National Institute for Health and Care Excellence

Draft for consultation

RRT and conservative management

Evidence review for decision support interventions

NICE guideline

Intervention evidence review

April 2018

Draft for Consultation

This evidence review was developed by the National Guideline Centre

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and, where appropriate, their carer or guardian.

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ISBN

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1 Decision support

1.1 Review question: What is the clinical and cost effectiveness of decision support interventions for people who may require renal replacement therapy?

1.2 Introduction

People have the right to be involved in discussions and make informed decisions about their, or their child's, treatment and care with their healthcare team. Decision aids are complex interventions designed to enable patients to become involved in decision making by providing information about the options and by clarifying personal values. In the context of people with kidney choosing between treatment options these represent a series of nested choices between RRT and CM, and if RRT is chosen then between transplant and dialysis, and if dialysis is chosen (or transplant not possible) then between the different dialysis modalities. Most renal units offer some form of structured education programme. However, the content, format and intensity of these programmes vary considerably. Decision aids and structured education programmes are intended to help people weigh up the possible advantages and disadvantages of the different options. This question relates to all people who need to make the decision about whether to undergo a transplant, choose between types of dialysis or receive conservative management instead of RRT. This question will look at the value of decision aids and structured education programmes in this process.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	Children, young people and adults with CKD stage 3 to 5
Interventions	Decision support aids Structured education programs
Comparisons	Any of the above strategies compared with any other or usual care (without decision support interventions). Active sham controls to be used for subgroup analysis in case of heterogeneity.
Outcomes	• Patient, family/carer health-related QoL • Mortality • Decision quality/conflict • Knowledge of relevant decision area • Psychological distress and mental wellbeing • Patient, family/carer experience of care
Study design	RCTs NRS, clinically efficacy outcomes only extracted if adjusted for key confounders (age, ethnicity, co-morbidities and baseline health)

1.4 Clinical evidence

1.4.1 Included studies

5 studies were included in the review; [1, 11, 22, 30, 61] these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3).

The majority of the studies (n=4) compared an education programme with usual care, and one study compared decision aids with usual care. Studies involving education programmes typically involved a combination of general education and education focused specifically on supporting decision making (i.e. the risks and benefits of various options). The only available study comparing decision aids with usual care was non-randomised. The studies comparing education programmes with usual care were RCTs. All the included studies looked at the adult population.

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Arriola, 2014 [1]	Education programme (n=149) standard transplant education materials with DVD of information from healthcare professionals and personal stories from donor/recipient pairs on process, risks and benefits of LDKT, 6 months Usual care (n=147) were shown an attention control DVD explaining how dialysis patients can improve their circumstances through exercise, no mention of	Adults (M=51.7 years old, Range = 20-76) USA Focussing on living donor kidney transplant education for patients scheduled for evaluation of a kidney transplant	Knowledge of decision area Reported 6 months after intervention	All participants were African American

Study	Intervention and comparison	Population	Outcomes	Comments
	transplants 6 months			
Devins, 2005 [11]	Education programme (n=172) via psychoeducational intervention of single one-on-one slide lecture presentation, delivered by a health educator specifically trained to deliver the pre dialysis intervention, providing information on function of kidney, kidney disease, dietary management and alternative modes of RRT including HD, PD and renal transplantation, 5 years Usual care (n=163) patients received relevant information from the attending physician via written materials or by special referral to a nurse clinician, information varied widely among hospitals, 5 years	Adults (M=51.41 years old, SD=16.53) Canada Patients receiving care in a pre-dialysis clinic received lecture presentation before choosing between different modalities of RRT	Mortality, Knowledge of decision area Reported at end of intervention and up to 20 years after intervention	Not stratified, but pre-specified
Ismail, 2014 [22]	Education programme (n=84) via 2 home-based educational meetings delivered by an educator, topics included general information on kidneys and dialysis as well as comparison of dialysis with transplantation, comparison of living with decease donor transplantation, 4 weeks	Adults (M=54.71 years old, SD=13.25) Netherlands Focussing on patients unable to find a living donor and newly listed for transplant preparation or already listed for deceased donor kidney transplant	Knowledge of decision area Reported at end of intervention	Results for participants stratified by BAME

Study	Intervention and comparison	Population	Outcomes	Comments
	Usual care (n=79) patients received consultations with a transplant nephrologist, coordinator and a social worker. Yearly check-ups and written educational material and DVD received, 4 weeks			
Manns, 2005 [30]	Education programme (n=35) via educational booklets (4 booklets, first of which on 'Choosing the type of dialysis best suited to you') and 15 minute video on self-care dialysis and a small group session involving patients and family members, nephrologist and a pre-dialysis nurse, 4 weeks Usual care (n=35) patients all received teaching about kidney disease, via a one on one session where patients are seen by a nurse, dietician and social worker, followed by nephrologist and multidisciplinary care team every 3 to 6 months, 4 weeks	Adults (M=64.4 years old) Canada Patients receiving care in a pre-dialysis clinic given education booklets before choosing between different modalities of RRT	Mortality Reported at end of intervention and after 1 year follow up	
Winterbottom, 2016 [61]	Decision aids (n=84) via pre-dialysis YoDDA leaflets, delivered by pre dialysis staff, designed for people to make decisions between home HD, in centre HD,	Adults (M=62.64 years old, SD=14.44) United Kingdom Patients referred to pre-dialysis services given	Decision quality/conflict, knowledge of decision area , experience of care	Non-randomised study

Study	Intervention and comparison	Population	Outcomes	Comments
	CAPD and CCPD. 6 weeks Usual care (n=105) involved education (e.g. consultations, leaflets/videos, peer meetings, home visits) about conservative care and renal replacement therapy options for patients delivered by pre dialysis staff, 6 weeks	decision aids before choosing between different modalities of RRT	Reported at end of intervention	

1 See appendix D for full evidence tables.

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1.4.4 Quality assessment of clinical studies included in the evidence review

Table 3: Clinical evidence summary: Education programme vs usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Education program (95% CI)
Knowledge of decision area (6 months Post treatment (PT), self-rated, 0-18, high is good)	296 (1 study) 6 months	LOW[1] due to risk of bias		The mean knowledge of decision area in the control groups was 14.53	The mean knowledge of decision area in the intervention groups was 0.2 higher (0.31 lower to 0.71 higher)
Knowledge of decision area (4 weeks PT, self-rated, 0-18, Rotterdam Renal Replacement Knowledge Test (R3K-T), high is good) - BAME	163 (1 study) 4 weeks	LOW[1] due to risk of bias		The mean knowledge of decision area in the control groups was 11.9	The mean knowledge of decision area in the intervention groups was 2.9 higher (2.73 to 3.07 higher)
Knowledge of decision area (4 weeks PT, self-rated, 0-18, R3K-T, high is good) - non-BAME	163 (1 study) 4 weeks	MODERATE[1] due to risk of bias		The mean knowledge of decision area in the control groups was 15.3	The mean knowledge of decision area in the intervention groups was 2.8 higher (2.58 to 3.02 higher)
Knowledge of decision area (5 years, self-rated, change score, KDQ form A, high is good)	179 (1 study) 5 years	LOW[1] due to risk of bias		The mean knowledge of decision area in the control groups was -0.26	The mean knowledge of decision area in the intervention groups was 2.88 higher (2.21 to 3.55 higher)
Mortality (1 year)	70 (1 study) 1 years	VERY LOW[1,2] due to risk of bias, imprecision	Peto OR 7.61 (0.47 to 124.15)	0 per 1000	60 more per 1000 in intervention group (from 30 fewer to 150 more)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Education program (95% CI)
Survival (20 years)	335 (1 study) 20 years	VERY LOW[1,2] due to risk of bias, imprecision	RR 1.32 (1 to 1.74)	- [3]	-

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
2 Downgraded by 1 increment if the confidence interval crossed one MID.
3 Control group risk not available

1

2 **Table 4: Clinical evidence summary: Decision aids vs usual care**

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Decision aids (95% CI)
Knowledge of decision area (6 weeks PT, 'information was enough for me to make a decision', self-rated, 0-6, high is good)	189 (1 study) 6 weeks	VERY LOW[1,2] due to risk of bias, imprecision		The mean knowledge of decision area in the control groups was 3.62	The mean knowledge of decision area in the intervention groups was 0.44 higher (0 to 0.88 higher)
Decisional quality/conflict (6 weeks PT, self-rated, 0-100, high is poor)	189 (1 study) 6 weeks	LOW[1] due to risk of bias		The mean decisional quality/conflict in the control groups was 13.83	The mean decisional quality/conflict in the intervention groups was 0.23 lower (2.98 lower to 2.52 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with Decision aids (95% CI)
Experience of care, satisfaction with pre-dialysis team (6 weeks PT, self-rated, 0-15, high is good)	189 (1 study) 6 weeks	VERY LOW[1,2] due to risk of bias, imprecision		The mean experience of care in the control groups was 8.13	The mean experience of care in the intervention groups was 0.53 higher (0.04 lower to 1.1 higher)

1 Downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
2 Downgraded by 1 increment if the confidence interval crossed one MID.

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2 See appendix F for full GRADE tables.

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1.5 Economic evidence

1.5.1 Included studies

No relevant health economic studies were included.

1.5.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in appendix G.

1.5.3 Summary of studies included in the economic evidence review

None.

1.5.4 Unit costs

The cost of a decision aid will relate to the cost of developing and maintaining it, potentially costs for using it or producing the materials (e.g. printing) and the time taken to use it.

A decision aid booklet is available from the Kidney Research UK website called 'Dialysis: Making the Right Choices for You'. The booklet was developed through a Kidney Research UK-supported study by the Yorkshire Dialysis Decision Aid (YoDDA) research team in collaboration with Baxter Healthcare Ltd, the British Renal Society and the Renal Association and so has no NHS costs for development. It is free to download for printing locally or to order individual booklets. Bulk orders cost 40p to £1.80 per booklet depending on the number ordered.

Internet-based decision aids were available in this area developed by the NHS shared decision making programme NHS RightCare (1. Established Kidney Failure; 2. Kidney Transplant; 3. Kidney Dialysis). These are freely available on the internet. However, the cost of developing and maintaining the NHS tools presumably falls on the NHS.

The cost of structured education programmes to support decision making will vary depending on how they are delivered; for example, in a group or individually, by whom, number of sessions/visits. Also if education to support decision making is part of a wider education programme the costs will not only relate to decision support.

1.6 Resource impact

No recommendations were made based on this review (Section 1.8).

1.7 Evidence statements

1.7.1 Clinical evidence statements

Education program compared to usual care

No evidence for patient, family/carer health-related QoL, decisional quality/conflict, psychological distress and mental wellbeing and patient, family/carer experience of care.

There was a clinically important benefit for knowledge of decision area (self-rated; 3 studies low to moderate quality).

There was no clinically important benefit for knowledge of decision area (self-rated; 1 study low quality).

There was a clinically important benefit for survival (1 study very low quality).

There was a clinically important harm for mortality (1 study very low quality).

Decision aids compared to usual care

No evidence for patient, family/carer health-related QoL, mortality, psychological distress and mental wellbeing.

There was no clinically important benefit for knowledge of decision area (PT self-rated; 1 study very low quality), decision quality/conflict (PT self-rated; 1 study low quality) and experience of care (PT self-rated; 1 study very low quality).

1.7.2 Health economic evidence statements

- No relevant economic evaluations were identified.

1.8 Recommendations

No recommendations,

1.8.1 Research recommendations

RR11. What is the clinical and cost effectiveness of using decision aids in the context of RRT?

See also the rationale in appendix J.

1.9 Rationale and impact

1.9.1 Why the committee did not make any recommendations

Limited evidence suggested a benefit of structured education programmes although results were inconsistent. The committee noted that decision aids are used in clinical practice but do not replace discussions between the patient, families and carers, and healthcare professionals when making decisions about RRT or conservative management. Education classes and peer support are also important to support decision-making. In the absence of evidence showing clinically important benefits, the committee were unable to recommend that decision aids should be used. They decided to make a research recommendation to inform future practice.

1.10 The committee's discussion of the evidence

1.10.1 Interpreting the evidence

1.10.1.1 The outcomes that matter most

The committee considered quality of life, mortality and decision quality/conflict to be critical outcomes. The committee considered knowledge, psychological distress/mental wellbeing and experience of care to be important outcomes. The committee noted that while interventions that improved clinical outcomes like mortality would certainly have a merit, the main aim of the interventions in these studies was to improve the quality of decisions – even if the decisions people made led them to say have a reduced life expectancy because they opted for conservative management over RRT.

1.10.1.2 The quality of the evidence

The overall quality of the evidence ranged from moderate to very low, with the majority being either low or very low quality. There was no randomised evidence on decision aids. There was no evidence in children or adults over the age of 70. The only outcomes available were mortality, knowledge and experience of care.

The committee noted that the usual care arms of the studies included in the review varied but in general involved some element of education, even if it was less intensive than the intervention arm. Therefore the treatment effects observed in the studies are likely to be less than in a true 'education/decision aid' versus nil comparison.

The committed noted that in the one study assessing decision aids, the principle aim of the research was to assess acceptability of the decision aid rather than to establish efficacy. The

committee agreed that any further research in the area should consider some element of efficacy on clinical outcomes as well as person preference and experience, this was incorporated into the research recommendation in this area.

1.10.1.3 Benefits and harms

There was a clinically important benefit of structured education programmes vs usual care for knowledge of decision area (in 2 studies) and survival but no clinically important difference for knowledge of decision area (in 1 study) and a clinically important harm for mortality. The committee noted that the one study showing a clinically important harm for mortality was based on extremely imprecise evidence from a study with only 70 participants. Although the evidence showing a benefit for survival was also very low quality, the committee agreed that a benefit was more biologically plausible than a harm.

The committee noted that for the knowledge of decision area outcomes the context and specific aims of the interventions in the 3 studies were quite different. The data were therefore not meta-analysed.

Overall the committee agreed that there was insufficient evidence of clinically important benefits to make specific recommendations on structured education programmes to support decision making. However they agreed that education and support in general is likely to lead to better outcomes and incorporated this into their recommendations on the information and support for people requiring RRT or conservative management.

There was no clinically important difference in terms of knowledge, decision quality and experience of care for the comparison of decision aids with usual care. Overall the committee concluded the evidence was insufficient to make a judgement regarding the benefits of decision aids for people requiring RRT or conservative management and that further research was needed.

1.10.2 Cost effectiveness and resource use

No economic evaluations were included.

There may be some costs to the NHS of delivering decision aids related to development and maintenance (if by the NHS) and production of materials (if printed). The committee did not think that consultation time would be impacted by the use of a decision aid. Given the uncertainty regarding the clinical evidence of decision aids the committee was unable to make a judgement regarding cost-effectiveness.

The cost of structured education programmes to support decision making will vary depending on how they are delivered; for example, in a group or individually, by whom, the number of sessions/visits involved. Also if education to support decision making is part of a wider education programme the costs will not only relate to decision support. The interventions in the included clinical studies varied. Given this and the limited clinical evidence it was considered difficult to make a judgement about the cost effectiveness of specific programmes. The committee noted that most renal services would say that they offered a structured education program currently but what exactly is offered will vary considerably and this will not be exclusively aimed at decision support therefore a recommendation specifying a particular structured education programme to support decision making would likely result in a substantial resource impact to the NHS.

1.10.3 Other factors the committee took into account

The committee noted that the quality of decision aids currently available is highly variable. They noted that there were no randomised or non-randomised studies showing a definitive benefit of a decision aid over and above usual care.

1 The committee made a research recommendation to inform future guidance.
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1 Appendices

2 Appendix A: Review protocols

3 **Table 5: Review protocol: Review protocol for decision support interventions**

Field	Content
Review question	What is the clinical and cost effectiveness of decision support interventions for people who may require renal replacement therapy or conservative management?
Type of review question	Intervention
Objective of the review	Determine the clinical and cost effectiveness of decision support interventions for people who may require renal replacement therapy or conservative management
Eligibility criteria – population / disease / condition / issue / domain	Children, young people and adults with CKD stage 3 to 5 Stratified by: • Age (<2, 2 to <18, 18 to <70, ≥70) • BAME vs non-BAME • DM vs no DM
Eligibility criteria – intervention(s) / exposure(s) / prognostic factor(s)	• Decision support aids (for example NHS Kidney Care Right Care) • Structured education programs (to involve >1 direct contact between healthcare professional and patient, aimed at decision support)
Eligibility criteria – comparator(s) / control or reference (gold) standard	Either of the above strategies compared with each other or usual care (without decision support interventions). Active sham controls to be used for subgroup analysis in case of heterogeneity.
Outcomes and prioritisation	Critical • Patient, family/carer health-related QoL (continuous) • Mortality (dichotomous and time to event) • Decisional quality/conflict (continuous) Important • Knowledge of relevant decision area (continuous) • Psychological distress and mental wellbeing (continuous) • Patient, family/carer experience of care (continuous) When outcomes are reported at multiple timepoints, the later timepoints will be prioritised. All outcomes must be reported after at least 4 weeks of the intervention under investigation. The outcomes of mortality and hospitalisation must be reported after at least 6 months. For quality of life, symptom scores/functional measures, psychological distress/mental wellbeing and experience of care, any validated measures will be accepted. Absolute MIDs of 30 per 1000 will be used for mortality and modality failure. Absolute MIDs of 100 per 1000 will be used for all other outcomes dichotomous outcomes. Where relative MIDs are required (if absolute effects are unavailable), 0.90 to 1.11 will be used for mortality and modality failure. The default relative MIDs of 0.8 to 1.25 will be

	used for all other dichotomous outcomes. Default continuous MIDs of 0.5x SD will be used for all continuous outcomes, except where published, validated MIDs exist.
Eligibility criteria – study design	RCTs only, if insufficient RCT evidence, NRS that adjust for key confounders (age, ethnicity, comorbidities and baseline health) will be included. Knowledge/decision making outcomes can be extracted from NRS without adjusting for all key confounders, but must adjust for any baseline differences in those factors.
Other inclusion exclusion criteria	
Proposed sensitivity / subgroup analysis, or meta-regression	• Different modalities of RRT
Selection process – duplicate screening / selection / analysis	No duplicate screening was deemed necessary for this question, for more information please see the separate Methods report for this guideline.
Data management (software)	• Pairwise meta-analyses were performed using Cochrane Review Manager (RevMan5). • GRADEpro was used to assess the quality of evidence for each outcome. • Endnote was used for bibliography, citations, sifting and reference management.
Information sources – databases and dates	Clinical search databases to be used: Medline, Embase, Cochrane Library Date: All years Health economics search databases to be used: Medline, Embase, NHSEED, HTA Date: Medline, Embase from 2014 NHSEED, HTA – all years Language: Restrict to English only Supplementary search techniques: backward citation searching Key papers: Not known
Identify if an update	Not an update
Author contacts	https://www.nice.org.uk/guidance/indevelopment/gid-ng10019
Highlight if amendment to previous protocol	Not an amendment
Search strategy – for one database	For details please see the separate search strategy appendices for the guideline.
Data collection process – forms / duplicate	A standardised evidence table format will be used, and published as appendices of the evidence report.
Data items – define all variables to be collected	For details please see evidence tables in Appendix D (clinical evidence tables) or H (health economic evidence tables) of the evidence report.
Methods for assessing bias at outcome / study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual.
Methods for quantitative analysis – combining	For details please see the separate Methods report for this guideline.

studies and exploring (in)consistency	
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
Rationale / context – what is known	For details please see the introduction to the evidence report.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by NGC and chaired by Jan Dudley in line with section 3 of Developing NICE guidelines: the manual. Staff from NGC undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the separate Methods report for this guideline.
Sources of funding / support	NGC is funded by NICE and hosted by the Royal College of Physicians.
Name of sponsor	NGC is funded by NICE and hosted by the Royal College of Physicians.
Roles of sponsor	NICE funds NGC to develop guidelines for the NHS in England.
PROSPERO registration number	Not registered

1 **Table 6: Health economic review protocol**

Review question	**All questions – health economic evidence**
Objectives	To identify economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the individual review protocol above. • Studies must be of a relevant economic study design (cost-utility analysis, cost-effectiveness analysis, cost-benefit analysis, cost-consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of economic evaluations. (Recent reviews will be ordered although not reviewed; the bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	An economic study search will be undertaken using population-specific terms and an economic study filter – see Appendix B.2 Health economics literature search strategy.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2001, abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in Appendix G of the 2012 NICE guidelines manual.[39] Each included study is summarised in an economic evidence profile and an evidence table. Any excluded studies are detailed in the excluded studies table with the reason for exclusion in Appendix I. **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline.

