

**Citation:**

Sinaiko AR, Gomez-Marin O, Prineas RJ. Effect of low sodium diet or potassium supplementation on adolescent blood pressure. *Hypertension*. 1993 Jun; 21(6 Pt2): 989-994.

**PubMed ID:** [8505112](#)

**Study Design:**

Randomized controlled trial

**Class:**

A - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To assess the feasibility of maintaining long-term sodium reduction or potassium supplementation among adolescents and to determine the effect of these interventions on blood pressure (BP) during normal adolescent development.

**Inclusion Criteria:**

- Fifth to eighth grade students at St. Paul and Minneapolis public schools
- Systolic blood pressure (SBP) at rescreening above 109mmHg for boys and 108mmHg for girls (approximately upper 15% of all children screened).

**Exclusion Criteria:**

None.

**Description of Study Protocol:****Recruitment**

Students in fifth to eighth grade who had blood pressure in upper 15% of those screened.

**Design**

Three-arm prospective cohort [low sodium (Na) diet group, potassium chloride (KCl) capsule group, placebo capsule group].

**Dietary Intake/Dietary Assessment Methodology**

Compliance with diet was assessed with urinary Na/K excretion analyses.

**Blinding Used**

Placebo group received capsules identical in shape and color to the KCl capsules (double blind).

### **Intervention**

- *Low sodium diet group*: Trained with nutritionists on the gradual reduction of sodium in diet to 1,600 mg per day
- *Potassium chloride capsule group*: Participants remained on their normal diets, received K supplementation of 1mmol per kg body weight per 24 hours (two equally divided doses per day)
- *Placebo capsule group*: Placebo group received capsules identical in shape and color to the KCl capsules and were treated the same as the potassium chloride capsule group.

### **Statistical Analysis**

- Independent or matched pairs T-tests to compare means between two groups
- ANOVA/ANCOVA to compare more than two groups
- For pairwise comparisons, nominal alpha levels were adjusted using the Bonferroni method
- Analyses used unadjusted BPs, and were repeated adjusting for BMI and baseline BP levels
- For analysis and comparison of BP slopes, a random-coefficient growth curve model was used
- Multivariate regression model fit
- Data presented as mean and standard error of the mean,  $P \leq 0.05$  considered significant.

### **Data Collection Summary:**

#### **Timing of Measurements**

- Blood pressure measured every three months
- Urinalysis and 24-hour urine collection every 12 months.

#### **Dependent Variables**

Compliance with intervention: Percentage of expected capsule use; 24-hour urinary sodium and sodium/potassium ratios.

#### **Independent Variables**

The averages of two measures of SBP and fifth phase diastolic blood pressure (DBP).

#### **Control Variables**

Body mass index (BMI).

### **Description of Actual Data Sample:**

- *Initial N*: Of 3,013 eligible for study, 210 entered into study
- *Attrition (final N)*: 210
- *Age*: Mean of 13 years (fifth to eighth grade students)
- *Ethnicity*: White:black ratio of 7.4:1
- *Other relevant demographics*: No significant (NS) differences between in intervention groups in age, Tanner score, body size or BP level at randomization
- *Location*: St. Paul and Minneapolis, Minnesota.

## Summary of Results:

### Key Findings

- In the low-sodium group, 24-hour UNa was changed from 142 to 162mmol for boys, and from 133 to 119mmol in girls
- In the placebo group, 24-hour UNa was changed from 159 to 178mmol in boys and from 150 to 128mmol in girls
- Change in SBP for the low-sodium group was SBP  $-1.98 \pm 1.32$ mmHg, and DBP  $-4.65 \pm 1.91$ mmHg
- The low sodium group of girls had a statistically significant negative slope compared with placebo. The slope for boys was similar in all treatment groups.

### Mean Rate of Increase of Systolic and Diastolic Blood Pressure (95% CI) in Boys and Girls Intervention Groups

Variables	Intervention Group	Intervention Group	Placebo Group
<b>Systolic Blood Pressure</b>	Low Sodium Boys: 2.2 (1.3, 3.2)* Girls: -0.5 (-1.3, 0.3)**+	Potassium chloride Boys: 1.9 (1.1, 2.7)* Girls: 0.5 (-0.2, 1.4)+	Boys: 1.6 (0.8, 2.5)* Girls: 1.4 (0.6, 2.2)*
	<b>Diastolic Blood Pressure</b>	Boys: 1.8 (0.3, 3.4)* Girls: -0.1 (-0.8, 1.1)**+	Boys: 1.6 (0.3, 3.0)* Girls: 0.9 (-0.1, 1.9)

\*  $P < 0.001$  test for zero slope.

\*\* $< 0.01$ , compared with slope for girls placebo group.

+ $< 0.01$ , compared with slope of boys with same intervention.

### Other Findings

Adjusting for BMI did not affect results.

## Author Conclusion:

- Although the participants and parents in the study had intensive education and training sessions, neither the girls nor boys low-sodium group were successful in reaching the target level of 70mmol of sodium per day
- It is doubtful that long-term sodium reduction, particularly in boys, is feasible in the US
- Dietary changes within the first two decades of life can reduce the rate of increase in BP among girls.

## Reviewer Comments:

### Strengths

- *Long-term nature of the interventions (three years)*
- *Blinding of BP observers.*

## Limitations

- Variable adherence (the trial was not a controlled feeding study)
- Neither girls nor boys in the low-sodium group were successful in reaching the target level of sodium intake
- There were few urinary sodium measures (only once every 12 months)
- Only 59% of boys and 74% of girls had 24-hour UNa measured at year three, though all had 24-hour UNa measured at baseline.

## Comments

- Children and parents chosen to participate in the study were those who had taken 75% or more of the capsules and followed the assigned series of tasks when compliance with the intervention was tested prior to randomization
- Previously published article on study design: Gómez-Marín O, Prineas RJ, Sinaiko AR. The Sodium-Potassium Blood Pressure Trial in Children. Design, recruitment, and randomization: The children and adolescent blood pressure program. *Control Clin Trials*. 1991 Jun; 12(3): 408-423.

## Research Design and Implementation Criteria Checklist: Primary Research

### Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	???

### Validity Questions

1.	<b>Was the research question clearly stated?</b>	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	<b>Was the selection of study subjects/patients free from bias?</b>	???

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
<b>3.</b>	<b>Were study groups comparable?</b>	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	N/A
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	Yes

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?</b>	<b>Yes</b>
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	<b>Yes</b>
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	???
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes