NHLBI Evidence Table: RF12-RCT

PMID First Author	Title Y	Year St	udy Type	CVD	RF by CQ	Country	гу	Setting	Blinding	Int Length	Total Study Duration	Main Study Objective	Total N Target Population	Eligibility Criteria	Patient Characteristics	Int. n at Baselin (n at Follow-up	ne Int. Type	Specific Intervention	Control n at Baseline (n at Follow-up)	Specific Control	Outcomes Measured	Results/CI	Significance	Safety and Adverse Events	Additional findings	Summary	Main Reported Findings by Critical Question
1465060 Kist-van Holbitetot Echter JE	Protein restriction affects faft in instale and serious lights in children with chronic renal failure	RC RC	T N	Jone Q1	(3 (RF5, RF9) Netherlan	nds Clin	P P	None/NR	12 mo	12 mo	Assess the effect of a protein- restricted det on tal inake and asserum lipid profiles in children with chronic renal failure	48 Pediatric' Young Adults	Children Chronic renal faillure	Meen age (SD): Amn 1:10 yer (5.0) Control Arm: 10.4 yr (4.4) Boys: 36 Glomerulonephritis: 6 Reffux nephropathy, obstructive uropathy and/or renal dysplasia: 31 Miscellaneous chronic renal failure diagnosis: 11		Behavioral	Arm 1: Protein restricted diet (INT) Advised to eat the safe levels for protein intake advised by the World Heath Organization (WHO) 1985. which varies from 0.8 to 1.1 g/kg/d, according to age and gender of the child	25 (NR)	Control Arm: Normal protein intake diet (CON) Advised to eat usual protein intake fhealthy Dutch children, correspondir to 1.5-20 times safe levels for protein intake according to age and weight	Mean fat intake [%E (SD)] or ng Secondary: n Mean calorie intake [% of recommended by	Primary: #1: INT-35(7): CON: 37(7) #2: INT-38(6): CON: 37(7) #2: INT-38(6): CON: 37(7) #2: INT-38(6): CON: 37(7) #2: INT-38(6): CON: 37(7) #2: INT-37(24): CON: 105(18) #1: INT-59(10): CON: 52(8) #1: INT-59(10): CON: 52(8) #1: INT-17(6): CON: 25(8) #1: INT-17(6): CON: 25(8) #1: INT-17(6): CON: 24(8) #1: INT-17(6): CON: 24(8) #1: INT-48(0.95): CON: 4.82(0.60) #1: INT-48(0.95): CON: 4.82(0.60) #1: INT-1.62(0.76): CON: 1.38(0.88) #2: INT-1.7(1.12): CON: 1.37(0.73) #1: INT-1.20(0.55): CON: 1.25(0.39) #2: INT-1.20(0.75): CON: 2.30(0.60) #1: INT-2.61(0.70): CON: 2.93(0.60) #1: INT-0.73(0.34): CON: 0.82(0.33) #2: INT-0.77(0.50): CON: 0.62(0.33)	NS NS NS NS NS NS S** S** by design NS	None reported	Significant improvement in PIS ratios were also noted	diet has favorable effects on the cholesterol intake	A protein-restricted diet has favorable effects on the choicesterol intake of children with chronic renal failure with thorois creal failure with no significant impact on serum lipids.
11956124 Bennett- Richards K	Does oral folic acid lower total 20 homocysteine levels and improve endothelia function in children with chronic renal failure?		T Fissover)	MD Q1	0 (RF5)	ик	Clin	nical E	Double	8 wk	Includes 8	Determine if oral folic acid lowers total homocysteine levels and improves endothelia function in children with chronic renal failure	Young Adults	Chronic renal failure (glomerular filtration rate 28.8±13.2 mL/min per 1.73 m2) of noninflammatory etiology Exclusions: Smokers Hypertensive Diabetic or nephrotic		25 (23)	Dietary Supplements	Intervention: Folic acid 5 mg/m2	25 (23)	Control: Placebo	Primary: Serum folate [umol/L(SD)] Red cell folate [umol/L(SD)] Total homocysteine [umol/L(SD)] Change in FMD [% (SD)] Change in vessel diameter [cm(SD)] Secondary: Total antioxidant activity [utrolox Eq(SD)] LDL lag times [min(SD)]	Primary: INT 13.1(8.1 to 635(519) CON: 17.0(8.9) to 12.4(6.0) INT: 364(195) to 2891(2693) CON: 9596(469) to 405(169) INT: 10.284.6(1) to 8.50(2.32) CON: 9.02(2.19) to 9.84(2.74) INT: 7.2(2.81) to 8.47(3.01) CON: 8.20(3.41) to 8.80(4.01) INT: 0.244(0.102) to 0.276(0.104) Secondary: No change in INT or CON INT: 58.4(18) to 68.4(25) CON: 62.8(17) to 63.2(13)	S** NS S** S NS N	None reported	any lipid	with folic acid for 8 weeks results in reduction in homocysteine levels, resistance	Supplementation with folic acid for 8 weeks results in reduction in homocysteine levels, resistance of LDL to oxidation, and increases in endothelial function in children with chronic renal failure.
12234308 Bennett- Richards KJ	Oral L-arginine does not improve endothelial dystanction in-different thronic renal failure	002 RC (cro	T Fissover)	MD Q1	3 (RF4, RF5) United Kingdom	Clin	nical E	Double	4 wk	Includes 4	Examine whether dietary L- arginine supplementation improves endothelial function in children with chronic renal failure	Young Adults	Chronic renal failure defined as glomerular filtration rate < 50 mt/min17.3 m² Endothelial dysfunction Normotensive Exclusions: Smokers Hypertensive Diabetic Nephrotic	Mean age (SD): 12 yr (3) Males: 14 Congenital structural causes of chronic renal failure: 24 Acquired (neonatal cortical necrosis) causes of chronic renal failure: 1	s	Dietary Supplements	Intervention: Oral L-arginine supplementation L-arginine given at 5 g/m² surface are to a maximum of 7 g tid; dose was adjusted to 2.5 g/m² tid in those with glomerular filtration rate < 35 mL/min/1.73 m²		Control: Placebo	Primary: Mean change in L-arginine level [umol/L[SD] Mean change in brachial artery diameter [mm(SD]] Mean change in FMD [% (SD)] Secondary: Mean TG [mmol/L (SD)] Mean TG [mmol/L (SD)] Mean HDL-C [mmol/L (SD)] Mean LDL-C [mmol/L (SD)] Mean SBP[mmHg(SD)] Mean DBP[mmHg(SD)]	Primary: INT: 104(110); CON:4(14.5) INT: 0.007(0.15); CON: -0.03(0.04) INT: 0.007(0.15); CON: -0.14(3.23) Secondary: No difference between measurements INT: -0.06(0.54); CON: 0.19(0.57) No difference between measurements No difference between measurements No difference between measurements No difference between measurements	S** NS NS NS NS NS NS NS NS NS		NO chemistry.	does not improve	Oral L-arginine does not improve brachial artery reactivity in the setting of chronic renal fallure despite elevated plasma arginine levels.