- If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline.
- If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included.

Where there is discretion

The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the Committee if required. The ultimate aim is to include economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the Committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. For example, if a high quality study from a UK perspective is available a similar study from another country's perspective may be excluded.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will have been excluded before being assessed for applicability and methodological limitations.

Economic study type:

- Cost-utility analysis (most applicable).
- Other type of full economic evaluation (cost-benefit analysis, cost-effectiveness analysis, cost-consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will have been excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2001 or later but that depend on unit costs and resource data entirely or predominantly from before 2001 will be rated as 'Not applicable'.
- Studies published before 2001 will have been excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the economic analysis:

- The more closely the clinical effectiveness data used in the economic analysis matches with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.
- The following will be rated as 'Very serious limitations' and excluded: economic analyses undertaken as part of clinical studies that are excluded from the clinical review; economic models where relative treatment effects are based entirely on studies that are excluded from the clinical review; comparative costing analyses that only look at the cost of delivering dialysis (as current UK NHS reference costs are considered a more relevant estimate of this for the guideline); within-trial economic analyses based on non-randomised studies that do not meet the minimum adjustment criteria outlined in the main review protocol.

Appendix B: Literature search strategies

B.1 Clinical search literature search strategy

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual 2014, updated 2017 https://www.nice.org.uk/guidance/pmg20/resources/developing-nice-guidelines-the-manual-pdf-72286708700869

For more detailed information, please see the Methodology Review.

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 7: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 11 December 2017	Exclusions Randomised controlled trials Systematic review studies Observational studies
Embase (OVID)	1974 – 11 December 2017	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2017 Issue 12 of12 CENTRAL to 2017 Issue 11 of12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None

1. Line 81 (Medline) and line 75 (Embase) were added to the search strategy to reduce the number of items retrieved for observational studies as the overall results from the search were very large.
   This was checked to ensure that relevant studies were not excluded.

Medline (Ovid) search terms

1.	exp Renal Replacement Therapy/
2.	((renal or kidney) adj2 replace*).ti,ab.
3.	(hemodiafilt* or haemodiafilt* or (biofilt* adj1 acetate-free)).ti,ab.
4.	(hemodialys* or haemodialys*).ti,ab.
5.	((kidney* or renal) adj3 (transplant* or graft*)).ti,ab.
6.	capd.ti,ab.
7.	dialys*.ti,ab.
8.	(artificial adj1 kidney*).ti,ab.
9.	or/1-8
10.	limit 9 to English language
11.	letter/

12.	editorial/
13.	news/
14.	exp historical article/
15.	Anecdotes as Topic/
16.	comment/
17.	case report/
18.	(letter or comment*).ti.
19.	or/11-18
20.	randomized controlled trial/ or random*.ti,ab.
21.	19 not 20
22.	animals/ not humans/
23.	Animals, Laboratory/
24.	exp animal experiment/
25.	exp animal model/
26.	exp Rodentia/
27.	(rat or rats or mouse or mice).ti.
28.	or/21-27
29.	10 not 28
30.	randomized controlled trial.pt.
31.	controlled clinical trial.pt.
32.	randomi#ed.ti,ab.
33.	placebo.ab.
34.	drug therapy.fs.
35.	randomly.ti,ab.
36.	trial.ab.
37.	groups.ab.
38.	or/30-37
39.	Clinical Trials as topic.sh.
40.	trial.ti.
41.	or/30-33,35,39-40
42.	Meta-Analysis/
43.	Meta-Analysis as Topic/
44.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
45.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
46.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
47.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
48.	(search* adj4 literature).ab.
49.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
50.	cochrane.jw.
51.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
52.	or/42-51
53.	29 and (41 or 52)
54.	exp Renal Replacement Therapy/

55.	((renal or kidney*) adj2 replace*).ti,ab.
56.	(hemodiafilt* or haemodiafilt* or haemofilt* or hemofilt*).ti,ab.
57.	(hemodialys* or haemodialys*).ti,ab.
58.	((kidney* or renal or pre-empt* or preempt*) adj3 (transplant* or graft*)).ti,ab.
59.	(capd or apd or ccpd or dialys*).ti,ab.
60.	or/54-59
61.	letter/
62.	editorial/
63.	news/
64.	exp historical article/
65.	Anecdotes as Topic/
66.	comment/
67.	case report/
68.	(letter or comment*).ti.
69.	or/61-68
70.	randomized controlled trial/ or random*.ti,ab.
71.	147 not 148
72.	animals/ not humans/
73.	Animals, Laboratory/
74.	exp Animal Experimentation/
75.	exp Models, Animal/
76.	exp Rodentia/
77.	(rat or rats or mouse or mice).ti.
78.	or/72-77
79.	60 not 78
80.	limit 79 to English language
81.	(mycophenolic acid or azathioprine or sirolimus or everolimus or tacrolimus or cyclosporin* or steroid or calcineurin inhibitor or anaemi* or anemi* or vitamin d or immunosuppres*).ti.[1]
82.	80 not 81
83.	Epidemiologic studies/
84.	Observational study/
85.	exp Cohort studies/
86.	(cohort adj (study or studies or analys* or data)).ti,ab.
87.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
88.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
89.	Controlled Before-After Studies/
90.	Historically Controlled Study/
91.	Interrupted Time Series Analysis/
92.	(before adj2 after adj2 (study or studies or data)).ti,ab.
93.	or/83-92
94.	Registries/
95.	Management Audit/ or Clinical Audit/ or Nursing Audit/ or Medical Audit/
96.	(registry or registries).ti,ab.

97.	(audit or audits or auditor or auditors or auditing or auditable).ti,ab.
98.	or/94-97
99.	93 or 98
100.	82 and 99
101.	100 not 53
102.	53 or 101

1 **Embase (Ovid) search terms**

1.	exp *renal replacement therapy/
2.	((renal or kidney) adj2 replace*).ti,ab.
3.	(hemodiafilt* or haemodiafilt* or (biofilt* adj1 acetate-free)).ti,ab.
4.	(hemodialys* or haemodialys*).ti,ab.
5.	((kidney* or renal) adj3 (transplant* or graft*)).ti,ab.
6.	capd.ti,ab.
7.	dialys*.ti,ab.
8.	(artificial adj1 kidney*).ti,ab.
9.	or/1-8
10.	limit 9 to English language
11.	letter.pt. or letter/
12.	note.pt.
13.	editorial.pt.
14.	case report/ or case study/
15.	(letter or comment*).ti.
16.	or/11-15
17.	randomized controlled trial/ or random*.ti,ab.
18.	16 not 17
19.	animal/ not human/
20.	nonhuman/
21.	exp Animal Experiment/
22.	exp Experimental Animal/
23.	animal model/
24.	exp Rodent/
25.	(rat or rats or mouse or mice).ti.
26.	or/18-25
27.	10 not 26
28.	random*.ti,ab.
29.	factorial*.ti,ab.
30.	(crossover* or cross over*).ti,ab.
31.	((doubl* or singl*) adj blind*).ti,ab.
32.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
33.	crossover procedure/
34.	single blind procedure/
35.	randomized controlled trial/
36.	double blind procedure/
37.	or/28-36
38.	systematic review/

39.	meta-analysis/
40.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
41.	((systematic or evidence) adj3 (review* or overview*)).ti,ab.
42.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
43.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
44.	(search* adj4 literature).ab.
45.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
46.	cochrane.jw.
47.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
48.	or/38-47
49.	27 and (37 or 48)
50.	*renal replacement therapy/
51.	((renal or kidney*) adj2 replace*).ti,ab.
52.	(hemodiafilt* or haemodiafilt* or haemofilt* or hemofilt*).ti,ab.
53.	(hemodialys* or haemodialys*).ti,ab.
54.	((kidney* or renal or pre-empt* or preempt*) adj3 (transplant* or graft*)).ti,ab.
55.	(capd or apd or ccpd or dialys*).ti,ab.
56.	or/50-55
57.	letter.pt. or letter/
58.	note.pt.
59.	editorial.pt.
60.	case report/ or case study/
61.	(letter or comment*).ti.
62.	or/57-61
63.	randomized controlled trial/ or random*.ti,ab.
64.	62 not 63
65.	animal/ not human/
66.	nonhuman/
67.	exp Animal Experiment/
68.	exp Experimental Animal/
69.	animal model/
70.	exp Rodent/
71.	(rat or rats or mouse or mice).ti.
72.	or/64-71
73.	56 not 72
74.	limit 73 to English language
75.	(mycophenolic acid or azathioprine or sirolimus or everolimus or tacrolimus or cyclosporin* or steroid or calcineurin inhibitor or anaemi* or anemi* or vitamin d or immunosuppres*).ti.[1]
76.	74 not 75
77.	Clinical study/
78.	Observational study/
79.	family study/

