

# Clinical trials of sodium reduction

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## 1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
<b>sodium reduction vs control</b>			
<b>HPT , 1990</b> n=196/196 follow-up: 3 years	dietary counseling versus no dietary counseling	normotensive healthy men and women aged 25 to 49 years, with diastolic blood pressures of 78 to 89 mm Hg	Parallel groups open USA
<b>TOHP I , 1992</b> n=327/417 follow-up: 18 months	sodium reduction versus unmasked nonintervention controls	men and women, aged 30 through 54 years, with diastolic blood pressure from 80 through 89 mm Hg	Parallel groups open USA
<b>TOHP II , 1997</b> n=594/596 follow-up: 3-4 years	sodium reduction intervention versus control	overweight people with high-normal blood pressure	Factorial plan open USA
<b>Chang , 2006</b> n=NA follow-up: 31 mo	potassium-enriched salt versus control	elderly veterans	open USA
<b>Morgan , 1978</b> n=35/42 follow-up: 2 years	moderate restriction of salt versus control	patients with a diastolic blood-pressure between 95 and 109 mm Hg	Parallel groups open Australia
<b>TONE , 1998</b> n=340/341 follow-up: 29 months	reduced sodium intake versus control	older persons with hypertension	Factorial plan open USA
<b>Ali , 1992</b> n=40/37 follow-up: 12 months	low-sodium diet versus usual diet	previously undiagnosed mildly hypertensive patients	Parallel groups open Italy
<b>Arroll , 1995</b> n=51/49 follow-up: 6 months	salt restriction versus without salt restriction	healthy adult volunteers with a sedentary lifestyle and on pharmacological therapy for hypertension	Parallel groups open New Zealand

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Costa , 1981 n=21/20 follow-up: 12 months	low-salt diet versus control	young patients with borderline hypertension	Parallel groups open Italy
DISH , 1985 n=NA follow-up: 56 weeks	sodium-restriction versus control	normotensive subject	Parallel groups open
Kumanyika , 1993 n=NA follow-up:	-	-	
Morgan , 1987 n=10/10 follow-up: 6 months	reduced sodium intake versus control	hypertensive patients previously well-controlled on drug therapy	Parallel groups open Australia
Paterna , 2008 n=114/118 follow-up: 180 days	low-sodium diet plus oral furosemide (250-500 mg, b.i.d.) versus normal-sodium diet plus oral furosemide 250-500 mg, b.i.d. (twice a day) and fluid intake of 1000 ml per day	compensated CHF patients	Parallel groups open
Silman , 1993 n=12/16 follow-up: 13 months	restricted sodium diet versus control	patients who had a sustained diastolic blood pressure of 95 to 104 mm Hg and who had no treatment for it for at least 13 months before the trial	Parallel groups open UK
Thaler , 1982 n=80/84 follow-up:	salt-restriction versus control	subjects aged 64 or less with a systolic blood pressure 138-179 mmHg including those on antihypertensive treatment	Parallel groups open New Zealand

More details and results :

- dietary salt reduction for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q518>

## References

### HPT, 1990:

The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. Hypertension Prevention Trial Research Group. Arch Intern Med 1990;150:153-62 [2404477]

Borhani NO, Tonascia J, Schlundt DG, Prineas RJ, Jefferys JL Recruitment in the Hypertension Prevention trial. Hypertension Prevention Trial Research Group. Control Clin Trials 1989;10:30S-39S [2680272]

Shah M, Jeffery RW, Laing B, Savre SG, Van Natta M, Strickland D Hypertension Prevention Trial (HPT): food pattern changes resulting from intervention on sodium, potassium, and energy intake. Hypertension Prevention Trial Research Group. *J Am Diet Assoc* 1990;90:69-76 [2404050]

#### **TOHP I, 1992:**

The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels. Results of the Trials of Hypertension Prevention, Phase I. *JAMA* 1992;267:1213-20 [1586398]

Cook NR, Cutler JA, Obarzanek E, Buring JE, Rexrode KM, Kumanyika SK, Appel LJ, Whelton PK Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *BMJ* 2007;334:885-8 [17449506] [10.1136/bmj.39147.604896.55](https://doi.org/10.1136/bmj.39147.604896.55)

Cook NR, Kumanyika SK, Cutler JA Effect of change in sodium excretion on change in blood pressure corrected for measurement error. The Trials of Hypertension Prevention, Phase I. *Am J Epidemiol* 1998;148:431-44 [9737555]

