** on kidney transplant waiting list

**Other information**
Interventions for improving health literacy in people with chronic kidney disease (Review)

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HOUSE CALLS 2012 (Continued)

- Participants were significantly younger than non-participants (P = 0.02). The intervention groups did not differ significantly in sociodemographic or clinical characteristics

## Interventions

### Intervention type

- Educational intervention: home versus group versus usual care

### Intervention group 1 (HOUSE CALLS)

- Occurred in the participant’s home with family and friends of their choosing

### Intervention group 2 (GROUP BASED)

- Session was held in the transplant centre and also included other study patients and their invited guests, mirroring the group-based living donor kidney transplant education done at some centres

### Intervention group 3 (INDIVIDUAL COUNSELLING)

- One-on-one education in the transplant centre

## Outcomes

### Knowledge

- Living donor kidney transplant knowledge

### Occurrence of living donor kidney transplant

- Within 2 years of intervention or 2 years after randomisation for patients who didn’t receive the allocated intervention; whether the patient had living donor inquiries; whether they had living donor evaluations by the 2-year endpoint; living donor kidney transplant readiness stage, living donor kidney transplant concerns, and willingness to talk to others about living donors

## Notes

### Conflict of interest

- “O.E. was a faculty member and transplant nephrologist at Beth Israel Deaconess Medical Center and Harvard Medical School during the development and initial implementation of the study. He is now employed as Clinical Research Medical Director for Amgen, Inc., although Amgen has not been involved in any way with the study reported in this article.”

### Funding source

- “The project described is supported by Award Number R01DK079665 from the National Institute of Diabetes and Digestive and Kidney Diseases (J.R.R.).” “This research was also supported, in part, by the Julie Henry Research Fund and the Center for Transplant Outcomes and Quality Improvement, The Transplant Institute, Beth Israel Deaconess Medical Center, Boston, MA.”

### Other information

- Not requested

## Risk of bias

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### HOUSE CALLS 2012 (Continued)

#### All outcomes

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<tr>
<th>Blinding of outcome assessment (detection bias) Subjective outcomes</th>
<th>High risk</th>
<th>Self report questionnaire with unblinded participants for outcomes willingness to talk about, living kidney donor transplant readiness stage, concerns</th>
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<td>Objective outcomes included knowledge, number of inquiries and evaluations</td>
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<td>Incomplete outcome data (attrition bias) All outcomes</td>
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<td>Quote: &quot;Participants were significantly younger than nonparticipants (P=0.02). In all, 87% and 89% completed the 1- and 6-week follow-up questionnaires, respectively. The 2-year endpoint was unknown for three patients, who transferred care to other centers and the final outcome could not be verified.&quot; Could be slightly more drop out from individual counselling group. Not much information on reasons why there was drop out</td>
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#### Huang 2007b

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - January 2005 to December 2006

- **Duration of follow-up**
  - 14 days

**Participants**

- **General information**
  - Setting: single centre
  - Country: China
  - Inclusion criteria: > 18 years; kidney transplant recipient; normal kidney function, SCr < 160 μmol/L; can talk and read without problems
  - Exclusion criteria: not reported

- **Baseline characteristics**
  - Number: intervention group (62); control group (62)
  - Mean age (range): 41 years (22 to 68)
  - Sex (M/F): 122/2
  - Stage of CKD: kidney transplant recipients

**Interventions**

- **Intervention type**
  - Education: one-on-one versus control
Intervention group
- Patient education about health in kidney transplant recipients

Control group
- Usual care

Outcomes
- Knowledge about kidney transplantation
- Ability to comprehend treatment and drug compliance

Notes
- Conflict of interest
  - Not reported

Funding source
- Not reported

Other information
- Not requested
- Chinese article

Risk of bias

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</table>

iChoose 2018

Study characteristics
Methods

**Study design**
- Parallel RCT

**Duration of study**
- Recruited December 2014 to October 2015

**Duration of follow-up**
- Immediately post-intervention

Participants

**General information**
- **Setting**: multicentre (3 sites)
- **Country**: USA
- **Inclusion criteria**: 18 to 70 years; no solid or multiorgan transplant; English speaking; no severe cognitive or visual impairment
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (226); control group (217)
- **Mean age ± SD (years)**: intervention group (51.1 ± 9.9); control group (50.1 ± 10.3)
- **Sex (M/F)**: intervention group (143/83); control group (134/83)
- **Stage of CKD**: ESKD

Interventions

**Intervention type**
- Clinical decision aid

**Intervention group**
- iChoose clinical decision aid used to improve patient’s knowledge about risk estimate of patient survival on dialysis versus kidney transplantation, and living versus deceased donor transplants

**Control group**
- Usual care

Outcomes

- Knowledge
- Covariates included health literacy via the Newest Vital Sign (*Weiss 2005*)

Notes

**Conflict of interest**
- "The authors of this manuscript have no conflicts of interest to disclose"

**Funding source**
- "We would like to thank Norman S. Coplon Satellite Healthcare Foundation for funding this project"

**Other information**
- Not requested

**Risk of bias**

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*Interventions for improving health literacy in people with chronic kidney disease (Review)*

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### iChoose 2018 (Continued)

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### InformMe 2017

**Study characteristics**

#### Methods

- **Study design**
  - Parallel RCT

- **Duration of study**
  - October 2013 to July 2014

- **Duration of follow-up**
  - 1-week post-test

#### Participants

- **General information**
  - Setting: multicentre (2 sites)
  - Country: USA
  - **Inclusion criteria**: ≥ 21 years; English speaking; never received a kidney from an IRD, reported “never,” “rarely,” or “sometimes” to the health literacy question: “How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?” and willingness and ability to use an iPad 2 tablet
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - Number: intervention group (133); control group (155)
  - Mean age ± SD (years): intervention group (51.2 ± 11.3); control group (50.5 ± 12.3)
  - Sex (M/F): intervention group (78/65); control group (97/58)
  - Stage of CKD: ESKD awaiting transplantation

#### Interventions

- **Intervention type**
  - Education: provision of materials versus control
Intervention group

- Inform Me: an iPad app which aimed to improve patient’s comprehension and informed consent about increased risk donor kidneys. Five chapters: introduction, definition of increased risk, screening for infection, risk and benefits, and treatment & follow-up. They also received standardised education

Control group

- Standardised education

Outcomes

<table>
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<th>Knowledge score</th>
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<tr>
<td>31-item multiple-choice test</td>
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<tr>
<td>Decisional conflict</td>
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<tr>
<td>Willingness to accept increased risk donor kidney</td>
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Notes

- **Conflict of interest**
  - “The authors declare no conflicts of interest”

- **Funding source**
  - “This publication was supported by the NINR/NLM (R21NR013660 to E.J.G.).”

- **Other information**
  - Not requested

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<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
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### INTENT 2014

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Recruitment March 2014 to July 2015

- **Duration of follow-up**
  - 12 months

**Participants**

- **General information**
  - Setting: single centre
  - Country: New Zealand
  - Inclusion criteria: kidney transplant recipients with stable graft function
  - Exclusion criteria: BMI > 40 kg/m² or < 18.5 kg/m²; significant malnutrition (requiring enteral/parenteral nutrition therapy); ongoing significant medical complications, as determined by the physician

- **Baseline characteristics**
  - Number: intervention group (18); control group (18)
  - Mean age ± SD (years): intervention group (49.2 ± 14.6); control group (48.3 ± 13.9)
  - Sex (M/F): intervention group (12/6); control group (13/5)
  - Stage of CKD: transplant recipients

**Interventions**

- **Intervention type**
  - Education and self-management: individual versus control

- **Intervention group**
  - Eight sessions with a renal dietitian, fortnightly for the first 3 months, then monthly for the next 3 months then second monthly for the last 3 months. Motivational interviewing, personalised action plans and patient-centred goals. Also included a tailored exercise program at 2, 3 and 6 months

- **Control group**
  - Standard care: a consultation during the inpatient stay and 1-3 more consultations focused on nutrition at 1, 3 and 12 months post-transplant

**Outcomes**

- Weight gain
- Biochemistry
- QoL
- Body composition
- Physical function

**Notes**

**Conflict of interest**
"The authors declare that they have no relevant financial disclosures or other conflicts of interest"

**Funding source**

"This study was funded by a project grant from the Auckland District Health Board Charitable Trust and a grant from the Australian and New Zealand Society of Nephrology."

**Other information**

- Not requested

### Risk of bias

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### Jasinski 2018

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - July 2015 to March 2016

- **Duration of follow-up**
  - 6 months
Participants

General information

- Setting: single centre
- Country: USA
- Inclusion criteria: inpatient with a family member or friend who was able to participate
- Exclusion criteria: delirium; inability to speak English

Baseline characteristics

- Number: intervention group (60); control group (60)
- Mean age ± SD (years): intervention group (58 ± 14); control group (57 ± 15)
- Sex (M/F): intervention group (30/30); control group (30/30)
- Stage of CKD: ESKD

Interventions

Intervention type

- Educational and self-management training: individual versus usual care

Intervention group

- In-person or telephone motivational counselling with both the participant and the support person prior to discharge. This included education about cognitive impairment, results of the cognitive assessment, support options and tailored information based on the results of the screening tools

Control group

- No intervention post-initial assessment

Outcomes

- Readmission within 30 days
- Unplanned hospital visit

Notes

- Conflict of interest
  - "None"

- Funding source
  - "This research was supported by the Blue Cross Blue Shield of Michigan Foundation and Wayne State University, and is on the basis of the doctoral dissertation of M.J.J., under the direction of M.A.L."

- Other information
  - Not requested

Risk of bias

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<td>Blinding of participants and</td>
<td>High risk</td>
<td>Unable to blind due to nature of intervention</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Jasinski 2018  (Continued)

<table>
<thead>
<tr>
<th>Objective outcomes</th>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Low risk</th>
<th>Outcome assessors were blinded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Low loss to follow-up and ITT analysis undertaken</td>
</tr>
<tr>
<td></td>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>No selective reporting found</td>
</tr>
<tr>
<td></td>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

Joost 2014*

Study characteristics

Methods
Study design
- Non-RCT

Duration of study
- August 2008 to July 2010

Duration of follow-up
- 1 year post-transplant hospital discharge

Participants
General information
- Setting: single centre
- Country: Germany
- Inclusion criteria: 18 years; German-speaking; independent of others for medication management or questionnaire completion and willing as well as able to repetitively visit the outpatient clinic for educational training, pharmacy refill and MEMS data collection; immunosuppressive regimen including MMF/MPA
- Exclusion criteria: not reported

Baseline characteristics
- Number: intervention group (32); control group (35)
- Mean age ± SD (years): intervention group (54 ± 11.9); control group (51 ± 13.3)
- Sex (M/F): intervention group (24/15); control group (27/8)
- Stage of CKD: ESKD, just had kidney transplant

Other information
- There were no significant differences between groups in terms of age, sex, marital status, employment, donor type, number of transplants, immunosuppressive drug therapy, antibody induction therapy

Interventions
Intervention type
- Education and self-management: one-on-one versus control

Intervention group
Educational, behavioural and technical interventions lead by a clinical pharmacist for a minimum of 3 sessions within the first 3 weeks after transplantation. Intensive care group patient training was individualised, repetitive and redundant, covered 12 months instead of 2 weeks and included more aspects, and practical strategies for medication management

**Control group**

- Standard care: written information via a handout; a standardised training session by the physician and a training session with the nurses. Regular follow up visits as per usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Progression of kidney disease</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>eGFR</td>
</tr>
<tr>
<td></td>
<td>HRQoL</td>
</tr>
<tr>
<td>Adherence</td>
<td>Assessed using SF-36</td>
</tr>
<tr>
<td>MEMS bottle adherence measurement with supplementary sheets to explain overestimation of non-adherence</td>
<td></td>
</tr>
<tr>
<td>Anxiety and depression</td>
<td>HADS-D</td>
</tr>
<tr>
<td>Number of biopsy-proven rejections</td>
<td></td>
</tr>
</tbody>
</table>

**Notes**

- **Conflict of interest**
  - "None declared"

- **Funding source**
  - "This work was supported by an AMGEN PhD student grant (R.J.) for the advancement of research in Clinical Pharmacy"

- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td>Outcomes</td>
</tr>
</tbody>
</table>

1. MEMS BOTTLE MEASUREMENTS
   a. Percentage of days with correct dosing of MMF/MPA
   b. Taking adherence (percentage of doses taken (bottle opening) in comparison to total number of doses prescribed)
   c. Timing adherence (percentage of doses taken within 3hrs before or after patients’ standard intake time)
   d. Number of drug holidays
   2. Adherence rates measured by pill count
   3. Self-reported adherence
   4. Transplant function (eGFR)
   5. Number of biopsy-proven rejections
   6. HRQoL

**Bias due to confounding**
Moderate: Probably still not comparable to a well-performed randomised trial, but reliability and validity of critically important domains were sufficient and we don’t expect serious residual confounding

**Bias in selection of participants into the study**
Low

**Bias in classification of interventions**
Low

**Bias due to deviations from intended interventions**
NI: Seems pretty good but some information missing regarding implementation fidelity

**Bias due to missing data**
Moderate: Data reasonably complete

**Bias in measurement of outcomes**
O1. Moderate: Adherence data recorder according the information on the documentation sheets - self-report introduces bias into an otherwise unbiased measurement tool
O2/O4/O5. Low

**Bias in selection of the reported result**
Moderate: Measured adherence in three ways

**Overall risk of bias judgement**
Serious: O3/O6 (Adherence questionnaire and QoL)
Moderate: O1/O2/O4/O5 (MEMS, pill count, GFR and rejections)

---

**Karamanidou 2008**

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-RCT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Setting: multicentre (3 sites)</td>
</tr>
<tr>
<td></td>
<td>Country: UK</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: on HD for at least 6 months; on phosphate-binding medication</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria: not reported</td>
</tr>
</tbody>
</table>
Baseline characteristics

- **Number**: intervention group (19); control group (20)
- **Mean age ± SD (years)**: intervention group (57.7 ± 14.86); control group (59.2 ± 16.92)
- **Sex (M/F)**: intervention group (10/9); control group (10/10)
- **Stage of CKD**: ESKD on HD

Other information

- No significant differences were found between the groups in terms of age, time on dialysis, marital status, employment status, ethnicity

Interventions

**Intervention type**

- Education: individual versus control

**Intervention group**

- Two components: a leaflet to improve patients' understanding of the effects of high phosphate and phosphate-binding medication, and a demonstration of the phosphate-binding medication in action using a transparent stomach-shaped container

**Control group**

- No intervention

Outcomes

**Bloods**

- Phosphate levels

**Knowledge**

- 12-item true/false questionnaire assessing the level of kidney patients' knowledge of phosphate level management

**Self-efficacy**

- Medication outcome efficacy belief: scored 1-7, where a higher score indicated a stronger self-efficacy

**Phosphate-binder coherence**

- Understanding problems of high phosphate levels, risk perceptions MARS

Notes

**Conflict of interest**

- Not reported

**Funding source**

- “This paper was supported by an unrestricted educational grant from Shire Pharmaceuticals.”

**Other information**

- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td>Outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Necessity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Risk perception</td>
</tr>
</tbody>
</table>
Karamanidou 2008* (Continued)

4. Understanding of high phosphate
5. Medication outcome efficacy
6. General understanding
7. Phosphate binder coherence
8. MARS
9. Phosphate levels

Bias due to confounding
Moderate: Study is sound for a non-randomised study but cannot be considered comparable to a well-performed randomised trial

Bias in selection of participants into the study
Low

Bias in measurement of interventions
Low

Bias due to departures from intended interventions
Low

Bias due to missing data
NI: Proportions of missing participants are not similar. However, there was analysis. Not enough information to come to a conclusion

Bias in measurement of outcomes
01/04/06/09. Low
02/03/05/07/08. Serious: Self-report questionnaires of subjective measures

Bias in selection of the reported result
Moderate

Overall bias: Serious
Serious: 02/03/05/07/08 (necessity, risk perception, efficacy, phosphate binder coherence, MARS)

Moderate: Knowledge, understanding, phosphate levels

Karavetian 2014

Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Parallel cluster RCT (randomised by HD units)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of follow-up</td>
<td>14 months</td>
</tr>
</tbody>
</table>
Setting: multicentre (12 sites)
Country: Lebanon
Inclusion criteria: ≥ 18 years; HD patients of Lebanese origin; free of life-threatening acute disease with life expectancy > 6 months; on HD > 3 months; full capacity of cognitive, psychiatric and physical ability for self-care and communication; capable of communicating either verbally or through writing; fully aware of procedure of the study; able to provide consent form
Exclusion criteria: not reported

Baseline characteristics
Number: intervention group 1 (133); intervention group 2 (299); control group (138)
Mean age: 59.28 years
Sex (M/F): intervention group 1 (73/60); intervention group 2 (174/125); control group (79/59)
Stage of CKD: ESKD On HD

Interventions
Intervention type
Education and self-management: one-on-on versus control

Intervention group 1 (dedicated dietician)
Individualised 15-minute education session twice/week for 6 months provided by renal dietitians within HD units

Intervention group 2 (trained hospital dietician)
Hospital dietitian education when available to do so. Dietitian was educated by the study investigator

Control group
Routine dietetic care in the hospital

Outcomes
Knowledge
Patient’s knowledge about kidney disease, renal diet, phosphate binders, vitamin D therapy and their perception of the importance of diet in their treatment assessed with Knowledge questionnaire

Self-management
Stages of behavioural change

QoL
SF-36

Adherence
Dietary non-adherence questionnaire adapted from the SPAN (School Physical Activity and Nutrition).

Nutrition
Dietary phosphorus and protein intake

Malnutrition Inflammation Score

Notes
Conflict of interest
Not reported

Funding source
“This work was supported by the National Council for Scientific Research (CNRS), Lebanon.”

Other information
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “Half of the patients in cluster 1 were randomly chosen according to their dialysis shift and assigned to the intensive protocol (dietitian dedicated—DD), and the other half served as control (existing practice—EP).” Randomised based on dialysis shift</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation concealment not usually an issue in cluster randomised trials</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Hospital staff were provided with the general aim of the study protocol for ethical reasons, but they were blinded to the specific patient-oriented dietary education, outcome assessors and data analysis - patients could have broken this, and the nature of this intervention could not have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Unblinded researcher collected information about stage of change, which is a subjective measurement. Five questionnaires - no mention of who administered or if validated</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Biochemical and frequency of dietitian visits were measured through hospital records</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Thirty per cent loss to follow-up, no mention if significant differences with those who completed the study. 176/570 participants did not complete the study, this was evenly divided between groups and reasons seem to be similar</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Not all stated outcomes were reported (from previous publication)</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Baseline characteristics were different between groups</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Methods

**Study design**
- Parallel RCT

**Duration of study**
- Not reported

**Duration of follow-up**
- 12 weeks

#### Participants

**General information**
- **Setting:** single centre
- **Country:** USA
- **Inclusion criteria:** 25 to 65 years, systolic BP > 150 mm Hg and diastolic BP > 90 mm Hg
Exclusion criteria: HD < 6 months; scheduled for transplant; history of illicit drug use, mental illness or dementia; lack of orientation to person time or place; having a major health problem such as terminal cancer or HIV

Baseline characteristics
- **Number**: intervention group (17); control group (17)
- **Mean age ± SD (years)**: intervention group (47.8 ± 9.9); control group (49.5 ± 11.9)
- **Sex (M/F)**: intervention group (5/12); control group (6/11)
- **Stage of CKD**: ESKD on HD

Other information
- No significant differences between the groups at baseline in terms of age, gender, education, marital status, income, and medications. No significant difference in systolic BP as baseline however, the home BP monitoring group had a lower average diastolic BP, which was taken into account in the analysis.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Self-monitoring</td>
</tr>
</tbody>
</table>

**Intervention group**
- Memory-equipped Omron IC automatic home BP monitor and asked to record their BP twice a day, taught how to use it in one session, then seen weekly for any questions and to test it was working correctly

**Control group**
- Usual care - BP assessment during each HD treatment and discussion about this at the time

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fluid gain</td>
</tr>
<tr>
<td></td>
<td>BP</td>
</tr>
<tr>
<td></td>
<td>Reduction in BP</td>
</tr>
</tbody>
</table>

Notes
- **Conflict of interest**
  - Not reported
- **Funding source**
  - “This study is funded by Blue Cross Shield of Michigan Foundation Student Award Program”
- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>Random numbers table</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Low risk</td>
<td>Quote: “sealed in an opaque envelope and stored in a file box”</td>
</tr>
</tbody>
</table>
### Kauric-Klein 2007 (Continued)

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Risk</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Cannot blind due to nature of intervention. Unclear as to whether PI knew which group patients were in initially but likely this would have been broken during PI meetings with all participants each week</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcome data was objective, so was at low risk of bias from unblinded participants or personnel</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Two patients dropped out of the study it does not day which group they are in. All other data accounted for</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcome data was reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

### Kauric-Klein 2012

#### Study characteristics

**Methods**

- **Study design**
  - Parallel cluster RCT

- **Duration of study**
  - Not reported

- **Duration of follow-up**
  - 12 weeks

**Participants**

- **General information**
  - **Setting**: multicentre (6 HD units)
  - **Country**: USA
  - **Inclusion criteria**: > 18 years, high BP average for four weeks, systolic BP > 150 mm Hg, diastolic BP > 90 mm Hg; read and spoke English
  - **Exclusion criteria**: HD < 6 months; scheduled for kidney transplant; illicit drug use history; history of mental illness; lack of orientation to person, time or place; major health problems such as terminal cancer or HIV; missing more than two HD treatments over a 4-week baseline screening period

- **Baseline characteristics**
  - **Number**: intervention group (59); control group (59)
  - **Mean age ± SD (years)**: intervention group (63.4 ± 16.4); control group (56 ± 14.8)
  - **Sex (M/F)**: intervention group (28/31); control group (32/27)
  - **Stage of CKD**: ESKD on HD

- **Other information**
  - The control group was entirely African American and significantly younger and had less yearly income than the treatment group

**Interventions**

- **Intervention type**
• Education and self-monitoring tool versus standard care

**Intervention group**

• Two education sessions, 12-week monitoring, goal setting and reinforcement and post-intervention follow-up period. The content of the sessions was based on the NKF clinical guidelines for hypertension in ESKD; pathophysiology, risks, self-care interventions/goals and role of self-regulation in behavioural change. Second session focused on BP, fluid and sodium. Asked to record the above and bring in results every week to HD. The investigator visited those in the treatment group every week, offering support and goal setting

**Control group**

• Standard care: BP monitoring and medication adjustments by the healthcare providers in the HD unit as needed

**Outcomes**

- Weight gain
  - IDWG, along with self-report questionnaire of fluid intake
- Knowledge
  - BP control in HD knowledge scale developed by the author
- Self-efficacy
  - BP control in HD self-efficacy scale adapted from the original scale used for diabetes
- Average BP
  - BP control self-monitoring was measured as adherence to recommended guidelines for monitoring BP twice daily, sodium and fluid twice weekly. BP control self-evaluation was measured as number of weekly goals met
- Medication adherence
  - MMAS
- HD adherence
  - Total number of HD missed
- Nutrition
  - Sodium intake self-report questionnaire; revised 16-item sodium intake scale

**Notes**

- **Conflict of interest**
  - Not reported
- **Funding source**
  - "Sources of funding support: ANNA Evidence Based Practice Research Grant, Graduate School and College of Nursing at Wayne State University Dissertation Research Support Grant"
- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>

*Interventions for improving health literacy in people with chronic kidney disease (Review)*

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### Kauric-Klein 2012 (Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Clusters randomised by flipping a coin</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No mention of allocation concealment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Cannot blind due to nature of intervention</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Unblinded participants self reporting levels of self-efficacy</td>
</tr>
<tr>
<td>Knowledge and BP thought to be objective measures, low risk of bias from lack of blinding</td>
<td>Low risk</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Many of the logs pertaining to fluid intake and sodium record were not completed the patients reported that filling out forms part of the intervention was too labour-intensive... No reported loss to follow-up, and results table does not show any dropouts</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcome data reported on</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Exclusion criteria said they excluded anyone who had missed more than 2 HD appointments in two week period. This could of skewed the participants in terms of adherence to therapy, as this is one of the outcomes this could create a bias in the results. This is a cluster study; the HD units were allocated at random but when the patients were asked if they wanted to be in the study - did they already know what group they would be in if they said yes? Also, there were significant differences between the control and intervention groups because of the difference between the HD units allocated to each group</td>
</tr>
</tbody>
</table>

### Kazawa 2015*

#### Study characteristics

**Methods**

- **Study design**
  - 2-group comparison study

**Duration of study**

- March 2010 to December 2012

**Duration of follow-up**

- 24 months

**Participants**

- **General information**
  - Setting: multicentre (20 sites)
  - Country: Japan
  - Inclusion criteria: eGFR 15 to 59 mL/min/1.73 m²; 20 to 74 years
### Exclusion criteria
- current KRT; cognitively impaired or mental disorders; pregnancy

### Baseline characteristics
- **Number**: intervention group (31); control group (31)
- **Mean age ± SD (years)**: intervention group (66.9 ± 4.3); control group (64.1 ± 5.8)
- **Sex (M/F)**: intervention group (20/11); control group (20/11)

### Other information
- Intervention group had additional requirement of being insured by the company running the trial. Control group was chosen from the same hospitals based on matching demographics

### Interventions

#### Intervention type
- Education and self-management: individual versus control

#### Intervention group
- Education was conducted via face-to-face interviews in the participant's home or the clinic every 2 weeks. Then phone calls every month from months 3 to 12. Education focused on diet, drug therapy, exercise/rest balance, lifestyle changes, stress and self-monitoring. It also included a booklet about CKD and self-management

#### Control group
- Usual care

### Outcomes

#### Progression of kidney disease
- eGFR; number initiating KRT

#### Bloods
- HBA1C, urea, nitrogen, Hb, protein, albumin, potassium, inorganic phosphate, non-HDL-cholesterol

#### Weight gain
- BMI

#### Self-management
- Percentage of day/month patients performed self-management behaviours

#### QoL
- WHOQOL-BREF

#### Self-efficacy
- Self-efficacy scale of health behaviour in patients with chronic disease

#### BP

### Notes

#### Conflict of interest
- "The authors declare that they have no conflicts of interest"

#### Funding source
- Not reported

#### Other information
- Not requested
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Initiation of KRT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Physiological indicators: HbA1c, SCr, eGFR, BUN, Hb, total protein, albumin,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>potassium, inorganic phosphate, non-HDL cholesterol, BP, BMI, urine protein</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Self-efficacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. QoL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Percentage of days self-management behaviour completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias due to confounding</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: This study has a potentially high risk of bias due to confounding. The</td>
</tr>
<tr>
<td></td>
<td></td>
<td>intervention group was chosen based on insurance cover, which means they could differ</td>
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<tr>
<td></td>
<td></td>
<td>from the control group in many ways however not enough information to make a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>judgement as there was no information about whether or not the control group was</td>
</tr>
<tr>
<td></td>
<td></td>
<td>insured. Also, there was a significant difference at baseline in relation to age and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>QoL</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias in selection of participants into the study</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NI: No information about the selection of participants into the study</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias in classification of interventions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias due to deviations from intended interventions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Low</td>
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<tr>
<td></td>
<td></td>
<td><strong>Bias due to missing data</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: Reasons for missing data are different between groups. Reason for on</td>
</tr>
<tr>
<td></td>
<td></td>
<td>drop out related to outcome</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias in measurement of outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>O1. Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O2. Serious: Measure taken sporadically by a nurse in control group and by assessor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in the intervention group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O3/O4. Serious: Self-report questionnaires of subjective measures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O5. Critical: Real bias relying on memory of subjects also performance bias as</td>
</tr>
<tr>
<td></td>
<td></td>
<td>subjects were not blinded</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bias in selection of the reported result</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Overall risk of bias judgement</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: O1/O2/O3/O4 (KRT initiation, physiological indicators, self-efficacy, QoL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Critical: O4 (self-management behaviour)</td>
</tr>
</tbody>
</table>