80.	longitudinal study/
81.	retrospective study/
82.	prospective study/
83.	cohort analysis/
84.	follow-up/
85.	cohort*.ti,ab.
86.	84 and 85
87.	(cohort adj (study or studies or analys* or data)).ti,ab.
88.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
89.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
90.	(before adj2 after adj2 (study or studies or data)).ti,ab.
91.	or/77-83,86-90
92.	register/
93.	medical audit/
94.	(registry or registries).ti,ab.
95.	(audit or audits or auditor or auditors or auditing or auditable).ti,ab.
96.	or/92-95
97.	91 or 96
98.	76 and 97
99.	98 not 49
100.	49 or 99

1 **Cochrane Library (Wiley) search terms**

#1.	MeSH descriptor: [Renal Replacement Therapy] explode all trees
#2.	((renal or kidney*) near/2 replace*):ti,ab
#3.	(hemodiafilt* or haemodiafilt* or haemofilt* or hemofilt*):ti,ab
#4.	(hemodialys* or haemodialys*):ti,ab
#5.	((kidney* or renal or pre-empt* or preempt*) near/3 (transplant* or graft*)):ti,ab
#6.	(capd or apd or ccpd or dialys*):ti,ab
#7.	(biofilt* near/1 acetate-free):ti,ab
#8.	(artificial near/1 kidney*):ti,ab
#9.	(or #1-#8)

B.2 Health Economics literature search strategy

2
3 Health economic evidence was identified by conducting a broad search relating to renal
4 replacement therapy population in NHS Economic Evaluation Database (NHS EED – this
5 ceased to be updated after March 2015) and the Health Technology Assessment database
6 (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for
7 Research and Dissemination (CRD). Additional searches were run on Medline and Embase
8 for health economics.

9 **Table 8: Database date parameters and filters used**

Database	Dates searched	Search filter used
Medline & Embase	2014 – 11 December 2017	Exclusions Health economics studies

Database	Dates searched	Search filter used
Centre for Research and Dissemination (CRD)	HTA & NHS EED- Inception – 11 December 2017	None

1 **Medline (Ovid) search terms**

1.	exp Renal Replacement Therapy/
2.	((renal or kidney) adj2 replace*).ti,ab.
3.	(hemodiafilt* or haemodiafilt* or (biofilt* adj1 acetate-free)).ti,ab.
4.	(hemodialys* or haemodialys*).ti,ab.
5.	((kidney* or renal) adj3 (transplant* or graft*)).ti,ab.
6.	capd.ti,ab.
7.	dialys*.ti,ab.
8.	(artificial adj1 kidney*).ti,ab.
9.	or/1-8
10.	limit 9 to English language
11.	letter/
12.	editorial/
13.	news/
14.	exp historical article/
15.	Anecdotes as Topic/
16.	comment/
17.	case report/
18.	(letter or comment*).ti.
19.	or/11-18
20.	randomized controlled trial/ or random*.ti,ab.
21.	19 not 20
22.	animals/ not humans/
23.	Animals, Laboratory/
24.	exp animal experiment/
25.	exp animal model/
26.	exp Rodentia/
27.	(rat or rats or mouse or mice).ti.
28.	or/21-27
29.	10 not 28
30.	Economics/
31.	Value of life/
32.	exp "Costs and Cost Analysis"/
33.	exp Economics, Hospital/
34.	exp Economics, Medical/
35.	Economics, Nursing/
36.	Economics, Pharmaceutical/
37.	exp "Fees and Charges"/
38.	exp Budgets/
39.	budget*.ti,ab.

40.	cost*.ti.
41.	(economic* or pharmaco?economic*).ti.
42.	(price* or pricing*).ti,ab.
43.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
44.	(financ* or fee or fees).ti,ab.
45.	(value adj2 (money or monetary)).ti,ab.
46.	or/30-45
47.	29 and 46

1 **Embase (Ovid) search terms**

1.	exp renal replacement therapy/
2.	((renal or kidney) adj2 replace*).ti,ab.
3.	(hemodiafilt* or haemodiafilt* or (biofilt* adj1 acetate-free)).ti,ab.
4.	(hemodialys* or haemodialys*).ti,ab.
5.	((kidney* or renal) adj3 (transplant* or graft*)).ti,ab.
6.	capd.ti,ab.
7.	dialys*.ti,ab.
8.	(artificial adj1 kidney*).ti,ab.
9.	or/1-8
10.	limit 9 to English language
11.	letter.pt. or letter/
12.	note.pt.
13.	editorial.pt.
14.	case report/ or case study/
15.	(letter or comment*).ti.
16.	or/11-15
17.	randomized controlled trial/ or random*.ti,ab.
18.	16 not 17
19.	animal/ not human/
20.	nonhuman/
21.	exp Animal Experiment/
22.	exp Experimental Animal/
23.	animal model/
24.	exp Rodent/
25.	(rat or rats or mouse or mice).ti.
26.	or/18-25
27.	10 not 26
28.	*health economics/
29.	exp *economic evaluation/
30.	exp *health care cost/
31.	exp *fee/

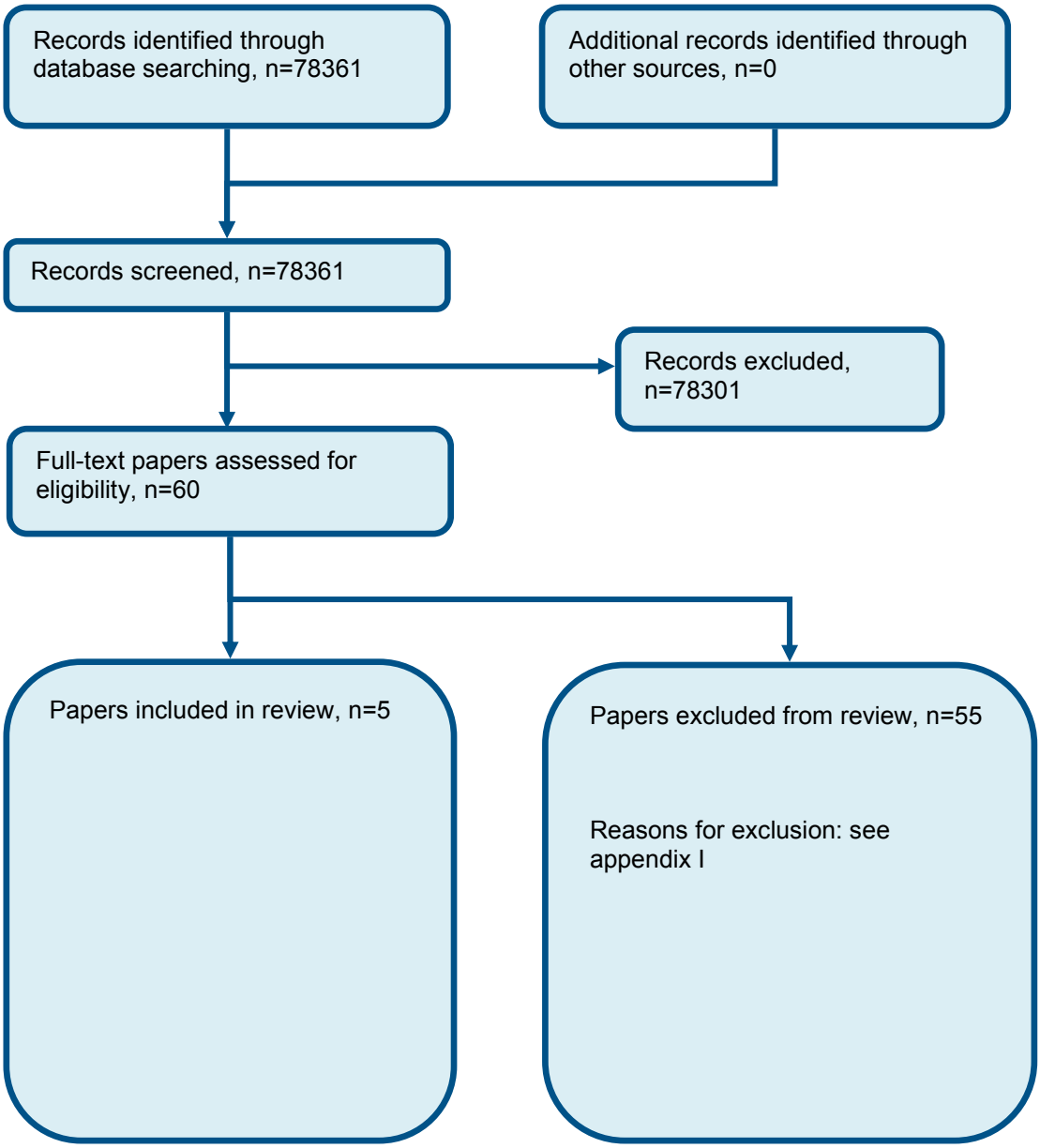
32.	budget/
33.	funding/
34.	budget*.ti,ab.
35.	cost*.ti.
36.	(economic* or pharmaco?economic*).ti.
37.	(price* or pricing*).ti,ab.
38.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
39.	(financ* or fee or fees).ti,ab.
40.	(value adj2 (money or monetary)).ti,ab.
41.	or/28-40
42.	27 and 41

