Supplementary

Appendix 1 – Search terms

Table 1: Search strategy and search terms used for MEDLINE

	Search term	Field
1	"Renal Dialysis"	TI, AB
2	Haemodialysis	TI, AB
3	Hemodialysis	TI, AB
4	Dialysis	TI, AB
5	Trial	TI, AB
6	"Randomized controlled trial"	TI, AB
7	"Randomised controlled trial"	TI, AB
8	(Parallel adj5 trial)	TI, AB
9	(Parallel-group adj5 trial)	TI, AB
10	(Crossover adj5 trial)	TI, AB
11	(Cross-over adj5 trial)	TI, AB
12	(Cluster adj5 trial)	TI, AB
13	(Stepped wedge adj5 trial)	TI, AB
14	(Stepped-wedge adj5 trial)	TI, AB
15	1OR2OR3OR4	
16	5OR6OR7OR8OR9OR10OR11OR12OR 13 OR 14	
17	15 AND 16	
18	Limit 17 to yr="2013-2019"	

TI, title; AB,abstract

Appendix 2 – Data Extraction Forms

Table 1: Table representing data items extracted for parallel-group studies, with notes to reviewer for data extraction

Data to be extracted	Notes to reviewer
Study ID	
Title	
Author	
Year Published	
Country	
Intervention type	Pharmacological, device, procedure, lifestyle or other
Type of trial	Pilot/Feasibility/Full trial
States how sample size was determined?	Yes/No
Number of participants recruited	Defined as number who consented
Number of participants that finished trial	
Achieved target recruitment?	Yes/No (note what target recruitment was)
Patient retention	Percentage: number of participants who finished trial/number of participants recruited
Patient attrition	Percentage: number of participants who were lost to follow up/number of participants recruited
Lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw their consent
Percentage lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw consent/total number of participants that left the trial
Use of CONSORT or flow diagram	Yes/No
Achieved statistically significant primary outcome	Yes/No
Length of trial	In months. State whether data is for length of trial or length of intervention

Table 2: Table representing data items extracted for crossover studies, with notes to reviewer for data extraction

Data to be extracted	Notes to reviewer
Study ID	
Title	
Author	
Year Published	
Country	
Intervention type	Pharmacological, device, procedure, lifestyle or other
Type of trial	Pilot/Feasibility/Full trial
States how sample size was determined?	Yes/No
Was within participant variability accounted for?	Yes/No
Number of participants recruited	Defined as number who consented
Number of participants that finished trial	
Achieved target recruitment?	Yes/No (note what target recruitment was)
Patient retention	Percentage: number of participants who finished trial/number of participants recruited
Patient attrition	Percentage: number of participants who were lost to follow up/number of participants recruited
Lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw their consent
Percentage lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw consent/total number of participants that left the trial
Use of CONSORT or flow diagram	Yes/No
Achieved statistically significant primary outcome	Yes/No
Length of trial	In months. State whether data is for length of trial or length of intervention

Table 3: Table representing data items extracted for cluster studies, with notes to reviewer for data extraction

Data to be extracted	Notes to reviewer
Study ID	
Title	
Author	
Year Published	
Country	
Intervention type	Pharmacological, device, procedure, lifestyle or other
Type of trial	Pilot/Feasibility/Full trial
Is there sample size justification?	Yes/No
Does it provide number of clusters in sample size calculation?	Yes/No
Does it provide cluster size?	Yes/No
Does it state if equal or unequal cluster sizes are assumed?	Yes/No
Does it state the ICC?	Yes/No
Does it state uncertainty in ICC?	Yes/No
How was the cluster formed?	Dialysis shift/HD centre
Number of participants recruited	Defined as number who consented
Number of participants that finished trial	
Achieved target recruitment?	Yes/No (note what target recruitment was)
Patient retention	Percentage: number of participants who finished trial/number of participants recruited
Patient attrition	Percentage: number of participants who were lost to follow up/number of participants recruited

Lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw their consent
Percentage lost to follow up due to withdrawal of consent	Number of participants that chose to withdraw consent/total number of participants that left the trial
Use of CONSORT or flow diagram	Yes/No
Achieved statistically significant primary outcome	Yes/No
Length of trial	In months. State whether data is for length of trial or length of intervention

Appendix 3 - Interview Topic Guide

UNIVERSITY OF LEICESTER

Patient Interview Topic Guide

Introduction

"Firstly, we would like to welcome you to the interview and thank you for agreeing to speak to us. The reason we have asked you to take part in this discussion is that we would like to understand more about different types of research in haemodialysis patients, and how they feel towards different types of research design. This is important because very little is currently known about patients' views on this subject. We will not be asking you for your personal experiences here, unless you want to offer them, but just your opinions as a patient. If you would like further information, please ask at the end.