Kazawa 2015* (Continued)
### Study characteristics

#### Methods

<table>
<thead>
<tr>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parallel RCT (stratified according to setting and disease)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group (19 to 997 days); intervention group (5 to 1010 days)</td>
</tr>
</tbody>
</table>

#### Participants

<table>
<thead>
<tr>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting: multicentre (2 sites)</td>
</tr>
<tr>
<td>Country: USA</td>
</tr>
<tr>
<td>Inclusion criteria: patients with congestive heart failure or ESKD receiving medical care and had clinical symptoms that indicated a risk of serious complication or death in the next 2 years; patients with ESKD had a serum albumin concentration &lt; 3.7 g/dL and a serious comorbidity</td>
</tr>
<tr>
<td>Exclusion criteria: &lt; 18 years; not able to make decisions; not able to speak or understand English</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number: intervention group (70); control group (64)</td>
</tr>
<tr>
<td>Mean age ± SD (years): intervention group (); control group ()</td>
</tr>
<tr>
<td>Sex (M/F): intervention group (); control group ()</td>
</tr>
<tr>
<td>Stage of CKD: ESKD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>No separate information about the demographics of the kidney patients, but the average age overall was late 50s, predominately female, married and protestant</td>
</tr>
</tbody>
</table>

#### Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational and self-management: group versus usual care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC-ACP: a 1-1.5h interview with the participant and a surrogate conducted by a trained facilitator focused on assessing understanding of and experiences with the illness, providing information about disease-specific treatment options, documenting and assisting the surrogate to understand the participants treatment preferences</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual care included assessment of an advance directive on admission and standard advance directive counselling</td>
</tr>
</tbody>
</table>

#### Outcomes

<table>
<thead>
<tr>
<th>Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation of dialysis treatment</td>
</tr>
</tbody>
</table>

#### Notes

<table>
<thead>
<tr>
<th>Conflict of interest/Funding source</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;This study was supported by 1 R01 HS013374–01 from the Agency of Health Care Research and Quality awarded to Dr. Kirchhoff. Dr. Hammes and Ms. Briggs are employed by the Gundersen Lutheran Medical Foundation, Inc. which owns the rights to the Respecting Choices program, of which the intervention used in the current study, Disease-Specific Advance Care Planning, is part. Dr. Kehl was supported by Grant 1UL1RR025011 from the Clinical and Translational Science Award program of the National Institutes of Health, National Center for Advancing Translational Sciences, to the University of Wisconsin-Madison Clinical and Translational Science Institute. The authors report no conflicts of interest. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.&quot;</td>
</tr>
</tbody>
</table>

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**Interventions for improving health literacy in people with chronic kidney disease (Review)**

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Kirchhoff 2010 (Continued)

Center for Research Resources, National Institutes of Health, during the final year of this project. Dr. Brown has no conflicts of interest. Karin T. Kirchhoff, Bernard J. Hammes, and Linda A. Briggs have been asked to speak on this topic and may have other grants funded as for this study. Hammes and Briggs do training workshops on the intervention at their institution.

Other information

- Received email from Kirchhoff explaining that the data was separated but only for the outcome of discontinuing dialysis - not an outcome we are interested in. The knowledge outcome was not separated so cannot use.

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “The project director generated the allocation sequence using a computerized random number generator.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: “using the sealed-envelope method within each setting and disease condition.”</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Could not have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Participants were not blinded, and the outcome (discontinuation of dialysis) is related to the intervention, aka planning for end-of-life care and discontinuation of dialysis</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>15 withdrew from control group compared to 1 from intervention group</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Subjective outcome measures all reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Quote: “Therefore, a total sample of approximately 560 patient–surrogate pairs evenly divided between the intervention group and the control group would be required to maintain a 0.10 b error level (power 0.90).”</td>
</tr>
</tbody>
</table>

Korniewicz 1994

Study characteristics

Methods

- Parallel RCT with pre-test/post-test

Duration of study

- Not reported

Duration of follow-up
## Participants

**General information**
- **Setting**: multicentre (6 sites)
- **Country**: USA
- **Inclusion criteria**: HD 3 times/week initiated in the last 6 months
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (46); pretest/post-test control (44); post-test-only control (45)
- **Mean age, range (years)**: intervention group (55, 35 to 75), pretest/post-test control (60, 40 to 80); post-test control (57, 37 to 77)
- **Sex (M/F)**: 66/69
- **Stage of CKD**: ESKD on HD

**Other information**
- There were no significant differences found in demographics at baseline, such as age, sex or marital status. However, there were significantly more patients that had obtained a high school diploma in the experimental group

## Interventions

**Intervention type**
- Self-management training: individual versus usual care

**Intervention group**
- HD education and support program by nurse facilitators: 12 educational support weekly sessions for 1 hour at the beginning of dialysis. Focused on self-care, activities of daily living, social activities, interactions with significant others, HD regimen compliance and perceived alienation

**Control group**
- No intervention

## Outcomes

**Adherence**
- HD regimen compliance scale

**Sickness impact profile**
- Changes in social function

**Exercise of self-care agency scale**
- Measure subject’s ability to perform activities of daily living

**Inventory of social functioning**
- Measure of ability to function in society and cope with chronic disease

**Dean alienation scale**
- Powerlessness, normallessness and social alienation

## Notes

**Conflict of interest**
- Not reported

**Funding source**
- Not reported
Korniewicz 1994 (Continued)

Other information

- Emailed author about randomisation method and blinding of personnel

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “Consenting individual were randomly assigned to either the experimental group, the pretest/posttest control group or the posttest control group” Does not state how it was randomised</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No mention of allocation concealment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Patients not blinded because of intervention type. No mention of blinding for personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self report questionnaires filled out by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>No reporting of numbers for dropouts - which group they were in Analysis of attrition bias indicates that those patients that dropped out prior to T3 had significantly higher education, but this was not repeated when analysing prior to T4. Reported a similar rate of dropout between all groups but no mention of % dropouts</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All prespecified outcome measures appear to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

Study characteristics

Methods

Study design

- Parallel RCT with pre-test/post-test

Duration of study

- March 2011 to March 2013

Duration of follow-up

- 6 months

Participants

General information

- Setting: single centre
- Country: The Netherlands
Inclusion criteria: ≥ 18 years and medically (e.g. no hospital admission) and mentally fit (e.g. no mental deterioration)

Exclusion criteria: not reported

Baseline characteristics
- Number: intervention group (84); control group (79)
- Mean age ± SD (years): intervention group (54.5 to 13.5); control group (54.9 ± 13.0)
- Sex (M/F): intervention group (47/32); control group (46/38)
- Stage of CKD: ESKD patients newly referred for transplant or already listed for DDKT unable to find a living donor

Other information
- Additional requirement of the family members and friends of the patients that were present at the home-based education to be mentally and medically fit. No significant differences between the group in terms of demographics such as age, gender, marital status, educational level, employment, dialysis modality, mean months of dialysis, history of LDKT

Interventions

Intervention type
- Education and self-management: group versus control

Intervention group
- Standard care plus home-based education intervention: 2 sessions at the patients home.
  - First visit 1 hour: family and social network discussed who to invite to second session
  - Second session 2.5 hours: provide information and support communication between attendees, not all invitees had to be potential donors, some participants had multiple sessions

Control group
- Standard care: consultation with nephrologist, transplant coordinator and social worker then yearly check ups. Also variety of written education materials and a DVD about transplantation options

Outcomes

Knowledge
- Rotterdam Renal replacement Knowledge Test

Self-efficacy
- Assessed using statements made for the study

Attitude social influence efficacy model
- Knowledge, risk perception, self-efficacy, attitude towards communication, communication on KRT, subjective norm and willingness to accept LDKT/donation

Access to LDKT
- Living donor enquiries, evaluations and actual LKDT

Notes

Conflict of interest
- "The authors of this manuscript have no conflicts of interest to disclose"

Funding source
- "This study is funded by the Netherlands Kidney Foundation"

Other information
- Author replied"The researchers who performed the house visits were not blind to the allocation to treatment or control group from the moment that patients consented onwards. The referring
transplant nephrologist, other staff members providing the care as usual and other participating researchers were however blind to the allocation up to the point that the patient informed them about their allocation (e.g. during a doctor’s visit)."

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Urn randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Received email from author: no allocation concealment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Some researchers blinded but only until doctors visit where patients could inform them of treatment group. Participants not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge, time to enquiry, evaluation or actual transplant are objective measures</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>Quote: &quot;The only difference in socio-demographics between participants and nonparticipants (8.9%) is that the later group is significantly older (years = 77.8, SD = 4.3). The dropout rate in the experimental group was 8/84 compared with 0/79 in the control group (p = 0.004). The majority of the dropouts (75%) left the study after the first home visit. The reasons for dropout were either that patients were unable to find individuals in their social network to be present during the educational session or that patients received a DDKT before receiving the educational session (2/8).&quot; Non-participants found to be significantly older, which could indicate intervention not the same for an older patient. Also, a much higher dropout from the experimental group; however, no dropout would be expected from the control group as not much extra effort needed to continue in this group. But this is significant between groups</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All prespecified outcome measures appear to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Methods

**Study design**
- Parallel, open-label RCT

**Duration of study**
- March 2008 to March 2013

**Duration of follow-up**
- 36 months
Participants

General information

- Setting: single centre
- Country: Australia
- Inclusion criteria: 18 to 75 years; moderate CKD; one or more uncontrolled cardiovascular risk factors such as BP exceeding target, overweight (BMI > 25 kg/m²), poor diabetic control (HbA1c > 7%) or lipids exceeding target
- Exclusion criteria: intervention for or symptomatic coronary artery disease (within 3 months); current heart failure (NYHA class III and IV) or significant valvular heart disease; pregnant or planning to become pregnant; life expectancy or anticipated time to dialysis or transplant < 6 months

Baseline characteristics

- Number: intervention group (79); control group (81)
- Mean age ± SD (years): intervention group (59.56 ± 9.9); control group (60.46 ± 10.2)
- Sex (M/F): intervention group (48/31); control group (43/38)
- Stage of CKD: moderate CKD eGFR 25 to 60 mL/min/1.73 m²

Other information

- There were no significant differences at baseline in terms of age, sex, eGFR, cause of CKD, risk factors, or medications

Interventions

Intervention type

- Self-management: group versus control

Intervention group

- Cardiovascular risk factor management provided by a multidisciplinary clinic.
- Exercise training: 150 minutes of moderate-intensity exercise per week supervised for 8 weeks
- Lifestyle intervention: 4 weeks of group behaviour and lifestyle modification focused on weight loss through diet and behavioural change

Control group

- Standard care: nephrologist recommended lifestyle modification but no specific information or education. Referral to allied health as needed

Co-interventions

- Exercise in the intervention group

Outcomes

Change in CKD
Lipids
Weight gain
Arterial stiffness
Ventricular vascular coping
Dietary assessment
BP

Notes

Conflict of interest

- "B. Douglas reports being a member of the Renal Society of Australasia (RSA) and Australian College of Nurse Practitioners; is a member of the editorial board of the RSA Journal and reports honoraria with Fresenius Medical Care. E.J. Howden is supported by a National Heart Foundation Australia Fu-
N. Isbel reports consultancy agreements with Alexion Pharmaceuticals; reports honoraria with Alexion; reports scientific advisor or membership with Alexion; is on the speakers bureau with Alexion; and reports being a member of the Australian and New Zealand Society of Nephrology (ANZSN) and the Transplantation Society of Australia and New Zealand. R. Krishnasamy reports personal fees from Amgen and Baxter Healthcare; reports grant support from Baxter, outside the submitted work; reports being a recipient of Queensland Advancing Clinical Research Fellowship; reports honoraria with Shire Australia; reports scientific advisor or membership with ANZSN (President Elect); and reports being a member of the International Society of Nephrology and CARI. T. Stanton reports scientific advisor or membership with Heart, Lung & Circulation. All remaining authors have nothing to disclose.”

Funding source

• “This research was supported by the National Health and Medical Research Council–funded Centre for Clinical Research Excellence–Vascular and Metabolic Health of the University of Queensland, as well as the Department of Nephrology at Princess Alexandra Hospital”

Other information

• Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“A 1:1 ratio using a computer random assignment program.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>There was no blinding of participants or personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-reported diet assessment completed by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective measures not thought to be influenced by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Quite a high dropout rate which brought the final analysis below the calculated in the power analysis. 13% to 14% loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All prespecified outcome measures appear to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

### Leon 2001

### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
</table>

Interventions for improving health literacy in people with chronic kidney disease (Review)  
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Leon 2001 (Continued)

- Parallel, cluster RCT
  - 13 dieticians at 8 centres were randomised to the intervention or control group

**Duration of study**

- Not reported

**Duration of follow-up**

- 6 months

### Participants

**General information**

- **Setting**: multicentre (8 freestanding dialysis facilities)
- **Country**: USA
- **Inclusion criteria**: > 18 years; HD > 6 months; most recent and mean serum albumin for the past 3 months both < 3.70 g/dL
- **Exclusion criteria**: not reported

**Baseline characteristics**

- **Number**: intervention group (52); control group (31)
- **Mean age (years)**: intervention group (62); control group (69)
- **Sex [F]**: intervention group (63%); control group (58%)
- **Stage of CKD**: ESKD on HD with low albumin

**Other information**

- Purposely selected more intervention than control patients because this is a pilot study. The four barriers were poor knowledge of protein-containing foods, poor appetite, needing help shopping or cooking, low fluid intake, and inadequate HD. Intervention patients were significantly younger and more likely to be black than control patients but did not differ in gender, cause of kidney failure, years on HD, number of comorbid conditions, baseline CRP or baseline albumin levels

### Interventions

**Intervention type**

- Education and self-management: one-on-one versus control

**Intervention group**

- Dietitians were trained to determine if each potential barrier was present for each patient, to attempt to overcome the barrier, and to monitor for improvements in the barrier:
  - Poor knowledge of protein-containing foods
  - Poor appetite
  - Needing help shopping or cooking
  - Low fluid intake
  - Inadequate HD

**Control group**

- Dietitians continued to provide usual care

### Outcomes

**Bloods**

- Change in serum albumin level; CRP

**Overcoming a specific barrier**

### Notes

**Conflict of interest**

- Not reported
Leon 2001 (Continued)

**Funding source**
- Not reported

**Other information**
- Received email from Dr Seghal: randomisation was completed using a computer-generated system. The dietitians were randomised, and then the patients that consented were put in the group that the dietitian was in.

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer random number generator to randomly assigned 13 dietitians into an intervention group and a control group. Received email from author: Patients of intervention dietitians who met eligibility criteria and wanted to participate were then assigned to the intervention group. Patients of control dietitians who met eligibility criteria and wanted to participate were then assigned to the control group.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>As both outcomes (albumin and CRP) are objective little ability to influence outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>There was a high dropout rate but no difference in the amount of dropouts between groups and no significant differences between those who dropped out and those who completed the trial. Quote: &quot;Seventy-five percent of eligible intervention patients and 67% of eligible control patients completed the trial (P = 0.27).&quot;</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Both stated outcome measures were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Difference between groups at baseline &quot;intervention patients were significantly younger, and more likely to be black than control patients&quot;</td>
</tr>
</tbody>
</table>

### Leon 2006

**Study characteristics**

**Methods**

**Study design**
- Parallel cluster RCT (44 facilities randomised)

**Duration of study**
- Recruited February 2002 to September 2003

**Duration of follow-up**
General information

- Setting: multicentre (44 facilities)
- Country: USA
- Inclusion criteria: mean serum albumin level for the previous 3 months were < 3.70 g/dL; 18 to 85 years and receiving dialysis for at least 9 months
- Exclusion criteria: new patients on HD; did not speak English; mentally impaired; likely to have unique nutritional issues (i.e. nursing home residents, patients with cirrhosis, HIV, active malignancy, terminal illness, tube feedings, and total parenteral nutrition)

Baseline characteristics

- Number: intervention group (86); control group (94)
- Mean age (years): intervention group (62); control group (60)
- Sex (M/F): intervention group (28/58); control group (31/53)
- Stage of CKD: ESKD on HD with low albumin

Other information

- Intervention and control patients had similar baseline demographics characteristics, medical characteristics, nutritional parameters and inflammatory marker levels and similar total and most common barriers
- The intervention patients were more likely to have low fluid intake and difficulty swallowing, whereas control patients were more likely to have a low appetite

Intervention type

- Educational and self-management intervention: individual versus control

Intervention group

- Educated about the meaning and importance of good nutritional status by the study coordinators during dialysis treatment and then monthly meetings. Content tailored to the barriers present out of the 10 following:
  - Poor nutritional knowledge
  - Poor appetite
  - Help needed with shopping and cooking
  - Low fluid intake
  - Inadequate dialysis dose
  - Depression
  - Difficulty chewing
  - Difficulty swallowing
  - GI symptoms
  - Acidosis

Control group

- Usual care: study coordinator met monthly to give out the questionnaires

Outcomes

- Bloods
  - Change in serum albumin level, CRP
- Weight gain
  - BMI, post-dialysis weight, inflammatory markers
- QoL
Leon 2006 (Continued)

- KDQoL instrument
- Death
- Survival x change in albumin

Nutrition

- Subjective global assessment, energy intake, protein intake

Overcoming a specific barrier using specific scales and analysis for each one

- Poor nutritional knowledge, poor appetite, help needed with shopping or cooking, low fluid intake, inadequate dialysis dose, depression, difficulty chewing, GI symptoms, acidosis

Notes

Conflicts of interest

- "None"

Funding source

- "Supported by grants DK51472 and GCRC M01 RR00080 from the National Institutes of Health, Bethesda, MD, and by the Leonard C. Rosenberg Renal Research Foundation, Cleveland, OH."

Other information

- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;random-number generator to assign the remaining 44 facilities to an intervention or control group.&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Cluster randomisation: allocation concealment not an issue</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither participants or personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Subjective outcomes such as global assessment, protein intake, energy intake, overcoming barriers could possibly be affected by the unblinded participants and personnel judging to domains</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcomes such as change in albumin, weight gain, BMI survival not thought to be affected by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;These 167 nonparticipants did not differ from the 180 participants in demographic characteristics, time receiving dialysis, or baseline albumin level.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Large dropout rate but analysis found no significant difference between the groups</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>No protocol available, all stated outcomes in paper were reported</td>
</tr>
</tbody>
</table>
Leon 2006 (Continued)

Other bias | Unclear risk | Financial incentives
---|---|---

Li 2014b

Study characteristics

Methods

- **Study design**
  - Parallel RCT

- **Duration of study**
  - 18 months (2010 to 2012)

- **Duration of follow-up**
  - 12 weeks

Participants

- **General information**
  - **Setting**: multicentre (2 sites)
  - **Country**: China
  - **Inclusion criteria**: Mandarin-speaking; able to communicate and access a telephone after discharge; agreed to participate
  - **Exclusion criteria**: receiving intermittent PD or HD and those with planned admissions for special treatment procedures; Tenckhoff catheters in situ for < 3 months; psychosis or dementia; dying or unable to communicate; transferred to another unit during their stay in hospital

- **Baseline characteristics**
  - **Number**: intervention group (69); control group (66)
  - **Mean age ± SD (years)**: intervention group (56.3 ± 12.4); control group (55.2 ± 11.9)
  - **Sex (M/F)**: intervention group (42/27); control group (37/29)
  - **Stage of CKD**: ESKD on PD

- **Other information**
  - No significant differences between groups at baseline

Interventions

- **Intervention type**
  - Self-management training: individual versus control

- **Intervention group**
  - In-depth discharge planning protocol followed by telephone support from a nurse for 6 weeks post-discharge

- **Control group**
  - Routine discharge care

Outcomes

- **Bloods**
  - Urea, creatinine, sodium, potassium, phosphate, albumin

- **QoL**
  - KDQoL
Li 2014b (Continued)

Number of hospitalisations
Complications

Notes

- **Conflict of interest**
  - "The authors have no financial conflicts of interest to declare"

- **Funding source**
  - Not reported

- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer-generated random numbers</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>QoL: self report questionnaire by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Blinding not thought to impact objective outcomes: bloods, number of hospitalisations</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Did not use ITT design. Attrition rate of 84.4% however, this seemed to be evenly spread between groups in terms of number and reason for dropout</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes appear to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Small sample size from two local hospitals in Guangzhou, China</td>
</tr>
</tbody>
</table>

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Not reported
**Duration of follow-up**
- 4 weeks after last session

**Participants**

**General information**
- **Setting**: multicentre (2 sites)
- **Country**: Taiwan
- **Inclusion criteria**: > 18 years; literate in Mandarin or Taiwanese languages; diagnosed with ESKD and receiving routine HD treatment; consented to participate
- **Exclusion criteria**: history of psychiatric disorders; severe systemic diseases; severe congestive heart failure; quadriplegic

**Baseline characteristics**
- **Number**: intervention group (20); control group (28)
- **Mean age ± SD (years)**: not reported
- **Sex (M/F)**: intervention group (10/10); control group (13/15)
- **Stage of CKD**: ESKD on HD

**Other information**
- There were no significant differences between groups in terms of demographics such as gender, age, education, marital status, employment or disease-related variables at baseline

**Interventions**

**Intervention type**
- Group intervention to improve QoL in HD patients

**Intervention group**
- Psychosocial interventions using CBT therapy and self-efficacy theory for 2 hours/week for 8 weeks in two small-group sessions (10–15/group) on Wednesdays and Saturdays for 8 weeks

**Control group**
- Routine nursing care and a self-care booklet

**Outcomes**

**QoL**
- Medical outcomes study SF-36

**Self-efficacy**
- SUPPH

**Anxiety and depression**
- BDI

**Notes**

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Emailed author about age of patients and blinding of people collecting data

**Risk of bias**
<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;This method combines the desirable features of fixed schedule and simple randomization assignment (Rudy et al. 1993). Both for dialysis on odd or even days, patients who are to enroll in the trial would be assigned in balanced pseudorandom fashion to different trials (e.g. ABBA, AABB or BABA) separately.&quot; &quot;random computer-generated list.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Computer-generated randomisation/permutated block randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Independent research assistant (unaware of the baseline data) carried out the concealed randomisation procedure using a random computer generated list&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Quote: &quot;...investigators would be blind to the underlying sequences and block length&quot;</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Unclear who conducted education sessions. Mentions blinding at allocation, but because of intervention type, personnel could not have been blinded. Participants not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self-report questionnaires completed by unblinded participants</td>
</tr>
<tr>
<td>Subjective outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Incomplete outcome data (attrition bias)  | High risk          | Quote: "patients in the treatment group who missed group therapy activities twice were dropped from the study. After intervention for eight weeks, there were 12 patients who dropped out, including 10 in the treatment group and two in the control group. This left 48 valid cases, with 20 valid cases in the experimental group and 28 in the control group. The total dropout rate was 20% (12 in 60)."
| All outcomes                             |                    | 20% dropout rate, high given small patient numbers. more dropouts in the intervention group, although similar demographics |
| Selective reporting (reporting bias)     | Unclear risk       | All stated outcomes seem to be reported                                                  |
| Other bias                               | Unclear risk       | Quote: "One group was held on Wednesday and the other group was conducted on Saturday to accommodate dialysis patients with differing schedules." |
|                                           |                    | Could have been different whether held on a Saturday or a Wednesday - this is a within group difference unclear about affect on bias |

**Liu 2007** (Continued)

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
<th>Duration of study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Parallel RCT</td>
<td>• 1 year</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Liu 2014c (Continued)

• Not reported

Participants

General information

• Setting: single centre
• Country: China
• Inclusion criteria: not reported
• Exclusion criteria: not reported

Baseline characteristics

• Number: intervention group (58); control group (58)
• Mean age: 37 years
• Sex (M/F): 64/52
• Stage of CKD: ESKD transplant recipients

Other information

• There was no statistical significance between patient characteristics however the data was not displayed

Interventions

Intervention type

• Self-management-training: individual versus usual care

Intervention group

• Targeted health education by nurses on admission, before surgery, after surgery and on discharge for kidney transplant recipients. Education was focused on diet, lifestyle, related diseases, and medication. Methods included education bedside talks, health topic seminars and pamphlet distribution

Control group

• Traditional education with no specification on the duration, content, and method of education

Outcomes

The evaluation system used in the study for health education outcomes is created by the Chinese people and is widely used within China. It looks at 3 aspects: knowledge, belief, and behaviour. There are a total of 42 components assessing the three aspects. The knowledge outcomes are measured in terms of 4 stages (very clear, moderately clear, mildly clear, unclear). Health belief and behaviour are also measured in 4 stages (very willing, moderately willing, mildly willing, unwilling)

Notes

Conflict of interest

• Not reported

Funding source

• Not reported

Other information

• Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
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</table>
### Liu 2014c (Continued)

<table>
<thead>
<tr>
<th>Allocation concealment (selection bias)</th>
<th>Unclear risk</th>
<th>Insufficient information to permit judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Insufficient information however probably not blinded due to nature of intervention</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Outcome would be significantly influenced if not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Data seems complete in tables or missing data not mentioned</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>They seem to report all primary and secondary outcomes specified</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>No mention of funding</td>
</tr>
</tbody>
</table>

### Liu 2016d

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - October 2011 to May 2012

- **Duration of follow-up**
  - 24 weeks

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: China
  - **Inclusion criteria**: > 18 years; HD duration > 3 months; HD regularly scheduled (2 or 3 times/week); stable clinical condition; could read and understand the questionnaire supplied
  - **Exclusion criteria**: severe cognitive dysfunction; who could not take care of themselves after kidney transplantation; serious cardiovascular and cerebrovascular disease

- **Baseline characteristics**
  - **Number**: intervention group (43); control group (43)
  - **Mean age ± SD (years)**: intervention group (44.3 ± 14.6); control group (41.7 ± 15.8)
  - **Sex (M/F)**: intervention group (26/18); control group (23/20)
  - **Stage of CKD**: stage 5

- **Other information**
  - No differences between groups at baseline

**Interventions**

- **Intervention type**
  - Interventions for improving health literacy in people with chronic kidney disease (Review)
Intervention group
- Self-management training and facilitated discussions by physicians and experts to assist participants in managing their own disease and take on correct health behaviours. Lectures given and educational materials distributed. Individual information and support given when indicated also. Topics included:
  - Disease-related knowledge intervention
  - Dietary knowledge
  - Psychological and social behaviours
  - Self-inspection index
  - Physical activity and behaviour intervention
  - AV fistula care
  - Medication use

Control group
- Routine health education: both oral and material based covering diet, medication, exercise, monitoring, prevention and treatment of complications

Outcomes
- Knowledge
  - 20-item questionnaire divided into absence of understanding, partial understanding, majority correct and complete

Parameters of chronic disease self-management
- 20 items

Notes
- **Conflict of interest**
  - "The authors declare that there are no conflicts of interest."

