CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	Page2, line 7 to 8	randomly divided by numeration table
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page2, line 6 to 33	
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page2, line 3 to 5	This study was to investigate the effect of high-flux hemodialysis (HD) combined with levocarnitine on vascular calcification, microinflammation, hepcidin, and malnutrition in elderly patients on maintenance HD (MHD).
	2b	Specific objectives or hypotheses	Page 2, line 3 to 5	high-flux hemodialysis (HD) combined with levocarnitine on vascular calcification, microinflammation, hepcidin, and malnutrition in elderly patients on maintenance HD (MHD).
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page4, line 4 to 7	The study group of 75 elderly patients on MHD admitted to hospital between September 2017 and July 2019 were randomly divided by numeration table into three groups: low-flux HD group (n=25), a high flux HD group (n=25), and a joint group (n=25).
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none	none
Participants	4a	Eligibility criteria for participants	Page4, line 7 to 24	Inclusion criteria were: (I) complying with the diagnostic criteria of the NKF-K/DOQI guidelines in the USA for chronic kidney disease, meeting the indication for MHD treatment of hemoglobin (Hb) <120 g/L (male) and Hb <110 g/L (female), and able to undergo MHD in hospital; (II) age⩾60 years; (III) duration of MHD⩾2 years; (IV) duration of low-flux MHD⩾3 months; (V) absence of severe infection or heart failure, antibiotic treatment, active diseases, and malignant tumors in the past 3 months; (VI) taking low-molecular-weight heparin calcium anticoagulation; (VII) undergoing three 4-h dialysis treatment per week and blood flow of 200–300 mL/min; (VIII) smooth blood circulation during dialysis, reaching or approaching the dry body mass; (IX) good

				treatment compliance and being able to follow medical staff instructions and sign informed consent. The exclusion criteria were: (I) use of glucocorticoids or immunosuppressants in the past 3 months; (II) bleeding or blood transfusion or taking antibiotics in the past 3 months; (III) hematologic disease; (IV) acute or chronic infection; (V) severe malnutrition; (VI) malignant tumors; (VII) severe heart failure or multiple organ failure; (VIII) sepsis, chronic hepatitis, tuberculosis, systemic lupus erythematosus, vasculitis, liver insufficiency, epilepsy, a family history of epilepsy; and (IX) blood flow during dialysis <200 mL/min.
	4b	Settings and locations where the data were collected	Page4, line 4 to 5	Department of Nephrology, The Affiliated Xiaolan Hospital of Southern Medical University, Zhongshan, China.
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page4, line 10 to 33 And Page5, line 1 to 2	Low-flux HD group; High-flux HD group; High-flux HD + levocarnitine (combination group)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	none	none
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none	none
Sample size	7a	How sample size was determined	According to the actual number of cases admitted	none
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none	none
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	none	none
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	none	none
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	none	none

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	none	none
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	none	none
	11b	If relevant, description of the similarity of interventions	none	none
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page7,line 28 to 34	The measurement data conforming to the normal distribution were expressed as (x±s) and tested with t test. Repeated measurement data were analyzed by repeated measurement variance and tested with F test. Comparison of multiple groups was performed using single factor variance. Comparison of two groups was performed by q test; χ2 test was used for comparison of count data; rank sum test was used for comparison of rank data. P<0.05 indicated a statistically significant difference.
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	none	none
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 2,line 6 to 29	Methods: 75 MHD elderly patients admitted to hospital between 1st September 2017 and 31st August 2019 were selected as the study subjects. They were randomly divided by digital table into three groups: low-flux group (n=25), high-flux group (n=25) and joint group (n=25). In the low-flux group, dialyzer had an ultrafiltration coefficient 12 mL/(h·mmHg) and effective surface area of 1.4 m2 compared with 59 mL/(h·mmHg) and 1.8 m2 in the high-flux group. After treatment, the calcification of blood vessels was examined by lateral X-ray, pelvic plain film and bilateral positive position. For patients in all groups, the concentrations of parathyroid hormone (PTH) and β 2-microglobulin (β 2-MG) in serum were measured by automatic chemiluminescence; levels of interleukin-6, C-reactive protein (CRP), and tumor necrosis factor alpha (TNF-α) were measured by ELISA before and after treatment; and the level of hepcidin was measured by ELISA. Before and 12 weeks after the treatment, the nutritional status of the patients was evaluated by modified quantitative subjective global

				assessment (MQSGA), hemoglobin (Hb) and red blood cell count (RBC). Complications in the three groups were recorded, including nausea, chest pain, hypotension, hypertension, pruritus, dry heat, muscle spasm, arrhythmia, and restless legs. Results: Vascular calcification in the joint group was better than the low-flux and high-flux groups (P<0.05). After treatment, the serum PTH and β 2-mg concentrations in the joint group were lower than those in the other two groups (P<0.05), and the levels of IL-6, CRP, TNF-α and hepcidin in the joint group were significantly lower than those before treatment (P<0.05). After treatment, the MQSGA scores in the joint group were lower than those in the low-flux and high-flux groups (P<0.05), and Hb and RBC were higher (P<0.05).. w
	13b	For each group, losses and exclusions after randomisation, together with reasons	none	none
Recruitment	14a	Dates defining the periods of recruitment and follow-up	none	none
	14b	Why the trial ended or was stopped	none	none
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 16,line 6 to 9	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	yes	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	none	none
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	none	none
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	none	none
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	none	none
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	none	none

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	none	none
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	none	none
Other information				
Registration	23	Registration number and name of trial registry	none	none

Protocol	24	Where the full trial protocol can be accessed, if available	none	none
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	Page 2, line 7 to 8	randomly divided by numeration table
Authors *	Contact details for the corresponding author	Page 1, line 25 to 27	Correspondence to: De-Liang Ding. Department of Nephrology, The Affiliated Xiaolan Hospital of Southern Medical University, No. 65 Jucheng Avenue, Xiaolan, Zhongshan 528415, China. Email: DLDing066@126.com.
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	none	none
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	none	none
Interventions	Interventions intended for each group	Page 2, line 9 to 11	In the low-flux group, dialyzer had an ultrafiltration coefficient 12 mL/(h·mmHg) and effective surface area of 1.4 m2 compared with 59 mL/(h·mmHg) and 1.8 m2 in the high-flux group.
Objective	Specific objective or hypothesis	Page 2, line 3 to 5	This study was to investigate the effect of high-flux hemodialysis (HD) combined with levocarnitine on vascular calcification, microinflammation, hepcidin, and malnutrition in elderly patients on maintenance HD (MHD)
Outcome	Clearly defined primary outcome for this report	Page 2, line 23 to 29	Results: Vascular calcification in the joint group was better than the low-flux and high-flux groups (P<0.05). After treatment, the serum PTH and β 2-mg

			concentrations in the joint group were lower than those in the other two groups (P<0.05), and the levels of IL-6, CRP, TNF-α and hepcidin in the joint group were significantly lower than those before treatment (P<0.05). After treatment, the MQSGA scores in the joint group were lower than those in the low-flux and high-flux groups (P<0.05), and Hb and RBC were higher (P<0.05)..
Randomization	How participants were allocated to interventions	Page 2, line 7 to 8	randomly divided by digital table
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	informed	
Results			
Numbers randomized	Number of participants randomized to each group	Page 2, line 8 to 9	25
Recruitment	Trial status	finish	
Numbers analysed	Number of participants analysed in each group	Page 2, line 8 to 9	25
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	none	none
Harms	Important adverse events or side effects	Page 19, line 23 to24	Table 7

Conclusions	General interpretation of the results	Page 2, line 30 to 33	The combination of high-flux HD and levocarnitine in elderly patients on MHD can increase the clearance of medium and large molecular toxins, effectively correct malnutrition, alleviate microinflammation, delay the progress of vascular calcification, and is safe.
Trial registration	Registration number and name of trial register	none	none
Funding	Source of funding	none	none

** this item is specific to conference abstracts*

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.