Before we begin we would like to remind you that whatever you say here will be anonymous. Your name and personal details will not be mentioned in any report.

We are using a digital recorder to record our conversation because it is difficult for us to write down everything you say. However, no personal identifiable data will be recorded and a participant number will be allocated to you. This will also enable us to give you our full attention and listen to what you have to say."

Any questions before we start?

1. Introductions (us and participants, name, and for patients, how long have you been a kidney patient, have you ever taken part in a clinical trial as a haemodialysis (or other) patient)

General Views on Research

2. Firstly, we would like to talk to you very generally about Research. To start us off, what comes to mind when you think of the word 'Research'?

3. What do you think are the benefits of research?
    a. For the participant
    b. For the wider public

4. What do you think are the disadvantages of research?

Introduce trial designs

Historically, studies involving participants with kidney disease have often failed to recruit enough patients and there is a high rate of participants leaving the study before it is over. There may be many reasons for this. However, it affects the strength of the study and how much information we can learn from it. Trials in this population are usually parallel group RCTs (will explain later). One proposal is that by changing the design of the trial, it may be

possible to improve recruitment and retention, so we wanted to discuss some alternative, novel trial designs and to get your views on them.

Run through the different trial designs on PowerPoint/paper copies. Explain parallel group is the traditional one and the ones that follow are newer designs and fewer studies in kidney patients have used them yet.

For **each** trial design

5. What do you think of this design?
6. What would make you want to join a study with this design?
7. What would put you off joining a study with design?
8. If you agreed to take part in a study of this design, what might make you leave the study early? What might encourage you to complete the study?
9. What do you think of the way participants are allocated to arms in this study design?
    a. How would this affect your decision to join a study, or to stay in the study?

After going through all trial designs:

10. As you can see in some study designs, as a participant you would receive the new treatment at some point, whereas in other studies, if you were allocated to the control, you wouldn't receive the new intervention during the study.
    a. How would this make you feel?
    b. How important is it to you that you get the treatment on offer?
    c. How would this impact your participation in the study?
    d. If you were allocated to an arm where you did not get the treatment/intervention on offer at all, how would you feel about this?
    e. How would it affect your motivation to stay in the study?
    f. How would you feel about being in a trial where you spent time having the treatment but also the control?

11. Would you prefer to be in a trial that ensured you had the treatment on offer even if it were a longer trial?

12. We know that some studies in HD patients managed to recruit the correct amount of people they needed for the study and other study designs were less able to do this. Does this surprise you? Why do you think this might be?

13. We also found that some studies had more people dropping out of studies compared to others, does this surprise you? Why do you think this might be?

14. How would the length of a trial affect your decision to join a study? What do you consider is 'too long' for a study follow up? What do you think is the ideal length of time to be in a study?
    a. How could the burden of follow up be reduced?

b. Would the amount of follow up factor into your decision on whether to join or continue with the study?

15. Are there any potential other factors to do with your health or management that might impact on you volunteering to take part in a trial?
    (if necessary to prompt)- some people have mentioned about being on the transplant list or perhaps concerned about switching dialysis times, how would you feel about that?
16. Anything else you would like to say/or any questions?
17. Is there anything you feel we have missed out or thought we would cover that you would like to discuss?

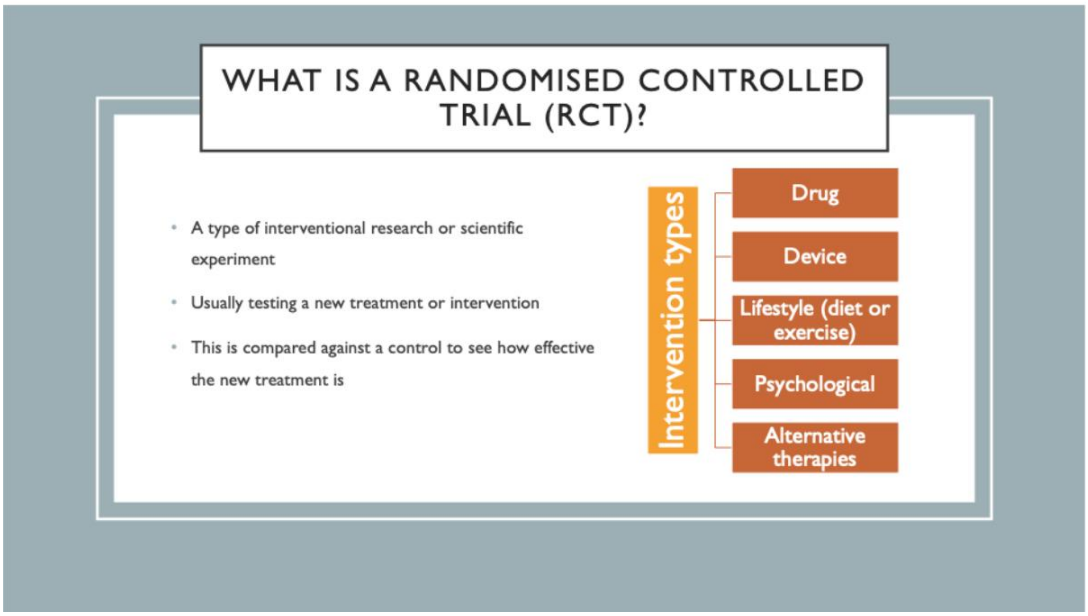
End

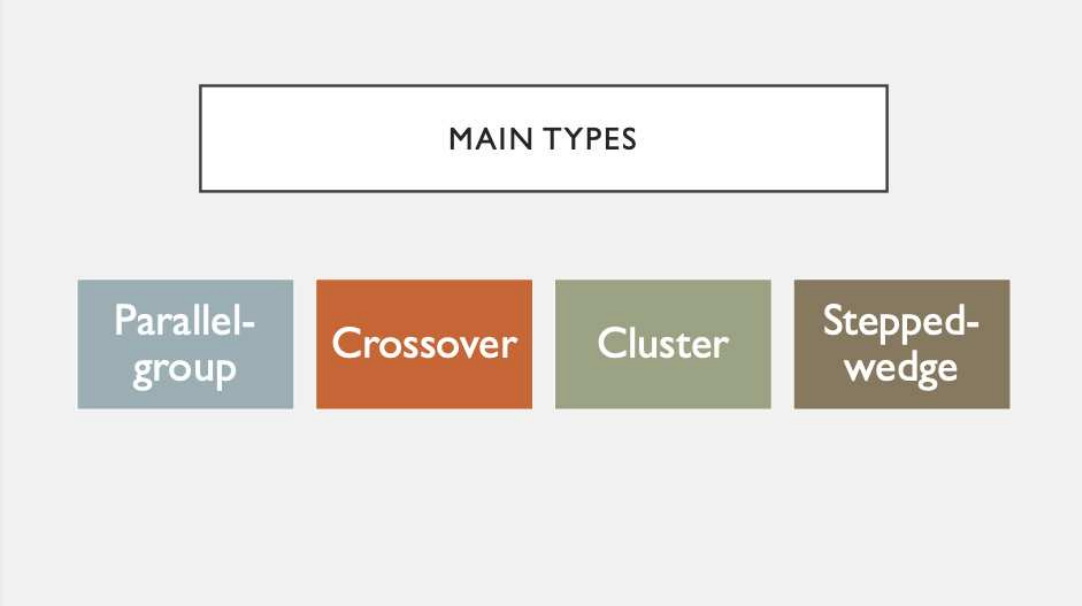
Closing and thanks - check that the participant is still happy for you to use all the information provided and offer the possibility to erase sections of the recording. **Reiterate anonymity etc.**