**Funding source**
- "This research received no specific grant from any funding agency either public or commercial"

**Other information**
- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
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<tbody>
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<td>Computer generated random numbers</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Not mentioned but could not of been blinded</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment</td>
<td>High risk</td>
<td>Self-management self report questionnaire by unblinded participants</td>
</tr>
<tr>
<td>Subjective outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Liu 2016d (Continued)

| Blinding of outcome assessment (detection bias) | Objective outcomes | Knowledge is an objective outcomes and not thought to be affected by blinding. Self report questionnaires |
| Incomplete outcome data (attrition bias) | Low risk | No dropouts |
| Selective reporting (reporting bias) | Unclear risk | All outcomes seem to be reported |
| Other bias | Unclear risk | Unclear if other bias |

Live and Learn 1993

Study characteristics

Methods

- Study design
  - Parallel RCT

Duration of study

- 10 years

Duration of follow-up

- 20 years

Participants

General information

- Setting: multicentre (number not reported)
- Country: Canada
- Inclusion criteria: not reported
- Exclusion criteria: refusal to volunteer; non-English or French speaking; death, moving, too ill

Baseline characteristics

- Number: intervention group (87); control group (92)
- Mean age (years): intervention group (48.5); control group (51.7)
- Sex (M/F): intervention group (58/29); control group (61/31)
- Stage of CKD: ESKD, just transferred from CKD

Other information

- There were no significant differences across participants in the three patient groups in domains such as age, sex, marital status, education, employment status, income, diagnosis or cause of kidney disease, uraemic symptoms, months between disease and the first intervention
- Two groups were created based on early and late referral for KRT, and it was not possible to assign participants to these groups randomly. This arose as a result of events independent of the study design and was studied retrospectively

Interventions

Intervention type

- Education: enhanced versus standard

Intervention group
Live and Learn 1993 (Continued)

- Enhanced education: individual lectures focused on kidney function, kidney disease, dietary management of kidney failure, current KRT and transplantation. Also provided in a 22-page booklet. This lasted 25 minutes and was presented by a trained research assistant

**Control group**

- Standard education group: no formal predialysis education program available therefore varied greatly between hospitals

**Co-interventions**

- Structured 2.5-hour psychosocial interview every year for 9 years

**Outcomes**

**Bloods**

- Creatinine, urea, potassium, inorganic phosphates, HCT

**Knowledge**

- KDQ form A and form B; long-term scores on KDQ

**Survival at 20-year follow-up**

**Duration between interview and initiation of dialysis; non-kidney health**

**Notes**

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Devins 2000: longitudinal follow-up analysing 47 individuals on the KDQ at 54 months. This study looked at early intervention versus late intervention using the same data
- Devins 2005: longitudinal follow-up at 20 years, analysing 335 patients from original study
- The studies all have different sample sizes, the 20-year follow-up has more than the 1993 report
- Have emailed the authors

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “patients were randomly assigned to one of our experimental conditions”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No mention of how they were randomised</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Blinding not possible for participants and a research assistant conducted education sessions which could not have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>May have influenced subjective measures (uraemia symptoms) but unlikely to have influenced objective (blood test, illness relevant knowledge) measures</td>
</tr>
</tbody>
</table>
**Live and Learn 1993 (Continued)**

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>May have influenced subjective measures (uraemia symptoms) but unlikely to have influenced objective (blood test, illness relevant knowledge) measures. Also the decision to initiate dialysis was made by the attending nephrologist, who was blind to all experimental manipulations.</td>
</tr>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Quote: &quot;These means may not adequately reflect actual differences in duration across groups because there were 31 patients for whom full durations could not be established&quot;</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>The 25 individuals were not assessed according the intention to treat but the pattern and range between groups was nearly identical.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcome measures reported - blood tests, uraemia and knowledge changes</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>May have been some contamination</td>
</tr>
</tbody>
</table>

**Living ACTS 2015**

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT; pre-test/post-test

- **Duration of study**
  - Recruitment over 8 months

- **Duration of follow-up**
  - 6 months

**Participants**

- **General information**
  - Setting: single centre
  - Country: USA
  - Inclusion criteria: ≥ 18 years; self-identify as Black/African American; a scheduled appointment to be evaluated for kidney transplant during the enrolment period
  - Exclusion criteria: not reported

- **Baseline characteristics**
  - Number: intervention group (136); control group (132)
  - Mean age, range (years): intervention group (50.9, 21 to 76); control group (52.5, 20 to 75)
  - Sex (M/F): intervention group (70/66); control group (77/55)
  - Stage of CKD: ESKD being assessed for transplant

- **Other information**
  - Patient demographics of marital status, education level, employment, income, private health insurance status, and length of time on dialysis seem to be balanced between the groups. None of the demographic variables were significantly related to study condition. The highest level of education, income, and health insurance status were significantly associated with knowledge, sex was significantly associated with willingness to talk to family, and sex and marital status were significantly associated with the perceived benefit of LDKT, so these variables were entered as covariates into their respective models.
### Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education:</strong> other versus control (provision of materials)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard transplant education materials plus the Living ACTS intervention</td>
<td></td>
</tr>
<tr>
<td>The Living ACTS DVD included addressing concerns raised by the focus group participants focused on the process, risks, and benefits of LDKT. There also were personal stories from donor/recipient pairs and discussion of financial resources available. The Living ACTS booklet provided additional information, which included resources and tips for starting conversations about LDKT with family members</td>
<td></td>
</tr>
<tr>
<td>Standard transplant education materials plus an exercise DVD (Exercise, Live Well, and Feel Better)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard transplant education materials plus an exercise DVD (Exercise, Live Well, and Feel Better)</td>
<td></td>
</tr>
</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td></td>
</tr>
<tr>
<td>Knowledge of living donor kidney transplant using 18 true/false items</td>
<td></td>
</tr>
<tr>
<td>Willingness to talk to family members about LDKT</td>
<td>9-item scale</td>
</tr>
<tr>
<td>Perceived benefits of LDKT</td>
<td>5-item scale</td>
</tr>
</tbody>
</table>

### Notes

- **Conflict of interest**
  - Not reported

- **Funding source**
  - "This research was supported by the Health Resources and Services Administration Division of Transplantation (grant 5 R39OT20066-03-00)"

- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>No mention of how randomised into control and intervention</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>No mention of blinding, would not have been possible for participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Willingness to talk to a family members about LDKT and perceived benefit are subjective outcomes and there was no blinding in the study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Knowledge is an objective outcome, blinding not thought to affect this</td>
</tr>
</tbody>
</table>
### Living ACTS 2015 (Continued)

#### Objective outcomes

<table>
<thead>
<tr>
<th>Objective outcomes</th>
<th>Risk level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: “A dropout analysis was done to determine whether those who were retained in the study (n = 268) were demographically different from those who were lost to follow-up (n = 28) and showed no significant differences.” Loss to follow-up similar in both groups, and no stat sig difference between dropouts and completes (&lt; 10% of the population dropped out)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Does not seem to be any additions to data or anything left out</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Monetary incentives and asked for people to contact to be involved so may not have been a representative population, but the 2 groups were even in demographics so may not have affected the results of the study</td>
</tr>
</tbody>
</table>

#### Study characteristics

**Methods**

**Study design**

- Parallel RCT

**Duration of study**

- Not reported

**Duration of follow-up**

- 6 months

**Participants**

**General information**

- **Setting**: multicentre (5 sites)
- **Country**: Spain
- **Inclusion criteria**: > 18 years; HD > 6 months without complications; absence of feeding difficulties and normal appetite; 3-month average serum phosphorus > 5.5 mg/dL
- **Exclusion criteria**: not reported

**Baseline characteristics**

- **Number**: intervention group (41); control group (39)
- **Mean age ± SD (years)**: intervention group (61.5 ± 15); control group (63 ± 16)
- **Sex (M/F)**: intervention group (21/20); control group (21/18)
- **Stage of CKD**: ESKD on HD

**Other information**

- Baseline characteristics were balanced in the areas of age, sex, diabetes, BMI, potassium, creatinine, phosphorus, calcium, PTH. The Hb levels were significantly lower in the control group

**Interventions**

**Intervention type**

- Education: individual versus control

**Intervention group**

- Dietitian lead instructions for menu options focused on quantities of food and how to prepare
Lou 2012  (Continued)

**Control group**
- Usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Phosphate levels, albumin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BMI, fat-free mass, dietary survey</td>
</tr>
</tbody>
</table>

**Notes**
- **Conflict of interest**
  - Not reported

**Funding source**
- Not reported

**Other information**
- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Some blinding but participants were not blinded so could easily be broken</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Dietary survey: self-report survey completed by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Allowed for 10% dropout. Reasons seem similar between groups. 12% loss to follow-up and no mention of whether these patients significantly different from those who completed</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Did not specifically mention all outcomes at beginning of paper</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Started off using cluster randomisation but where groups were not even 'switched' to individualised based on dialysis shift at one of the hospitals. Did complete multivariate adjustment for potential confounders</td>
</tr>
</tbody>
</table>

**MAGIC 2016**

**Study characteristics**
MAGIC 2016 (Continued)

Methods

Study design
- Parallel RCT

Duration of study
- 12 January 2015 to 14 April 2017

Duration of follow-up
- 12 months

Participants

General information
- Setting: multicentre (5 sites)
- Country: USA
- Inclusion criteria: ≥ 18 years; received a kidney-only transplant; self-administered at least one prescribed immunosuppressive medication taken twice daily with a functioning kidney transplant; not in the hospital; no diagnosis that would immediately shorten the lifespan; needed access to a telephone; ability to speak, hear and understand English; the ability to open an EM medication cap; agreement from the transplant physician and nephrologist to participate; required to score ≥ 4 on the 6-item Telephone Mental Status Screen Derived from the Mini-Mental Status Exam
- Exclusion criteria: not reported

Baseline characteristics
- Number: intervention group (45); control group (44)
- Mean age ± SD (years): intervention group (53 ± 11.2); control group (50.7 ± 9.7)
- Sex (M/F): intervention group (30/15); control group (22/22)
- Stage of CKD: transplant recipients

Interventions

Intervention type
- Self-management: individual versus control

Intervention group
- In-person intervention to redesign the personal environmental system and daily health behaviour routine using Deming’s Plan-Do-Check-Act cycle with the intention of improving medication adherence

Control group
- Attention control: the same amount of time spent by the research assistant with the participants, but this group spent the time discussion education material about healthy living in transplant participants

Co-interventions
- Both groups used the Medication Event Monitoring SmartCap

Outcomes

Primary
- Medication adherence

Secondary
- Kidney failure, creatinine, BUN, death, transplant reactions, infections, perceived health status

Notes

Conflict of interest
- “The authors declare that they have no competing interests”

Funding source

Interventions for improving health literacy in people with chronic kidney disease (Review)
MAGIC 2016 (Continued)

- "National Institutes of Health-National Institute of Diabetes, Digestive, and Kidney Diseases. Research Grant Number: 1 R01 DK093592-01A1."

Other information
- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer generated block randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Patients were not given information about the arms of the study, which was intervention and which was control</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Participants were blinded, personnel were not</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcomes not thought to be affected by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>ITT analysis with 82% retention</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All outcomes were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Design and rational article available for review, information included about changed to study design</td>
</tr>
</tbody>
</table>

Manns 2005

Study characteristics

Methods

- Study design
  - Parallel RCT

Duration of study

- Not reported

Duration of follow-up

- 4 weeks

Participants

- General information
  - Setting: single centre
  - Country: Canada
  - Inclusion criteria: had been seen at least once by this multidisciplinary progressive renal care team and had a GFR < 30 mL/min/1.73 m²
Manns 2005 (Continued)

- **Exclusion criteria**: cognitive dysfunction; non-English-speaking patients; not personally independent based on assessment by study nurse; currently on dialysis; unable or unwilling to provide informed consent

**Baseline characteristics**

- **Number**: intervention group (35); control group (35)
- **Mean age, range (years)**: intervention group (65.2, 60.1 to 70.3); control group (63.6, 58.0 to 69.1)
- **Sex (M/F)**: intervention group (21/14); control group (17/18)
- **Stage of CKD**: Stage 4 CKD (GFR < 30 mL/min/1.73 m²)

**Other information**

- There were no significant differences between groups at baseline in terms of gender, marital status, employment, comorbidities, GFR, month in clinic

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Education versus standard care</td>
</tr>
</tbody>
</table>

**Intervention group**

- A two-phase patient-centred educational intervention
  - Phase 1: educational booklets
  - Phase 2: 90-minute small group interactive educational session on self-care dialysis
- Focused on pre-dialysis education and preparation for dialysis

**Control group**

- Standard education in the form of one 3-hour session where participants saw a nurse, dietitian and social worker

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Knowledge and attitudes about starting dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whether the patient intended to start dialysis</td>
</tr>
<tr>
<td></td>
<td>Perceived advantages of self-care dialysis that were associated with selecting self-care dialysis as a treatment for CKD (free text responses)</td>
</tr>
<tr>
<td></td>
<td>Effect of our educational intervention on perceived advantages of self-care dialysis</td>
</tr>
</tbody>
</table>

**Conflict of interest**

- Not reported

**Funding source**

- "Dr. Manns is supported by a CIHR New Investigator Award. This research was supported by the Southern Alberta Renal Program, Calgary Health Trust Funds"

**Other information**

- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Randomization was done in blocks of 6 using a computer-generated scheme to ensure concealment.&quot;</td>
</tr>
</tbody>
</table>

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Interventions for improving health literacy in people with chronic kidney disease (Review) 175

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**Manns 2005 (Continued)**

<table>
<thead>
<tr>
<th>Allocation concealment (selection bias)</th>
<th>Low risk</th>
<th>There was allocation concealment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Quote: &quot;Given the nature of the intervention, patients were not blinded.&quot;</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Subjective outcomes from self report questionnaires and both parties are unblinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge questionnaires were given 2 weeks after contact with staff, objective outcome thought not to be affected by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>11.4% of patients did not complete all outcome measures, fairly even in both intervention and control groups. There were more participants dropped out of the intervention group than the control group. However, on analysis, this does not seem to affect the effect size of the primary outcome</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All mentioned outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
</tr>
</tbody>
</table>

**Massey 2015**

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Cross-over RCT</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of study</strong></td>
</tr>
<tr>
<td></td>
<td>• February 2011 to February 2013</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of follow-up</strong></td>
</tr>
<tr>
<td></td>
<td>• 8 weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Setting: multicentre (4 sites)</td>
</tr>
<tr>
<td></td>
<td>• Country: The Netherlands</td>
</tr>
<tr>
<td></td>
<td>• Inclusion criteria: &gt;18 years; primary KRT required within the coming 12 months; MDRD &lt; 25 mL/min</td>
</tr>
<tr>
<td></td>
<td>• Exclusion criteria: previously undergone KRT; were not eligible for transplantation or chose not to pursue KRT</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Number: intervention group (40); control group (40)</td>
</tr>
<tr>
<td>• Mean age ± SD (years): intervention group (59.4 ± 11.1); control group (56.7 ± 12.1)</td>
</tr>
<tr>
<td>• Sex (M/F): intervention group (24/16); control group (20/20)</td>
</tr>
<tr>
<td>• Stage of CKD: ESKD needing KRT within the next 12 months</td>
</tr>
</tbody>
</table>
Other information

- There were no significant differences between the groups in demographic characteristics at baseline in terms of age, gender, ethnicity, marital status, education, psychosocial variables

Interventions

Intervention type

- Education: group versus control

Intervention group

- Group education session on KRT options held at the patients home given by social workers. Topics discussed during the session were: the function of the kidney, types and causes of kidney disease, consequences of kidney disease, advantages and disadvantages of each treatment modality and consideration of living donation. Leaflets on each KRT option were provided

Control group

- Usual care

Outcomes

Knowledge

- Rotterdam renal replacement knowledge test

Self-efficacy

- Perceived behaviour control

Type of KRT

Communication was assessed using some scales based on the theory of planned behaviour

- Frequency of communication, intention to communicate, subjective and moral norms, attitudes, anticipate effects

Notes

Conflict of interest

- "The authors have no financial disclosures to declare in relation to this study."

Funding source

- "Supported by a grant from the Dutch Kidney Foundation"

Other information

- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Subsequently, patients were randomly assigned by the main researcher (E.K.M.) to Group 1 or Group 2 using a computer generated, stratified (per centre), restricted (1: 1) randomization.”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Educators were not blind to condition as subsequent intervention planning was determined by group assignment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Participants could not be blinded</td>
</tr>
</tbody>
</table>
Massey 2015 (Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-efficacy, communication, subjective and moral norms, attitudes, anticipate effect were measured self-report questionnaire and participants were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge and type of KRT are objective measures so blinding should not effect outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Small dropout rates with drop outs having similar demographics</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Cross-over design with only 4 weeks between each phase, however we only analysed the first phase</td>
</tr>
</tbody>
</table>

MASTERPLAN 2005

Study characteristics

Methods

- **Study design**
  - Parallel RCT

Duration of study

- 5 years

Duration of follow-up:

- Mean follow-up: 4.6 years

Participants

- **General information**
  - Setting: multicentre (9 sites)
  - Country: The Netherlands
  - Inclusion criteria: ≥ 18 years; diagnosed with CKD with a CrCl 20 to 70 mL/min; willing to provide written informed consent
  - Exclusion criteria: transplant in the last 12 months; AKI or RPGN established by the treating physician; any malignancy < 5 years before inclusion other than BCC or SCC of the skin; participation in other clinical trials requiring the use of study medication

Baseline characteristics

- Number: intervention group (395); control group (393)
- Mean age ± SD (years): intervention group (58.9 ± 13.1); control group (59.3 ± 12.8)
- Sex (M/F): intervention group (267/126); control group (265/130)
- Stage of CKD: moderate to severe CKD

Other information

- Baseline characteristics were balanced between the groups, apart from a history of cardiovascular disease, which was more common in the intervention group, and current smoking, which was less prevalent in the intervention group
• Self-management: individual versus control

**Intervention group**

• Nurse practitioner lead self-management intervention focused on lifestyle interventions (physical activity, nutritional counselling, weight reduction and smoking cessation), cardioprotective medication current guidelines. Treatment monitoring and tailoring based on regular check-ins to see if goals are being met

**Control group**

• Usual care, which included provision of information about cardiovascular risk factors

**Outcomes**

Progression of kidney disease

• Creatinine, eGFR

QoL

BP

Markers of vascular damage and other more specific markers of cardiovascular risk

**Notes**

**Conflict of interest**

• Not reported

**Funding source**

• "This study is supported by the Dutch Kidney Foundation (Nierstichting Nederland), grant number pv-01, and Netherlands Heart Foundation (Nederlandse Hartstichting), grant number 2003B261. Unrestricted grants were provided by Amgen, Genzyme, and Pfizer."

**Other information**

• Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Web-based randomisation module and performed in predefined blocks of certain numbers of patients</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>High risk</td>
<td>Quote: &quot;Patient, NP and physician were familiar with the treatment allocation.&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Nurse practitioners would not be blinded, unlikely physicians could be as they need to be supervised. No information about whether these people are involved in data analysis. Intervention blinding is not possible for patients or physicians. This is unavoidable since some physicians will be treating or supervising both physician care and nurse practitioner care patients</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>QoL: self report questionnaire filled out by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcome assessors were blinded and these outcomes thought not to be affected by blinding as they are objective</td>
</tr>
</tbody>
</table>
Complete outcome data (attrition bias)

All outcomes

Low risk

Loss to follow-up under the amount required for powerful analysis. Reasons seem similar between groups. ITT analysis

Selective reporting (reporting bias)

High risk

The QoL data was not published

Other bias

Unclear risk

Unsure about affect of baseline differences on outcome as some outcome related to CVD “history of cardiovascular disease which was more prevalent in the intervention group and current smoking which was less prevalent in the intervention group”

Mathers 1999

Study characteristics

Methods

Study design

- Pilot, parallel RCT (pre/post)

Duration of study

- Not reported

Duration of follow-up

- 4 weeks after last intervention

Participants

General information

- Setting: single centre
- Country: USA
- Inclusion criteria: ≥ 65 years, HD ≥ 3 months, 3 times/week; read to level of least 9th grade; not legally blind
- Exclusion criteria: not reported

Baseline characteristics

- Number: intervention group (5); control group (5)
- Age range: 68 to 75 years
- Sex (M/F): intervention group (2/3); control group (2/3)
- Stage of CKD: ESKD on HD

Interventions

Intervention type

- Educational and self-management training: individual versus usual care

Intervention group

- Seven psychosocial educational sessions via audiotape lasting about 20 minutes which included information on social support networks, healthcare, vocational adjustment, sexuality, recreation, self-esteem and domestic tranquillity 2 days/week during the HD treatment for 4.5 weeks

Control group

- No intervention

Outcomes

Psychosocial adjustment to illness scale
### Mathers 1999 (Continued)

#### Notes

- **Conflict of interest**
  - Not reported

- **Funding source**
  - Not reported

- **Other information**
  - Not requested

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Claims to be random but insufficient information</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Researcher was present while participants undertook education sessions</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Patients not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Patients were not blinded: self-report questionnaire</td>
</tr>
<tr>
<td>Subjective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>Only 6 of the original 10 participants complete the study. High dropout rate and small sample size</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Extremely small sample size</td>
</tr>
</tbody>
</table>

### MESMI 2010

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Recruitment August 2008 to June 2009

- **Duration of follow-up**
  - 12 months

**Participants**

- **General information**
  - Setting: single centre
Country: Australia
Inclusion criteria: ≥ 18 years; able to comprehend English; mentally competent; type 1 or type 2 diabetes; eGFR ≤ 60 mL/min/1.73 m² and/or diabetic kidney disease; systolic hypertension ≥ 130 mm Hg for the previous 2 clinic visits and prescribed antihypertensive medication
Exclusion criteria: impending dialysis; eGFR < 15 mL/min/1.73 m²; pregnancy; new diagnosis of cancer; mental illness not stabilized with medication

Baseline characteristics
- Number: intervention group (39); control group (41)
- Mean age ± SD (years): intervention group (68 ± 8.3); control group (66 ± 10.8)
- Sex (M/F): intervention group (22/17); control group (23/13)
- Stage of CKD: eGFR > 15 and < 60 mL/min/1.73 m²

Other information
- There were no baseline differences between groups at baseline

Interventions

Intervention type
- Education and self-management: individual versus control

Intervention group
- Nurse-led multifactorial intervention consisting of self-monitoring of BP, a medication review, a 20-minute DVD, and fortnightly motivational interviewing follow-up telephone contact for 12 weeks to support BP control and optimal medication self-management

Control group
- Usual care

Outcomes

Progression of kidney disease
- HbA1c, eGFR, creatinine
- BP
  - Measured at each data collection point (looking for improved BP control)

Adherence
- Medication adherence to all long-term prescribed medications was measured by pill counts. Insulin and over-the-counter medications such as calcium and vitamin supplements were not included in pill counts; four-Item MMAS was used to measure adherence to all prescribed medications with 'yes' and 'no' responses

Notes

Conflict of interest
- "No conflict of interest has been declared by the authors"

Funding source
- "This research was supported by an Australian Research Council (Linkage) Grant (LP0774989), Sigma Theta Tau International Small Grant, Nurses Memorial Centre Australian Legion of Ex-Servicemen and Women Scholarship, and the Mona Menzies Nurses Board of Victoria Grant"

Other information
- Not requested

Risk of bias

Interventions for improving health literacy in people with chronic kidney disease (Review)

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### MESMI 2010 (Continued)

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;stratified block randomization was conducted according to gender, age and systolic blood pressure ... recorded at recruitment&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The identity of all participants who were enrolled and randomized to receive the intervention was kept in a locked cabinet in the chief researcher’s office.&quot;</td>
</tr>
</tbody>
</table>
| Blinding of participants and personnel (performance bias) All outcomes | High risk          | Quote: "Participants in the intervention group could not be blinded and were asked to not disclose their group allocation to the research assistant during data collection."

The renal nurse was not blinded to treatment group but was not involved in the study, also only saw one group

<table>
<thead>
<tr>
<th>Blinding of outcome assessment (detection bias) Subjective outcomes</th>
<th>High risk</th>
<th>Self report questionnaire completed by unblinded participants</th>
</tr>
</thead>
</table>
| Blinding of outcome assessment (detection bias) Objective outcomes | Low risk  | Quote: "Research assistant was trained to collect data and was blinded to group assignment...participants...were asked not to disclose their group allocation to the research assistant during data collection"

Outcome assessor was blinded to treatment group; objective measurements

<table>
<thead>
<tr>
<th>Incomplete outcome data (attrition bias) All outcomes</th>
<th>Low risk</th>
<th>Small dropout rate: 1 withdrew from control group, 1 from intervention group; 1 died in control group, 2 in intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>No reporting of QoL (SF12), medication adherence self-efficacy scale or health care utilisation in paper as were outlined in protocol</td>
</tr>
</tbody>
</table>
| Other bias                                          | High risk| Quote: "the sample-size calculation yielded 51 participants per group with 80% power [\(\alpha = 0.05\) (one-tailed)], including 5% attrition, totaling 108 participants in all."

Small sample size; not enough patients for 80% power

---

### Moattari 2012

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Not reported

- **Duration of follow-up**
  - 6 weeks

**Participants**

- **General information**
  - Setting: single centre
Interventions for improving health literacy in people with chronic kidney disease (Review)

Moattari 2012 (Continued)

- **Country**: Iran
- **Inclusion criteria**: diagnosed with ESKD and treated with HD for at least 3 months; 18 to 60 years; lived at home; were able to read and write; had no psychiatric or cognitive disorders; willing to participate in the study
- **Exclusion criteria**: acute illnesses or hospitalised

**Baseline characteristics**

- **Number**: intervention group (25); control group (25)
- **Mean age ± SD (years)**: intervention group (38.56 ± 11.4); control group (37.3 ± 12.79)
- **Sex (M/F)**: intervention group (15/10); control group (16/7)
- **Stage of CKD**: ESKD on HD

**Other information**

- No significant difference between groups at baseline in terms of age, sex, marital status, educational status, dialysis treatments/week, renal risk markers, hypertension, diabetes, renal stones, infection

### Interventions

#### Intervention type

- Self-management: group and individual versus control

#### Intervention group

- Six-week empowerment program that consisted of 4 individual and 2 group counselling sessions
  - Individual sessions: focused on the development of skills and self-awareness in goal setting and problem-solving. During individual sessions, each patient was provided feedback regarding their clinical indicators and laboratory tests
  - Group counselling: focused on stress management, coping strategies, social support and motivation

#### Control group

- Usual care

### Outcomes

#### Bloods

- Sodium, potassium, creatinine, BUN, phosphorous, calcium, Hb and HCT

#### Weight gain

- IDWG

#### QoL

- Questionnaire that was developed in 1984 by Carol Estwing Ferrans and Marjorie Powers
- Self-efficacy
  - Self-care SUPPH
  - BP

### Notes

#### Conflict of interest

- "The authors declare that they have no competing interests."

#### Funding source

- Not reported

#### Other information

- M oattari 2012 (Continued)
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: “randomization method on a 1:1 ratio to receive either usual care (control, n = 25) or an empowerment program (experimental, n = 25).” Une qualities of the exact randomisation technique however, alternate allocation is not an adequate randomisation technique</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information but probably not done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants could not be blinded. Whilst nurse who was present during outcome measure collection was blinded, likely this could have been broken</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Nurses were blinded but patients were not - this is a subjective measurement</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Nurse was blinded and objective measurements</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Small loss to follow-up with reasons stated and they do not seem to be related to intervention</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

### Molaison 2003

#### Study characteristics

**Methods**

**Study design**

- Parallel, cluster RCT
  - Five dieticians manage 10 units; 5 units were randomly selected to receive the intervention and 5 received the control

**Duration of study**

- Not reported

**Duration of follow-up**

- 12 weeks

**Participants**

**General information**

- Setting: multicentre (10 sites)
Molaison 2003 (Continued)

- **Country:** USA
- **Inclusion criteria:** not reported
- **Exclusion criteria:** did not have the mental capacity to answer the questions; patients who continued to produce urine

**Baseline characteristics**

- **Number:** intervention group (216); control group (100)
- **Mean age ± SD (years):** intervention group (54.8 ± 15); control group (52.8 ± 14.5)
- **Sex (M/F):** intervention group (107/109); control group (54/46)
- **Stage of CKD:** on dialysis; intervention group (3.7 ± 3.7 years); control group (4.4 ± 3.6 years)

**Other information**

- The groups did not differ significantly based on demographic data

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Educational and self-management training: group versus control</td>
</tr>
</tbody>
</table>

**Intervention group**

- Nutrition education aimed at increasing adherence to fluid restriction lasting 12 weeks. Included bulletin board displays (part of group education sessions) and handouts

**Control group**

- Usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IDWG (&lt; 2.5 kg as criteria for fluid compliance)</td>
</tr>
</tbody>
</table>

**Knowledge**

- Knowledge scores as assessed by questionnaire about appropriate fluid intake, appropriate interdialytic weight fluid gain, and complications associated with fluid overload

**Self-efficacy**

- Progression through Stage of Change model as assessed by questionnaire

**Notes**

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
</tbody>
</table>
### Molaison 2003 (Continued)

<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Outcome</th>
<th>Risk of Bias</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
<td></td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Dietitians who covered units in study were involved in education for both intervention and control groups Patients not blinded</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Stage of change is a subjective outcome; neither patients nor assessor were blinded</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>There was no blinded but not thought to affect objective outcomes</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>No reporting on loss to follow-up One person dropped out from each group, it looks like in the table but no analysis or explanation given</td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes stated seem to be reported on</td>
<td></td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Cluster randomised study population sizes different in control versus intervention</td>
<td></td>
</tr>
</tbody>
</table>

### Navaneethan 2017

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parallel RCT</td>
<td></td>
</tr>
</tbody>
</table>

| Duration of study | |
| July 2012 to December 2013 |

| Duration of follow-up | |
| 24 months |

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting: multicentre (6 sites)</td>
<td></td>
</tr>
<tr>
<td>Country: USA</td>
<td></td>
</tr>
<tr>
<td>Inclusion criteria: English speaking; 18 to 80 years; eGFR 15 to 45 ml/min/1.73 m²</td>
<td></td>
</tr>
<tr>
<td>Exclusion criteria: cancer or other terminal illness; on dialysis; received a kidney transplant in the past</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number: intervention group 1 (53); intervention group 2 (50); intervention group 3 (49); control group (57)</td>
<td></td>
</tr>
<tr>
<td>Median age, range (years): intervention group 1 (71, 64 to 75); intervention group 2 (67, 61 to 72); intervention group 3 (69, 62 to 73); control group (68, 54 to 72)</td>
<td></td>
</tr>
<tr>
<td>Sex (M/F): intervention group 1 (20/33); intervention group 2 (25/25); intervention group 3 (28/21); control group (18/39)</td>
<td></td>
</tr>
</tbody>
</table>
Navaneethan 2017 (Continued)

- **Stage of CKD**: eGFR 15 to 45 mL/min/1.73 m²

### Interventions

**Intervention type**

- Educational and self-management training: individual versus usual care

**Intervention group 1**

- Patient navigator group: navigators assisted with overcoming barriers as identified during interviews

**Intervention group 2**

- Enhanced personal health record group: use of a personal health record, including online educational material

**Intervention group 3**

- Patient navigator group and enhanced personal care record group: both of the above interventions

**Control group**

- Encouraged to use their personal health record

### Outcomes

- **eGFR**
  - Change over a 2-year period
- **Bloods**
  - Hb, phosphorous, 25-hydroxy vitamin D, PTH, LDL, cholesterol, HbA1c, UACR
- **Death**
- **Number of hospitalisations and emergency room visits**
- **Referral rates to nephrologists and vascular surgeons and kidney transplant assessments**
- **BP control**
- **Prescription of kidney-protective medications**

### Notes

- **Conflict of interest**
  - "None"

- **Funding source**
  - Not reported

- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer generated randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Randomisation allocation was concealed</td>
</tr>
</tbody>
</table>
### Navaneethan 2017 (Continued)

<table>
<thead>
<tr>
<th>Blinding of participants and personnel (performance bias)</th>
<th>High risk</th>
<th>Participants and personnel were not blinded</th>
</tr>
</thead>
<tbody>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Low risk</th>
<th>Outcome assessors were blinded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incomplete outcome data (attrition bias)</th>
<th>Low risk</th>
<th>All data was accounted for</th>
</tr>
</thead>
<tbody>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Low risk</th>
<th>No selective reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other bias</th>
<th>High risk</th>
<th>Quote: &quot;we did not power the study specifically to estimate the interaction of the 2 interventions&quot;</th>
</tr>
</thead>
</table>

### Nozaki 2005*

**Study characteristics**

**Methods**

- **Study design**
  - Non-RCT; divided into groups using block design; parallel intervention/control

- **Duration of study**
  - 29 April to 16 October 2001

- **Duration of follow-up**
  - 22 weeks

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: Japan
  - **Inclusion criteria**: urine output < 500 mL/day; daily body weight increase of ≥ 1.5%, patients who were not treated with high-Na dialysis and patients who scored ≥ 50% on HD therapy knowledge test
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - **Number**: intervention group (12); control group (12)
  - **Mean age ± SD (years)**: intervention group (53.3 ± 8.9); control group (52.4 ± 10)
  - **Sex (M/F)**: intervention group (6/6); control group (6/6)
  - **Stage of CKD**: ESKD on HD

- **Other information**
  - No significant differences between groups with respect to age, history of dialysis, body weight increase rates, daily salt intake and knowledge tests, sex, primary diseases and occupations

**Interventions**

- **Intervention type**
  - Unable to classify
Intervention group

- Cognitive behaviour therapy-based self-management programme involving a self-monitoring method, a shaping method, assertion training and response prevention

Control group

- Standard patient education, including discussion and instruction using a self-management pamphlet

Outcomes

Weight gain

- Differences in the daily body weight gain rates both between and within the two groups in the baseline phase at 4 and 12 weeks were calculated

Daily salt intake

- Calculated from blood Na concentration, body weight and the increase in body weight during the interval between dialyses, where the fluid volume comprised 60% of the body weight

Notes

Conflict of interest

- Not reported

Funding source

- Not reported

Other information

- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td>Outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Daily body weight gain rates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Daily salt intake</td>
</tr>
<tr>
<td>Bias due to confounding</td>
<td></td>
<td>Moderate: Days of the week could be an issue</td>
</tr>
<tr>
<td>Bias in selection of participants into the study</td>
<td></td>
<td>Serious: Patients selected based on scoring at least 50% on a HD therapy knowledge test</td>
</tr>
<tr>
<td>Bias in classification of interventions</td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Bias due to deviations from intended interventions</td>
<td></td>
<td>NI</td>
</tr>
<tr>
<td>Bias due to missing data</td>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Bias in measurement of outcomes</td>
<td></td>
<td>01/02. Moderate: The outcome assessors were not blinded; however, the outcomes assessed were objective</td>
</tr>
</tbody>
</table>
Nozaki 2005* (Continued)

Bias in selection of the reported result

Moderate

Overall risk of bias judgement

Serious: All outcomes judged at serious risk of bias in at least one domain

Paes-Barreto 2013

Study characteristics

Methods

Study design

• Parallel RCT

Duration of study

• Screened May 2009 to January 2011

Duration of follow-up

• Up to 27 months

Participants

General information

• Setting: single centre
• Country: Brazil
• Inclusion criteria: ≥ 18 years; eGFR < 60 mL/min/1.73 m²; at least 1 medical appointment with the clinic’s nephrologist
• Exclusion criteria: serious communication or intellectual impairment; acute inflammatory disease or other comorbidities; previously seen by a renal dietitian

Baseline characteristics

• Number: intervention group (43); control group (46)
• Mean age ± SD (years): intervention group (62.2 ± 12.2); control group (64.4 ± 9.3)
• Sex (M/F): intervention group (22/21); control group (24/22)
• Stage of CKD: CKD stages 3 to 5 (eGFR < 60 mL/min/1.73 m²)

Interventions

Intervention type

• Educational and self-management training: individual versus usual care

Intervention group

• Intense counselling
  o dietary counselling program
  o nutrition education program with monthly follow-up visits to reinforce the information

Control group

• Normal counselling
  o dietary counselling program

Co-interventions

• Both groups received the same dietary counselling program
Paes-Barreto 2013 (Continued)

### Outcomes

<table>
<thead>
<tr>
<th>Bloods</th>
<th>Weight gain</th>
<th>Nutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Serum albumin levels</td>
<td>• BMI, standard midarm muscle circumference, body composition (body fat, waist circumference)</td>
<td>• Adherence to prescribed low protein intake assessed by 24-hour food recall during each of 5 appointments</td>
</tr>
</tbody>
</table>

### Notes

**Conflict of interest/funding**

- "J.J.C. acknowledges grant support from the Swedish Medical Research Council. The other authors declare that they have no relevant financial interest"

**Other information**

- Contacted the author who confirmed the study was not blinded

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;A randomisation list with a number sequence was generated by computer software&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The allocated group was concealed during the study&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Dietitians counselled both intervention and control groups but not sure if they knew which group they were in - both groups had baseline counselling</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Dietitians could do a more in-depth review of patients in the intervention groups. Same dietitians did 24-hour recall for all patients</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Whilst some of the body composition measures could be done differently by different assessors, states the same assessor took these measurements. Objective outcome thought not to be affected by blinding</td>
</tr>
</tbody>
</table>
| Incomplete outcome data (attrition bias) | High risk | Quote: "Of the entire sample, 23 patients left the study during the intervention—13/56 (23%) from the intense counseling group and 10/56 (18%) from the normal counseling group. No significant differences were found regarding the demographics of patients who completed the study and those who did not (data not shown)."

There were 6 dropouts because of unwillingness to continue in the study from the intensive group and none for this reason from the control group. Also, there was more than the allocated 20% dropout from the intervention group; this will affect the power of the effect analysis |

| Selective reporting (reporting bias) | Unclear risk | All stated outcomes seem to be reported on |
| Other bias | Low risk | No other bias identified |
## Study characteristics

### Methods

**Study design**
- Parallel RCT

**Duration of study**
- Not reported

**Duration of follow-up**
- 4 months

### Participants

**General information**
- **Setting:** multicentre (21 sites)
- **Country:** USA
- **Inclusion criteria:** speak English; assessed as competent; > 18 years; not yet have completed an advanced directive
- **Exclusion criteria:** not reported

**Baseline characteristics**
- **Number:** 280 patients were eligible; 237 agreed to participate; 203 completed the study; numbers per group not reported
- **Mean age, range (years):** intervention group 1 (44, 20 to 83); intervention group 2 (44, 23 to 74); control group (45, 20 to 80)
- **Sex (F):** intervention group 1 (54%); intervention group 2 (46%); control group (46%)
- **Stage of CKD:** ESKD on dialysis

**Other information**
- There were no significant differences in distributions of characteristics or underlying causes of CKD among experimental groups

### Interventions

**Intervention type**
- Educational intervention: individual versus usual care

**Intervention group 1**
- Received advanced directive information through peer mentoring

**Intervention group 2**
- Received printed advanced directive information at the midpoint of the study

**Control group**
- Routine information provided by the dialysis unit

### Outcomes

**QoL**
- Subjective well-being assessed based on patient ratings by using 5 statements from the Diener scale assessing the current level of life satisfaction, including “the conditions of my life are excellent” and “I am satisfied with my life,” rated on a 5-point scale ranging from 1 (strongly disagree) to 5 (strongly agree)

**Anxiety and depression**
### Perry 2005 (Continued)

- Depression: 6 questions assessing such symptoms as dysphoria, somatic symptoms, and hopelessness
- Anxiety: 2 items measuring such symptoms as feeling trapped, and suicidal ideation (1 question) were assessed by using a modified version of the Hopkins Symptom Checklist

Number completing an Advance Directive; of those not completing an Advance Directive, the number who desire to do so (assessed by survey)

### Notes
- **Conflict of interest**
  - Not reported
- **Funding source**
  - “Supported in part by the Robert Wood Johnson Foundation; National Kidney Foundation of Michigan; and National Institute of Mental Health Career Grant no. K01-MH065423 (S.B.).”
- **Other information**
  - Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Claims randomisation but doesn't explain how it was done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>and personnel (performance bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-report questionnaires conducted patients and facilitated by unblinded social workers in relation to QoL and anxiety and depression</td>
</tr>
</tbody>
</table>
| Incomplete outcome data (attrition bias)     | Unclear risk       | Quote: "A small number of patients did not have follow-up data and are excluded. For example, in group 1, a total of 41 patients did not complete an AD, 37 of 41 patients had follow-up data, and 25 of these 37 patients reported a desire to complete an AD. In group 2, a total of 52 patients did not complete an AD, 49 of 52 patients had follow-up data, and 20 of these 49 patients reported a desire to complete an AD. In group 3, a total of 73 patients did not complete an AD, 69 of 73 patients had follow-up data, and 26 of 49 patients reported a desire to complete an AD."
| All outcomes                                 |                    | Quote: "5 instances, patients assigned to the peer-intervention group were moved to a control group by the social worker because of dialysis-schedule conflicts that prevented peer intervention. In addition, the peer mentor at 1 unit became ill early in the study and could not carry out the peer intervention; therefore, patients at this unit were assigned to the other 2 groups. Of 237 patients who agreed to participate, 203 patients completed all phases of the study and provided follow-up data. Thirty-four patients could not complete the study because of complications or changes in clinical status common among patients with ESRD, including death or hospital admission (25 patients), kidney transplantation (6 patients), and transfer to a different dialysis facility (3 patients)." |
This is not ITT - swapping between groups apparent. There was no loss to follow-up about whether the participants had completed an advanced directive but some for the follow-up survey - this is what we are interested in. 17% loss to follow-up; however, sample population still 203.

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>Only showed psychosocial changes with participants split by race - not just changes over all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Quote: &quot;Many participating social workers and all 17 participating peers attended a regional AD workshop.&quot; Not all social workers undertook the workshop that all the peers did. Sample population sizes different peer intervention n=63 printed materials n=59 control n=81 short duration</td>
</tr>
</tbody>
</table>

**PREPARED 2012**

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Recruitment April 2012 to July 2013

- **Duration of follow-up**
  - 6 months

**Participants**

- **General information**
  - **Setting**: multicentre (11 sites)
  - **Country**: USA
  - **Inclusion criteria**: initiated HD within 2 years of the date of screening; spoke English; ≥ 18 years; self-reported African American race
  - **Exclusion criteria**: self or HD nurse-reported dementia, objective cognitive impairment, prior kidney transplant, or medical exclusions from receiving LDKT

- **Baseline characteristics**
  - **Number**: intervention group 1 (30); intervention group 2 (31); control group (31)
  - **Mean age ± SD (years)**: intervention group 1 (53 ± 16); intervention group 2 (55 ± 13); control group (53 ± 14)
  - **Sex (M/F)**: intervention group 1 (15/15); intervention group 2 (12/19); control group (18/13)
  - **Stage of CKD**: ESKD on HD

**Interventions**

- **Intervention type**
  - Provision of materials: education versus control

- **Intervention group 1**
  - A book and DVD with information about LDKT and other kidney replacement treatment options from the perspectives of patients and families who had the relative treatment

- **Intervention group 2**
### Outcomes
- Self-reported consideration or pursuit of LDKT, discussion about LDKT, completion of LDKT, identification of a donor, beliefs and concerns

### Notes
- **Conflict of interest**
  - "Dr. Weir reports personal fees from Relypsa, personal fees from ZS Pharma, during the conduct of the study; personal fees from Akebia, personal fees from Janssen, personal fees from AstraZeneca, personal fees from Amgen, personal fees from MSD, personal fees from AbbVie, personal fees from Novartis, personal fees from Boston Scientific, personal fees from Sandoz, outside the submitted work."

- **Funding source**
  - "Research reported in this publication was supported by the National Institute of Diabetes and Digestive and Kidney Diseases under Award Number R01DK079682 (Drs. Boulware, Rabb, Powe, Wang, and Ms. Ephraim), and the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR001117 (Drs. Davenport and Choudhury)."

### Other information
- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Sequence blocked randomisation with sequentially numbered opaque sealed envelopes</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation was concealed to the research staff enrolling the participants</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self report outcomes by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Objective outcomes not thought to be affected by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Loss to follow-up numbers differed between groups with varying reasons</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All outcomes were reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Did not meet recruitment goal, may be underpowered</td>
</tr>
</tbody>
</table>
## Raiesifar 2014

### Study characteristics

#### Methods

<table>
<thead>
<tr>
<th>Study design</th>
<th>Parallel RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of study</td>
<td>Recruitment from 2009 to 2010</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>3 months</td>
</tr>
</tbody>
</table>

#### Participants

<table>
<thead>
<tr>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting: multicentre (4 sites)</td>
</tr>
<tr>
<td>Country: Iran</td>
</tr>
<tr>
<td>Inclusion criteria: ≥ 18 years; no history of any QoL-affecting disease or condition; Persian as the first language; admitted the first time for transplant</td>
</tr>
<tr>
<td>Exclusion criteria: failed transplant; re-hospitalised; did not wish to continue the</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number: intervention group (45); control group (45)</td>
</tr>
<tr>
<td>Mean age ± SD (years): 7.5 ± 12.9 years</td>
</tr>
<tr>
<td>Sex (M/F): 66/24</td>
</tr>
<tr>
<td>Stage of CKD: receiving kidney transplant</td>
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</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>No significant difference was detected between the two groups when evaluating the frequency distribution of demographic variables</td>
</tr>
</tbody>
</table>

#### Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational and self-management training: group versus usual care</td>
</tr>
</tbody>
</table>

**Intervention group**

- Continuous care model (4 stages) applied for 3 months

**Control group**

- Routine care

#### Outcomes

| QoL |
| Kidney transplant questionnaire (KTQ-25) compared monthly between treatment and control groups |

#### Notes

**Conflict of interest**

- "None declared"

**Funding source**

- Not reported

**Other information**
### Rasiesifar 2014 (Continued)

- Not requested

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Claims randomisation but no explanation of how this was done</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self report questionnaire completed by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Of a total of 90 participants, 4 in the experimental group were excluded from the study (2 were unwilling and 2 had to be hospitalized) and 8 of the controls were excluded (2 unwilling and 6 hospitalized).&quot; Small loss to follow-up</td>
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<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
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</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
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</table>

### Rasgon 1993*

#### Study characteristics

**Methods**

- **Study design**
  - Quasi-RCT

- **Duration of study**
  - 2009 to 2010

- **Duration of follow-up**
  - 3 months

**Participants**

- **General information**
  - **Setting**: multicentre (number of sites unclear)
  - **Country**: USA
  - **Inclusion criteria**: 18 to 65 years; employed prior to beginning maintenance HD treatment, had been receiving dialysis for 6 months or more; able to speak English or Spanish; all participants were members of the same HMO and had the same insurance benefits. Patients from the treatment centre and control centres had the same opportunity to choose the type of dialysis modality, and all had the same opportunity to be referred for transplant evaluation
  - **Exclusion criteria**: not reported
Baseline characteristics

- **Number**: intervention group (45); control group (57)
- **Mean age (years)**: intervention group (49); control group (51)
- **Sex (M/F)**: intervention group (28/17); control group (35/22)
- **Stage of CKD**: ESKD on HD

Other information

- No significant demographic differences between groups

Interventions

**Intervention type**

- Self-management: group versus control (family invited)

**Intervention group**

- A multidisciplinary predialysis education and orientation program aimed at blue-collar workers which focused on integrating dialysis into their lives and maintaining employment. Provided by a social worker at least twice prior to dialysis treatment

**Control group**

- No predialysis program

Outcomes

**QoL**

- Assessed by questionnaire based on modified QoL index developed for use in studies of patients with cancer and other chronic illnesses. Scale items revised so that index could be administered by phone

**Self-esteem**

- Rosenberg Self-Esteem Scale (10 items)

**Functional status**

- Modified version of the Karnofsky Scale of Physical Performance, attitude towards work, employment status

Notes

**Conflict of interest**

- Not reported

**Funding source**

- "Supported by the Department of Education and Research, Kaiser Foundation, Los Angeles, CA (S.R. and A.J-R.)."

**Other information**

- Not requested

Risk of bias

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<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
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<tr>
<td></td>
<td></td>
<td>1. Employment status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Functional status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. attitudes towards work</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. QoL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Self-esteem</td>
</tr>
</tbody>
</table>

**Interventions for improving health literacy in people with chronic kidney disease (Review)**

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
Bias due to confounding
Moderate: Allocation based on location could confound, although analysed differences between groups on many variables

Bias in selection of participants into the study
Serious: Selected based on whether they were employed or not was also an outcome

Bias in classification of interventions
NI

Bias due to deviations from intended interventions
Serious: Said social workers had some educational sessions but did not mention explicit training or clear content to be covered

Bias due to missing data
Moderate: Low dropout rate, do not give reasons for dropout

Bias in measurement of outcomes
01. Low: objective measure and type of employment judged by blinded assessors
02/03/04/05. Serious: self-report questionnaires for subjective measures

Bias in selection of the reported result
Serious: Reported same outcome in different ways. Unclear as to what cohort falls into what subgroup

Overall risk of bias judgement
Serious: All outcomes judged at serious risk of bias in at least one domain

Reedy 1998

Study characteristics

Methods

<table>
<thead>
<tr>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parallel RCT</td>
</tr>
</tbody>
</table>

Duration of study

- Not reported

Duration of follow-up

- Not reported

Participants

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<th>General information</th>
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<tr>
<td>Setting: not reported</td>
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<tr>
<td>Country: USA</td>
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<tr>
<td>Inclusion criteria: not reported</td>
</tr>
<tr>
<td>Exclusion criteria: not reported</td>
</tr>
</tbody>
</table>
Baseline characteristics

- Number: 83 randomised, 56 completed the study
- Mean age ± SD (years): not reported
- Sex (M/F): not reported
- Stage of CKD: not reported

Interventions

**Intervention type**

- Education: visual aids versus no visual aids
- Both got an intervention; cannot tell if group education

**Intervention group**

- Nutrition education with visual aids

**Control group**

- Nutrition education with no visual aids

Outcomes

Knowledge on phosphorus knowledge test, Ca, phosphate

Notes

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Have emailed author requesting more information as this is just an abstract

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
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</table>
Reedy 1998 (Continued)

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>Insufficient information to permit judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
</tbody>
</table>

Robinson 2011

**Study characteristics**

**Methods**

- **Study design**
  - Parallel RCT

**Duration of study**

- Recruited during 2009

**Duration of follow-up**

- 1 month

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
  - **Inclusion criteria**: received a kidney transplant 1 to 1.2 years or 3 to 7 years prior to the visit; ≥ 18 years; being able to read English and to see newspaper-size print clearly; being willing to answer a telephone survey 1 month after the visit
  - **Exclusion criteria**: history of skin cancer; being under the care of a dermatologist

**Baseline characteristics**

- **Number**: intervention group (38); control group (37)
- **Median age (range)**: 60 years (25 to 79)
- **Sex (M/F)**: 44/31
- **Stage of CKD**: kidney transplant recipients

**Other information**

- There were no significant differences between the 2 groups (1 to 1.2 years or 3 to 7 years) for these variables

**Interventions**

- **Intervention type**
  - Educational and self-management training: provision of materials versus usual care

**Intervention group**

- Educational intervention: reading workbook on REACT skin cancer mnemonic, post-intervention survey

**Control group**

- Usual care

**Outcomes**

- **Knowledge**
  - True/false responses to 4 items regarding skin cancer

**Self-management**
**Skin self-examination tendencies** were assessed by 4 yes/no questions at baseline and 1-month follow-up; likelihood of asking partner for assistance was assessed on 5-point Likert scale.

**Self-efficacy**

- Asked how confident they felt that they could recognise a SCC on a 5-point Likert scale ranging from not at all confident (0) to extremely confident (4)

**Cancer concerns**

- Assessed with Response options ranging from not at all concerned (0) to very concerned (3); attitude towards skin self-exam assessed with two 4-point scales

### Notes

**Conflict of interest**

- “Dr Robinson is the Editor of the Archives of Dermatology. She was not involved in the editorial evaluation or editorial decision to accept this work for publication.”