1 **NHS EED and HTA (CRD) search terms**

#1.	MeSH DESCRIPTOR Renal Replacement Therapy EXPLODE ALL TREES
#2.	(((renal or kidney) adj2 replace*))
#3.	((hemodiafilt* or haemodiafilt* or (biofilt* adj1 acetate-free)))
#4.	((hemodialys* or haemodialys*))
#5.	(((kidney* or renal) adj3 (transplant* or graft*)))
#6.	(capd)
#7.	(dialys*)
#8.	((artificial adj1 kidney*))
#9.	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of co-ordinating care



Appendix D: Clinical evidence tables

Study (subsidiary papers)	Devins 2005[11] (Binik 1993[3], Devins 2000[9])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=361 randomised, 47 at final follow-up)
Countries and setting	Conducted in Canada; Setting: Five participating renal centres and their satellite units in Alberta and Quebec, 1983-1988
Line of therapy	Adjunctive to current care
Duration of study	5 years. Follow up (post intervention): Outcomes available at time of intervention, and a range of time up to a mean 8.5y after intervention
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not stratified but pre-specified: Analyses early presenting and late presenting patients separately
Inclusion criteria	Chronic deteriorating kidney disease, with a creatinine of 350umol or over, and an expectation that they would need RRT
Exclusion criteria	Not defined
Recruitment/selection of patients	Randomised when identified, then approached about study. 261 identified, 57 excluded as declined (22), language barrier (10), death (4) or illness (18), or moving away from centre (4). Later study includes 588 patients, of whom 400 entered the study (unclear where extra people came from, as identical setting and recruitment dates, and refers to earlier papers as having more details on the cohort).
Age, gender and ethnicity	Age - Range of means: mean 51.7 (int), mean 48.5 (control). Gender (M:F): 139 male, 65 female consented (female 32%). Ethnicity: Not stated
Further population details	
Extra comments	Group randomised to education had better health rating that control (mean 6.3(1.49) vs 6.0(1.50), and this was adjusted for in survival analyses. Marital status, employment and education did not differ between randomised groups, but did between early- and late-presenting. The 400-strong cohort is split into 172 early referred (saw a nephrologist >3 months prior to dialysis), and 163 late referred (within three months), with remaining not progressing to RRT (mostly as too ill)
Indirectness of population	No indirectness: Note randomised and then consented

Interventions	(n=172) Intervention 1: Education program. Predialysis psychoeducation programme (PPE): One-to-one meeting lasting 60-75 minutes with a Bachelor-level health educator with training specifically to deliver the PPE. Consisted of a slide-lecture presentation about the kidneys, dietary management of renal disease, and alternative methods of RRT, including haemodialysis, peritoneal dialysis and renal transplantation, with limited coverage of pharmaceutical regimen and fluid restriction. Patient was given ample opportunity to ask questions in the contents of the presentation and received a 22-page booklet to take home for future reference. Any questions about problems or symptoms were referred back to the treating physician. Duration Single session (60 minutes). Concurrent medication/care: As usual Comments: 39 of 172 pts randomised to PPE did not receive it. Earlier papers report 87 pts in this arm. (n=163) Intervention 2: Usual care. Standard education: None of the hospitals at the time had a formal pre-dialysis education programme. Information was available through the attending physician, through written materials, or via a referral to the nurse clinician if the nephrologist felt it appropriate. Thus the actual education received was likely to vary within and between hospitals. Duration No control intervention. Concurrent medication/care: As usual. Indirectness: Serious indirectness; Indirectness comment: It is acknowledged that this is no longer usual care Comments: In earlier papers, 92 participants
Funding	Principal author funded by industry (National health research and development program (Canada), two main authors also supported by Ortho-Biotech Inc)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION PROGRAM versus USUAL CARE

Protocol outcome 1: Mortality
- Actual outcome: Survival from time of pre-dialysis education (corrected for age and non-renal health) at 20 years; RR; 1.32 (95%CI 1 to 1.74) (Mortality would be inverse of these values, i.e. 0.76 (0.57-1.00): median survival 7.84 (PPE) 5.07 (usual)) , Comments: 67% died during follow-up;
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - Unclear randomisation procedure. Reports ITT (excludes those who were excluded after randomisation and before the intervention, but includes those who did not attend scheduled education in intervention group) - ? plausible that no missing data for survival at 20 years. Hazard ratio would be preferable method of reporting for this length of follow-up with high mortality. Inconsistency in numbers between papers. Stratifies by early/late presenters, but then gives one summary stat.; Indirectness of outcome: No indirectness ; Baseline details: health at baseline reported to be different, and subsequently corrected for.; Group 1 Number missing: 39, Reason: Did not attend education session; Group 2 Number missing: 0

Protocol outcome 2: Knowledge of decision area
- Actual outcome: Changes in ESRD-Related knowledge and the 'education effect' - KDQ form A at 5 years; Group 1: mean 2.62 (SD 2.47); n=87, Group 2: mean -0.26 (SD 2.06); n=92

Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - Unclear randomisation procedure. Reports ITT (excludes those who were excluded after randomisation and before the intervention, but includes those who did not attend scheduled education in intervention group) - ? plausible that no missing data for survival at 20 years. Hazard ratio would be preferable method of reporting for this length of follow-up with high mortality. Inconsistency in numbers between papers. Stratifies by early/late presenters, but then gives one summary stat.; Indirectness of outcome: No indirectness ; Baseline details: health at baseline reported to be different, and subsequently corrected for.; Group 1 Number missing: 25, Reason: 8 - refused to participate in rest of experiment, 5 - because of language or intellectual difficulties in understanding the educational program, 10 - because of experimental error and 2 - because they became too ill during the period of time when the education program was to be administered. ; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life ; Decisional quality/conflict ; Psychological distress/mental wellbeing ; Experience of care

Study	Ismail 2014[22]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=163)
Countries and setting	Conducted in Netherlands; Setting: Consisted of 2 sessions at the patients home.
Line of therapy	Adjunctive to current care
Duration of study	Intervention + follow up: 4 weeks + 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligible candidates were either newly referred for transplant preparation or already listed for DDKT from both Western and non-Western descent. Eligible candidates were required to be >18 years and medically (e.g. no hospital admission) and mentally fit (e.g. no mental deterioration).
Exclusion criteria	Not stated.
Recruitment/selection of patients	Patients were invited to participate by the home educators after at least two consultations with one of the transplant nephrologists.
Age, gender and ethnicity	Age - Mean (SD): 54.71 (13.25). Gender (M:F): 93 male, 70 female. Ethnicity: Dutch 65, Antillean 29, Moroccan 17, Turkish 15, Cape Verdean 7, Asian 15 and other 15.
Further population details	
Indirectness of population	No indirectness
Interventions	(n=84) Intervention 1: Education program. Home-based education program - Consisted of 2 sessions at the patients' home. During the first visit (approximately 1 hr) the family network of the patients was depicted on a sociogram by the educators in order to familiarize themselves with the family structure and to recognize the values of that particular social system. At the end of the first session, the educators helped the patient to make a list of individuals who they were going to invite for the second session. The goal of the second session (approximately 2.5 h) was to provide information and support communication; therefore, it was not necessary that all the invitees were potential donors. The process of the intervention was based on principles and communication techniques drawn from multi systemic therapy (MST). The educators stimulated an open communication between the patient and the family members and used the strengths and possibilities of the natural network of the patient. The objective of MST is to achieve a lasting consensus on the patient's goals and how these goals can be reached with engagement and/or support of his/her social ecology. The second session was organized in such a way that the educators had to do ''whatever it takes,'' in line with one of the

	basic principles of MST, to achieve that lasting consensus on the various renal replacement therapies. . Duration 4 weeks . Concurrent medication/care: Both groups received standard care. . Indirectness: No indirectness (n=79) Intervention 2: Usual care. Standard care - all newly registered patients visiting our pre transplantation outpatient clinic receive consultations with a transplant nephrologist, a transplant coordinator and a social worker. After that all patients receive a yearly check-up with the nephrologist or a nurse practitioner. In addition to verbal information, patients receive a variety of written educational material and a DVD regarding the various living donation and transplantation programs (e.g. national exchange). Duration 4 weeks. Concurrent medication/care: Both groups received standard care. . Indirectness: No indirectness
Funding	Other (This study is funded by the Netherlands Kidney Foundation.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION PROGRAM versus USUAL CARE Protocol outcome 1: Knowledge of decision area - Actual outcome for BAME: Knowledge - assessed with the Rotterdam Renal Replacement Knowledge Test (R3K-T). at 4 weeks PT; Group 1: mean 14.8 (SD 0.5); n=84, Group 2: mean 11.9 (SD 0.6); n=79 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: Control - 14.9, Experimental - 16.3; Group 1 Number missing: 8, Reason: 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). ; Group 2 Number missing: 0, Reason: N/A - Actual outcome for non-BAME: Knowledge - assessed with the Rotterdam Renal Replacement Knowledge Test (R3K-T). at 4 weeks PT; Group 1: mean 18.1 (SD 0.8); n=84, Group 2: mean 15.3 (SD 0.6); n=79 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: Control - 11.7, Experimental - 11.2; Group 1 Number missing: 8, Reason: 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). ; Group 2 Number missing: 0, Reason: N/A	
Protocol outcomes not reported by the study	Quality of life ; Mortality ; Decisional quality/conflict ; Psychological distress/mental wellbeing ; Experience of care