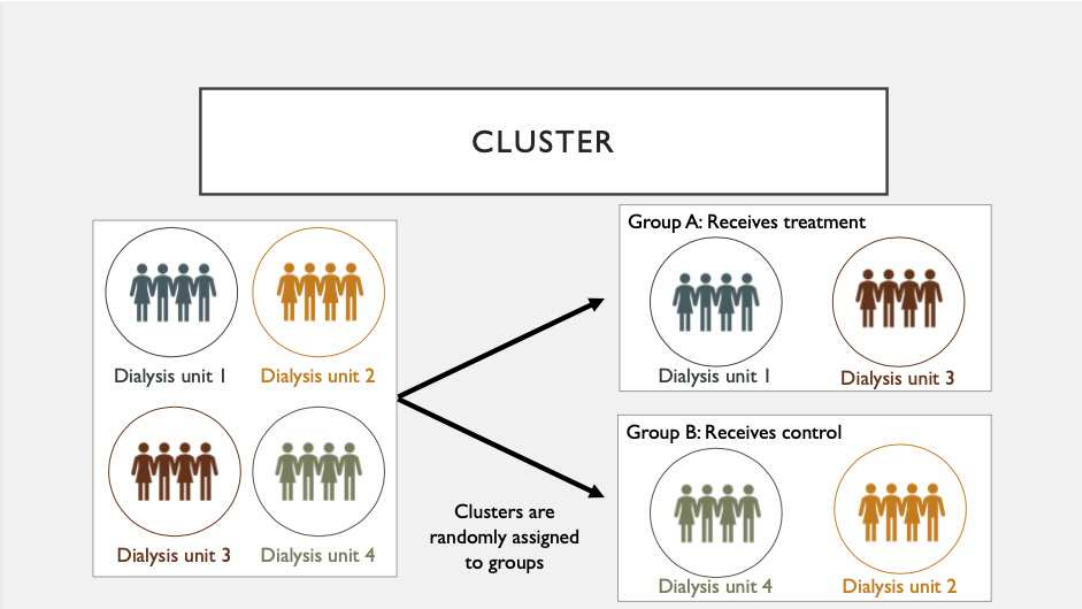
Thank them for their time and contribution.

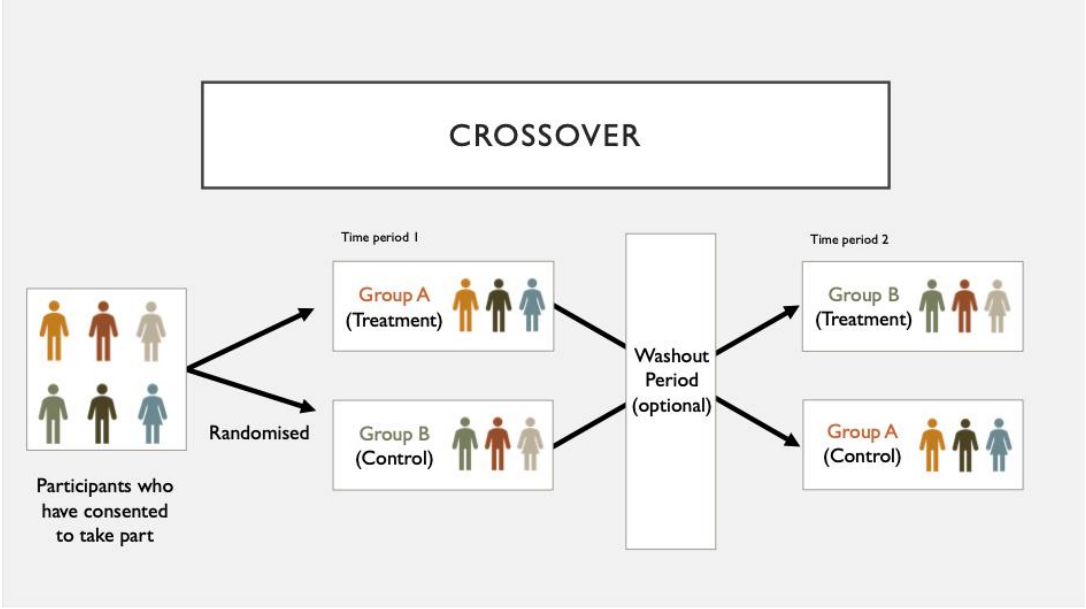
Contact details and what next.

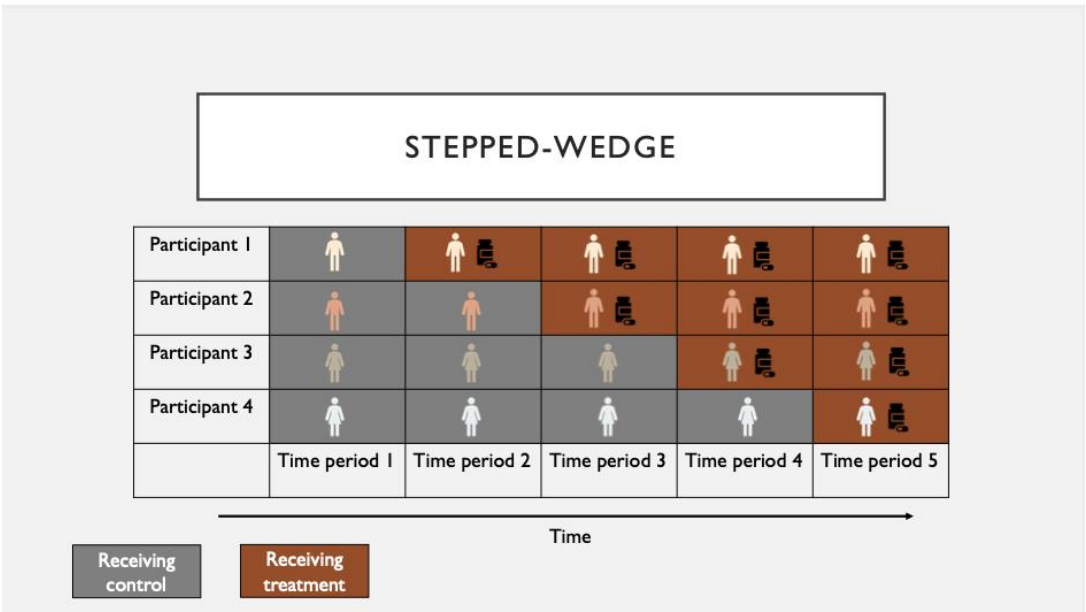
Appendix 4 – Visual Aids for Interviews

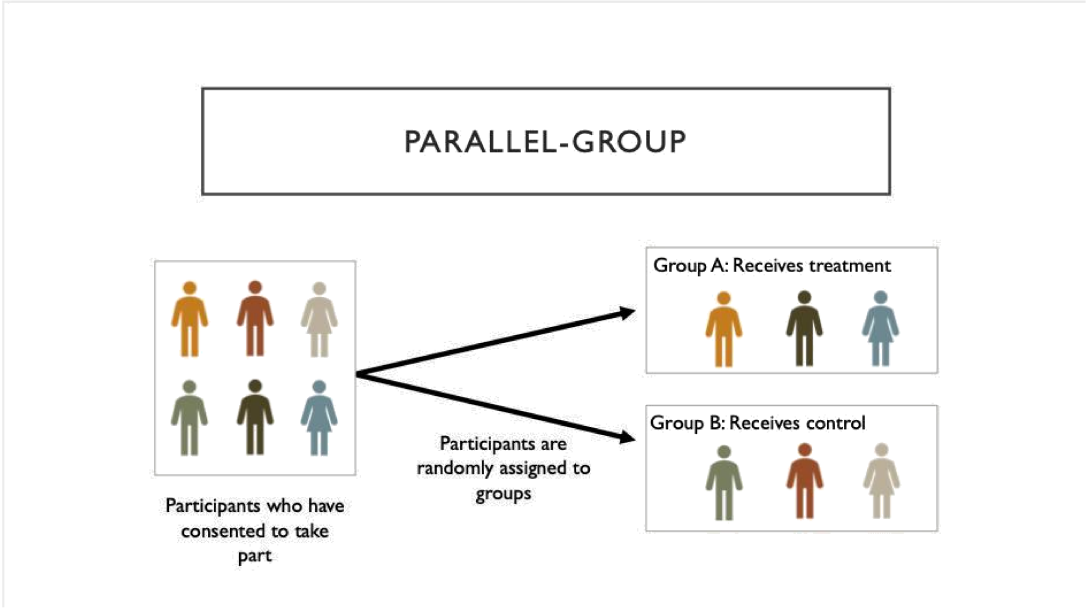



MAIN TYPES
Parallel-group
Crossover
Cluster
Stepped-wedge


CLUSTER
Dialysis unit 1
Dialysis unit 2
Dialysis unit 3
Dialysis unit 4
Clusters are randomly assigned to groups
Group A: Receives treatment
Dialysis unit 1
Dialysis unit 3
Group B: Receives control
Dialysis unit 4
Dialysis unit 2


CROSSOVER
Time period 1
Time period 2
Group A
(Treatment)
Group B
(Control)
Washout
Period
(optional)
Group B
(Treatment)
Group A
(Control)
Randomised
Participants who
have consented
to take part


STEPPED-WEDGE
Participant 1
Participant 2
Participant 3
Participant 4
Time period 1
Time period 2
Time period 3
Time period 4
Time period 5
Time
Receiving
control
Receiving
treatment


PARALLEL-GROUP
Participants who have consented to take part
Participants are randomly assigned to groups
Group A: Receives treatment
Group B: Receives control

Appendix 5 – Included studies

Table 1: Individually randomised parallel-group trials selected for review

Author	Year	Country	InterventionType	Study groups	LoS in mths	Justification ofSS	No. of ppts atstart	No. of ppts atend	Achieved targetrecruitment	Retention rate(%)	% of ppts lostdueto WoC	Use of flowdiagram	Achieved stat.sig.endpoint
Akrami et al (6)	2016	Iran	Lifestyle	1: FP 2: Placebo	4	No	79	63	NR	79.8	87.5	Yes	Yes
Bacci et al (7)	2018	Brazil	Procedure	1: RICP 2: Ctrl	NR	No	47	NR	Yes	NR	NR	No	No
Bansal et al (8)	2014	India	Pharm	1: Cholecalciferol 2: Ctrl	5	Yes	45	27	Yes	60	0	Yes	No
Gaweda et al (9)	2014	USA	Pharm	1: Ctrl 2: SAM	17	Yes	62	52	Yes	83.9	10	Yes	Yes
Gobo-Oliveira et al (10)	2018	Brazil	Pharm	1: Gabapentin 2: DEX	17	Yes	60	58	Yes	96.7	0	Yes	No
Hassanzadeh et al (11)	2018	Iran	Other (Alt.)	1: Relaxation 2: Aromatherapy 3: Ctrl	10	Yes	105	NR	Yes	NR	NR	No	Yes
Huan-Sheng et al (12)	2016	Taiwan	Device	1: BCM-BIS 2: SC	12	Yes	298	251	No	84.2	27.7	Yes	No
Khosroshahi et al (5)	2013	Iran	Lifestyle	1: Omega-3 2: Placebo	NR	Yes	100	88	Yes	88	0	No	Yes
Lenglet et al (13)	2017	France	Pharm	1: Nicotinamide 2: Sevelamer	60	Yes	100	73	No	73	NR	Yes	No
Loutradis et al (14)	2019	Slovenia and Greece	Procedure	1: Lung US 2: Ctrl	NR	Yes	71	67	Yes	94.4	0	Yes	Yes

Makhlough et al (15)	2016	Iran	Pharm	1: Hybrid therapy 2: Standard triple therapy	NR	No	40	40	NR	100	0	Yes	Yes
Martins do Valle et al (16)	2019	Brazil	Lifestyle	1: ID Ex 2: Ctrl	NR	No	24	19	NR	79.2	0	Yes	No
Momennasab et al (17)	2018	Iran	Other (Alt.)	1: ID Music 2: Music at night 3: Ctrl	8	Yes	105	102	Yes	97.1	33.3	Yes	Yes
Morena et al (18)	2017	France	Device	1: HFHD 2: OLHDF	84	Yes	381	261	Yes	68.5	NR	Yes	Yes
Nahidi et al (19)	2018	Iran	Other (Alt.)	1: Acupuncture 2: Sham	24	Yes	30	26	Yes	86.7	100	Yes	Yes
Obi et al (20)	2016	Japan	Lifestyle	1: Vitamin B6 2: Ctrl	NR	Yes	60	44	NR	73.3	0	Yes	Yes
Rad et al (21)	2017	Iran	Procedure	1: Cool dialysate 2: Ctrl	4	Yes	60	60	Yes	100	0	Yes	Yes
Rhee et al (22)	2017	USA	Lifestyle	1: High protein 2: Low protein	NR	Yes	110	106	Yes	96.4	NR	Yes	Yes
Ronco et al (23)	2017	Italy	Device	1: NV dialyzer 2: Standard	NR	Yes	19	17	No	89.5	0	No	No
Schardong et al (24)	2017	Brazil	Procedure	1: NMES 2: Ctrl	9	Yes	24	21	Yes	87.5	100	Yes	Yes
Schlosser et al (25)	2016	Germany	Procedure	1: TPTX + AT 2: TPTX	72	Yes	100	74	Yes	74	34.6	Yes	Yes
Siriopol et al (26)	2017	Romania	Device	1: Lung US 2: SC	25	Yes	250	241	No	96.4	0	Yes	No
Tayebi et al (27)	2019	Iran	Lifestyle	1: Ctrl 2: BCAA + Ex 3: Ex	NR	No	51	48	NR	94.1	NR	Yes	Yes
Thadhani et al (28)	2017	USA	Lifestyle	1: Oral Vitamin D 2: Placebo	5	Yes	62	53	Yes	85.5	22.2	Yes	Yes

Xavier et al (29)	2015	Brazil	Device	1: CPAP 2: Ctrl	NR	No	40	37	NR	92.5	66.7	Yes	Yes
Ziaee et al (30)	2019	Iran	Pharm	1: Spironolactone 2: Ctrl	NR	No	48	43	NR	89.6	0	No	Yes

Alt., alternative therapies; BCAA, branched chain amino acids; BCM-BIS, bioimpedance spectroscopy; CPAP, continuous positive airway pressure; Ctrl, control; DEX, dexchlorpheniramine; Ex, exercise; FP, fumaria parviflora L; HFHD, high-flux haemodialysis; ID, intradialytic; LoI, length of intervention; LoS, length of study; Mnths, months; NMES, neuromuscular electrical stimulation; No., number; NR, not reported; OLHDF, online hemodiafiltration; Pharm, pharmacological; Ppt(s), participant(s); RICP, remote ischaemic preconditioning; SAM, smart anaemia manager; SC, standard care; SS, sample size; SSC, sample size calculation; Stat. sig., statistically significant; TPTX + AT, total parathyroidectomy with autotransplantation; TPTX, total parathyroidectomy; UC, unclear; US, ultrasound; WoC, withdrawal of consent

Table 2: Crossover trials selected for review

Author	Year	Country	InterventionType	Study groups	LoS in mths	Justification ofSS	Within ppt variability accounted for	No. of ppts at start	No. of ppts at end	Achieved target recruitment	Retention rate(%)	% of ppts lost due to WoC	Use of flow diagram	Achieved stat.sig. endpoint
De Sequera et al (31)	2019	Spain	Pharm	1: CDF 2: ADF	8	No	No	56	46	NR	82.1	UC	Yes	No
Eljaoudi et al (32)	2015	Morocco	Other (Alt.)	1: Argan oil 2: Ctrl	NR	Yes	No	37	NR	Yes	NR	NR	No	Yes
Ettema et al (33)	2018	The Netherlands	Procedure	1: Standard HD 2: HD with BF	6	Yes	No	30	29	Yes	96.7	0	Yes	Yes
Jeong et al (34)	2018	USA	Lifestyle	1: Ctrl 2: ID Ex in 1st hr 3: ID Ex in 3rd hr	UC	No	No	12	8	NR	66.7	75	No	NR
Leung et al (35)	2017	Canada	Device	1: Ctrl 2: HD with BF	12	Yes	No	35	26	Yes	74.3	0	Yes	No
Orcy et al (36)	2014	Brazil	Lifestyle	1: Ctrl 2: ID Ex	9	No	No	24	22	NR	91.7	0	Yes	No
Razeghi et al (37)	2015	Iran	Pharm	1: Sertraline 2: Placebo	20	No	No	NR	12	NR	NR	UC	No	Yes
Rivara et al (38)	2015	USA	Lifestyle	1: Pom juice 2: Pom extract	8	No	No	35	20	NR	57.1	46.7	Yes	Yes
Shahgholian et al (39)	2014	Iran	Device	1: Standard HD 2: SSUF 3: SDFR	NR	No	No	NR	32	NR	NR	NR	No	No
Smith et al (40)	2017	USA	Pharm	1: 4 mEq/L Ac 2: 8 mEq/L Ac	UC	Yes	No	11	10	Yes	90.9	100	Yes	Yes

Thompson et al (41)	2016	Canada	Device	1: Two high flux 2: Standard HD	UC	Yes	No	33	31	Yes	93.1	0	Yes	No
Tsai et al (42)	2019	Taiwan	Lifestyle	1: VLP diet 2: LP diet	6	Yes	No	35	29	Yes	82.9	83.3	Yes	No
Wu et al (43)	2013	Taiwan	Procedure	1: SLED 2: CVVH	NR	Yes	Yes	12	10	Yes	83.3	0	Yes	No