**Funding source**

- "None reported"

**Other information**

- Received email from Dr Robinson about randomisation and allocation concealment and results for control group post-intervention for QoL and self-efficacy outcomes

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomised by computer program</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation concealed using an envelope</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>The subjective outcomes were completed over the phone with unblinded personnel and the participants were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>High risk</td>
<td>Knowledge is an objective outcome, however, completed over the phone with unblinded personnel instead of self-reported by participants: high risk of bias</td>
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<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>No loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All states outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Small sample size, limited time period, so results may not be generalisable demographic diff between control and intervention groups, no external verification of participant’s attendance at dermatologist’s office following intervention limited external validity</td>
</tr>
</tbody>
</table>
### Robinson 2014a

#### Study characteristics

**Methods**

**Study design**

- Parallel RCT

**Duration of study**

- May 2013 to July 2013

**Duration of follow-up**

- 6 weeks

**Participants**

**General information**

- Setting: unclear
- Country: USA
- **Inclusion criteria:** 18 to 85 years; history of kidney transplantation within the last 2 to 24 months; spoke and read English; could see to read; lived in the greater Chicago area
- **Exclusion criteria:** prior history of skin cancer, as noted in the medical record or self-reported; history of dermatologic disease treated with ultraviolet light, e.g. psoriasis, atopic dermatitis; under the care of a dermatologist within the last 5 years

**Baseline characteristics**

- **Number:** intervention group (52); control group (51)
- **Mean age, range (years):** intervention group (54, 44 to 62); control group (54, 44 to 60)
- **Sex (M/F):** intervention group (34/18); control group (34/17)
- **Stage of CKD:** kidney transplant recipient

**Other information**

- There were no significant demographic differences between the educational intervention and standard of care groups in terms of demographic variables, time since transplantation, living outside the Midwest or the USA, and work-related sun exposure

**Interventions**

**Intervention type**

- Educational and self-management training: provision of materials versus usual care

**Intervention group**

- Culturally sensitive educational workbook, 3 seasonal sun protection reminders by text message or email over 5 weeks

**Control group**

- Standard care sun protection recommendations

**Outcomes**

**Knowledge**

- Knowledge of skin cancer and sun protection; survey at baseline and 6-week follow-up

**Self-management**

- Sun protection behaviour (hours spent outdoors/week, use of sunscreen, wearing protective clothing, seeking shade); willingness to use sun protection - survey at baseline and 6-week follow-up

**Notes**

**Conflict of interest**
### Funding source

- "This study was supported by R03 CA-159083 to JKR, from the National Cancer Institute. ClinicalTrials.gov NCT01646099. IRB: STU00069552."

### Other information

- Not requested

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomisation using computer generated system with stratification</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation concealed using sealed envelopes</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Personnel blinded to group allocation but participants not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Sun protection behaviours and willingness to use sun protection and subjective measures and self-report questionnaires, therefore, not blinded For the melanin index, the assessors were blinded: low risk of bias for this outcome</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge is an objective measurement therefore blinding not thought to affect outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Very small loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Quote: &quot;Participants received a $20 check after the first visit and a $40 check after the second visit in appreciation of their time along with a 6-h parking voucher for each visit.&quot; Received monetary reimbursement for participation Did not reach power calculation. Small sample size</td>
</tr>
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</table>

### Study characteristics

#### Methods

- **Study design**
  - Parallel RCT
Robinson 2015 (Continued)

Duration of study

• 30 May to 15 July 2014

Duration of follow-up

• 6 weeks

Participants

General information

• Setting: multicentre (2 sites)
• Country: USA
• Inclusion criteria: 18 to 85 years, history of kidney transplantation within the past 2 to 24 months; spoke and read English or Spanish; could see to read a newspaper; lived in the greater Chicago area; self-identified as white, black, or Hispanic
• Exclusion criteria: previous history of skin cancer self-reported or noted in their medical record; received education about sun protection or participated in our previous educational sun protection study; experienced kidney rejection; visually impaired; comorbid diseases prevented participation

Baseline characteristics

• Number: intervention group (84); control group (86)
• Mean age ± SD (years): intervention group (51 ± 12.5); control group (49 ± 14.2)
• Sex (M/F): intervention group (45/39); control group (56/30)
• Stage of CKD: kidney transplant recipients

Interventions

Intervention type

• Education and self-management: provision of materials versus control

Intervention group

• Electronic interactive sun protection program

Control group

• Usual care

Outcomes

Knowledge

• Skin cancer and sun protection knowledge assessed at baseline and during the educational program

Self-management

• Sun protection behaviours (self-report)

Attitudes towards sun protection behaviour

Notes

Conflict of interest

• “The authors declare no conflicts of or competing interests”

Funding source

• “Supported by R21 CA-173196 to June K. Robinson, MD, from the National Cancer Institute”

Other information

• Received email from Dr Robinson randomisation was completed using a computer-generated system

Risk of bias

Interventions for improving health literacy in people with chronic kidney disease (Review)
### Robinson 2015 (Continued)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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<td>Low risk</td>
<td>Random allocation sequence</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Software program gave the participants their allocation. No mention of whether research team were aware of allocation but probably done because author uses concealed methods in other studies</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Quote: “The software program gave the participants their allocation, and thus, the kidney transplant recipients were not blinded to their condition” The RA was blinded to group however likely this could of been broken during the phone conversation</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-reported willingness to change is a subjective measure that is related to the intervention and completed by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge and health literacy are thought to be objective measures and should not be affected by blinding</td>
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<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>All participants in the baseline assessments completed the 2-week follow-up</td>
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<tr>
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<td>Unclear risk</td>
<td>All outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Short follow-up period self reported outcomes collected in 2 different ways - initially on a tablet, follow-up by a phone interview - may have introduced observer effect. Latino sample under powered</td>
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### Rodrigue 2007

**Study characteristics**

<table>
<thead>
<tr>
<th>Methods</th>
<th></th>
</tr>
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<td>Study design</td>
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<tr>
<td>Duration of study</td>
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**Participants**

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<tbody>
<tr>
<td>Setting: single centre</td>
</tr>
<tr>
<td>Inclusion criteria: medical approval for transplant listing; ≥ 21 years; lived within 90 miles of the transplant centre; residential telephone or cell phone service</td>
</tr>
</tbody>
</table>
Baseline characteristics

- **Number**: intervention group (63); control group (69)
- **Mean age ± SD (years)**: intervention group (50.7 ± 11.8); control group (53.4 ± 11.8)
- **Sex [M/F]**: intervention group (34/35); control group (34/29)
- **Stage of CKD**: medically approved for transplant listing

Other information

- Dropout rates varied significantly by group: 10% for CB patients versus 31% for HB patients
- Study completers and dropouts did not differ significantly on sociodemographic characteristics or baseline measures, except that African Americans were more likely to drop out compared to White patients (P = 0.03)

Interventions

**Intervention type**

- Educational intervention: group versus usual care

**Intervention group**

- Clinic-based education
  - Brief discussion about LDKT with the transplant surgeon and/or nephrologist during a clinic visit, a 60-minute group education session and written materials
- Home-based education: home visits by educators with participants and their social networks within 6 weeks of study with a ‘roundtable’ discussion format alone with a videotape called “A Gift for Life: Living Kidney Donation”

**Control group**

- Clinic-based education

**Co-interventions**

- Both groups received clinic-based education

Outcomes

**Knowledge**

- Patients’ LDKT knowledge, LDKT knowledge was measured using 15 true–false items

**Proportion of patients with living donor inquiries**

- Any verbal or written expression (e.g. return of a health history questionnaire) of possible donor interest received by one of the kidney transplant coordinators on behalf of an enrolled patient

**Living donor evaluations**

- Initiation of the donor workup that is part of the transplant centre’s clinical pathway

Notes

**Conflict of interest**

- "There are no conflicts of interest to report"

**Funding source**

- "This research was supported by a grant from the U.S. Department of Health and Human Services, Health Resources and Services Administration (Division of Transplantation, 5H39OT00115)."

**Other information**

- Rodrigue 2008 is a secondary analysis looking at the differential effectiveness in blacks and whites of a home-based (HB) LDKT educational approach
### Rodrigue 2007 (Continued)

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;stratified randomization by race (White, African American) in order to best balance the two intervention groups.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quote: &quot;randomized into two groups&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient information about exactly how randomisation took place</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants not blinded; home visits conducted by trained health educators usual care conducted by nephrologists, nurses not clear how researchers were involved other than recruitment and if they were blinded</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Amount of patients who have enquired about living kidney donation is subjective as no parameters about what entails an enquiry were specified</td>
</tr>
<tr>
<td>Subjective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Knowledge is an objective outcome</td>
</tr>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>High rate of drop out in home-base group (31%) and only 10% in clinic-based group</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
<td>Completers and drop outs different with respect to race</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Self selection bias. Single centre study so may not be generalisable</td>
</tr>
</tbody>
</table>

#### Rodrigue 2011

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

**Duration of study**

- Enrolled January 2007 to February 2009

**Duration of follow-up**

- 12 weeks

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
Interventions for improving health literacy in people with chronic kidney disease (Review)

Inclusion criteria: 18 to 70 years; CKD or ESKD; medically approved for kidney transplant; living within 60 miles of transplant centre

Exclusion criteria: already receiving psychological treatment; had received a prior transplant; listed for LDKT; did not speak English; had known cognitive impairment

Baseline characteristics

- Number: intervention group 1 (22); Intervention group 2 (20); control group (20)
- Mean age ± SD (years): intervention group 1 (53.2 ± 11.1); Intervention group 2 (48.6 ± 11.9); control group (52.7 ± 12.7)
- Sex (M/F): intervention group 1 (12/10); Intervention group 2 (8/12); control group (9/11)
- Stage of CKD: CKD or ESKD

Other information

- Baseline sociodemographic and medical characteristics were similar across the 3 groups. Fewer QoLT patients had ≥ 12 years of education compared with ST and SC patients

Interventions

<table>
<thead>
<tr>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-management: QoL therapy versus supportive therapy versus control</td>
</tr>
</tbody>
</table>

**Intervention group 1**

- QoL training: therapist worked with the patient to identify specific areas of life contributing to the patient’s overall QoL. Once weekly, face-to-face, for ~50 minutes/session, with participants receiving 8 individual treatment sessions over 2 months. Six sessions or more were recorded as a ‘full dose’ of treatment

**Intervention group 2**

- Supportive therapy: emotional and educational support delivered in a structured way focused on coping with the demands of waiting for KT. Session topics included the transplant process, medications and their effects, illness and transplantation, emotional issues, issues of death and dying, communication, and navigating the healthcare system. Once weekly, face-to-face, for ~50 minutes/session, with participants receiving 8 individual treatment sessions over a 2-month time period. Six sessions or more were recorded as a ‘full dose’ of treatment

**Control group**

- Standard care: no intervention

Outcomes

<table>
<thead>
<tr>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety and depression</td>
</tr>
<tr>
<td>Profile of mood states</td>
</tr>
<tr>
<td>Number of unhealthy mental health days</td>
</tr>
<tr>
<td>Miller social intimacy scale</td>
</tr>
</tbody>
</table>

Notes

**Conflict of interest**

- "None declared"

**Funding source**

- Not reported

**Other information**

- Not requested
**Rodrigue 2011** (Continued)

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Quote: &quot;After the baseline assessment (T1), patients were randomised to QOLT, ST or SC.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient information about how randomisation actually took place</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information; probably not done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>Unclear risk</td>
<td>Personnel were blinded but participants were not</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>small sample which did not reach power</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Possible self selection bias</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Only 1 centre</td>
</tr>
</tbody>
</table>

**Russell 2002**

**Study characteristics**

**Methods**

**Study design**

- Parallel RCT

**Duration of study**

- 1997 to 1999

**Duration of follow-up**

- 6 months

**Participants**

**General information**

- **Setting**: single centre
- **Country**: USA
- **Inclusion criteria**: on the cadaveric kidney transplantation waiting list at a university-affiliated hospital in the Midwest
- **Exclusion criteria**: < 18 years; previous kidney transplant; no functional telephone in the home
**Baseline characteristics**

- **Number**: 50 (numbers per group not reported)
- **Mean age ± SD**: 48.5 ± 12.6 years
- **Sex (M/F)**: 35/15
- **Stage of CKD**: awaiting cadaveric kidney transplant

**Interventions**

**Intervention type**

- Educational intervention: provision of materials versus usual care

**Intervention group**

- Received phone calls and mailings once a month for 6 months

**Control group**

- Standard care

**Outcomes**

**Hope**

- Measured on the Herth Hope Index (12 items)

**Uncertainty**

- Measured by Mishel's Uncertainty in Illness Scale for Adults (32 items) evaluated at beginning of study and 6 months later

**Notes**

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Claims randomisation but does not explain how this was carried out</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants were not blinded, unsure about personnel</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Not sure if personnel were blinded to treatment group, but self-report measures completed by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>No mention of loss to follow-up</td>
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</tbody>
</table>
### Russell 2002 (Continued)

<table>
<thead>
<tr>
<th>All outcomes</th>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>All stated outcomes seem to be reported</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Predominantly men and majority white and married</td>
</tr>
</tbody>
</table>

### Russell 2011

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Not reported

- **Duration of follow-up**
  - 6 months

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
  - **Inclusion criteria**: ≥ 21 years; prescribed at least 1, twice daily prescribed immunosuppressive medication; non-adherent with immunosuppressive medication; functioning kidney transplant; transplant physician and nephrologists assent that recipient can participate in the study; ability to speak, hear, and understand English; able to open an electronic medication cap; administers immunosuppressive medications to self; has a telephone or has access to a telephone; no cognitive impairment; no other diagnoses that may shorten the life span
  - **Exclusion criteria**: not reported

- **Baseline characteristics**
  - **Number**: intervention group (8); control group (7)
  - **Mean age ± SD (years)**: intervention group (55 ± 12.1); control group (44 ± 15.7)
  - **Sex (M/F)**: intervention group (4/4); control group (3/4)
  - **Stage of CKD**: kidney transplant patients

- **Other information**
  - The groups did not differ with respect to the medication adherence scores determined at the screening stage

**Interventions**

- **Intervention type**
  - Self-management training: individual versus usual care

- **Intervention group**
  - Continuous self-improvement intervention: focus on changing the systems in which the person lives using the plan-do-check-act process. Initiated during the initial home visit and reviewed each month during the 6-month intervention

- **Control group**
• Attention control: provision of educational brochures focused on healthy post-transplant behaviours once a month, first by home visit, then by mail
• Monthly telephone calls were made to review the information in the brochures

Outcomes

Adherence

• Medication adherence measured by MEMS

Notes

Conflict of interest

• Not reported

Funding source

• “This study was supported by grants from American Nephrology Nurses Association, National Kidney Foundation, Interdisciplinary Center on Aging at the University of Missouri, University of Missouri Research Council, and Iowa Gerontological Nursing Intervention Research Center.”

Other information

• Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Block randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Person allocating was blinded</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants not blinded; didn’t say whether research personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Unblinded but objective outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>All randomised participants completed the study</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Quote: “A monetary gift was provided to thank participants for their time.” Financial incentive given for participation Small sample population, single centre</td>
</tr>
</tbody>
</table>

Russell 2011 (Continued)

Saeedi 2014

Study characteristics
Methods

Study design
- Parallel RCT

Duration of study
- Not reported

Duration of follow-up
- 10 weeks

Participants

General information
- Setting: single centre
- Country: Iran
- Inclusion criteria: 18 to 65 years; a history of HD for at least 6 months 2 to 3 times/week; acceptable ability to learn sleep hygiene program
- Exclusion criteria: unwilling to continue to participate in the study; suffering from known mental diseases including deep anxiety and depression; cognitive impairment; experiencing an unpredictable crisis or disease during the study

Baseline characteristics
- Number: intervention group (41); control group (41)
- Mean age ± SD (years): intervention group (52.27 ± 17.32); control group (57.87 ± 13.95)
- Sex (M/F): intervention group (15/23); control group (20/18)
- Stage of CKD: ESKD on HD

Interventions

Intervention type
- Educational intervention: individual and group versus usual care

Intervention group
- 6 weekly sessions of half-hour sleep hygiene training program. Direct teaching methods, a combination of face-to-face methods, lectures, and group discussions

Control group
- Not reported

Outcomes

Sleep quality
- Assessed by the Pittsburgh Sleep Quality Index before and after the intervention (subjective sleep quality, sleep latency, sleep efficiency, sleep duration, sleep disturbances, use of sleep medications, and daytime dysfunction)

Notes

Conflict of interest
- "None declared"

Funding source
- "Arak University of Medical Sciences supported the study by a grant."

Other information
- Emailed about randomisation and allocation concealment

Risk of bias
### Saeedi 2014 (Continued)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>Unclear risk</td>
<td>Probably not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;Six of 82 patients (3 in the intervention group and 3 in the control group) were excluded from the study and data of 76 patients were analyzed&quot; Small even dropout rate; reasons unknown</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

### Sathvik 2007

#### Study characteristics

**Methods**

**Study design**

- Cross-over RCT
  - Phase I: 8-week intervention to group 1; none to group 2
  - Phase II: intervention removed from group 1; group 2 received intervention for 8 weeks

**Duration of study**

- April 2003 to June 2004

**Duration of follow-up**

- 16 weeks

**Participants**

**General information**

- Setting: multicentre (2 sites)
- Country: India
- Inclusion criteria: 18 to 80 years; regular HD as an outpatient; received scheduled medications for the past month
- Exclusion criteria: multiple organ system failures; memory impairment; unconscious; severe disability; short-term or irregular dialysis; unable to speak or understand the local language, Kannada or English; unwilling to participate

**Baseline characteristics**

- Number: intervention group (45); control group (45)
Sathvik 2007 (Continued)

• Mean age ± SD (years): intervention group (50.69 ± 13.69); control group (47.29 ± 17.78)
• Sex (M/F): intervention group (31/14); control group (37/8)
• Stage of CKD: ESKD on HD

Other information
• The baseline difference in gender, age, education, number of medications, duration of dialysis, residing of the patient and medication knowledge score between the groups was not significant

Interventions

Intervention type
• PLEASE COMPLETE

Intervention group
• Participants were counselled verbally by a pharmacist regarding their medications for 8 weeks, twice a week for 15-20m during HD. Written educational materials provided like patient information leaflets and take-home medication chart in the local language

Control group
• No clinical pharmacist education during phase I of the study just usual care through the health service

Outcomes

Knowledge
• Medication knowledge assessment questionnaire developed by investigators

Notes

Conflict of interest
• Not reported

Funding source
• Not reported

Other information
• Emailed author about additional information with no response to date

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The eligible patients were randomised using a block design&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants not blinded; no mention whether pharmacist was part of research team</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Unclear risk</td>
<td>Unclear how knowledge questionnaire was delivered. Outcome assessors were not blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Out of 102 HD patients enrolled, 90 patients completed the study, 12 patients were considered dropouts (6 died, 4 moved out of the city, and 2 shifted to another hospital for treatment).</td>
</tr>
</tbody>
</table>
### Sathvik 2007 (Continued)

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>All outcomes seem to be reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Cross-over design with no mention of how long between each time point, could be contaminated</td>
</tr>
</tbody>
</table>

### Sehgal 2002

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Cluster RCT (by nephrologist)</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of study</strong></td>
</tr>
<tr>
<td></td>
<td>• April 1999 to June 2000</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of follow-up</strong></td>
</tr>
<tr>
<td></td>
<td>• 6 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• <strong>Setting</strong>: multicentre (29 sites; 53 nephrologists)</td>
</tr>
<tr>
<td></td>
<td>• <strong>Country</strong>: USA</td>
</tr>
<tr>
<td></td>
<td>• <strong>Inclusion criteria</strong>: ≥ 18 years; previous Kt/V and mean Kt/V for the previous 3 months were both less than the monthly goal for that facility; receiving HD for at least 6 months</td>
</tr>
<tr>
<td></td>
<td>• <strong>Exclusion criteria</strong>: new patients; declined to participate; did not speak English; mentally impaired</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Number</strong>: intervention group (85); control group (84)</td>
</tr>
<tr>
<td>• <strong>Mean age ± SD (years)</strong>: intervention group (55 ± 14); control group (54 ± 14)</td>
</tr>
<tr>
<td>• <strong>Sex (M/F)</strong>: intervention group (63/22); control group (62/22)</td>
</tr>
<tr>
<td>• <strong>Stage of CKD</strong>: ESKD on HD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Intervention and control patients had similar demographic and medical characteristics, baseline Kt/V and facility Kt/V goals, and specific barriers to adequate HD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Educational intervention: individual versus usual care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study coordinator educated all intervention patients about the meaning and importance of adequate dialysis dose. They then provided feedback and recommendations to both participants and their nephrologists. Information provided was based on specific barrier(s) present (low prescription, shortened treatment time, catheter use)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standard care</td>
</tr>
</tbody>
</table>

| Outcomes | Progression of kidney disease |
Sehgal 2002 (Continued)

- Change in Kt/V QoL
- 7 subscales examined at baseline and final follow-up
Changes in barriers
- Prescribed dialysis dose, catheter use, shortened treatment time

Notes

Conflict of interest
- Not reported

Funding source
- “This study was supported by grants DK51472 and DK51478 from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Bethesda, MD”

Other information
- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Random-number generator to assign these nephrologists to an intervention or control”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants not blinded. Study coordinator not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Quote: “Because the study coordinator carried out the intervention, it was not possible for her to be blinded to subjects' assignment to intervention vs control groups.” Subjective self-report questionnaire with neither personnel nor participants blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Catheter use, Kt/V and treatment time</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Small loss to follow-up. Not clear how many patients declined to participate versus dropped out of study. Similar in all demographics except for age</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Did not report statistics about QoL</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Quote: “We obtained informed consent from eligible patients, and they were each given $10 at the beginning and again at the end of the trial to thank them for their participation.” Financial incentive</td>
</tr>
</tbody>
</table>
### Study characteristics

#### Methods

**Study design**
- Cluster RCT

**Duration of study**
- November 2003 to March 2004

**Duration of follow-up**
- 4-week treatment phase, then 10-week follow-up

#### Participants

**General information**
- **Setting**: multicentre (4 sites; 10 clusters)
- **Country**: UK
- **Inclusion criteria**: ≥ 18 years; receiving HD 3 times/week for at least 3 months; living in a home setting; willing to participate; no severe cognitive disorders; no significant vision or hearing impairments; ability to speak and/or read English; not currently receiving any additional psychotherapeutic treatment from another source
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group (29, 5 clusters); control group (27, 5 clusters)
- **Mean age ± SD (years)**: intervention group (56.05 ± 12.73); control group (52.52 ± 12.70)
- **Sex (M/F)**: intervention group (18/11); control group (20/7)
- **Stage of CKD**: ESKD on HD

**Other information**
- Baseline analysis showed no significant differences between the immediate and deferred groups for sex, age, marital status, occupational status, education, time on dialysis therapy, baseline IDWG, and all HADS subscales. From the SF-36, no significant differences were shown, with the exception of Role–Emotional

#### Interventions

**Intervention type**
- Educational and self-management training: group versus usual care

**Intervention group**
- Immediate treatment: intervention administered in a group format (3 to 8 people) for hour-long sessions once a week for 4 weeks. The education was focused on fluid restriction. Behavioural and cognitive techniques were used to improve self-monitoring. A muscle relaxation tape was also provided

**Control group**
- Deferred treatment: standard care for 4 weeks before starting treatment

#### Outcomes

**Weight gain**
- IDWG
- QoL
- SF-36

**Self-efficacy**
Sharp 2005 (Continued)

- VAS, participants were requested to rate questions relating to health beliefs and attributions associated with fluid restrictions
- Anxiety and depression
- HADS

Notes

Conflicts of interest
- Not reported

Funding source
- Not reported

Other information
- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Shi/f_ts, or clusters, were allocated on an individual basis to either the ITG or DTG according to an automated computer-generated randomization procedure.&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Allocation concealment was ensured because recruitment of participants was performed in ignorance of the group to which the cluster would be assigned.&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Quote: &quot;As active recipients of the intervention, participants could not be ignorant of treatment administration. &quot;The evaluator was not blinded to treatment allocation.&quot;</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>The subjective outcomes were completed by unblinded participants in self-report questionnaires</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>The primary outcome measure, IDWG, was a routine objective measure calculated by renal nursing staff independent of the trial</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Small loss to follow-up and ITT</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Bias in randomising shifts however at baseline both groups similar and only different in 1 SF-36 subgroup</td>
</tr>
</tbody>
</table>

Shi 2013

Study characteristics
Methods

**Study design**
- Parallel RCT

**Duration of study**
- June 2009 to March 2011

**Duration of follow-up**
- 6 months

Participants

**General information**
- **Setting**: multicentre (2 sites)
- **Country**: China
- **Inclusion criteria**: ≥ 18 years; clinical diagnosis of CKD and receiving long-term HD for at least 6 months; latest serum phosphorus level and mean serum phosphorus level for previous 3 months both > 178 mmol/L; prescribed phosphate binders
- **Exclusion criteria**: unable or unwilling to give informed consent or comply with the intervention; severe somatic diseases

**Baseline characteristics**
- **Number**: intervention group (40); control group (40)
- **Mean age ± SD (years)**: intervention group (54.75 ± 11.86); control group (51.85 ± 13.51)
- **Sex (M/F)**: intervention group (21/19); control group (23/17)
- **Stage of CKD**: ESKD on HD

**Other information**
- Sociodemographic and relevant clinical characteristics were comparable across the groups. After randomisation, the two groups of participants had similar demographic characteristics and relevant clinical characteristics

Interventions

**Intervention type**
- Educational intervention: individual and group versus usual care

**Intervention group**
- Individual intensive educational programme by a nephrology nurse 20 to 30 minutes, 2 to 3 times/week for 6 consecutive months
- Group educational sessions for participants or their relatives monthly for 6 months at the HD units of 2 hospitals

**Control group**
- Usual care

Outcomes

**Bloods**
- Serum phosphorus, Ca x P product, serum calcium, PTH, albumin levels

**Knowledge**
- Chinese-language questionnaire containing 17 items that cover four domains: harmfulness of hyperphosphataemia, knowledge related to phosphorus food restriction, knowledge of phosphate binders and subjects’ compliance with diet and medication

Notes

**Conflict of interest**
Shi 2013 (Continued)

- "No conflict of interest exists in the submission of this manuscript"

**Funding source**

- Not reported

**Other information**

- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Random number table</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The sequence was concealed from all investigators with opaque sealed envelopes, and these envelopes were given to a nurse who was not involved in the study&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>The participants were not blinded however some of the personnel were</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;A nephrology nurse collecting and assessing data was blinded to the random procedure, and she did not involve in the care of patients&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The outcome assessor was blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Used ITT; 7.5% loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No other bias identified</td>
</tr>
</tbody>
</table>

**Slowik 2001**

**Study characteristics**

**Methods**

**Study design**

- Non-RCT

**Duration of study**

- August 1997 to June 1999

**Duration of follow-up**

- Not reported

**Participants**

**General information**

- Setting: single centre
Country: USA
Inclusion criteria: eGFR < 30 mL/min or were projected to need dialysis in the next 12 months
Exclusion criteria: not reported

Baseline characteristics
Number: intervention group (57); control group (57)
Mean age ± SD (years): intervention group (62.6 ± 16); control group (59.1 ± 14.7)
Sex [M/F]: intervention group (25/32); control group (32/25)
Stage of CKD: eGFR < 30 mL/min

Interventions
Intervention type
• Education and self-management group and one-on-one versus control

Intervention group
• Healthy Start Program: education and clinical interventions from a multidisciplinary team
  • Basic clinic: 3-hour educational sessions to groups of about 6 patients and their significant others
    focused on increasing awareness of kidney disease and discussing methods of preventing the progression of renal failure and interventions for treatment.
  • Advanced clinic: individual one-hour sessions with the social worker, dietician, and nurse focused on improving short-term outcomes and assisting with the initiation of dialysis

Control group
• Patients who began dialysis during the same period but who did not enrol in the program

Outcomes
Progression of kidney disease
• Albumin
Whether fistula was placed prior to starting dialysis, and fistula used to initiate dialysis

Notes
Conflict of interest
• Not reported

Funding source
• "...supported by a financial grant from Amgen Inc."