He J, Whelton PK, Appel LJ, Charleston J, Klag MJ Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension. *Hypertension* 2000;35:544-9 [10679495]

Kumanyika SK, Hebert PR, Cutler JA, Lasser VI, Sugars CP, Steffen-Batey L, Brewer AA, Cameron M, Shepek LD, Cook NR Feasibility and efficacy of sodium reduction in the Trials of Hypertension Prevention, phase I. Trials of Hypertension Prevention Collaborative Research Group. *Hypertension* 1993;22:502-12 [8406655]

Sacks FM, Hebert P, Appel LJ, Borhani NO, Applegate WB, Cohen JD, Cutler JA, Kirchner KA, Kuller LH, Roth KJ Short report: the effect of fish oil on blood pressure and high-density lipoprotein-cholesterol levels in phase I of the Trials of Hypertension Prevention. *J Hypertens* 1994;12:209-13 [8021472]

Satterfield S, Cutler JA, Langford HG, Applegate WB, Borhani NO, Brittain E, Cohen JD, Kuller LH, Lasser NL, Oberman A Trials of hypertension prevention. Phase I design. *Ann Epidemiol* 1991;1:455-71 [1669525]

Stevens VJ, Corrigan SA, Obarzanek E, Bernauer E, Cook NR, Hebert P, Mattfeldt-Beman M, Oberman A, Sugars C, Dalcin AT Weight loss intervention in phase I of the Trials of Hypertension Prevention. The TOHP Collaborative Research Group. *Arch Intern Med* 1993;153:849-58 [8466377]

Whelton PK, Buring J, Borhani NO, Cohen JD, Cook N, Cutler JA, Kiley JE, Kuller LH, Satterfield S, Sacks FM The effect of potassium supplementation in persons with a high-normal blood pressure. Results from phase I of the Trials of Hypertension Prevention (TOHP). Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol* 1995;5:85-95 [7795836]

Whelton PK, Kumanyika SK, Cook NR, Cutler JA, Borhani NO, Hennekens CH, Kuller LH, Langford H, Jones DW, Satterfield S, Lasser NL, Cohen JD Efficacy of nonpharmacologic interventions in adults with high-normal blood pressure: results from phase I of the Trials of Hypertension Prevention. Trials of Hypertension Prevention Collaborative Research Group. *Am J Clin Nutr* 1997;65:652S-660S [9022561]

#### **TOHP II, 1997:**

Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high-normal blood pressure. The Trials of Hypertension Prevention, phase II. The Trials of Hypertension Prevention Collaborative Research Group. *Arch Intern Med* 1997;157:657-67 [9080920]

Appel LJ, Hebert PR, Cohen JD, Obarzanek E, Yamamoto M, Buring J, Stevens V, Kirchner K, Borhani NO Baseline characteristics of participants in phase II of the Trials of Hypertension Prevention (TOHP II). Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol* 1995;5:149-55 [7795833]

Hebert PR, Bolt RJ, Borhani NO, Cook NR, Cohen JD, Cutler JA, Hollis JF, Kuller LH, Lasser NL, Oberman A Design of a multicenter trial to evaluate long-term life-style intervention in adults with high-normal blood pressure levels. Trials of Hypertension Prevention (phase II). Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol* 1995;5:130-9 [7795831]

Hunt SC, Cook NR, Oberman A, Cutler JA, Hennekens CH, Allender PS, Walker WG, Whelton PK, Williams RR Angiotensinogen genotype, sodium reduction, weight loss, and prevention of hypertension: trials of hypertension prevention, phase II. *Hypertension* 1998;32:393-401 [9740601]

Lasser VI, Raczynski JM, Stevens VJ, Mattfeldt-Beman MK, Kumanyika S, Evans M, Danielson E, Dalcin A, Batey DM, Belden LK Trials of Hypertension Prevention,

phase II. Structure and content of the weight loss and dietary sodium reduction interventions. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. *Ann Epidemiol* 1995;5:156-64 [[7795834](#)]

**Chang, 2006:**

Chang HY, Hu YW, Yue CS, Wen YW, Yeh WT, Hsu LS, Tsai SY, Pan WH Effect of potassium-enriched salt on cardiovascular mortality and medical expenses of elderly men. *Am J Clin Nutr* 2006;83:1289-96 [[16762939](#)]

**Morgan, 1978:**

Morgan T, Adam W, Gillies A, Wilson M, Morgan G, Carney S Hypertension treated by salt restriction. *Lancet* 1978;1:227-30 [[74660](#)]

Morgan TO, Adams WR, Hodgson M, Gibberd RW Failure of therapy to improve prognosis in elderly males with hypertension. *Med J Aust* 1980;2:27-31 [[7432261](#)]

**TONE, 1998:**

Whelton PK, Appel LJ, Espeland MA, Applegate WB, Ettinger WH Jr, Kostis JB, Kumanyika S, Lacy CR, Johnson KC, Folmar S, Cutler JA Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled trial of nonpharmacologic interventions in the elderly (TONE). TONE Collaborative Research Group. *JAMA* 1998;279:839-46 [[9515998](#)]

Appel LJ, Espeland M, Whelton PK, Dolecek T, Kumanyika S, Applegate WB, Ettinger WH Jr, Kostis JB, Wilson AC, Lacy C Trial of Nonpharmacologic Intervention in the Elderly (TONE). Design and rationale of a blood pressure control trial. *Ann Epidemiol* 1995;5:119-29 [[7795830](#)]

Appel LJ, Espeland MA, Easter L, Wilson AC, Folmar S, Lacy CR Effects of reduced sodium intake on hypertension control in older individuals: results from the Trial of Nonpharmacologic Interventions in the Elderly (TONE). *Arch Intern Med* 2001;161:685-93 [[11231700](#)]

4 Espeland MA, Whelton PK, Kostis JB, Bahnson JL, Ettinger WH, Cutler JA, Appel LJ, Kumanyika S, Farmer D, Elam J, Wilson AC, Applegate WB Predictors and mediators of successful long-term withdrawal from antihypertensive medications. TONE Cooperative Research Group. Trial of Nonpharmacologic Interventions in the Elderly. *Arch Fam Med* 1999;8:228-36 [[10333818](#)]

**Alli, 1992:**

Alli C, Avanzini F, Bettelli G, Bonati M, Colombo F, Corso R, Di Tullio M, Gentile MG, Sangalli L, Taioli E Feasibility of a long-term low-sodium diet in mild hypertension. *J Hum Hypertens* 1992;6:281-6 [[1433163](#)]

**Arroll, 1995:**

Arroll B, Beaglehole R Salt restriction and physical activity in treated hypertensives. *N Z Med J* 1995;108:266-8 [[7637923](#)]

**Costa, 1981:**

Costa FV, Ambrosioni E, Montebugnoli L, Paccaloni L, Vasconi L, Magnani B Effects of a low-salt diet and of acute salt loading on blood pressure and intralymphocytic sodium concentration in young subjects with borderline hypertension. *Clin Sci (Lond)* 1981;61 Suppl 7:21s-23s [[7032811](#)]

**DISH, 1985:**

Langford HG, Blafox MD, Oberman A, Hawkins CM, Curb JD, Cutter GR, Wassertheil-Smoller S, Pressel S, Babcock C, Abernethy JD Dietary therapy slows the return of hypertension after stopping prolonged medication. *JAMA* 1985;253:657-64 [[3881608](#)]

**Kumanyika, 1993:**

Kumanyika SK, Hebert PR, Cutler JA, Lasser VI, Sugars CP, Steffen-Batey L, Brewer AA, Cameron M, Shepek LD, Cook NR Feasibility and efficacy of sodium reduction in the Trials of Hypertension Prevention, phase I. Trials of Hypertension Prevention Collaborative Research Group. *Hypertension* 1993;22:502-12 [[8406655](#)]

**Morgan, 1987:**

Morgan T, Anderson A Sodium restriction can delay the return of hypertension in patients previously well-controlled on drug therapy. *Can J Physiol Pharmacol* 1987;65:1752-5 [[3319111](#)]

**Paterna, 2008:**

Paterna S, Gaspare P, Fasullo S, Sarullo FM, Di Pasquale P Normal-sodium diet compared with low-sodium diet in compensated congestive heart failure: is sodium an old enemy or a new friend? *Clin Sci (Lond)* 2008;114:221-30 [[17688420](#)] [10.1042/CS20070193](#)

**Silman, 1993:**

Silman AJ, Locke C, Mitchell P, Humpherson P Evaluation of the effectiveness of a low sodium diet in the treatment of mild to moderate hypertension. *Lancet* 1983;1:1179-82 [[6133987](#)]

**Thaler, 1982:**

Thaler BI, Paulin JM, Phelan EL, Simpson FO A pilot study to test the feasibility of salt restriction in a community. *N Z Med J* 1982;95:839-42 [[6962371](#)]