Ac, acetate; ADF, dialysis fluid containing acetate; Alt., alternative therapies; BF, biofeedback; CDF, dialysis fluid containing citrate; Ctrl, control; CVVH, continuous veno-venous haemofiltration; Ex, exercise; HD, haemodialysis; ID, intradialytic; LoI, length of intervention; LoS, length of study; LP, low phosphate; Mnths, months; No., number; NR, not reported; Pharm, pharmacological; Pom, pomegranate; Ppt(s), participant(s); SC, standard care; SDFR, stepwise dialysis solution flow rate profiles; SLED, sustained low-efficiency dialysis; SS, sample size; SSC, sample size calculation; SSUF, stepwise sodium and ultrafiltration profiles; Stat. sig., statistically significant; UC, unclear; VLP, very low phosphate; WoC, withdrawal of consent

Table 3: Cluster trials for review

Author	Year	Country	Intervention Type	Study groups	LoS (LoI) in mths	SS requirements from CONSORT statement						Cluster formation	No. of ppts at start	No. of ppts at end	Achieved targetrecruitment	Retention rate (%)	% of ppts lost due toWoC	Use of flow diagram	Achieved stat. sig.endpoint
						Justification of SS	Stated no. ofclustersinSSC	Stated CS	Stated if equal orunequalCSassumed	Stated ICC	Stated uncertaintyinICC								
Bennett et al (45)	2013	Australia	LS	1: NS 2: SC	UC	No	No	No	No	No	No	HDC	96	81	Yes	84.4	0	No	Yes
Bennett et al (44)	2015	Australia	LS S/W	3 groups ID Ex	UC (36)	Yes	Yes	Yes	No	Yes	No	HDC	228	113	Yes	49.6	27.8	Yes	Yes
Birdee et al (46)	2015	USA	LS	1: ID Yoga 2: E/P	UC	No	No	No	No	No	No	D/S	31	26	Yes	83.9	40	Yes	Yes
Griva et al (47)	2018	Singapore	Other (PBE)	1: S/M 2: SC	39	No	No	No	No	No	No	D/S	259	195	NR	82.1	57.8	Yes	Yes
Griva et al (48)	2019	Singapore	Other (PBE)	1: SC 2: S/M	NR	No	No	No	No	No	No	D/S	44	42	No	95.5	0	Yes	Yes
Huang et al (49)	2018	China	Other (PBE)	1: S/M 2: SC	UC	No	No	No	No	No	No	D/S	90	83	Yes	92.2	28.6	Yes	Yes
Karavetian et al (50)	2013	Lebanon	Other (PBE)	1: SMDC 2: EG 3: Ctrl	NR (2)	No	No	No	No	No	No	D/S	122	87	NR	72	11.4	No	Yes
Karavetian et al (51)	2015	Lebanon	Other (PBE)	1: Full 2: SC 3: Partial	12	Yes	No	Yes	No	No	No	D/S	570	394	No	69.1	18.2	Yes	Yes
Weisbord et al (52)	2013	USA	Other	1: F/B 2: NM	28 (12)	Yes	No	No	No	No	No	D/S	315	186	NR	59	27.1	Yes	No

Wileman et al (53)	2016	UK	Other (PBE)	1: S/A 2: Ctrl	UC	Yes	No	No	No	No	No	D/S	91	60	Yes	65.9	UC	Yes	Yes
Wileman et al (54)	2014	UK	Other (PBE)	1: S/A 2: Ctrl	UC	Yes	No	No	No	No	No	D/S	119	90	Yes	75.6	17.2	Yes	No

Alt., alternative therapies; CS, cluster size; Ctrl, control; D/S, dialysis shift; E/G, educational games; E/P, educational program; Ex, exercise; F/B, feedback arm; HDC, haemodialysis centre; ICC, intracluster correlation coefficient; ID, intradialytic; LoI, length of intervention; LoS, length of study; LS, lifestyle; Mngt, management; Mths, months; NM, nurse management; No., number; NR, Not reported; NS, nutrition screening; PBE, Psychological, behavioural and educational; Pharm, pharmacological; Ppt(s), participant(s); S/A, self-affirmation; S/M, self-management; S/W, stepped-wedge; SC, standard care; SMDC, self-management dietary counselling; SS, sample size; SSC, sample size calculation; Stat.sig., statistically significant; UC, unclear; WoC, withdrawal of consent

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