Other information
• Emailed centre in which the research took place to try and get more information about splitting the groups and relation to Self 1999 study

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td>Outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Albumin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Vascular access</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias due to confounding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious: Confounding is very likely here because the groups were divided into those who chose to enter healthy start, those who did not, or doctors referral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bias in selection of participants into the study</td>
</tr>
</tbody>
</table>
Slowik 2001* (Continued)

Low

Bias in classification of interventions
Low

Bias due to deviations from intended interventions
NI

Bias due to missing data
NI

Bias in measurement of outcomes
Low for both outcomes: objective measures

Bias in selection of the reported result
Serious: Did not separate reporting for the two Health Start Streams

Overall risk of bias judgement
Serious: All outcomes judged at serious risk of bias in at least one domain

SMART 2006

Study characteristics

Methods

Study design
- Pilot, parallel RCT

Duration of study
- 9 months

Duration of follow-up
- 6 months

Participants

General information
- Setting: multicentre (2 sites)
- Country: Switzerland
- Inclusion criteria: nonadherent to their immunosuppressive regimen; ≥ 18 years; followed up at the University Hospital Basel, Cantonal Hospital; speak German or French; literate; undergone kidney transplant surgery at least 1 year prior to the study; able to self-administer immunosuppressive drugs; reside within a 180 km radius of Basel; provide written informed consent
- Exclusion criteria: not reported

Baseline characteristics
- Number: intervention group (12); control group (6)
- Mean age ± SD (years): not reported
- Sex (M/F): not reported
- Stage of CKD: ESKD patients who have undergone transplant at least one year prior to the study

Other information
### SMART 2006 (Continued)

- Patients in the intervention group and enhanced usual care group were comparable in view of age, time post-transplant and baseline adherence levels

### Interventions

#### Intervention type
- Home visit with phone calls

#### Intervention group
- One home visit and 3 follow-up calls monthly aimed at increasing patients' self-efficacy in medication adherence

#### Control group
- Enhanced usual care

### Outcomes

#### Adherence
- Dose taken, effect of intervention (open-ended question)

### Notes

#### Conflict of interest
- Not reported

#### Funding source
- Not reported

#### Other information
- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Adequate randomisation using random number tables</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation concealment undertaken using sealed envelopes</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>There was no blinding of participants or research associate collecting the data</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>At risk of influence from assessors asking the questions also unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective outcome using the digital medication cap thought not to be influenced by unblinded participants or personnel</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>Dropout rates were high (30% Intervention and 20% in control) in comparison to total sample size Even though ITT analysis was performed still high risk of bias just based on numbers</td>
</tr>
</tbody>
</table>
Selective reporting (reporting bias)  
- Unclear risk
- Insufficient information to permit judgement

Other bias  
- High risk
- Small study sample

So 2006

Study characteristics

Methods
- **Study design**
  - Parallel RCT

  **Duration of study**
  - 23 days

  **Duration of follow-up**
  - Not reported

Participants
- **General information**
  - Setting: single centre
  - Country: South Korea
  - Inclusion criteria: not reported
  - Exclusion criteria: previous history of mental illness; communication problems

  **Baseline characteristics**
  - Number: intervention group (30); control group (30)
  - Mean age ± SD (years): intervention group (< 40 (5), 40 to 60 (14), > 60 (11)); control group (< 40 (8), 40 to 60 (11), > 60 (11))
  - Sex (M/F): intervention group (10/20); control group (15/15)
  - Stage of CKD: ESKD on HD > 1 month

Interventions
- **Intervention type**
  - Educational intervention: group versus usual care

  **Intervention group**
  - Group education on medication indications, administration and side effects twice a week after dialysis for 2 weeks with tests and feedback at the end of each session

  **Control group**
  - Usual care

Outcomes
- Knowledge of medications
- Survey on compliance

Notes
- **Conflict of interest**
  - Not reported

Funding source

Interventions for improving health literacy in people with chronic kidney disease (Review)

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Personnel and participants were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Survey on compliance completed by unblinded participants</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Unclear risk</td>
<td>Knowledge thought to be an objective measure however unclear how this was delivered, if verbal could be affected by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Small dropout; 3 people from treatment group dropped out of the study because of their busy schedule, and 1 dropped out after severe hypotension following HD; 3 people from the control group dropped out because they longer wanted to participate in surveys (questionnaires)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Methods

**Study design**
- Cluster RCT

**Duration of study**
- 52 days

**Duration of follow-up**
- Not reported

#### Participants

**General information**
- Setting: single centre
Cochrane Database of Systematic Reviews

Country: South Korea

Inclusion criteria: on dialysis > 1 month experiencing pruritus, itch scale score ≥ 3

Exclusion criteria: previous history of mental illness; communication problems; sight or hearing problems; have used anti-itch medications to treat HD itch before

Baseline characteristics

- **Number**: intervention group (21); control group (22)
- **Mean age ± SD (years)**: intervention group (< 40 (4), 40 to 60 (9), > 60 (8)); control group (< 40 (1), 40 to 60 (14), > 60 (7))
- **Sex (M/F)**: intervention group (10/11); control group (11/11)
- **Stage of CKD**: ESKD on HS > 1 month

Other information

- Does not state the mean age, but it does state that there was little difference in the age of participants between the two groups

Interventions

**Intervention type**

- Educational intervention: group versus usual care

**Intervention group**

- Group educational sessions on pruritus causes, treatment and complications twice a week for 50 minutes after dialysis for 2 weeks at a time; 12 sessions total. Sessions included the use of booklets and PowerPoint presentations with animations. At the end of each session, there was a group discussion to share experiences

**Control group**

- Usual care

Outcomes

- Questionnaire of management of pruritus and level of satisfactions with quality of sleep

Notes

**Conflict of interest**

- Not reported

**Funding source**

- Not reported

**Other information**

- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Personnel and participants were not blinded</td>
</tr>
</tbody>
</table>

Interventions for improving health literacy in people with chronic kidney disease (Review)
### So 2007 (Continued)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self report questionnaire completed by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
</tbody>
</table>

### Song 2010

#### Study characteristics

**Methods**

- **Study design**: Parallel RCT  
- **Duration of study**: Not reported  
- **Duration of follow-up**: 1 week

**Participants**

- **General information**
  - **Setting**: single centre  
  - **Country**: USA  
  - **Inclusion criteria**: receiving either centre HD or home PD > 3 months; > 18 years; had a surrogate decision maker > 18 years  
  - **Exclusion criteria**: not reported  
- **Baseline characteristics**
  - **Number**: intervention group (11); control group (8)  
  - **Mean age ± SD**: 52.82 ± 15.5 years  
  - **Sex (M/F)**: 10/9  
  - **Stage of CKD**: ESKD on dialysis (HD or PD)

**Interventions**

- **Intervention type**: Educational and self-management training: group versus usual care  
- **Intervention group**
  - Patient-centred advanced care planning: in-depth 1-hour interview with a nurse and the patient-surrogate dyad  
  - Focus on 5 elements of the representational approach
    - Represenational assessment of participants’ beliefs about their illness condition along the five dimensions of illness representation  
    - Exploration of gaps or misunderstandings regarding CKD and its progression and life-sustaining treatment, including dialysis  
    - Creation of conditions for conceptual change
### Introduction of replacement information

- Introduction of replacement information
- Summarization of the discussion

### Control group

- Usual care: written information on advance directives was provided, and completed advance directives were placed in the medical record.

### Outcomes

<table>
<thead>
<tr>
<th>QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psycho-spiritual well-being of the patient and surrogate was measured using the 28-item Self-Perception and Relationship Tool</td>
</tr>
</tbody>
</table>

### Decisional conflict

- Patients' level of difficulty in making choices was measured using the 13-item decisional conflict scale. They responded on a 5-point scale from 1 (strongly agree) to 5 (strongly disagree)

### Patient-surgeon congruence in treatment preferences

- Presented 3 vignettes specific to patients with CKD undergoing dialysis, and for each vignette, patients and their surrogates were asked to independently choose one of three options for each of the vignettes, “Continue all treatment to prolong my life,” “Stop all treatment,” and “Don’t know.”
- Surrogate's level of comfort in decision-making was measured using the decision-making confidence scale developed for this study. The instrument consists of five items with response options from 0 (not confident at all) to 4 (very confident)

### Notes

- **Conflict of interest**
  - Not reported

- **Funding source**
  - "This study was supported by the University of Pittsburgh Central Research Development Fund and was conducted at the University of Pittsburgh School of Nursing."

- **Other information**
  - Emailed author about randomisation - was it sequential order or a random pattern?
  - Study duration unclear

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Claims randomisation but says sequential order, unclear</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Random assignment occurred by sequential, opaque, numbered envelopes prepared by an individual not associated with the study.&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Neither participants nor personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>This is a self report questionnaire, the assessors were blinded however the patients could not be</td>
</tr>
</tbody>
</table>
Incomplete outcome data (attrition bias) | Unclear risk | High rate of attrition before intervention commenced; 10% loss to follow-up after commencement. No mention of how data of loss to follow-up treated or whether these participants were significantly different to completers

Selective reporting (reporting bias) | Unclear risk | All outcomes seem to be reported

Other bias | Unclear risk | Financial incentives provided
Predominantly single men and may not be representative of the population
Small sample size
Short follow-up

### Sullivan 2009

**Study characteristics**

**Methods**

- **Study design**
  - Cluster RCT
  - Randomised according to dialysis shift

- **Duration of study**
  - Recruited between May and October 2007

- **Duration of follow-up**
  - 3 months

**Participants**

- **General information**
  - **Setting**: multicentre (14 sites)
  - **Country**: USA
  - **Inclusion criteria**: most recent serum phosphorus level and mean serum phosphorus level for the previous 3 months were both > 5.5 mg/dL; ≥ 18 years; HD > 6 months
  - **Exclusion criteria**: new patients; did not speak English; mentally impaired; likely to have unique nutritional requirements (nursing home resident, AIDS, active malignancy, terminal illness)

- **Baseline characteristics**
  - **Number**: intervention group (145); control group (134)
  - **Mean age ± SD (years)**: intervention group (54 ± 13); control group (52 ± 13)
  - **Sex (M/F)**: intervention group (83/62); control group (88/46)
  - **Stage of CKD**: ESKD on dialysis

**Interventions**

- **Intervention type**
  - Educational and self-management training: individual versus usual care

- **Intervention group**
  - Education on avoiding foods with phosphorus additives when purchasing groceries or visiting fast-food restaurants

- **Control group**
Outcomes

- Usual care

Bloods

- Serum phosphorus levels: change after 3 months

Food knowledge score

- Asked intervention and control participants to identify high-phosphorus foods from the same list of 20 foods used as part of the baseline assessment

Self-management

- Reading nutrition facts labels: asked participants about how often they read nutrition facts labels, read ingredient lists, and ate meals from fast-food restaurants

Notes

**Conflict of interest**

- "None reported"

**Funding source**

- "This work was supported by grant DK51472 from the National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland, and by the Leonard C. Rosenberg Renal Research Foundation, Cleveland, Ohio"

**Other information**

- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| Random sequence generation (selection bias)    | Low risk           | Quote: "For each of these facilities, a data manager used a random number generator to assign one randomly selected shift to the intervention group and the other shift to the control group."
| Allocation concealment (selection bias)        | Unclear risk       | Insufficient information to permit judgement                                           |
| Blinding of participants and personnel (performance bias) | High risk          | Neither the participants nor the personnel were blinded                                 |
| Blinding of outcome assessment (detection bias) | High risk          | Self-management outcome thought to be subjective and could of been affected by unblinded participants |
| Blinding of outcome assessment (detection bias) | Low risk           | Objective outcomes not thought to be affected by blinding                              |
| Incomplete outcome data (attrition bias)       | Low risk           | ITT analysis: 7 patients withdrew from intervention group and 3 from control           |
| Selective reporting (reporting bias)           | Unclear risk       | All outcomes seem to be reported                                                      |
Sullivan 2009 (Continued)

Other bias High risk  
$10 financial incentive twice throughout the study  
Possible contamination between intervention and control groups  
Short follow-up time period

Sullivan 2012

Study characteristics

Methods

Study design
- Cluster RCT

Duration of study
- Recruited between January 2009 and August 2009

Duration of follow-up
- 24 months

Participants

General information
- Setting: multicentre (23 sites)
- Country: USA
- Inclusion criteria: community-dwelling patients; 18 to 70 years no absolute contraindications to kidney transplantation
- Exclusion criteria: > 70 years; absolute contraindications to kidney transplantation (systemic infections, extreme obesity, and active or recent malignancy); nursing home residents; patients with chronic systemic infections; BMI > 40 kg/m²; malignancies within the last 2 years; had already made a first visit to a transplant centre or received a kidney transplant in the past; had communication barrier (e.g. mentally incompetent, didn’t speak English)

Baseline characteristics
- Number: intervention group (92); control group (75)
- Mean age ± SD (years): intervention group (18 to 44 (14), 45 to 54 (31), 55 to 64 (39), 65 to 70 (8)); control group (18 to 44 (9), 145 to 54 (18), 55 to 64 (30), 65 to 70 (18))
- Sex (M/F): intervention group (47/45); control group (47/28)
- Stage of CKD: ESKD in need of a kidney transplant

Interventions

Intervention type
- Educational and self-management training: individual versus usual care

Intervention group
- Transplant navigators (kidney transplant recipients who were trained) met monthly individually with participants during dialysis; they reviewed the medical record and determined the current step. They tailored the intervention based on the current step identified

Control group
- Usual care

Outcomes

Number of steps in the kidney transplant process completed
Medical suitability, interest in transplant, referral to a transplant centre, first visit to centre, transplant workup, successful candidate, waiting list or identify living donor, and receiving transplant, defined as the difference between final and baseline steps; impediments to step completion among intervention participants. (e.g. medical limitations, such as acute or chronic conditions, that they wanted to address before calling; concerns about cost)

### Notes

**Conflict of interest**
- “S.D.N. reports receiving grant support from Genzyme. D.E.H. reports receiving payments for lectures from Novartis and Genentech.”

**Funding source**
- “This work was supported by grants DKS1472002265 and RR024989 from the National Institutes of Health, Bethesda, Maryland. The funding organization had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript.”

**Other information**
- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Adequate randomisation: “a data manager used a random number generator”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither participants nor personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>All outcomes are subjective and could of been affected by unblinded participants and personnel</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Four patients withdrew from the intervention group and none from the control group</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Financial incentives. Sample population was different to those who declined to be involved. Large amount of imputed data</td>
</tr>
</tbody>
</table>

### Taghavi 1995*

#### Study characteristics

**Methods**

**Study design**
- Non-RCT; pre-post static group design
## Taghavi 1995* (Continued)

### Duration of study

- Not reported

### Duration of follow-up

- Not reported

### Participants

#### General information

- **Setting**: single centre
- **Country**: Iran
- **Inclusion criteria**: not reported
- **Exclusion criteria**: not reported

#### Baseline characteristics

- **Number**: intervention group (15); control group (15)
- **Mean age ± SD (years)**: not reported
- **Sex (M/F)**: not reported
- **Stage of CKD**: kidney transplant recipients

### Interventions

#### Intervention type

- Education: individual versus control

#### Intervention group

- Structured preoperative teaching from a registered nurse focused on postoperative care and kidney disease

#### Control group

- Unstructured preoperative teaching by nurses

### Outcomes

#### Knowledge

- Tested by questionnaire 24 and 72 hours postoperatively

#### Hospitalisations

- **Length of hospital stay**
- **Ability to cough and deep breathe**
- Measured by vital capacity, maximum expiratory flow rate, and forced expiratory volume

### Notes

#### Conflict of interest

- Not reported

#### Funding source

- Not reported

#### Other information

- Received email from Dr Taghavi and Dr Ghereifi; no additional information about randomisation, there were no dropouts, teaching was one-on-one and focused on postoperative care

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>

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*Interventions for improving health literacy in people with chronic kidney disease (Review)

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Taghavi 1995* (Continued)

<table>
<thead>
<tr>
<th>Non-RCT overall judgement</th>
<th>Unclear risk</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. Length of hospital stay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Knowledge</td>
</tr>
</tbody>
</table>

**Bias due to confounding:** NI

NI: Does not explain what they mean by selective sampling

**Bias in selection of participants into the study**

NI: Does not mention anything about recruitment or patient characteristics

**Bias in measurement of interventions**

Low

**Bias due to departures from intended interventions**

NI

**Bias due to missing data**

NI

**Bias in measurement of outcomes**

O1/O2. NI

**Bias in selection of the reported result**

NI

**Overall bias**

NI: Not enough information in this study to make an overall risk of bias assessment

### TALK 2011

**Study characteristics**

#### Methods

**Study design**

- 3-arm, parallel RCT

**Duration of study**

- February 2009 and March 2011

**Duration of follow-up**

- 6 months

#### Participants

**General information**

- **Setting:** multicentre (number of sites not reported)
- **Country:** USA
- **Inclusion criteria:** 18 to 70 years; no evidence of cancer within 2 years prior to recruitment date; no evidence of stage IV congestive heart failure; no evidence of end-stage liver disease; no evidence of unstable coronary artery disease; no evidence of pulmonary hypertension; no evidence of severe pe-
Peripheral vascular disease; no history of HIV; no chronic (debilitating) infections; no prior kidney transplant

**Exclusion criteria:** not reported

**Baseline characteristics**

- **Number:** intervention group 1 (44); intervention group 2 (43); control group (44)
- **Mean age, range (years):** intervention group 1 (60, 52 to 65); intervention group 2 (59, 53 to 67); control group (60, 52 to 65)
- **Sex (M/F):** intervention group 1 (17/26); intervention group 2 (17/26); control group (18/26)
- **Stage of CKD:** progressive CKD stage 3, 4 or 5 not on dialysis

**Other information**

- Baseline demographic characteristics between groups were presented but not formally analysed. Upon examination, there seem to be no significant differences between groups in areas such as age, sex, race, education, health insurance, employment, household income, health literacy, clinical characteristics, family characteristics, prior information about living kidney donor, length and intensity of relationship with nephrologist, or prior discussion about dialysis

### Interventions

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention group 1</strong></td>
<td></td>
</tr>
<tr>
<td>TALK educational; 20-minute video and booklet encouraging patients to talk about living donor kidney transplantation with their families and health care providers. Video featured patients and family members discussing LKDT and health professionals. Booklet was designed to be read by those with low to moderate health literacy</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention group 2</strong></td>
<td></td>
</tr>
<tr>
<td>TALK social worker: above plus 60-minute social worker visits with participants and families discussing ways to overcome self-identified barriers to pursuing living kidney donor kidney transplantation</td>
<td></td>
</tr>
<tr>
<td><strong>Control group</strong></td>
<td></td>
</tr>
<tr>
<td>Usual clinical care by nephrologists</td>
<td></td>
</tr>
</tbody>
</table>

### Outcomes

- Discussing living donor kidney transplantation with at least one family member
- Discussing living donor kidney transplantation with their physicians
- Initiating the clinical evaluation for potential living donor kidney transplant recipients
- Completing the clinical evaluation for potential living donor kidney transplant recipients
- Identifying a potential live kidney donor

### Notes

- "The authors declare that they have no other relevant financial interests"

### Funding source

- "This work was funded by grant R39OT07537 from the Health Resources and Services Administration and grant K23DK070757 from the National Center for Minority Health and Health Disparities and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK; Dr Boulware); grant K01HL076644 from the National Heart, Lung, and Blood Institute (Dr Hill-Briggs); and grant K24502643 from the NIDDK (Dr Powe)."

### Other information

**Conflict of interest**

- "The authors declare that they have no other relevant financial interests"

**Funding source**

- "This work was funded by grant R39OT07537 from the Health Resources and Services Administration and grant K23DK070757 from the National Center for Minority Health and Health Disparities and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK; Dr Boulware); grant K01HL076644 from the National Heart, Lung, and Blood Institute (Dr Hill-Briggs); and grant K24502643 from the NIDDK (Dr Powe)."
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “randomly assigned with equal probability...using block randomisation” Adequate randomisation</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Allocation was concealed from research staff enrolling participants until the home visit, at which time a study coordinator not involved in data collection or performing home visits revealed group assignments.”</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants not blinded. Personnel blinded until initial assessment completed, after which they were not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Not blinded: self-report questionnaire completed over the phone with unblinded research personal</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>On examination, dropout reasons appear similar between groups. ITT analysis undertaken</td>
</tr>
<tr>
<td></td>
<td></td>
<td>About 25% loss of follow-up and no mention of whether these participants are similar to those who completed</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Changes from protocol were explained. Does not seem to be any outcomes that were not reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
</tr>
</tbody>
</table>

### Tanner 1998

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parallel RCT; pre-post group</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of study</th>
<th>Not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of follow-up</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Setting: single centre</td>
</tr>
<tr>
<td></td>
<td>Country: USA</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: not compliant with fluid restriction IDWG ≥ 3 kg on weekdays and ≥ 4 kg on weekends for 6 of 12 dialysis sessions and/or monthly serum phosphate levels of ≥ 5.9 mg/dL</td>
</tr>
</tbody>
</table>
### Baseline characteristics

- **Number**: intervention group (30); control group (10)
- **Mean age (years)**: intervention group (47.6); control group (52.7)
- **Sex (M/F)**: intervention group (17/11); control group (6/4)
- **Stage of CKD**: ESKD on HD

### Interventions

**Intervention type**
- Educational and self-management training: individual versus usual care

**Intervention group**
- Training in self-monitoring: monthly progress reports and contracts reviewed by participants and investigator. Feedback included:
  - Posting of subject’s phosphorus level and number of acceptable IDWG on the monthly progress report
  - Provision of rewards, if indicated (candy/stickers)
  - Review of subject’s phosphorus and IDWG
  - Discussion of acceptable and unacceptable phosphorus values and IDWG
  - Instruction on recommended dietary behaviours
  - Setting of goals written on the contract
  - Review of previous month’s contract goals and progress

**Control group**
- Not reported

### Outcomes

**Bloods**
- Phosphorus levels (monthly)
- IDWG (monthly)

**Knowledge Survey**
- Evaluated each subject’s pre-intervention and postintervention knowledge of phosphorus restrictions, fluid restrictions, and taking phosphate binders. The format of this survey consisted of nine multiple-choice questions with a varied number of correct responses

**Self-Efficacy/Health Beliefs Survey**
- Assessed perceptions of self-efficacy for self-monitoring and subjects’ beliefs and attitudes toward health before and after receiving intervention. It consisted of 22 open-ended questions (9 health belief/13 self-efficacy) with rank-ordered responses using a three-point Likert scale. Two scores were derived from this survey: (1) an SE score to assess self-efficacy for self-monitoring, and (2) an HB score to assess health beliefs, attitudes, and values of subjects in relation to health

### Notes

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Tanner 1998 (Continued)
### Tanner 1998

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>Claims randomisation but unclear how this was done</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Whilst no clear mention of the fact that the control group had significantly less</td>
</tr>
<tr>
<td></td>
<td></td>
<td>than the intervention group would likely mean a poor randomisation process</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither participants nor personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-efficacy questionnaire</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Knowledge, PO4, weight gain. Objective measures</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Only two participants dropped out of study</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Small sample population</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short follow-up</td>
</tr>
</tbody>
</table>

### Teng 2013

**Study characteristics**

**Methods**

**Study design**
- Parallel RCT

**Duration of study**
- November 2008 to October 2009

**Duration of follow-up**
- 12 months

**Participants**

**General information**
- **Setting:** multicentre (4 sites)
- **Country:** Taiwan
Inclusion criteria: > 20 years; could communicate in Mandarin or Taiwanese; aware of CKD diagnosis; only invited those who were not good at diet and exercise to participant

Exclusion criteria: heart, lung, neurological or skeletal muscular disease, psychiatric problems; needed assistance in basic activities of daily living

Baseline characteristics

- Number: intervention group (52); control group (51)
- Mean age ± SD (years): intervention group (61.2 ± 14.0); control group (65.65 ± 11.2)
- Sex (M/F): intervention group (33/19); control group (40/11)
- Stage of CKD: CKD with normal, mild or moderate reduction in GFR

Other information

- At baseline the groups were similar in terms of age, sex, BMI, kidney function knowledge, GFR. They differed slightly in waist-to-hip ratio, six-minute walking distance and some aspects of the Health Promoting Lifestyle Profile–II Chinese version questionnaire

Interventions

Intervention type

- Self-management: individual versus control (control had some education)

Intervention group

- Participants readiness to change was assessed using the stage-of-change construct. Lifestyle Modification Program was aimed at improving the motivation-to-change behaviour. Discussions were had about any difficulties participants were having adhering to the goals set and consequences of non-adherence

Control group

- Educational booklet on kidney protection

Outcomes

Stage of change

- Self-reported questionnaire, BMI, waist-hip ratio, kidney protection knowledge, Health promotion lifestyle questionnaire, six-minute walking distance measure of functional exercise capacity

Notes

Conflict of interest

- “The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article”

Funding source

- “The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research was funded by National Science Council, Taiwan NSC95-2314-B-006-082-MY3”

Other information

- Received email from authors with kidney protection knowledge results

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Paper ballot generated number</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
</tbody>
</table>
### Teng 2013 (Continued)

<table>
<thead>
<tr>
<th>Bias Type and Outcomes</th>
<th>Risk Assessment</th>
<th>Reasoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Unclear whether RAs blinded to study allocation but likely this would have been broken. Participants were not blinded.</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-reported stage of change</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Questionnaires, biochemistry, physical assessment</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
<td>High rate of loss to follow-up. Attrition rates are similar between groups.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Self report recall bias and social desirability limit findings. Provided with gift when enrolled in study. Only 4 centres in Taiwan therefore not generalisable.</td>
</tr>
</tbody>
</table>

### Trofe-Clark 2017

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT
- **Duration of study**
  - Started March 2016
- **Duration of follow-up**
  - 4 months

**Participants**

- **General information**
  - **Setting**: single centre
  - **Country**: USA
  - **Inclusion criteria**: post-transplant recipients
  - **Exclusion criteria**: not reported
- **Baseline characteristics**
  - **Number**: 24 (numbers per group not reported)
  - **Mean age ± SD**: 54 ± 11 years
  - **Sex (M/F)**: 59%/41%
  - **Stage of CKD**: kidney transplant recipients
- **Other information**
Almost half of the participants were classified as having mild cognitive impairment, and 28% had NVS scores indicative of limited health literacy.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Educational intervention: individual versus control</td>
<td>Insufficient information to permit judgment</td>
</tr>
</tbody>
</table>

**Intervention group 1**
- Transplant provider education group: additional education provided by transplant coordinators and transplant provider and medication list group

**Intervention group 2**
- Transplant provider education and medication list group: additional education provided by transplant coordinator and provided a medication list from MedActionPlanTM (MAP) program at the 3-month visit

**Control group**
- Usual care

**Outcomes**
- Medication knowledge self-report questionnaire

**Notes**

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Abstract-only publication

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
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</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information but probably not blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>24 patients completed all visits and 5 completed 1st visits, however not sure of final drop out scores</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgment</td>
</tr>
</tbody>
</table>
Trofe-Clark 2017 (Continued)

Other bias Unclear risk Insufficient information to permit judgement

Tsay 2003

Study characteristics

Methods

Study design
- Parallel RCT

Duration of study
- August 2000 to July 2001

Duration of follow-up
- 6 months

Participants

General information
- Setting: multicentre (3 sites)
- Country: Taiwan
- Inclusion criteria: ≥ 18 years; routine HD 3 times/week; able to walk and eat without assistance; living in a home setting; willing to participate
- Exclusion criteria: hospitalised individuals; acute illness, psychological or cognitive disorders; physical limitations in self-care

Baseline characteristics
- Number: intervention group (31); control group (31)
- Mean age ± SD (years): intervention group (57.51 ± 11.41); control group (57.94 ± 11.62)
- Sex: 58.1% female
- Stage of CKD: ESKD on HD

Other information
- There were no statistically significant differences in gender, age, education levels, current use of medication, length of dialysis, symptoms, biochemical data, urea kinetic modelling (Kt/V), types of dialysers used and number of chronic diseases between the groups; however, baseline body weight change was significantly different between the groups

Interventions

Intervention type
- Educational and self-management: group versus control

Intervention group
- Educational program focused on pathophysiology of kidney failure, HD, medications, complications, nutrition, fluid restriction, thirst and stress management. Audiotaped muscles relaxation instructions. Discussion about dietary habits, fluid intake, weight gain with setting of goals with associated rewards. Individual counselling was offered focusing on the stress and emotional adjustment associated with the illness.
- 12 sessions, each lasting 1 hour, and conducted 3 times/week by 2 nephrology nurses during dialysis

Control group
- Usual care
### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Patients were randomised but insufficient information about how this was done</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Participants were not blinded. Only the researcher knew which treatment patients were receiving, and care providers (physicians, nurses, dieticians, social workers) were not informed of participants' treatment groups</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Outcome was weight gain - this is objective so blinding not though to affect outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>One patient from each group dropped out because of hospitalisation or relocation during the study. Thus, a total of 62 finished the study. Small loss to follow-up.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All outcomes seem to be reported</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
</tr>
</tbody>
</table>

### Study characteristics

#### Methods

**Study design**
- Parallel RCT; pre/post

**Duration of study**
- 9 months

**Duration of follow-up**
- 6 weeks
Participants

**General information**
- **Setting**: multicentre (2 sites)
- **Country**: Taiwan
- **Inclusion criteria**: ≥ 18 years; treated with HD for at least 3 months; living in a home setting; able to read and write; willing to participate
- **Exclusion criteria**: acute illness or hospitalised; reported psychiatric or cognitive disorders; physical limitations in self-care

**Baseline characteristics**
- **Number**: intervention group (25); control group (25)
- **Mean age ± SD**: 51.18 ± 9.75 years
- **Sex (M/F)**: intervention group (9/16); control group (11/14)
- **Stage of CKD**: ESKD on HD

**Interventions**

**Intervention type**
- Self-management training: individual versus control

**Intervention group**
- Empowerment program: behavioural change program focused on the development of skills and self-awareness in goal setting, problem-solving, stress management, coping, social support and motivation

**Control group**
- Only given the information package and shown what it contained

**Outcomes**

**Self-care self-efficacy**
- Strategies used by people to promote health (SUPPH) scale contains 29 five-point adjective ratings and includes dimensions of coping, stress reduction, making decisions, and enjoyment of life. Subjects were asked to give responses ranging from little confidence (1) to quite a lot of confidence (5)

**Depression**
- BDI note how much they have been bothered or distressed by problems and complaints during the past week, on a scale from not at all (0) to extremely (4)

**Empowerment**
- Empowerment Scale comprised of 28-items with 3 subscales and charts the management of the psychosocial aspects of the disease, assessment of dissatisfaction and readiness to change, and the setting and the achievement of goals

**Notes**

**Conflict of interest**
- Not reported

**Funding source**
- "National Science Counsel of Taiwan provided funding, NSC 91-2314-B-227-004"

**Other information**
- Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>

Tsay 2004c (Continued)

Interventions for improving health literacy in people with chronic kidney disease (Review)

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Random sequence generation (selection bias)
- **Risk:** Low risk
- **Description:** Randomisation based upon SPSS statistical randomisation

### Allocation concealment (selection bias)
- **Risk:** Unclear risk
- **Description:** Insufficient information to permit judgement

### Blinding of participants and personnel (performance bias)
- **Risk:** Unclear risk
- **Description:** Personnel not blinded, says it was double blinded so maybe participants didn’t know what the other group was receiving

### Blinding of outcome assessment (detection bias)
- **Risk:** Unclear risk
- **Description:** The data collector was a trained research assistant who was left purposely unaware of a patient’s experimental or control group status to maintain double-blind accuracy, depression scale and empowerment scale both self-reported by unblinded participants

### Incomplete outcome data (attrition bias)
- **Risk:** Low risk
- **Description:** No reported loss to follow-up

### Selective reporting (reporting bias)
- **Risk:** Unclear risk
- **Description:** Insufficient information to permit judgement

### Other bias
- **Risk:** Unclear risk
- **Description:** Short term follow-up. Sample population representative

---

## Tsay 2005

### Study characteristics

#### Methods
- **Study design:** Parallel RCT
- **Duration of study:** Not reported
- **Duration of follow-up:** 3 months

#### Participants
- **General information:**
  - **Setting:** multicentre (3 sites)
  - **Country:** Taiwan
  - **Inclusion criteria:** ≥ 18 years; receiving HD for at least the last 6 months; no DSM IV psychiatric diagnoses; no major chronic illness such as insulin-dependent diabetes, cancer, or lupus erythematosus
  - **Exclusion criteria:** not reported

- **Baseline characteristics:**
  - **Number:** intervention group (33); control group (33)
  - **Mean age ± SD (years):** intervention group (); control group ()
  - **Sex (M/F):** intervention group (14/16); control group (13/14)
  - **Stage of CKD:** ESKD on HD

- **Other information**
There were no differences between groups at baseline in terms of sex, education, marital status, working status or test scores for outcome-related tests.

### Interventions

**Intervention type**
- Self-management: group versus control

**Intervention group**
- Two-hour once/week session including an educational component, based on needs assessment, cognitive behaviour modification, problem-solving, and stress management

**Control group**
- Usual care (similar across all 3 sites)

### Outcomes

**QoL**
- SF-36, stress
- HD stressor scale
- Depression
- BDI

### Notes

**Conflict of interest**
- Not reported

**Funding source**
- "We would like to thank the National Science Counsel of Taiwan for providing funding"

**Other information**
- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Randomised but did not explain process</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information, probably not done</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants were not blinded and personnel probably would not of been because of nature of study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>Unclear risk</td>
<td>Outcome assessor was blinded - but the measures are all subjective self report questionnaires filled out by unblinded participants</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>Small loss to follow-up but withdrew patients that did not attend enough sessions in the intervention group - not ITT model</td>
</tr>
</tbody>
</table>
### Tsay 2005 (Continued)

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>All outcomes seem to be reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Withdrew patients because of non-attendance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Did not report age of patients short follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Small sample size from only one geographical area</td>
</tr>
</tbody>
</table>

### Tsuji-Hayashi 2000

#### Study characteristics

**Methods**
- **Study design**
  - Parallel RCT
- **Duration of study**
  - Not reported
- **Duration of follow-up**
  - 4.5 months

**Participants**
- **General information**
  - Setting: not reported
  - Country: USA
  - Inclusion criteria: ESKD on HD
  - Exclusion criteria: not reported
- **Baseline characteristics**
  - Number: 95 enrolled, 58 completed
  - Mean age ± SD (years): not reported
  - Sex (M/F): not reported
  - Stage of CKD: ESKD on HD

**Interventions**
- **Intervention type**
  - Education and self-management: provision of materials versus control
- **Intervention group**
  - Received education booklet: written to help dialysis patients understand their disease and treatment, and to encourage self-management of symptoms
- **Control group**
  - No booklet provided

**Outcomes**
- HCT
- Albumin
- KT/V
- QoL
**Tsuji-Hayashi 2000 (Continued)**

Pain

Daily activities

**Notes**

**Conflict of interest**
- Not reported

**Funding source**
- Not reported

**Other information**
- Abstract-only publication. Sent email to first author asking for number in each group

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Probably not blinded based on design of study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>Unclear risk</td>
<td>Probably not blinded based on design of study</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Objective measures not thought to be influences by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>High loss to follow-up, no information whether similar to those who completed</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
</tbody>
</table>

**Tucker 1989**

**Study characteristics**

**Methods**

**Study design**
- Parallel RCT

**Duration of study**
- Not reported
### Participants

**General information**
- **Setting**: single centre
- **Country**: USA
- **Inclusion criteria**: average inter-dialysis fluid weight gain in last 3 months ≥ 4 pounds
- **Exclusion criteria**: not reported

**Baseline characteristics**
- **Number**: intervention group 1 (26); intervention group 2 (26); intervention group 3 (26); control group (25)
- **Mean age ± SD**: 53.4 ± 14.7 years
- **Sex (M/F)**: 44/59
- **Stage of CKD**: ESKD on HD

### Interventions

**Intervention type**
- Self-management individual versus control

**Intervention group 1**
- Self-monitoring, nurse praise, monetary rewards and self-reinforcement

**Intervention group 2**
- Self-monitoring, nurse praise, monetary rewards and self-reinforcement
- Behavioural control technique

**Intervention group 3**
- Self-monitoring, nurse praise, monetary rewards and self-reinforcement
- Behavioural control technique
- Family support

**Control group**
- Usual care

### Outcomes

- Potassium
- Daily fluid gain
- Social support scale
- Compliance

### Notes

**Conflict of interest**
- Not reported

**Funding source**
- "Supported by grant DK35280-02 from the National Institutes of Health"

**Other information**
- Not requested
### Tucker 1989

(Continued)

#### Risk of bias

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</tr>
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<td>Low risk</td>
<td>Randomised block procedure</td>
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<td>Insufficient information to permit judgement</td>
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<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants were not blinded. No mention of whether staff blinded Nursing staff giving intervention could not have been blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
<td>Self reported fluid intake</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
<td>Medical record data for IDWG</td>
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<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>No mention of loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Monetary gifts, short follow-up period</td>
</tr>
</tbody>
</table>

### Tzvetanov 2014

#### Study characteristics

**Methods**

**Study design**

- Parallel RCT

**Duration of study**

- Not reported

**Duration of follow-up**

- 12 months

**Participants**

**General information**

- **Setting**: single centre
- **Country**: USA
- **Inclusion criteria**: 18 to 65 years; successful kidney transplant at least 1 month before enrolment; normal and stable kidney function; BMI ≥ 30
- **Exclusion criteria**: ambulatory or significant orthopaedic problems; cardiac or pulmonary disease that contraindicated physical training; contraindications to exercise testing; and inability to comply with the rehabilitation program
### Baseline characteristics

- **Number**: intervention group (9); control group (8)
- **Mean age ± SD (years)**: intervention group (46 ± 6.9); control group (45 ± 19)
- **Sex (M/F)**: intervention group (5/5); control group (3/5)
- **Stage of CKD**: ESKD post-transplantation

### Other information

- There were no significant differences between groups in terms of age, BMI, race, type of transplantation, type of donor or ABO incompatibility

### Interventions

#### Intervention type

- Self-management group versus control (with exercise)

#### Intervention group

- Coaching using motivational and cognitive behavioural techniques aimed at behavioural change

#### Control group

- Usual care: additional dietary and exercise counselling by the transplant physicians at post-transplantation clinic visits

### Outcomes

#### Physiological

- BMI, muscle mass, percentage of fat, carotid thickness

#### Lab testing

- GFR, creatinine, cholesterol, LDL, HDL, triglycerides, fasting blood glucose, Hb

#### Psychological

- SF-36

### Notes

#### Conflict of interest

- Not reported

#### Funding source

- Not reported

#### Other information

- Not requested

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;Randomisation performed using restricted procedure which was managed using prepared sealed envelopes containing a card indicating the allocation treatment group&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;prepared sealed envelopes&quot;</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Participants were unblinded</td>
</tr>
</tbody>
</table>
### Tzvetanov 2014 (Continued)

<table>
<thead>
<tr>
<th>All outcomes</th>
<th>No mention of whether those providing the exercise program were involved in collecting outcome assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High risk</td>
</tr>
<tr>
<td>Subjective outcomes</td>
<td></td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low risk</td>
</tr>
<tr>
<td>Objective outcomes</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>High risk</td>
</tr>
<tr>
<td>All outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
</tr>
</tbody>
</table>

### Urstad 2012

#### Study characteristics

<table>
<thead>
<tr>
<th>Methods</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Parallel RCT</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of study</strong></td>
</tr>
<tr>
<td></td>
<td>- Recruitment from October 2007 to March 2009</td>
</tr>
<tr>
<td></td>
<td><strong>Duration of follow-up</strong></td>
</tr>
<tr>
<td></td>
<td>- 6 months</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- <strong>Setting</strong>: single centre</td>
</tr>
<tr>
<td></td>
<td>- <strong>Country</strong>: Norway</td>
</tr>
<tr>
<td></td>
<td>- <strong>Inclusion criteria</strong>; &gt; 18 years; able to speak, understand and read Norwegian; mentally able to participate in the study</td>
</tr>
<tr>
<td></td>
<td>- <strong>Exclusion criteria</strong>; concurrent participation in drug (immunosuppressive medication) studies (except CENTRAL)</td>
</tr>
<tr>
<td></td>
<td><strong>Baseline characteristics</strong></td>
</tr>
<tr>
<td></td>
<td>- <strong>Number</strong>: intervention group (77); control group (82)</td>
</tr>
<tr>
<td></td>
<td>- <strong>Mean age ± SD</strong>: 50 ± 14 years</td>
</tr>
<tr>
<td></td>
<td>- <strong>Sex (M/F)</strong>: 95/44</td>
</tr>
<tr>
<td></td>
<td>- <strong>Stage of CKD</strong>: kidney transplant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Intervention type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Educational and self-management training: individual versus usual care</td>
</tr>
</tbody>
</table>
Intervention group

- Five 40-60 minute individual sessions with transplant nurse every week for 4 weeks (except for the last session which was held 2 weeks from the second last). Between the fourth and the fifth (last) session, there was a period of 2 weeks.
- Education on medication, rejection, and lifestyle was provided along with discussions about individual issues and problems. Written information also provided on these topics

Control group

- Usual care: patient education during hospitalisation

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Knowledge questionnaire for kidney recipients. Four items in the questionnaire were focused on immunosuppressive medication, four on rejection, and 11 on lifestyle. When scoring the questionnaire, only completely correct answers were given points. A total score of correct answers was summarized</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QoL</th>
<th>SF-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td></td>
</tr>
<tr>
<td>Measured by “The General Self-efficacy Scale,” designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life</td>
<td></td>
</tr>
</tbody>
</table>

Adherence

- Compliance was measured by the number of patient observations and was measured by counting number of missed observations from observations start and during a period of 7 to 8 weeks

Notes

Conflict of interest

- "None"

Funding source

- Not reported

Other information

- Not requested

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: &quot;The participants were randomized in blocks of 20 (a series of 20 patients contained 10 in each group).&quot;</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Neither participants nor personnel were blinded</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Self-efficacy, QoL: self report measures by unblinded participants</td>
</tr>
</tbody>
</table>
**Urstad 2012 (Continued)**

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk</th>
<th>Outcome Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>Low</td>
<td>Compliance: number of missed self observations entered in chart and knowledge</td>
</tr>
<tr>
<td>Objective outcomes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Incomplete outcome data (attrition bias)                                  | Unclear | Quote: "Based on an effects size of 0.5 standard deviations, a significance level of 5% and a power of 80%, we initially estimated that 64 participants were needed in each group."
| All outcomes                                                               |       | Quote: "In total, 159 renal recipients were randomized to the intervention (N = 77) or control group (N = 82). A total of 139 participants reached second measure point (7–8 wk post-Tx), and 120 participants reached third measure point (six months post-Tx). The intervention consisted of five (75% response rate from baseline)."
| Selective reporting (reporting bias)                                      | Unclear | All outcomes seem to be reported                                                    |
| Other bias                                                                | Unclear | Sample population may not be representative                                       |

**Wang 2011**

**Study characteristics**

**Methods**

- **Study design**
  - Non-RCT; repeated measures design, with intervention and comparison groups
- **Duration of study**
  - Not reported
- **Duration of follow-up**
  - 8 weeks

**Participants**

- **General information**
  - Setting: multicentre (6 sites)
  - Country: Taiwan
  - **Inclusion criteria**: > 20 years; HD < 1 year and undergoing 3 HD sessions/week; without visual or hearing disabilities, able to communicate in Mandarin or Taiwanese; willing to join in the study and to sign informed consent
  - **Exclusion criteria**: not in a clear state of mind and those unwilling to receive the CD
- **Baseline characteristics**
  - **Number**: intervention group (30); control group (30)
  - **Mean age ± SD (years)**: intervention group (50.13 ± 14.75); control group (62.2 ± 10.45)
  - **Sex (M/F)**: intervention group (11/19); control group (15/15)
  - **Stage of CKD**: ESKD on HD

**Interventions**

- **Intervention type**
  - Education (other): provision of materials versus control
- **Intervention group**

---

**Interventions for improving health literacy in people with chronic kidney disease (Review)**

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Wang 2011* (Continued)

- Use of an interactive multimedia CD with tailored instructions for 4 weeks, participants could watch at their leisure during HD sessions. Focused on normal kidney function, definitions, and reasons for kidney failure, signs and symptoms and HD information

**Control group**

- Usual care

**Outcomes**

<table>
<thead>
<tr>
<th>Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire of dialysis self-care knowledge</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaire of dialysis self-care behaviours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAT scale was used to evaluate respondents’ feelings of powerlessness and the source of their strength. Higher scores correlated with reduced feelings of powerlessness</td>
</tr>
</tbody>
</table>

**Notes**

- **Conflict of interest**
  - Not reported

- **Funding source**
  - “The authors thank the National Science Counsel of Taiwan for providing funding (NSC 94-2314-B-242-005).”

- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-RCT overall judgement</td>
<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Self-care knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Self-care behaviours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Feelings of powerlessness</td>
</tr>
</tbody>
</table>

- **Bias due to confounding**
  - Moderate: Allocated using day of dialysis. Also age was significantly different but they analysed this

- **Bias in selection of participants into the study**
  - NI

- **Bias in classification of interventions**
  - Low

- **Bias due to deviations from intended interventions**
  - NI

- **Bias due to missing data**
  - NI

---

**Interventions for improving health literacy in people with chronic kidney disease (Review)**

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Wang 2011* (Continued)

Bias in measurement of outcomes

O1. Low
O2/O3. Serious: Self report questionnaire for subjective outcomes

Bias in selection of the reported result

NI

Overall risk of bias judgement

Serious: O2/O3 (behaviours, powerlessness)
Moderate: O1 (knowledge)

Welch 2013

Study characteristics

Methods

Study design
• Parallel RCT

Duration of study
• Not reported

Duration of follow-up
• 16 weeks

Participants

General information
• Setting: single centre
• Country: USA
• Inclusion criteria: ≥ 18 years; alert and oriented; able to read and converse in English; currently receiving outpatient HD as their primary treatment modality; had been on HD for ≥ 3 months; willing to use technology; self-reported difficulty following at least one aspect of their dietary and fluid prescription
• Exclusion criteria: living in an assisted or extended-care facility; receiving HD on a temporary basis following a PD complication or an episode of transplant rejection; reported having no intent to comply with dietary or fluid restrictions; were receiving home HD

Baseline characteristics
• Number: intervention group (24); control group (20)
• Mean age ± SD (years): intervention group (53.0 ± 15.1); control group (47.1 ± 11.5)
• Sex (M/F): intervention group (12/12); control group (13/7)
• Stage of CKD: ESKD on HD

Other information
• There were no differences found between groups as baseline in terms of gender, race, dialysis unit, age, IDWG, subjective outcome measures

Interventions

Intervention type
• Self-management provision of materials: one-on-one versus control (mobile application)

Intervention group
Welch 2013 (Continued)

- Provided with an Electronic Dietary Intake Monitoring Application (DIMA): with a nutrition database and a Universal Product Code database that could be used to look up food information from packaging. Feedback about participants' intake in relation to their dietary prescriptions included. DIMA computed totals removing the need for in-depth reading of food labels and mathematical calculations.

**Control group**

- Provided with a Daily Activity Monitoring Application (DAMA) to monitor daily activity so that time spent on intervention was similar between groups.

**Outcomes**

- Perceived benefits, perceived control, diet and fluid intake, acceptability
- Self-efficacy
  - Cardiac self-efficacy instrument for diet self-efficacy and fluid self-efficacy scale, IDWG

**Notes**

- **Conflict of interest**
  - Not reported

- **Funding source**
  - "Grants from NIH/National Institute of Biomedical Imaging and Bioengineering (R21EB007083), a T32 Postdoctoral Training Grant (NIH T32 NR007066), and Indiana University School of Nursing Research Investment Funds."

- **Other information**
  - Not requested

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
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<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomisation was blocked and stratified by dialysis unit</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Research assistants assisted patients with data collection - participant data was collected by RAs. RAs read questionnaire items to each participant who responded verbally</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) Subjective outcomes</td>
<td>High risk</td>
<td>Subjective measurements such as self-efficacy and perceived control were completed by self-report questionnaire by unblinded participants</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) Objective outcomes</td>
<td>Low risk</td>
<td>Weight gain not thought to be influenced by blinding</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Quote: &quot;Of the 24 participants in the DIMA Group, five did not receive the intervention and three discontinued the intervention. All participants in the control group received the DAMA intervention but three discontinued the intervention before the end of the intervention period. Thus, there was an overall attrition rate of 25% by the end of the 8-week follow-up. There were no statistically significant differences in age, gender, race, dialysis unit, or group between those who continued in the study and those who did not&quot;</td>
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</table>
Welch 2013 (Continued)

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>Insufficient information to permit judgement</th>
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</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>Underpowered, small sample size, possible error in measures, lack of direct self-efficacy statements to participants in DIMA group and interactions between participants in intervention and control groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Predominantly African-American from 2 geographical areas: not generalisable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Person was re-assigned into the control group because of limited ability to engage in activities due to leg amputation</td>
</tr>
</tbody>
</table>

Wingard 2009*

Study characteristics

Methods

- **Study design**
  - Non-RCT
- **Duration of study**
  - Not reported
- **Duration of follow-up**
  - 365 days

Participants

- **General information**
  - **Setting**: multicentre (39 sites)
  - **Country**: USA
  - **Inclusion criteria**: not reported
  - **Exclusion criteria**: seasonal and transient patients; patients with poor cognitive function resulting in an inability to learn as judged by the staff administering the RightStart program

Baseline characteristics

- **Number**: intervention group (918); control group (1020)
- **Mean age ± SD (years)**: intervention group (62 ± 16); control group (62 ± 17)
- **Sex (M)**: intervention group (46%); control group (46%)
- **Stage of CKD**: Chronic HD patients in the 1st 90 days of treatment

Interventions

- **Intervention group**
  - Educational and self-management versus control

  **Intervention group**
  - A 3-month intervention 1-2 times per week for the first month they every 1-2 weeks for 2 more months. The RightStart program consists of an intensive education program by a case manager. Specific interventions in relation to anaemia management, adequate dialysis dose, nutrition, reduction of catheter use, medications, logistical support and psychosocial assessment. Participants were encouraged to improve their self-care and partake in rehabilitation services

  **Control group**
  - Patients from non-RightStart clinics
### Outcomes

Knowledge (no control group)
- 23-question Dialysis Knowledge Test designed specifically for the RightStart program was administered at baseline, 3, and 6 months

QoL (no control group)
- KDQoL-SF administered during the first 3 (baseline) and for 6 months only

Death

Hospitalisations
- Measured by cumulative hospitalisation days for each group according to the different exposure times

Vascular access type

### Notes

**Conflict of interest**
- "is the Vice President of Quality Initiatives, Fresenius Medical Services"

**Funding source**
- "This article is supported by a financial grant from Amgen."

**Other information**
- Not requested

### Risk of bias

<table>
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<th>Bias</th>
<th>Authors' judgement</th>
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<td>Unclear risk</td>
<td><strong>Outcomes</strong></td>
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<tr>
<td></td>
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<td>1. Hb URR, albumin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. KDQoL-SF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Dialysis Knowledge test</td>
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<tr>
<td></td>
<td></td>
<td>4. Death</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Hospitalisations</td>
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<td>6. Vascular access type</td>
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<td>Moderate: Assigned based on hospital but adjusted in analysis</td>
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<tr>
<td><strong>Bias in selection of participants into the study</strong></td>
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<tr>
<td><strong>Bias in classification of interventions</strong></td>
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<tr>
<td><strong>Bias due to deviations from intended interventions</strong></td>
<td>NI</td>
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<tr>
<td><strong>Bias due to missing data</strong></td>
<td>NI</td>
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</table>
Wingard 2009* (Continued)

O2. Serious: Subjective measure using self-report questionnaire

Bias in selection of the reported result

NI

Overall risk of bias judgement

Serious: O2 (QOL)

Moderate: O1/O3/O4/O5/O6

---

Wong 2010

Study characteristics

Methods

Study design

- Parallel RCT

Duration of study

- Not reported

Duration of follow-up

- 13 weeks

Participants

General information

- Setting: multicentre (2 sites)
- Country: Hong Kong
- Inclusion criteria: communicable; alert and oriented; could be contacted by telephone at home; lived in the hospital service area
- Exclusion criteria: on intermittent PD or HD; old-age home residents

Baseline characteristics

- Number: intervention group (60); control group (60)
- Mean age: 62.4 years
- Sex (M/F): 52%/46%
- Stage of CKD: ESKD on CAPD

Other information

- There was no significant difference in the background characteristics between the control and study groups.

Interventions

Intervention type

- Educational and self-management training: individual versus usual care

Intervention group

- Disease management programme included all the features of the four-Cs model: comprehensiveness, collaboration, coordination and continuity

Control group
Wong 2010 (Continued)

- Routine care

Outcomes

Bloods
- Symptom control included presence of oedema, existence of peritonitis, exit site condition and weight gain (blood chemistry including urea, creatinine, sodium, potassium, phosphate and albumin)

QoL
- KDQoL-SF (translated)

Adherence
- Dialysis diet and fluid non-adherence questionnaire

Satisfaction scale
- La Monica-Oberst Patient Satisfaction Scale

Notes

Conflict of interest
- "None declared"

Funding source
- "This research was funded by Research Grants Council of Hong Kong (PolyU 5435/05H)."

Other information
- Not requested

Risk of bias

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<td>Low risk</td>
<td>120 sets of computer-generated random numbers were used</td>
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<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Renal nurses and General nurses contacted the study participants on a regular basis and provided the education</td>
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<td>Could not have been blinded</td>
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<tr>
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<td>High risk</td>
<td>Subjective measures and therefore at risk of bias; however, a blinded research assistant administered questionnaires and gathered data from records</td>
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<tr>
<td></td>
<td></td>
<td>Data collected in interviews and blinding would likely have been broken with RA discussions with participants</td>
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<td>Low risk</td>
<td>Objective data collected from hospital records</td>
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<td>Incomplete outcome data (attrition bias) All outcomes</td>
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<td>No mention of attrition or loss to follow-up</td>
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### Wong 2010 (Continued)

<table>
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<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
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</table>

### Wu 2009

#### Study characteristics

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - July 2007 to 30 June 2011

- **Duration of follow-up**
  - 6 months

**Participants**

- **General information**
  - *Setting*: single centre
  - *Country*: Taiwan
  - *Inclusion criteria*: 18 to 80 years
  - *Exclusion criteria*: kidney graft failure

- **Baseline characteristics**
  - *Number*: intervention group (287); control group (286)
  - *Mean age ± SD (years)*: intervention group (67.5 ± 11.4); control group (61.8 ± 15)
  - *Sex (M/F)*: intervention group (116/116); control group (105/108)
  - *Stage of CKD*: predialysis CKD patients

**Interventions**

- **Intervention type**
  - Education: individual versus control

- **Intervention group**
  - Integrated course involving individual lectures on renal health from a case-management nurse. The lectures focused on nutrition, lifestyle, nephrotoxin avoidance, diet and medications

- **Control group**
  - Usual care

**Outcomes**

- **Progression of kidney disease**
  - Progression to ESKD requiring KRT, GFR

- **Bloods**
  - Creatinine, potassium, eGFR, Hb, albumin, calcium, phosphate, PTH, iron

- **Death**

- **Hospitalisation**
Wu 2009 (Continued)

- Frequency of hospitalisation, number of times hospitalised, length of hospitalisation; cause of 1st hospitalisation
  
Number of outpatient visits; cost of outpatient service, log cost of inpatient service, log total costs of medical service; cause of first surgery

Notes

Conflict of interest

- "The authors have declared that no competing interests exist"

Funding source

- "Chang Gung Memorial Hospital at Keelung provided grant support for this research (CM-RPG280323/CMRPG2A0422)"

Other information

- Not requested

Risk of bias

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<td>Insufficient information to permit judgement</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>Participants and personnel were not blinded</td>
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<td>Low risk</td>
<td>All measurements were objective therefore blinding not though to affect outcome</td>
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<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Low loss to follow-up</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>All stated outcomes were reported</td>
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<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Significant differences between groups at baseline - age, access type however this was controlled for in analysis and differences did not impact results</td>
</tr>
</tbody>
</table>

Yamagata 2010

Study characteristics

Methods

- Cluster RCT

Duration of study

- Not reported
### Yamagata 2010 (Continued)

**Duration of follow-up**
- 3.5 years

### Participants

**General information**
- **Setting:** multicentre (49 clusters)
- **Country:** Japan
- **Inclusion criteria:** 40 and 74 years; CKD stage 1, 2, 4, or 5 (UPCR 0.3 g/g or proteinuria 1+) and diabetes OR stage 3 CKD with proteinuria (UPCR > 0.3 g/g or proteinuria >1+) and hypertension
- **Exclusion criteria:** dialysis patients; kidney transplant patients; did not consent

**Baseline characteristics**
- **Number:** intervention group (1195); control group (1184)
- **Mean age ± SD (years):** intervention group (63.17 ± 8.55); control group (62.79 ± 8.25)
- **Sex (M/F):** intervention group (850/345); control group (862/322)
- **Stage of CKD:** CKD any stage

**Other information**
- Quote: "The characteristics of the groups were similar at baseline except for CKD stage and serum uric acid level. The proportion of cases of CKD stage 1+2 in group A was 49.4%, but it was 43.1% in group B, and the proportion of Stage 3 CKD in group A was 40.7%, but it was 47.4% in group B, while the average eGFR and average Scr levels were identical in the two groups. Uric acid in group B was 6.25 ± 1.67, while it was 6.08 ± 1.48 in group A”

### Interventions

**Intervention type**
- Self-management: individual versus control

**Intervention group**
- Three interventions
  - 30-minute educational sessions from dieticians at the GP every three months
  - Bimonthly CKD treatment report
  - The GPs’ received comments about their patients’ data

**Control group**
- Usual care

**Co-interventions**
- GP intervention

### Outcomes

**Discontinuation of clinical visits, proportion of patients under co-treatment from a GP and a nephrologist**

**Progression of CKD stage**
- Annual GFR changes

**Adherence to treatment guide**
- BP goals, reduction in urinary protein, creatinine, KRT, CVD events

### Notes

**Conflict of interest**
- Not reported

**Funding source**

---

_interventions for improving health literacy in people with chronic kidney disease (Review)_

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Yamagata 2010 (Continued)

- "This study was supported by a grant for a strategic outcome study project from the Ministry of Health, Labor, and Welfare of Japan."

Other information
- Not requested

Risk of bias

<table>
<thead>
<tr>
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<th>Support for judgement</th>
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<td>Unclear risk</td>
<td>Insufficient information to permit judgement</td>
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<tr>
<td>Allocation concealment (selection bias)</td>
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<td>Insufficient information; probably not done</td>
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<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>High risk</td>
<td>No mention of blinding; probably not done</td>
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<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Low risk</td>
<td>All outcomes were objective measures; no blinding but thought not to affect outcome</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>There was about 10% loss to follow-up in both groups but the reasons for withdrawal for the treatment group seemed initially to be related to the intervention Quote: &quot;After randomization, 68 patients in group B chose to withdraw, while only 13 patients in group A did so. Most of the patients in group B withdrew just after randomization due to an aversion to the educational intervention.&quot;</td>
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<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>2016 paper is similar to 2010 paper in methods and outcomes</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>No evidence to suggest other forms of bias</td>
</tr>
</tbody>
</table>

Ye 2011a

Study characteristics

Methods
- **Study design**
  - Parallel RCT
- **Duration of study**
  - 1 September 2009 to 30 November 2010
- **Duration of follow-up**
  - Not reported

Participants
- **General information**
  - Setting: single centre
  - Country: China
Inclusion criteria: diagnosed with CKD, receiving HD treatment awaiting cadaveric kidney transplant; no cognitive impairment; no psychiatric conditions; able to complete and understand research questionnaire

Exclusion criteria: not reported

Baseline characteristics

Number: intervention group (63); control group (62)

Mean age ± SD (years): intervention group (34.2 ± 13.3); control group (36.8 ± 14.1)

Sex (M/F): intervention group (41/22); control group (38/24)

Stage of CKD: ESKD on HD awaiting kidney transplant

Interventions

Intervention type

Educational intervention: individual and group versus usual care

Intervention group

Preoperative education during hospitalisation by nurses about diet and kidney transplantation with follow-up guidance

Control group

Traditional health education

Outcomes

Psychological status of patients before and after

Zung self-rating anxiety scale and Zung self-rating depression scale

Nutritional status of patients before and after

Triceps skinfold thickness, mid-arm muscle circumference

Biochemistry

Hb, albumin

Notes

Conflict of interest

Not reported

Funding source

Not reported

Other information

Not requested

Risk of bias

<table>
<thead>
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<th>Bias</th>
<th>Authors' judgement</th>
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<tbody>
<tr>
<td>Random sequence generation</td>
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<tr>
<td>(selection bias)</td>
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<td>Allocation concealment</td>
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<td>Insufficient information to permit judgement</td>
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<tr>
<td>(selection bias)</td>
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<tr>
<td>Blinding of participants and</td>
<td>High risk</td>
<td>Probably not blinded because of nature of intervention</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
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</tr>
</tbody>
</table>
Ye 2011a (Continued)

All outcomes

| Blinding of outcome assessment (detection bias) Subjective outcomes | High risk | Anxiety and depression: not blinded and subjective self report questionnaire |
| Blinding of outcome assessment (detection bias) Objective outcomes | Low risk | Nutritional status: not affected by blinding |
| Incomplete outcome data (attrition bias) All outcomes | Unclear risk | Data seems complete in tables; missing data not mentioned |
| Selective reporting (reporting bias) | Unclear risk | Insufficient information to permit judgement |
| Other bias | Unclear risk | Insufficient information to permit judgement |

ACEI: angiotensin-converting enzyme inhibitor; AKI: acute kidney injury; APD: automated peritoneal dialysis; ARB: angiotensin receptor blocker; BCC: basal cell carcinoma; BDI: Beck's Depression Index; BMI: body mass index; BP: blood pressure; BUN: blood urea nitrogen; Ca x P/PO₄: calcium x phosphorous/phosphate; CAPD: continuous ambulatory peritoneal dialysis; CKD: chronic kidney disease; CrCl: creatinine clearance; CRP: C-reactive protein; CSA: cyclosporin A; DBI: Beck's Depression Index; eGFR: estimated glomerular filtration rate; EM: electronic monitoring; ESKD: end-stage kidney disease; GI: gastrointestinal; HADS: Hospital Anxiety and Depression Scale; Hb: haemoglobin; HbA1c: haemoglobin A1c (glycated); HCT: haematocrit; HD: haemodialysis; HDL: high-density lipoprotein; HIV: human immunodeficiency virus; HRQoL: health-related quality of life; IDWG: interdialytic weight gain; IQR - interquartile range; ITT: intention to treat; KDQOL: Kidney Disease Quality of Life; KRT: kidney replacement therapy; LDKT: living donor kidney transplant; M/F: male/female; MARS: Medication adherence self-report; MDRD: Modification of Diet in Renal Disease; MEMS: Medication Events Monitoring System; MMAS: Morisky Medication Adherence Scale; MMF: mycophenolate mofetil; MPA: mycophenolic acid; NYHA: New York Heart Association; PC-ACP: patient-centred advance care planning; PD: peritoneal dialysis; PDA: personal digital assistant; PTH: parathyroid hormone; QoL: quality of life; RCT: randomised controlled trial; RPGN: rapidly progressive glomerulonephritis; SCC: squamous cell carcinoma; SCR: serum creatinine; SD: standard deviation; SE: standard error; SF-36: short form 36; SGA: subjective global scale; SUPPH: Strategies Used by People to Promote Health 29-item questionnaire; TAC: tacrolimus; UACR: urinary albumin:creatinine ratio; UPCR: urinary protein:creatinine ratio; URR: urea reduction ratio; VAS: visual analogue scale

Characteristics of excluded studies [ordered by study ID]

<table>
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<tr>
<td>Abdel-Kader 2011</td>
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<tr>
<td>Alkema 2007</td>
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<td>Baraz 2014</td>
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<td>Bissonnette 2013</td>
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<td>Bond 2011</td>
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<td>Briggs 2004</td>
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<td>Cargill 2003</td>
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<td>Curatola 2011</td>
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<td>Doulton 2015</td>
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<tr>
<td>Garcia-Garcia 2015</td>
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<td>Gillis 1995</td>
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<td>Gray 2016</td>
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### Characteristics of studies awaiting classification [ordered by study ID]

#### Gordon 2016

**Methods**

- **Study design**
  - Parallel RCT; pre-post test

- **Duration of study**
  - May 2013 to February 2015

- **Duration of follow-up**
  - 3 weeks

**Participants**

- **General information**
  - **Setting:** multicentre (2 sites)
  - **Country:** USA
  - **Inclusion criteria:** ≥ 18 years; self-identified as Hispanic/Latino; never received an organ transplant or formal education about transplantation at a transplant centre; were sighted; reported “never” or “rarely” or “sometimes” to the health literacy questions; responded affirmatively to the computer literacy question; could read and interact with the website
Baseline characteristics

- Number: intervention group (62); control group (61)
- Mean age ± SD (years): not reported
- Sex (M/F): not reported
- Stage of CKD: waiting for kidney transplant

Interventions

**Intervention group**
- Viewed Informate (www.informate.org) before attending routine transplant education sessions

**Control group**
- Education sessions only

Outcomes

Knowledge
- Knowledge score

Notes

**Conflict of interest**

"This publication was supported by Eleanor Wood Prince Grants Initiative (to EJ Gordon), and by the U.S. Department of Health and Human Services, Health Resources and Services Administration’s Division of Transplantation (R39OT22059 to EJ Gordon)"

- **Funding source**
- "The authors declare no conflicts of interest"

**HED-START 2021**

Methods

**Study design**
- Parallel RCT

**Duration of study**
- January 2021 to September 2022

**Duration of follow-up**
- 3 months

Participants

**General information**
- Setting: multicentre
- Country: Singapore
- Inclusion criteria: ≥ 21 years; diagnosed with kidney failure; ≤ 6 months since HD placement; speak and read English or Mandarin
- Exclusion criteria: unwilling or unable to give consent or refuse to be randomised; have cognitive impairments or psychiatric conditions that preclude consent as noted in medical records or evidenced in the screening visit; currently involved in other intervention trials; failing on dialysis and approaching end of life (palliative care pathway); participants with social/living circumstances that would preclude attendance of intervention sessions (e.g. nursing homes or institutionalised care settings)
- Target number: 148 incident HD patients
- Stage of CKD: ESKD on HD
### HED-START 2021 (Continued)

**Interventions**

**Intervention group**
- HED-Start: will combine elements of cognitive behavioural therapy (psycho-education on mood and interplay of thoughts, emotions and actions, cognitive reframing), and positive psychology (e.g. strength-based activities (affirmations, social resources), positive coping strategies, gratitude, acceptance) and self-management (i.e. emphasis on own agency/self-responsibility, skill(s) acquisition)

**Control group**
- Usual care

**Outcomes**
- Anxiety
- Depression
- Positive and negative affect
- QoL
- Illness perceptions
- Self-efficacy
- Self-management skills
- Benefit finding
- Resilience

**Notes**

**Conflict of interest**
- "None declared"

**Funding source**
- "This research is supported by the National Kidney Foundation Singapore under its Venerable Yen Pei-NKF Research Fund (NKFRC/2018/01/02). NKF Singapore provided the patients and venue for the HED-Start intervention sessions."

---

### KARE 2015

**Methods**

**Study design**
- 2 x 2 factorial RCT examining the impact of a multi-level intervention on health outcomes

**Duration of study**
- Not reported

**Duration of follow-up**
- 12 months

**Participants**

**General information**
- **Setting:** multicentre (2 sites)
- **Country:** USA
- **Inclusion criteria:** low-income English, Spanish and Cantonese-speaking patients with CKD in a safety net system
**Interventions**

- Primary care provider teams were randomly assigned to access a CKD registry with point-of-care notifications and quarterly feedback or a usual-care registry for 12 months. Patients within provider teams were randomly assigned to participate in a CKD self-management support program or usual care for 12 months
- The intervention includes (1) implementation of a primary care electronic CKD registry that notifies practice teams of patients’ CKD status and employs a patient profile and quarterly feedback to encourage the provision of guideline-concordant care at point-of-care and via outreach; and (2) a language-concordant, culturally-sensitive self-management support program that consists of automated telephone modules, provision of low-literacy written patient-educational materials and telephone health coaching.

**Outcomes**

- Changes in BP and BP control
- Understanding of CKD
- Participation in healthy behaviours
- Delivery of guideline-concordant CKD care

**Notes**

- **Conflict of interest**
  - No relevant financial interests

- **Funding source**
  - "This work was supported by K23DK094850, R01DK104130, and R34DK093992 Planning Grants for Translating CKD Research into Improved Clinical Outcomes, all from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr Hsu is additionally supported by K24DK-92291. Drs Schillinger and Handley are additionally supported by P60MD006902 from the National Institute of Minority Health and Health Disparities and P30DK092924 from the NIDDK. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript."

---

**Schaffhausen 2020**

**Methods**

- **Study design**
  - Focus groups then randomised survey

- **Duration of study**
  - Not reported

- **Duration of follow-up**
  - Not reported

**Participants**

- **General information**
  - **Setting**: multicentre (3 sites)
  - **Country**: USA
  - **Inclusion criteria**: ≥ 18 years; kidney, liver, heart and lung transplant; stratified into candidates and recipients
  - **Exclusion criteria**: non-English speaking

**Interventions**

- **Intervention group**
**Schaffhausen 2020 (Continued)**

- "A series of organ-specific focus groups of kidney, liver, heart, and lung patients helped to develop and refine potential displays of center outcomes and understand patient perceptions"

**Control group**

- Unclear

**Outcomes**

**Notes**

**Conflict of interest**

- "The authors declare no conflicts of interest."

**Funding source**

- "The research was partially supported by R01 HS 24527 (A.I.)."

---

**TALKS 2015**

**Methods**

**Study design**

- Parallel RCT

**Duration of study**

- September 2015 to May 2017

**Duration of follow-up**

- Not reported

**Participants**

**General information**

- Setting: single centre
- Country: USA
- Inclusion criteria: speak English; ≥ 18 years; actively registered on the Duke deceased donor kidney transplant waiting list; identified as being of African American race through self-report
- Exclusion criteria: prior live donor kidney transplant

**Baseline characteristics**

- Number: 300
- Median age (IQR): 52 years (45 to 60)
- Sex: 56% male
- Stage of CKD: transplant waiting list

**Interventions**

**Intervention group 1**

- A self-directed educational module (video and book), which transplant candidates were encouraged to review alone and with friends and family
- A social worker led brief behavioural support intervention for patients and their family members. Social workers meet once with transplant candidates to discuss their self-identified barriers to LDKT and are invited to meet a second time with social workers with family members or friends in attendance

**Intervention group 2**

- Intervention 1 + living donor financial assistance

**Control group**
**TALKS 2015 (Continued)**

- Usual care

**Outcomes**

- Donor activation events

**Notes**

- **Conflict of interest**
  - No conflicts of interests to disclose

- **Funding source**
  - National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases [R01DK098759-01]
  - Grant Number UL1TR002553 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research

**Waterman 2015**

**Methods**

- **Study design**
  - Parallel RCT

- **Duration of study**
  - Not reported

- **Duration of follow-up**
  - 10 months

**Participants**

- **General information**
  - **Setting**: multicentre
  - **Country**: USA
  - **Inclusion criteria**: 18 to 74 years; self-identify as Black or White race; currently on dialysis; household income at or below 250% of the federal poverty level; able to speak and read in English
  - **Exclusion criteria**: visual and/or hearing impairment; has had a previous kidney transplant; has previously told that they are not a candidate for transplant

- **Baseline characteristics**
  - Enrolment target: 180
  - **Sex (M/F)**: both
  - **Stage of CKD**: ESKD on HD

**Interventions**

- Standard-of-care transplant education provided by the dialysis centre
- Patient-guided explore transplant at home program
- Health educator-guided explore transplant at home program

**Outcomes**

- "Transplant knowledge, decisional balance, self-efficacy, informed decision-making, decisional conflict, and any steps they may have taken to learn about staying on dialysis, DDKT, or LDKT"

**Notes**

- **Conflict of interest**
  - "no competing interests"

- **Funding source**
**YPT 2014**

**Methods**

<table>
<thead>
<tr>
<th>Study design</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Parallel RCT</td>
<td></td>
</tr>
</tbody>
</table>

**Duration of study**

- May 2014 to May 2017

**Duration of follow-up**

- 8 months

**Participants**

<table>
<thead>
<tr>
<th>General information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Setting: single centre</td>
<td></td>
</tr>
<tr>
<td>• Country: USA</td>
<td></td>
</tr>
<tr>
<td>• Inclusion criteria:</td>
<td></td>
</tr>
<tr>
<td>- presentation for transplant evaluation; self-identification as White, Black, or Hispanic</td>
<td></td>
</tr>
<tr>
<td>• Exclusion criteria:</td>
<td></td>
</tr>
<tr>
<td>- &lt; 18 years; unable to speak or read English; previously deemed ineligible for kidney transplant; on the waitlist at another centre; pursuing multiorgan transplant; no telephone</td>
<td></td>
</tr>
</tbody>
</table>

**Baseline characteristics**

- Number: 802
- Mean age ± SD: 53.3 ± 13.1 years
- Sex (M/F): 486/316
- Stage of CKD: kidney transplant waitlist

**Interventions**

<table>
<thead>
<tr>
<th>Intervention group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Computer-tailored coaching intervention</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standard care</td>
<td></td>
</tr>
</tbody>
</table>

**Outcomes**

| Readiness to pursue LDKT or DDKT |          |

**Notes**

- "Amy D. Waterman, PhD, owns the intellectual property to the transplant education product Explore Transplant and has licensed it at no cost to a nonprofit, Health Literacy Media (HLM), who retains all revenue as to their sales. She serves as an unpaid consultant to HLM to ensure the accuracy of educational content. All other authors declare that they have no competing interests"

- "National Institutes of Health (R01DK088711; T32DK104687)"

BP: blood pressure; CKD: chronic kidney disease; DDKT: deceased donor kidney transplant; ESKD: end-stage kidney disease; HD: haemodialysis; IQR: interquartile range; LDKT: living donor kidney transplant; M/F: male/female; QoL: quality of life; RCT: randomised controlled trial; SD: standard deviation
### Characteristics of ongoing studies [ordered by study ID]

#### KFTT-TALK 2017

<table>
<thead>
<tr>
<th>Study name</th>
<th>KTFT-TALK study to reduce racial disparities in kidney transplant evaluation and living donor kidney transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Quasi-experimental design to test the effectiveness of the Kidney Transplant Fast track (KTFT), and a RCT of the Talking About Live Kidney Transplant (TALK) intervention</td>
</tr>
<tr>
<td>Participants</td>
<td>Patients who schedule a kidney transplant evaluation appointment at any of the 3 sites included in our study. Male and female, English-speaking, ESKD patients ≥ 18 years, who have not previously received a kidney transplant and have not been accepted for kidney transplantation in another centre</td>
</tr>
<tr>
<td>Interventions</td>
<td>TALK versus no TALK intervention</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Kidney transplant rates, time to kidney transplant, survival, cost effectiveness</td>
</tr>
<tr>
<td>Starting date</td>
<td>Not reported</td>
</tr>
<tr>
<td>Contact information</td>
<td>University of Pittsburgh, School of Medicine</td>
</tr>
<tr>
<td></td>
<td>E-mail address: <a href="mailto:myaskov@pitt.edu">myaskov@pitt.edu</a> (L. Myaskovsky)</td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
</tbody>
</table>

#### NCT00394576

<table>
<thead>
<tr>
<th>Study name</th>
<th>Assessing novel methods of improving patient education of nutrition: ehealth, health literacy and chronic kidney disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Test the effect of a web-based nutritional educational intervention, Kidney School (KS), to improve phosphorous knowledge and control phosphorous intake in CKD patients</td>
</tr>
<tr>
<td>Participants</td>
<td>54 participants</td>
</tr>
<tr>
<td>Interventions</td>
<td>Internet-based nutrition module</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Phosphorous knowledge, serum electrolytes, dietary compliance</td>
</tr>
<tr>
<td>Starting date</td>
<td>November 2006</td>
</tr>
<tr>
<td>Contact information</td>
<td>Jonathan B Jaffery</td>
</tr>
<tr>
<td></td>
<td>School of Medicine and Public Health, University of Wisconsin</td>
</tr>
<tr>
<td>Notes</td>
<td>Completed; no results posted</td>
</tr>
</tbody>
</table>

#### NCT00782847

| Study name | Evaluation study for the programme DiaNe for people with diabetic nephropathy (DiaNe) |

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*Interventions for improving health literacy in people with chronic kidney disease (Review)*

Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
Evaluate the effect of a patients' educational program called DiaNe® for consultation and support people with diabetic kidney disease in an early stage

<table>
<thead>
<tr>
<th>Participants</th>
<th>125 participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
<td>DiaNe consultation and support program</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Kidney function, HbA1c</td>
</tr>
<tr>
<td>Starting date</td>
<td>July 2004</td>
</tr>
<tr>
<td>Contact information</td>
<td>Ludwig F Merker, MD</td>
</tr>
<tr>
<td></td>
<td>Diabetes- und Nierenzentrum Dormagen</td>
</tr>
<tr>
<td>Notes</td>
<td>Completed; no results posted</td>
</tr>
</tbody>
</table>

CKD: chronic kidney disease; ESKD: end-stage kidney disease; HbA1c: haemoglobin A1c (glycated); RCT: randomised controlled trial

**HISTORY**


**CONTRIBUTIONS OF AUTHORS**

1. Draft the protocol: ZC, JS, KM, JJ, KC, VL, AW
2. Study selection: ZC, JS, SK
3. Extract data from studies: ZC, JS, SK
4. Enter data into RevMan: ZC, JS, SK
5. Carry out the analysis: ZC
6. Interpret the analysis: ZC, JS, SK, KM, JJ, KC, VL, AW
7. Draft the final review: ZC, JS, SK, KM, JJ, KC, VL, AW
8. Disagreement resolution: AW
9. Update the review: ZC

**DECLARATIONS OF INTEREST**

- Zoe C Campbell: no relevant interests were disclosed
- Jessica K Stevenson: no relevant interests were disclosed
- Suzanne M Kirkendall: no relevant interests were disclosed
- Kirsten J McCaffery: no relevant interests were disclosed
- Jesse Jansen: no relevant interests were disclosed
- Katrina L Campbell: no relevant interests were disclosed
- Vincent WS Lee: no relevant interests were disclosed
- Angela C Webster: no relevant interests were disclosed

**SOURCES OF SUPPORT**

**Internal sources**

- No sources of support provided

**External sources**

- No sources of support provided
DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol outlined multiple subgroup analyses that were planned. Due to the unforeseen number of studies and comparisons in this review, the authors chose to focus on just one sub-group analysis; mode of delivery.

INDEX TERMS

Medical Subject Headings (MeSH)
*Health Literacy; *Renal Insufficiency, Chronic [therapy]

MeSH check words
Humans