Study	Living ACTS trial: Arriola 2014[1]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=296)
Countries and setting	Conducted in USA; Setting: Single centre transplant programme
Line of therapy	Adjunctive to current care
Duration of study	Intervention + follow up: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: All awaiting outpatient evaluation for kidney transplant
Stratum	BAME: All Black ethnicity, 93% Black American
Subgroup analysis within study	Not applicable
Inclusion criteria	Age 18 or over. Awaiting output transplant evaluation. Self-identify as Black.
Exclusion criteria	Not medically suitable for transplant, DNA evaluation appointment, decline to participate
Recruitment/selection of patients	8-month period until met desired study size (unclear when, before 2014). 762 considered, 466 excluded due to not meeting inclusion (263), DNA (105), not approached (85), declined (13)
Age, gender and ethnicity	Age - Mean (range): 51.7 (20-76). Gender (M:F): 11:9. Ethnicity: All self-identifying as Black/African American
Further population details	
Extra comments	Other characteristics: married 40%, high school degree 89%, professional degree 6%, unemployed 78%, private health insurance 41%, at least 60% participants had already been on dialysis at least six months, at least 36% have been on dialysis for over 2y
Indirectness of population	No indirectness
Interventions	(n=149) Intervention 1: Education program. Shown DVD: Living ACTS - About Choices in Transplantation and Sharing. General premise was live donor transplantation is practical treatment option to explore among patients requiring RRT. Vehicle is personal stories that emphasise the role of family and factual information from health care professionals. Key points: Live donors/recipients discuss the decision to pursue living donation; medical practitioners discuss the benefits of live donor transplant over deceased donor transplant; transplant social worker discusses the process; medical provider discusses importance of preventing organ rejection; signpost to resources. Shown during evaluation appointment, then given lunch bag with Living ACTS DVD and Living ACTS information booklet. Duration Once, further follow-up at six months. Concurrent medication/care: Both groups received standard transplant material, written and via online course, which included information about the process of transplant, risk and benefits of transplant (both live and deceased donor), and living with a new kidney. Indirectness: Serious indirectness; Indirectness comment: Regarding the decision of live donor transplantation only

	Comments: 13 lost to follow-up (n=147) Intervention 2: Usual care. Shown DVD (for attention control): Exercise, Live Well and Feel Better. General premise, dialysis patients can improve their circumstances through exercise. Vehicle, personal stories (no mention of transplant). Duration Once, with follow up at 6 months. Concurrent medication/care: Both groups received standard transplant material, written and via online course, which included information about the process of transplant, risk and benefits of transplant (both live and deceased donor), and living with a new kidney. Indirectness: No indirectness Comments: 15 lost to follow-up
Funding	Academic or government funding (Health Resources and Services Administration Division of Transplantation)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION PROGRAM versus USUAL CARE Protocol outcome 1: Knowledge of decision area - Actual outcome for BAME: Knowledge of LDKT at 6 months; Group 1: mean 14.73 (SD 2.14); n=149, Group 2: mean 14.35 (SD 2.37); n=147; Knowledge of LKDT 0-18 Top=High is good outcome Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - Randomisation/allocation not described, not blinded but objective measure. Unvalidated scale.; Indirectness of outcome: No indirectness, Comments: Score is index devised by authors using 18 true-false questions, with number of correct items summed; Baseline details: Knowledge at baseline similar: Int 14.41(2.12) control 14.30(2.02), as are education level and health insurance; Blinding details: Attention control provides some blinding, but would be aware they are being tested on something they had seen or not; Group 1 Number missing: 13, Reason: lost to follow-up; Group 2 Number missing: 15, Reason: lost to follow-up	
Protocol outcomes not reported by the study	Quality of life ; Mortality ; Decisional quality/conflict ; Psychological distress/mental wellbeing ; Experience of care

Study	Manns 2005[30]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=70)
Countries and setting	Conducted in Canada
Line of therapy	Adjunctive to current care
Duration of study	Intervention time: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients who had been seen at least once by this multidisciplinary progressive renal care team (and therefore received standard teaching about the dialytic modality choices) and had a GFR <30 mL/min/1.73m2 were eligible for enrolment.
Exclusion criteria	Exclusion criteria included the following: patients with cognitive dysfunction (i.e. significant dementia), non-English speaking patients (unless they had family members who spoke English and could translate since all education materials were written in English), patients who were not personally independent based on assessment by study nurse (i.e. unable to do own activities of daily living), patients who were currently on dialysis (since our educational materials and small group sessions were focused on pre-dialysis education), and patients who were unable or unwilling to provide informed consent.
Recruitment/selection of patients	Patients were enrolled from the Southern Alberta Renal Program (SARP) progressive renal care clinic.
Age, gender and ethnicity	Age - Other: Mean - 64.4 (59.05, 69.7). Gender (M:F): 38 male, 32 female. Ethnicity: Not stated.
Further population details	
Indirectness of population	No indirectness
Interventions	(n=35) Intervention 1: Education program. Standard Care and Educational intervention - Patients received 4 written manuals and a 15 minute video, produced locally, which detailed visually the different types of dialysis and the potential advantages and disadvantages of self-care dialysis, including patient testimonials that described the impact of the different modalities on everyday life. The second component of the education, which occurred 2 weeks after the educational material was given to patients, involved a 90 minute small group interactive session involving 3 to 6 patients (plus family members), a nephrologist and a pre-dialysis nurse. The main teaching format was problem-based learning in small groups focused around cases that were representative of the local population. The session began with a brain storming session in which the participants described the advantages and disadvantages of self-care dialysis based on their current knowledge. Following this, the participants separated into 2 smaller groups where they “problem-

	solved" a "dialysis scenario". The educational intervention was specifically designed to incorporate both predisposing interventions (written manuals and video; phase 1) and an enabling intervention (small group session; phase 2). Duration 1 year . Concurrent medication/care: All patients receive teaching about kidney disease, including dietary instructions and detailed information about the different modalities of renal replacement therapy. This occurs via an initial 3 hour one on one session where patients are seen by a nurse, dietician and social worker. Patients are then followed by their nephrologist and the multidisciplinary care team every 3 to 6 months. Indirectness: No indirectness (n=35) Intervention 2: Usual care. All patients receive teaching about kidney disease, including dietary instructions and detailed information about the different modalities of renal replacement therapy. This occurs via an initial 3 hour one on one session where patients are seen by a nurse, dietician and social worker. Patients are then followed by their nephrologist and the multidisciplinary care team every 3 to 6 months. . Duration 1 year . Concurrent medication/care: All patients receive teaching about kidney disease, including dietary instructions and detailed information about the different modalities of renal replacement therapy. This occurs via an initial 3 hour one on one session where patients are seen by a nurse, dietician and social worker. Patients are then followed by their nephrologist and the multidisciplinary care team every 3 to 6 months. Indirectness: No indirectness
Funding	Study funded by industry (This research was supported by the Southern Alberta Renal Program, Calgary Health Trust Funds.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION PROGRAM versus USUAL CARE Protocol outcome 1: Mortality - Actual outcome: Mortality at 1 year PT ; Group 1: 2/35, Group 2: 0/35 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7, Reason: 2 died, 1 started PD, 2 transplanted, 2 did not return second questionnaire. ; Group 2 Number missing: 1, Reason: Started PD.	
Protocol outcomes not reported by the study	Quality of life ; Decisional quality/conflict ; Knowledge of decision area ; Psychological distress/mental wellbeing ; Experience of care

Study	Winterbottom 2016[61]
Study type	Non randomised study
Number of studies (number of participants)	1 (n=189)
Countries and setting	Conducted in United Kingdom; Setting: In referral centres.
Line of therapy	Adjunctive to current care
Duration of study	Intervention time: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	All adult patients with chronic kidney disease referred to the Yorkshire-Humber pre dialysis services over the study period were eligible for inclusion in this study, an estimated 67 patients per month.
Exclusion criteria	N/A.
Recruitment/selection of patients	Patients referred to pre dialysis services. Research nurses informed patients of the study either at the clinic or by mail.
Age, gender and ethnicity	Age - Mean (SD): 62.64 (14.44). Gender (M:F): 120 male, 69 female. Ethnicity: 170 white, remainder other
Further population details	
Indirectness of population	No indirectness
Interventions	(n=84) Intervention 1: Decision aids. Usual care and YoDDA - Included usual pre dialysis care plus a copy of the YoDDA booklet, or the YoDDA booklet with additional self-report questions about their lifestyle and values (VT), delivered by pre dialysis staff. The YoDDA booklet was developed using a systematic method. They applied decision support techniques to identify and structure the decision-relevant information in the context of disease management (48–50), de-bias the information presented, and encourage active reasoning about options in accordance with a person's values. The YoDDA booklet can be used independently by patients, their carers and their family, and/or with staff delivering pre-dialysis care. It is 44 pages long with 5 sections. Duration 6 weeks . Concurrent medication/care: Both groups received usual care. Usual care involved education (e.g. consultations, leaflets/videos, peer meetings, home visits) about conservative care and renal replacement therapy options for patients delivered by pre dialysis staff. Indirectness: No indirectness (n=105) Intervention 2: Usual care. Usual care involved education (e.g. consultations, leaflets/videos, peer meetings, home visits) about conservative care and renal replacement therapy options for patients delivered by pre dialysis staff. Duration 6 weeks. Concurrent medication/care: Both groups received usual care. Usual

	care involved education (e.g. consultations, leaflets/videos, peer meetings, home visits) about conservative care and renal replacement therapy options for patients delivered by pre dialysis staff. Indirectness: No indirectness
Funding	Study funded by industry (Unrestricted projects were provided by: Kidney Research UK, in partnership with Baxter Health Care Ltd, the British renal society and renal association; the Yorkshire Kidney research fund, UK; informed medical decisions foundation, USA.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE

Protocol outcome 1: Decisional quality/conflict
- Actual outcome: Patients' decisional conflict scores at 6 weeks PT; Group 1: mean 13.6 (SD 9.75); n=84, Group 2: mean 13.83 (SD 9.37); n=105
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Key confounders: Age, ethnicity, co-morbidities and baseline health; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Knowledge of decision area
- Actual outcome: Patients views of pre dialysis written information by study group - 'the information was enough to make a decision' at 6 weeks PT; Group 1: mean 4.06 (SD 1.39); n=84, Group 2: mean 3.62 (SD 1.73); n=105
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Key confounders: Age, ethnicity, co-morbidities and baseline health; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Experience of care
- Actual outcome: Satisfaction with the pre dialysis team at 6 weeks PT; Group 1: mean 8.66 (SD 1.67); n=84, Group 2: mean 8.13 (SD 2.34); n=105
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Key confounders: Age, ethnicity, co-morbidities and baseline health; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life ; Mortality ; Psychological distress/mental wellbeing

Appendix E: Forest plots

E.1 Education programme vs usual care

Figure 2: Knowledge of decision area (6 months PT, self rated, 0-18, high is good)

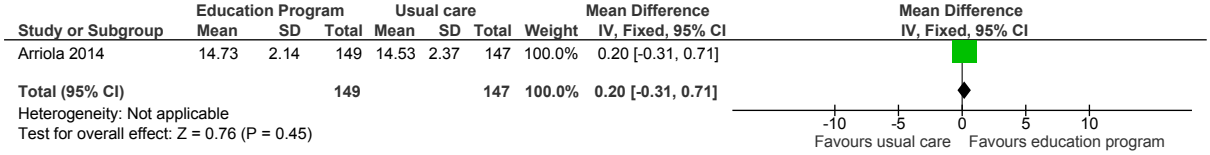


Figure 3: Knowledge of decision area (4 weeks PT, self rated, 0-18, R3K-T, high is good)

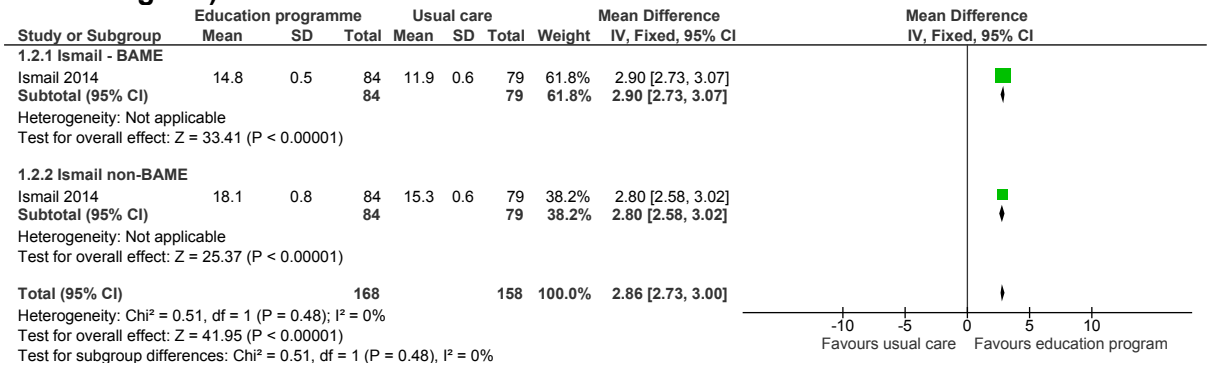


Figure 4: Knowledge of decision area (5 years, self rated, change score, KDQ form A, high is good)

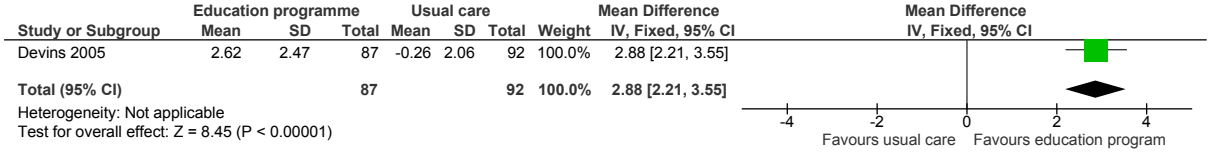


Figure 5: Mortality (1 year PT)

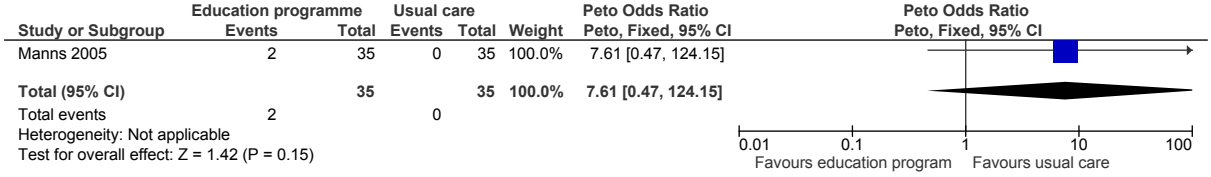
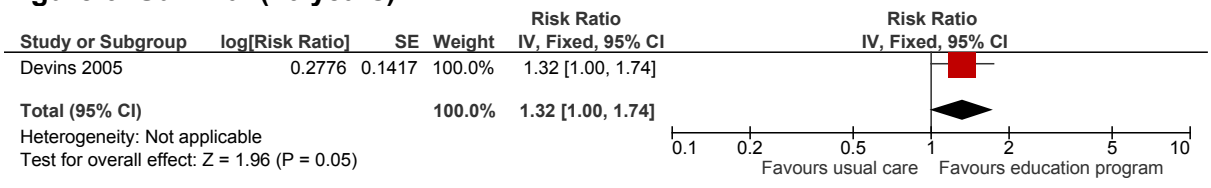
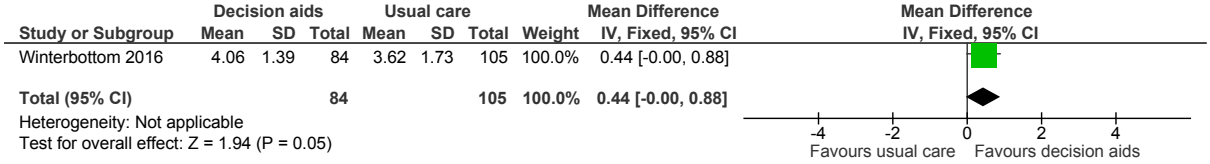


Figure 6: Survival (20 years)



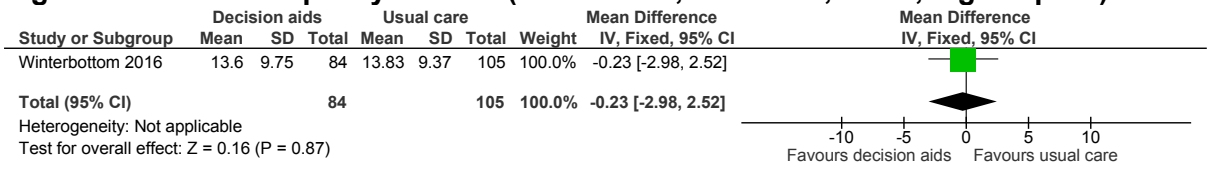
E.21 Decision aids vs usual care

Figure 7: Knowledge of decision area (6 weeks PT, self rated, 0-6, high is good)



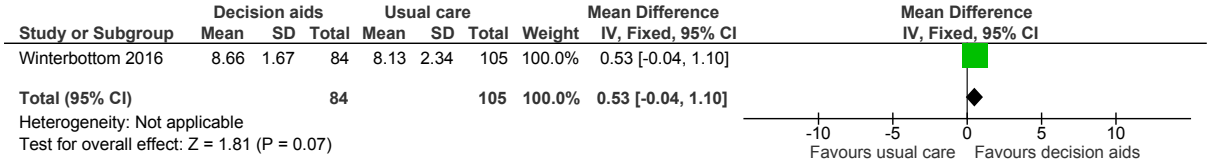
2

Figure 8: Decisional quality/conflict (6 weeks PT, self-rated, 0-100, high is poor)



3

Figure 9: Experience of care (6 weeks PT, self rated, 0-15, high is good)



4

5

1 Appendix F: GRADE tables

2 Table 9: Clinical evidence profile: Education programme versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Education program	Usual care	Relative (95% CI)	Absolute		
Knowledge of decision area (6 months PT, self rated, 0-18, high is good) (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	149	147	-	MD 0.2 higher (0.31 lower to 0.71 higher)	⊕⊕OO LOW	CRITICAL
Knowledge of decision area (4 weeks PT, self rated, 0-18, R3K-T, high is good) - Ismail - BAME (follow-up 4 weeks; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	84	79	-	MD 2.9 higher (2.73 to 3.07 higher)	⊕⊕OO LOW	CRITICAL
Knowledge of decision area (4 weeks PT, self rated, 0-18, R3K-T, high is good) - Ismail non-BAME (follow-up 4 weeks; Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	84	79	-	MD 2.8 higher (2.58 to 3.02 higher)	⊕⊕⊕O MODERATE	CRITICAL
Knowledge of decision area (5 years, self rated, change score, KDQ form A, high is good) (follow-up 5 years; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	87	92	-	MD 2.88 higher (2.21 to 3.55 higher)	⊕⊕OO LOW	CRITICAL
Mortality (1 year PT) (follow-up mean 1 years)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	2/35 (5.7%)	0%	RR 5 (0.25 to 100.53)	-	⊕OOO VERY LOW	CRITICAL
Survival (20 years) (follow-up 20 years; Better indicated by higher values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	172	163	-	SMD 0.8551 higher (0.63 to 1.08 higher)	⊕⊕OO LOW	CRITICAL

[1] Downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 increment if the majority of the evidence was at high risk of bias.
[3] Downgraded by 1 increment if the confidence interval crossed one MID.

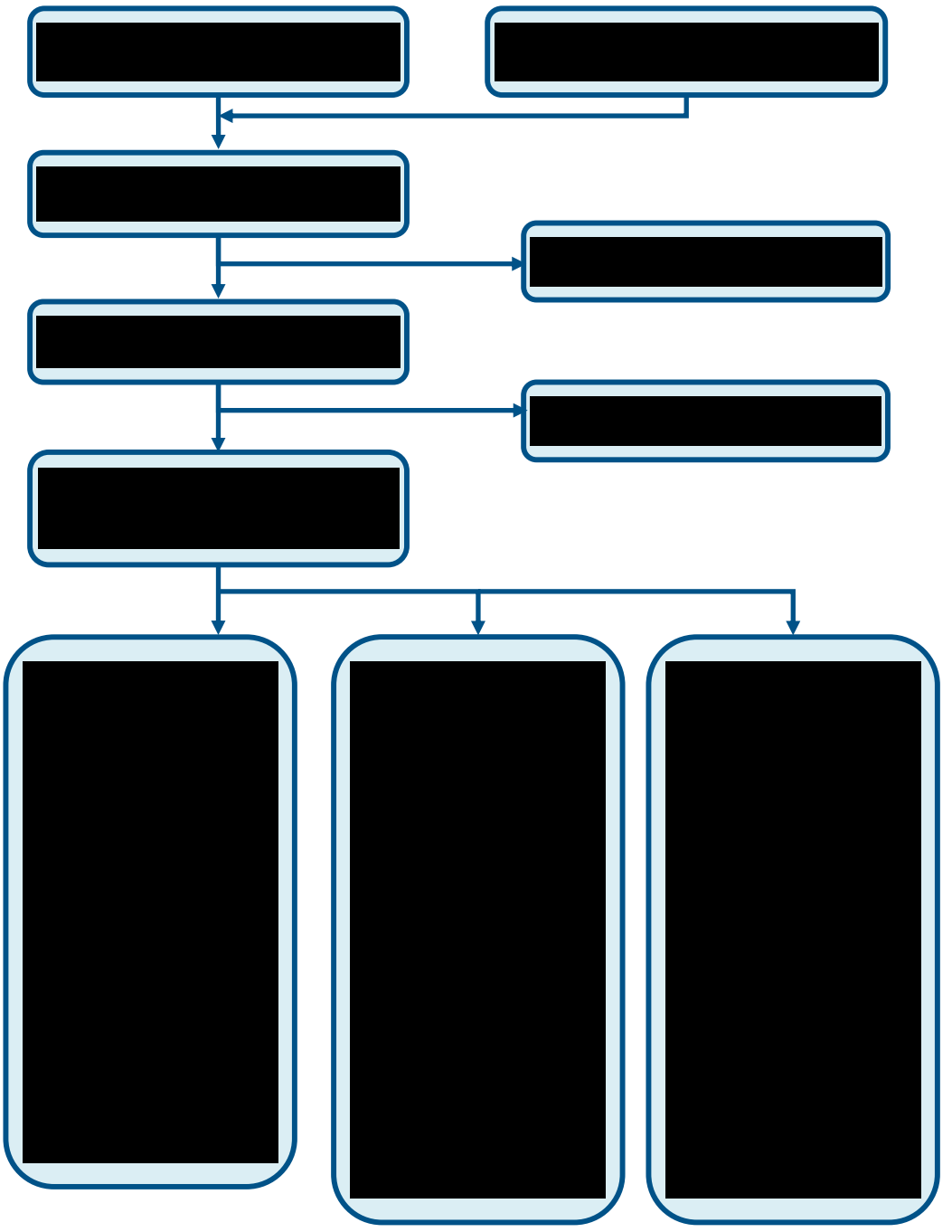
Table 10: Clinical evidence profile: Decision aids versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Decision aids**	**Usual care**	**Relative (95% CI)**	**Absolute**		
Knowledge of decision area (6 weeks PT, self rated, 0-6, high is good) (follow-up 6 weeks; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	84	105	-	MD 0.44 higher (0 to 0.88 higher)	⊕OOO VERY LOW	CRITICAL
Decisional quality/conflict (6 weeks PT, self rated, 0-100, high is poor) (follow-up 6 weeks; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	84	105	-	MD 0.23 lower (2.98 lower to 2.52 higher)	⊕⊕OO LOW	CRITICAL
Experience of care (6 weeks PT, self rated, 0-15, high is good) (follow-up 6 weeks; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	84	105	-	MD 0.53 higher (0.04 lower to 1.1 higher)	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 increment if the confidence interval crossed one MID.

Appendix G: Health economic evidence selection

Figure 10: Flow chart of economic study selection for the guideline



A = starting RRT
B = modality of RRT, subgroups and CM
C = sequencing
D = planning for RRT
E = When to assess
F = what to assess
G = Indicators for switching or stopping RRT
I = diet and fluids
J = frequency of review
L = decision support interventions
M = coordinating care

Note: Reviews H and K do not have an economic component

Appendix H: Health economic evidence tables

None.

1 Appendix I: Excluded studies

I.1 2 Excluded clinical studies

3 **Table 11: Studies excluded from the clinical review**

Study	Exclusion reason
Barnieh 2011[2]	No usable outcomes
Boulware 2013[4]	Intervention not DM
Butler 2014[5]	Review, not systematic
Cho 2012[6]	Not decision-making
Dahlerus 2016[7]	Not intervention trial
Davis 2017[8]	Review, not systematic
Devins 2003[10]	No usable outcomes
Devoe 2016[12]	Review, references checked
Dusseux 2015[13]	risk tool for clinicians
Engelen 2016[14]	review, full-text order cancelled
Fortnum 2015[15]	No control (pre/post)
Gander 2017[16]	Review, LDKT resources only
Gomez 1999[17]	NRS w/o adeq adjustment
Goovaerts 2005[18]	no control arm
Gordon 2016[19]	Time-point
Hanko 2011[20]	Time-point
Hussain 2015[21]	non-relevant review
Ismail 2012[23]	protocol
Kazawa 2015[24]	Aims to improve pre-RRT care, decision-making not mentioned
Klang 1999[25]	NRS, RCTs available
Korniewicz 1994[26]	Intervention not DM
Kutner 1982[27]	Not decision-making
Lacson 2011[28]	NRS w/o adeq adjustment
Machowska 2017[29]	NRS w/o adeq adjustment
Marron 2005[31]	NRS w/o adjustment
Mason 2008[32]	review, references checked
Massey 2016[33]	No usable outcomes
Mathers 1999[34]	Intervention not DM
Mehrotra 2005[35]	No specific intervention
Mollicone 2013[36]	NRS w/o adeq adjustment
Mooney 2009[37]	Compares two different decision aids
Murray 2009[38]	review
Parvan 2015[40]	Intervention not DM
Patzer 2014[42]	randomisation and outcomes at centre level
Patzer 2016[41]	Protocol
Perry 2005[43]	Intervention not DM
Pradel 2008[44]	Time-point
Ravani 2003[45]	Aims to improve pre-RRT care, decision-making not mentioned
Ravani 2003[46]	Incorrect interventions

Study	Exclusion reason
Richards 2015[47]	review, references checked
Rodrigue 2007[49]	Compares two different education program interventions.
Rodrigue 2008[48]	Compares two different education program interventions.
Rodrigue 2014[50]	Compares two different education program interventions
Song 2009[51]	Intervention not DM
Stacey 2017[52]	review
Sullivan 2012[53]	Intervention not DM
Tsay 2004[54]	Intervention not DM
Tsay 2005[55]	Intervention not DM
Urstad 2013[56]	non-relevant review
Waterman 2008[57]	Cross-sectional survey
Waterman 2014[59]	protocol
Waterman 2015[58]	protocol
Wileman 2016[60]	Fluid-management intervention
Wu 2009[62]	Aims to improve pre-RRT care, decision-making not mentioned
Zolfaghari 2015[63]	Not decision-making

I.2 Excluded health economic studies

Studies that meet the review protocol population and interventions and economic study design criteria but have not been included in the review based on applicability and/or methodological quality are summarised below with reasons for exclusion.

Table 12: Studies excluded from the health economic review

Reference	Reason for exclusion
None.	

Appendix J: Research recommendations

J.1 Effectiveness of decision aids

Research question: What is the clinical and cost effectiveness of using decision aids in the context of RRT?

Why this is important: The committee were unable to make a recommendation on the effectiveness of decision aids for RRT due to limited evidence identified in this review. Recommendations in this area are important to ensure the most clinical and cost effective decision making tools are efficiently provided.

Criteria for selecting high-priority research recommendations:

PICO question	Population: Children, young people and adults with CKD stage 3 to 5 considering starting RRT or conservative management Intervention: Decision aids with integration into care path, staff training + usual care Comparison: Usual care (information delivered only as standard face to face communication +/- leaflets) Outcomes: patient, family/carer health-related QoL, mortality, decision quality/conflict, decisional regret, knowledge of relevant decision area, psychological distress and mental wellbeing, patient, family/carer experience of care, resource use
Importance to patients or the population	If decisions aids were shown to be clinically and cost effective interventions, there would be a stronger evidence base on which to promote their use and thereby increasing patient knowledge and effective decision making.
Relevance to NICE guidance	There is current uncertainty concerning the clinical and cost effectiveness of decision aids for RRT.
Relevance to the NHS	Research in this area will inform NICE recommendations for service delivery and provide information about clinical and cost-effectiveness.
Current evidence base	There is little evidence on the clinical and cost effectiveness of decision aids for RRT. It is important to have sufficient information on the effectiveness of decision aids so further evidence based information can be given in regards to the different RRT options.
Equality	Not applicable
Study design	RCT
Feasibility	No obvious feasibility issues
Other comments	Not applicable
Importance	• Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates.