JAMA Internal Medicine | Original Investigation | HEALTH EQUITY

# Food Insecurity Interventions to Improve Blood Pressure
## The Healthy Food First Factorial Randomized Clinical Trial

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**IMPORTANCE** Food insecurity is associated with worse blood pressure control, but the optimal design for a food insecurity intervention to improve blood pressure is unknown.

**OBJECTIVE** To inform food insecurity intervention design by comparing different intervention elements: type of food resources provided, whether to offer lifestyle counseling, and intervention duration.

**DESIGN, SETTING, AND PARTICIPANTS** A 2 × 2 × 2 factorial comparative effectiveness randomized clinical trial was carried out including adults with hypertension and systolic blood pressure (SBP) of 130 mm Hg or higher, who spoke English or Spanish, and reported food insecurity in 2 clinical networks across 364 clinical sites in North Carolina.

**INTERVENTIONS** Food resources included healthy food subsidy redeemable at grocery stores vs biweekly healthy food box home delivery. The lifestyle intervention included either no intervention or offering telephone-based lifestyle counseling. The intervention duration included 6 months vs 12 months.

**MAIN OUTCOMES AND MEASURES** The primary outcome was SBP. Secondary outcomes were diastolic blood pressure (DBP) and food security. The primary time point was 6 months from randomization. Twelve and 18 months were secondary time points.

**RESULTS** Overall, 458 individuals were randomized. The mean (SD) age was 49.7 (10.7) years and 345 (75.3%) were female individuals. Fewer than 11 participants identified as American Indian/Alaska Native; 11 (2.4%) identified as Asian, 237 (51.7%) identified as Black, 20 (4.4%) identified with multiple races, fewer than 11 participants identified as Native Hawaiian/Pacific Islander, 165 (36.0%) identified as White, and 22 (4.8%) did not report a racial identity. Twenty two participants (4.8%) identified as Hispanic ethnicity. Mean (SD) preintervention SBP and DBP were 138.2 (11.9) and 87.4 (9.1) mm Hg, respectively. The food subsidy, compared with the food box, led to moderately lower SBP at the 6-month primary time point (132.8 vs 135.3 mm Hg; difference −2.5 mm Hg; 95% CI −4.1 to −0.9; *P* = .003). DBP was also lower at 6 months (80.5 vs 82.1 mm Hg; difference −1.5 mm Hg; 95% CI, −2.5 to −0.6). The food subsidy group also had lower SBP and DBP at 18 months (SBP difference, −2.1 mm Hg; 95% CI, −4.2 to −0.05; DBP difference, −1.6 mm Hg; 95% CI −2.8 to −0.3). SBP and DBP differences at 12 months were in favor of the food subsidy, but not significantly different. Offering lifestyle counseling did not produce significantly lower SBP or DBP than not offering counseling at any time point. The 12-month duration did not produce significantly lower SBP or DBP than 6-month duration at any time point. 6-, 12-, and 18-month food security scores decreased from baseline in all groups, and did not differ significantly between groups.

**CONCLUSIONS AND RELEVANCE** In this randomized comparative effectiveness trial, a food subsidy produced a moderate reduction in SBP and DBP compared with a delivered food box. Offering lifestyle counseling and a longer benefit duration did not produce better blood pressure outcomes. Food insecurity declined from baseline in all groups, but did not differ between groups.

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+ Visual Abstract
Editor's Note page 1433
+ Supplemental content

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Food insecurity, uncertain access to the food needed for an active, healthy life,[1] affected more than 47 million people in the US in 2023.[1] Food insecurity is associated with numerous poor health outcomes, including greater prevalence and worse control of cardiometabolic conditions like hypertension, type 2 diabetes, congestive heart failure, and chronic kidney disease.[2-11]

High blood pressure is a key risk factor for cardiovascular morbidity and mortality, affecting half of all adults, yet more than 75% of people in the US with hypertension have higher blood pressure than recommended despite treatment.[12,13] Food insecurity can worsen blood pressure through at least 3 pathways.[14,15] First, through a nutrition pathway, it can incentivize consumption of more affordable but less healthful foods. Second, through a compensatory pathway, it can force individuals to make trade-offs between food, medications, and other items necessary for good health. Finally, through a psychological pathway, it can increase stress, anxiety, and depressive symptoms and worsen overall quality of life, all of which are known to increase blood pressure.

Given the health impacts of food insecurity, there is little doubt that addressing it improves health in general. However, there are many unanswered questions regarding the effect of specific versions of food insecurity interventions on blood pressure outcomes.

To help inform how to design a food insecurity intervention that could be implemented as an insurance benefit, we conducted a pragmatic, factorial comparative effectiveness randomized clinical trial. We examined 3 dimensions of treatment in which there are unanswered questions. The first dimension was the modality of food resources provided—either a food subsidy individuals could use to purchase healthy foods of their choice at local supermarkets, or a home-delivered food box containing fresh produce and other healthy food items such as olive oil and nuts. The second dimension was lifestyle—either an offer to receive telephone-based implementation of a previously tested lifestyle intervention[16-19] delivered by community health workers, or no offer for lifestyle counseling. The third dimension was duration—receiving the assigned intervention for 6 months or 12 months. For each dimension, we expected that the more resource-intensive intervention (food box, offer of lifestyle counseling, and 12 months duration, respectively) would lead to lower systolic and diastolic blood pressure and lower food insecurity than the less resource-intensive intervention.

## Key Points

**Question** When designing a food insecurity intervention to improve blood pressure, does a food subsidy lead to better control than a food box; does the offer of lifestyle counseling improve outcomes relative to not offering lifestyle counseling; and does longer duration of intervention improve outcomes relative to shorter duration?

**Findings** In this randomized comparative effectiveness trial including 458 participants, a food subsidy produced better blood pressure control than a delivered food box. Offering lifestyle counseling and a longer benefit duration did not produce better blood pressure outcomes.

**Meaning** A food subsidy improved blood pressure control compared with a food box, but offering lifestyle counseling or longer intervention duration did not lead to better outcomes.

## Methods

### Study Design

The trial protocol is available in Supplement 1. This was a 2 × 2 × 2 full factorial pragmatic randomized clinical trial designed to compare the effectiveness of different dimensions of food insecurity interventions meant to improve blood pressure.[20-22] The objective was to generate information that informs how to structure an insurance benefit to address food insecurity. The rationale for a factorial trial was to efficiently evaluate several dimensions of food insecurity interventions simultaneously. We did not design the study with the anticipation of synergistic interactions between components, but our analytic strategy did allow for the possibility of interactions. The study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

### Recruitment, Eligibility, Enrollment, and Randomization

Participants in this study were enrolled from 2 health care clinical networks in central North Carolina. Eligible participants were adults (age ≥18 years) who had a diagnosis of hypertension and a systolic blood pressure of 130 mm Hg or higher in the past year, spoke English or Spanish, and reported food insecurity on the 2-item Hunger Vital Sign.[23] Recruitment began in October 2021, the last participant was enrolled in January 2023, and follow-up data collection ended in August 2024. Participants provided verbal informed consent. The University of North Carolina at Chapel Hill institutional review board approved this study. This trial was registered on ClinicalTrials.gov as NCT05048836 prior to enrollment of the first participant. After providing informed consent and completing baseline assessment, participants were randomly assigned to 1 of 8 treatment arms in a 1:1:1:1:1:1:1:1 ratio. A study team member not involved with enrollment prepared randomization tables using a computer-generated random number sequence prior to the first participant's enrollment, which were concealed from all other study staff using the randomization function within REDCap.[24] Randomization used a permuted block algorithm with blocks of size 8 and 16 in unpredictable order, and was stratified by sex (female or not), race and ethnicity (non-Hispanic White or not), and preintervention systolic blood pressure (>150 mm Hg or not). Analyses were conducted from October 2024 to April 2025.

### Intervention

This factorial trial had 3 dimensions of interventions, with an individual assigned to 1 of 2 treatment conditions for each dimension, resulting in 8 possible combinations of treatment conditions. These dimensions were food resources, lifestyle, and duration. For each dimension, 1 intervention was intentionally less resource-intensive than the other and was considered the reference arm.

Along the food resources dimension, a participant could be assigned to either a food subsidy intervention or a food box intervention. The food subsidy intervention consisted of a $40-monthly food subsidy loaded onto an electronic card that could be used to purchase fruits, vegetables, nuts, or legumes with no added sugar, salt, or fat at a local grocery store chain. Unused funds carried over from month to month until the end of the intervention. The food box arm consisted of home delivery, every other week, of a healthy food box containing produce and alternately a prepared meal or 1 dozen eggs. At the start of the intervention, participants received a stock up box with no-salt seasonings and healthy fats such as olive oil and nuts. The approximate value in the food box arm was $115-monthly ($100 for food, $15 for delivery costs). The food subsidy was the reference arm for this dimension.

Along the lifestyle dimension, participants could be assigned to either be offered or not be offered telephone-based lifestyle counseling focused on improving diet quality delivered by health care system–based community health workers. The curriculum was an adaptation of the Med-South Lifestyle Program, which focuses on achieving heart-healthy Mediterranean diet patterns using foods that are affordable and familiar to individuals living in the southeastern US.[16-19,25-28] Participants offered the counseling received a printed version of this curriculum, which included both healthy recipes and links to videos demonstrating meal preparation. The Med-South Lifestyle Program has demonstrated both high acceptability and efficacy in achieving diet quality improvements in prior randomized studies.[16-19,25-27] The intervention consisted of monthly sessions (eTable 1 in Supplement 2). Not receiving an offer for lifestyle counseling was the reference arm for this dimension.

Along the duration dimension, individuals could be assigned to receive their intervention (defined along the other 2 dimensions) for either 6 or 12 months. The 6-month arm was the reference arm for this dimension.

## Outcomes and Data Collection

The primary outcome was systolic blood pressure (SBP), recorded in routine outpatient care and extracted from the clinical data warehouses of the participating health care systems. Diastolic blood pressure (DBP) was extracted similarly. As pragmatic assessments, blood pressure observations were made during routine care, rather than on a set schedule. Those measuring the blood pressure in clinics were generally unaware of an individual's participation in the study or study arm.

A second stream of data collection came from surveys completed by participants at 4 time points: baseline (prior to randomization), and 6, 12, and 18 months after randomization. These surveys collected participant-reported information not available in the clinical data warehouse. The main outcome for these surveys was food insecurity, measured using the 10-item US Department of Agriculture (USDA) Household Food Security Survey Module with a 30-day look-back period.[29] Other outcomes included health-related quality of life as indicated by the Patient-Reported Outcomes Measurement Information System (PROMIS) preference (PROPr) score[30-32] (which indicates overall health-related quality of life and has subdomains of cognitive function, depressive symptoms, fatigue, pain interference, physical function, ability to participate in social roles, and sleep), and indicators of cost-related medication underuse and trade-offs between food and medications.[33,34] To help understand mechanisms whereby intervention dimensions may have produced effects (particularly for the lifestyle dimension), we also measured diet quality, diet self-efficacy, and diet self-perception.[16,35-39] Telephone surveys were administered by the Carolina Survey Research Lab, and those administering the surveys were unaware of study arm assignment while collecting outcome measures.

## Statistical Analysis

For sample size determination, we targeted having 80% or greater power to detect a difference in systolic blood pressure of 3 mm Hg or greater for analyses along 1 dimension of intervention (eg, comparing food subsidy to food box groups). A sample size of 280 total participants was sufficient to provide this level of power, and enrolling a sample of this size was our primary recruitment goal. To have the same power to test hypotheses by groups defined along all 3 dimensions of intervention (eg, comparing the food subsidy with not offering lifestyle counseling for 6 months duration to the food box with offering lifestyle counseling for 12 months groups), a sample size of 1400 would have been required. We were unable to recruit a sample of 1400 owing to slower than anticipated recruitment during the COVID-19 public health emergency. The study team made the decision to halt enrollment prior to reaching this higher number of participants based on rates of enrollment and the time available to complete study activities.

We used an intention-to-treat analytic approach, analyzing all randomized participants as part of the treatment arms to which they were assigned. The estimand of interest was an average treatment effect comparing one treatment arm to another (eg, food subsidy compared with food box) while standardizing over the other treatment arms. We prespecified that all models would include interaction terms between treatment dimensions, and so all estimates allow for the possibility of interactions between treatment arms.

For blood pressure analyses (statistical analysis in Supplement 2; eTable 24, model outpout in Supplement 3), we fit models with indicators for each treatment arm and interactions between the 3 dimensions. To help increase precision, we included the randomization stratification variables, a baseline measure of the outcome (eg, SBP for SBP analyses), and indicators of health insurance and health care system. We modeled time relative to baseline flexibly using splines with knots at 6 and 12 months after baseline, which allowed the relationship between treatment arm and time to vary at key study time points.[40-42] We fit linear models with generalized least squares, with a first-order continuous autoregressive correlation structure within subject because measurements closer together in time may be more similar than measurements further apart in time.[43] This longitudinal modeling approach is robust to missing data within individuals under the equivalent of a missing at random assumption,[44] so we did not implement an additional missing data strategy for these analyses. After fitting the models, we used least-squares means (also called "marginal effects") to create estimates at key study time points (6 [primary], 12 [secondary], and 18 [secondary] months), and contrasted them.[45,46] The purpose of the 18-month time point was to examine the durability of intervention effects.

For analyses of the participant-reported outcomes, we used a similar approach, except we fit models using generalized estimating equations, which can accommodate binary outcomes.[43,47] To account for missing data in these analyses, we used multiple imputation with chained equations, creating 100 imputed datasets, conducting analyses in each of them, and combining estimates using Rubin rules.[48-50]

We considered the SBP outcome for the food dimension at the 6-month time point to be the primary outcome and time point for type I error purposes, and report a *P* value for this analysis. We used a statistical significance threshold of <.05 with a 2-sided test. For other analyses, we report 95% CIs. Because we did not conduct global comparisons (eg, at least 1 of the more intensive treatment conditions is superior to the least intensive treatment condition), we did not implement adjustments for family-wise error.[51-53] Analyses were conducted in SAS statistical software (version 9.4; SAS Institute, Inc) and R statistical software (version 4.3.1; R Foundation). Statistical code for all models was developed with the analysts masked to treatment assignments, and data were only unmasked after the analytic code was finalized.

## Results

Overall, 2792 individuals were assessed, 525 enrolled, and 458 were randomized after completing baseline assessments; 67 dropped out prior to randomization (**Figure 1**; eTable 2 in Supplement 1). The 458 randomized participants formed the intention-to-treat cohort that was analyzed.

The mean (SD) age of those randomized was 49.7 (10.7) years and 345 (75.3%) were female individuals. Fewer than 11 participants identified as American Indian/Alaska Native; 11 (2.4%) identified as Asian, 237 (51.7%) identified as Black, 20 (4.4%) identified with multiple races, fewer than 11 participants identified as Native Hawaiian/Pacific Islander, 165 (36.0%) identified as White, and 22 (4.8%) did not report a racial identity. Twenty two participants (4.8%) identified as Hispanic ethnicity. The mean (SD) SBP in the year prior to randomization was 138.2 (11.9) mm Hg and mean (SD) DBP was 84.8 (9.1) mm Hg (**Table 1**; eTables 3-7 in Supplement 2). Participants came from 2 clinical networks (421 from the UNC health system, 37 from the Duke health system) and data were observed across a total of 364 clinical sites within those 2 networks. In this low-risk study, participants did not report any adverse events.

For the food dimension, participants redeemed a median 91% (25th percentile: 65%, 75th percentile: 100%) of the available food subsidy funds, and participants received a median 100% (25th percentile: 96%, 75th percentile: 100%) of the available food boxes. For the lifestyle dimension, participants attended a median 17% (25th percentile: 8%, 75th percentile: 50%) of available sessions (eTable 8 in Supplement 2).

For the food dimension, the mean SBP and DBP for the food subsidy arm at 6 months was SBP: 132.8 (95% CI, 131.6-134.0) mm Hg and DBP: 80.5 (95% CI, 79.8-81.2) mm Hg. For the food box at 6 months, mean SBP was 135.3 (95% CI, 134.1-136.4) mm Hg and mean DBP was 82.1 (95% CI, 81.4-82.8) mm Hg (**Figure 2**; **Table 2**; eTable 9 in Supplement 2). The food box arm had significantly higher SBP (difference in means, 2.5 mm Hg; 95% CI, 0.9-4.1; *P* = .003) than the food subsidy arm. DBP was also higher (difference in means, 1.6 mm Hg; 95% CI, 0.6-2.5). Results were similar at 18 months, but the difference between arms was smaller at 12 months. There were no meaningful differences between the food subsidy and food box with regard to food security (**Figure 3**), diet self-efficacy, diet perception, diet quality, and health-related quality of life (eTables 10-11 in Supplement 2).

For the lifestyle dimension, study outcomes were similar between the groups that were and were not offered lifestyle counseling at all time points. For the duration dimension, study outcomes were similar between the groups that received 12 and 6 months of intervention at all time points. Results by 2-dimension and 3-dimension combinations of study arms are presented in eTables 12 to 23 in Supplement 2.

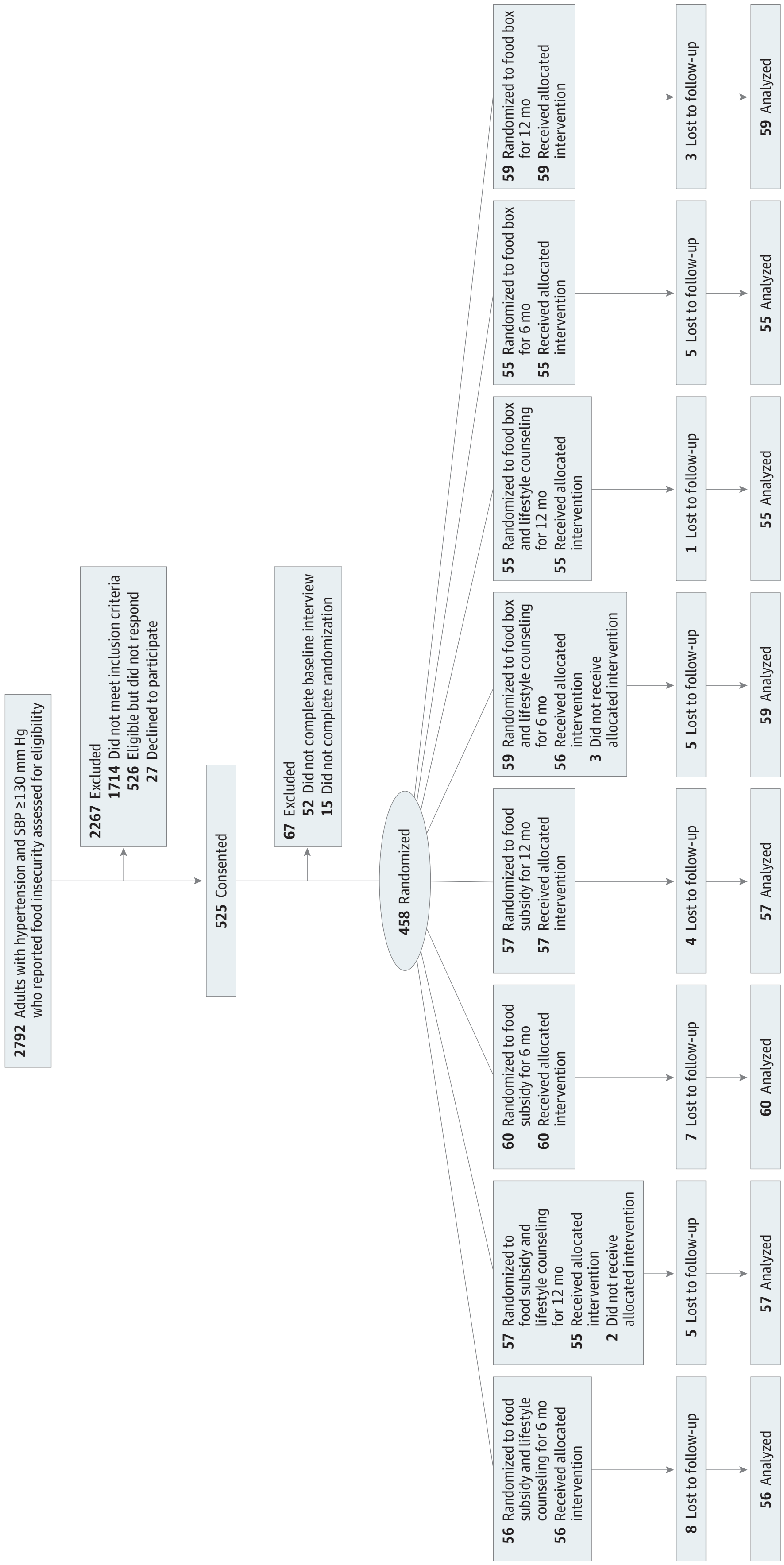
## Discussion

In this pragmatic randomized comparative effectiveness trial, we found that a food subsidy led to lower blood pressure than a home-delivered food box. We did not find that offering lifestyle counseling improved outcomes relative to not offering it, though actual use of counseling was low, which makes results for this dimension somewhat inconclusive. We did not find that providing 12 months of food insecurity intervention led to lower blood pressure than providing 6 months. Of note, all study arms saw an average decrease in blood pressure and food insecurity, which could represent a common effect of the food insecurity interventions or regression to the mean.

Why food subsidies led to lower blood pressures than food boxes despite similar changes in food insecurity is an interesting question. Prior theoretical work suggests 2 possible explanations. First, food security is likely necessary but insufficient for improving diet.[54] That is, although it is difficult to improve diet when food insecure, increasing food security does not inherently improve diet—the key pathway to lower blood pressure in this case.[55] Second, although all food insecurity interventions address food insecurity—that is not all they do. Different food insecurity interventions may have different impacts in other areas relevant for blood pressure. For instance, the greater flexibility that food subsidies provided may have allowed participants to consume healthy diets more in accord with their preferences, even though both interventions made healthy food more available.

This study extends prior literature on food insecurity and high blood pressure. Prior studies have found that food insecurity is associated with worse blood pressure control and adverse cardiovascular outcomes for which increased blood pressure is a key mechanism.[2-7] However, how best to address food insecurity to improve blood pressure was not clear. This study

**Figure 1. CONSORT Diagram**




CONSORT diagram presenting flow of participants through the study. Loss to follow-up was defined as providing no postrandomization data for analysis. Because of the analytic strategies used, participants who were lost to follow-up were still included in analyses. eTable 2 in Supplement 2 reports survey completion by group across study time points.

Table 1. Demographic Characteristics of Study Sample

| Characteristic | Overall (n = 458) | Dimension, No. (%) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Food | | Lifestyle | | Length | |
| | | Food subsidy (n = 230) | Food box (n = 228) | Not offered counseling (n = 231) | Offered counseling (n = 227) | 6 mo (n = 230) | 12 mo (n = 228) |
| Age at randomization, mean (SD), y | 49.7 (10.7) | 48.2 (11.8) | 51.2 (9.2) | 49.6 (10.5) | 49.8 (11.0) | 50.3 (10.7) | 49.0 (10.7) |
| Sex | | | | | | | |
| Female | 345 (75.3) | 172 (74.8) | 173 (75.9) | 173 (74.9) | 172 (75.8) | 173 (75.2) | 172 (75.4) |
| Male | 112 (24.5) | 57 (24.8) | 55 (24.1) | 57 (24.7) | 55 (24.2) | 56 (24.3) | 56 (24.6) |
| Not reported | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] |
| Race | | | | | | | |
| American Indian/Alaska Native | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] |
| Asian | 11 (2.4) | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] |
| Black | 237 (51.7) | 118 (51.3) | 119 (52.2) | 117 (50.6) | 120 (52.9) | 123 (53.5) | 114 (50.0) |
| Multiple races | 20 (4.4) | 12 (5.2) | 8 (3.5) | 13 (5.6) | 7 (3.1) | 10 (4.3) | 10 (4.4) |
| Native Hawaiian/Pacific Islander | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] |
| Not reported | 22 (4.8) | 12 (5.2) | 10 (4.4) | 9 (3.9) | 13 (5.7) | 8 (3.5) | 14 (6.1) |
| White | 165 (36.0) | 81 (35.2) | 84 (36.8) | 83 (35.9) | 82 (36.1) | 83 (36.1) | 82 (36.0) |
| Ethnicity | | | | | | | |
| Hispanic | 22 (4.8) | 12 (5.2) | 10 (4.4) | 10 (4.3) | 12 (5.3) | 11 (4.8) | 11 (4.8) |
| Not Hispanic or Latino | 435 (95.0) | 217 (94.3) | 218 (95.6) | 221 (95.7) | 214 (94.3) | 218 (94.8) | 217 (95.2) |
| Not reported | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] | NA[a] |
| Annual household income, mean (SD), $ | 42 473 (30 477) | 42 990 (31 708) | 41 965 (29 280) | 42 223 (29 034) | 42 729 (31 956) | 40 819 (28 808) | 44 141 (32 053) |
| UNC health system | 421 (91.9) | 212 (92.2) | 209 (91.7) | 214 (92.6) | 207 (91.2) | 215 (93.5) | 206 (90.4) |
| Commercial health insurance | 414 (90.4) | 208 (90.4) | 206 (90.4) | 213 (92.2) | 201 (88.5) | 205 (89.1) | 209 (91.7) |
| Received SNAP in last year | 139 (30.5) | 73 (32.0) | 66 (28.9) | 67 (29.3) | 72 (31.7) | 65 (28.3) | 74 (32.7) |
| Receiving SNAP at time of enrollment | 101 (22.1) | 57 (25.0) | 44 (19.3) | 43 (18.8) | 58 (25.6) | 49 (21.3) | 52 (23.0) |
| Monthly SNAP benefit, mean (SD), $ | 255.83 (168.73) | 261.41 (180.36) | 249.83 (156.42) | 259.30 (176.71) | 252.61 (162.17) | 257.72 (180.34) | 254.18 (159.11) |
| Preintervention systolic blood pressure, mean (SD), mm Hg | 138.19 (11.88) | 138.42 (12.41) | 137.96 (11.35) | 137.90 (11.65) | 138.49 (12.14) | 138.13 (11.39) | 138.25 (12.38) |
| Preintervention diastolic blood pressure, mean (SD), mm Hg | 84.75 (9.11) | 84.87 (9.09) | 84.62 (9.15) | 85.05 (9.53) | 84.43 (8.67) | 84.85 (8.82) | 84.64 (9.42) |
| Food insecure[b] | 361 (79.2) | 181 (79.4) | 180 (78.9) | 180 (78.6) | 181 (79.7) | 182 (79.1) | 179 (79.2) |
| Food security score, mean (SD) | 4.91 (2.73) | 4.98 (2.75) | 4.83 (2.71) | 4.86 (2.75) | 4.95 (2.71) | 4.99 (2.77) | 4.82 (2.68) |
| Diet self-efficacy score, mean (SD)[c] | 23.54 (3.01) | 23.57 (3.08) | 23.51 (2.94) | 23.76 (2.88) | 23.32 (3.13) | 23.48 (3.03) | 23.60 (3.00) |
| Diet perception score, mean (SD)[d] | 6.12 (1.60) | 6.16 (1.61) | 6.08 (1.59) | 6.07 (1.57) | 6.17 (1.63) | 6.07 (1.58) | 6.17 (1.62) |
| Diet quality score, mean (SD)[e] | 5.74 (1.92) | 5.70 (1.99) | 5.78 (1.85) | 5.86 (1.93) | 5.62 (1.90) | 5.78 (1.93) | 5.70 (1.92) |
| Put off buying food to afford medications | 204 (44.7) | 98 (43.0) | 106 (46.5) | 97 (42.4) | 107 (47.1) | 107 (46.5) | 97 (42.9) |
| Put off medications to afford food | 190 (41.7) | 88 (38.6) | 102 (44.7) | 92 (40.2) | 98 (43.2) | 100 (43.5) | 90 (39.8) |
| PROPr HRQoL score, mean (SD)[f] | 0.37 (0.18) | 0.37 (0.19) | 0.37 (0.18) | 0.39 (0.18) | 0.35 (0.19) | 0.36 (0.18) | 0.38 (0.19) |

Abbreviations: NA, not applicable; PROPr HRQoL, PROMIS-Preference Health Related Quality of Life instrument; SNAP, Supplemental Nutrition Assistance Program; UNC, University of North Carolina.

[a] Actual count is fewer than 11 and has been masked for low cell sizes.

[b] All study participants screened positive for food insecurity on the 2-item hunger vital sign prior to enrollment. Results for this row report food security status as assessed at study baseline with a more detailed food insecurity instrument.

[c] Diet self-efficacy scores range from 7 to 28 with higher scores indicating greater self-efficacy.

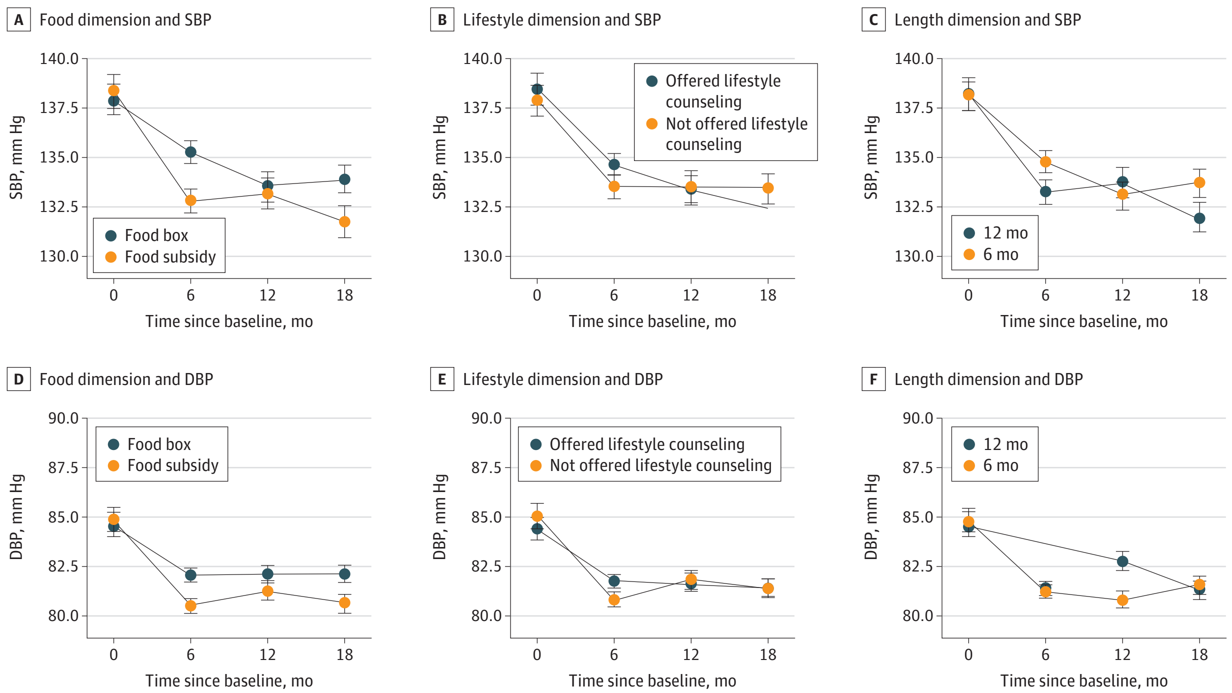
[d] Diet perception scores range from 3 to 12 with lower scores indicating that a greater match between a respondent's perception of a healthy diet and nutritional recommendations.

[e] Diet quality scores range from 0 to 12 with higher scores indicating greater diet quality.

[f] PROPr HRQoL scores range from 0.0 to 1.0 with 1.0 indicating perfect health. The overall PROPr score is created from subscores in 7 different domains: cognitive, depressive symptoms, fatigue, pain interference, sleep, ability to participate in social roles, and physical health.

adds to that literature by suggesting that a food subsidy can lower blood pressure, compared with a food box. At the population level, differences in systolic blood pressure of the magnitude seen in this study have been associated with long-term benefits.[56] For example, Hardy et al[56] demonstrated that a 2-mm Hg decrease in SBP would be expected to reduce the rate of coronary heart disease by 27 per 100 000 person-years among non-Hispanic Black individuals and by 18 per 100 000 person-years among non-Hispanic White individuals. Had there been an arm with no food insecurity intervention, there may have been a greater SBP differential, as prior studies have found,[57] but leaving food insecurity unad-

Figure 2. Blood Pressure Results




The mean systolic and diastolic blood pressure, with standard error bars, by treatment at baseline, 6-month, 12-month, and 18-month time points. Results are from marginal models with an autoregressive correlation structure for repeated observations within individuals and including the following covariates as fixed effects: food dimension assignment, lifestyle dimension assignment, duration dimension assignment, all 2-way and 3-way interaction terms for treatment assignments, time, sex indicator, race and ethnicity indicator, high baseline blood pressure indicator, clinical network indicator, insurance type indicator, and mean blood pressure (systolic or diastolic, depending on the model's outcome) in the baseline period.

Table 2. Mean Blood Pressure and Difference in Means Between Groups[a]

| Dimension | Time point: 6 mo | | | 12 mo | | | 18 mo | | |
|---|---|---|---|---|---|---|---|---|---|
| Food | Food subsidy | Food box | Difference (95% CI) | Food subsidy | Food box | Difference (95% CI) | Food subsidy | Food box | Difference (95% CI) |
| SBP | 132.8 | 135.3 | 2.5 (0.9 to 4.1) | 133.2 | 133.5 | 0.3 (−1.8 to 2.5) | 131.7 | 133.9 | 2.2 (0.1 to 4.3) |
| DBP | 80.5 | 82.1 | 1.6 (0.6 to 2.5) | 81.3 | 82.1 | 0.8 (−0.5 to 2.1) | 80.7 | 82.1 | 1.5 (0.3 to 2.7) |
| Lifestyle | Not offered counseling | Offered counseling | Difference (95% CI) | Not offered counseling | Offered counseling | Difference (95% CI) | Not offered counseling | Offered counseling | Difference (95% CI) |
| SBP | 133.5 | 134.7 | 1.2 (−0.5 to 2.8) | 133.5 | 133.3 | −0.2 (−2.3 to 2.0) | 133.4 | 132.4 | −1.0 (−3.1 to 1.0) |
| DBP | 80.9 | 81.8 | 0.9 (0.0 to 1.9) | 81.9 | 81.7 | −0.1 (−1.4 to 1.1) | 81.4 | 81.5 | 0.1 (−1.2 to 1.3) |
| Duration | 6 mo | 12 mo | Difference (95% CI) | 6 mo | 12 mo | Difference (95% CI) | 6 mo | 12 mo | Difference (95% CI) |
| SBP | 134.8 | 133.2 | −1.6 (−3.2 to 0.1) | 133.1 | 133.7 | 0.6 (−1.5 to 2.8) | 133.7 | 132.0 | −1.7 (−3.8 to 0.3) |
| DBP | 81.3 | 81.4 | 0.1 (−0.8 to 1.1) | 80.9 | 82.8 | 1.9 (0.7 to 3.2) | 81.6 | 81.3 | −0.3 (−1.5 to 1.0) |

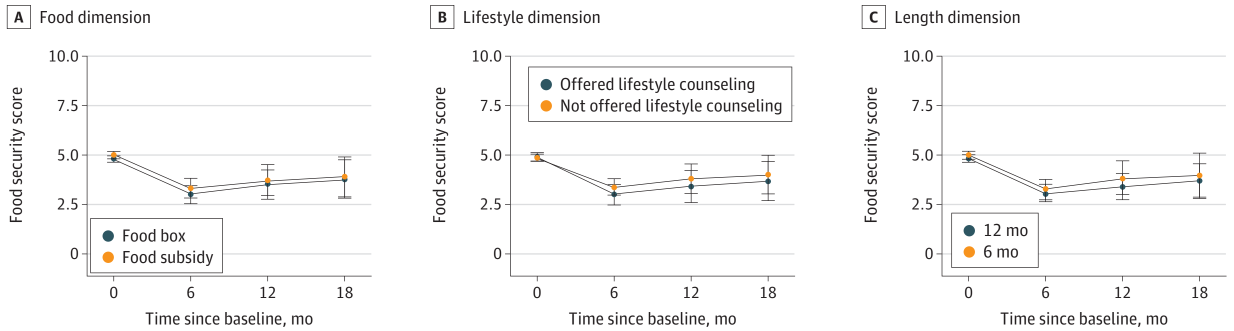
Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

[a] Blood pressure values, reported in mm Hg, represent least squares mean estimates from marginal models with an autoregressive correlation structure for repeated observations within individuals and including the following covariates as fixed effects: food dimension assignment, lifestyle dimension assignment, duration dimension assignment, all 2-way and 3-way interaction terms for treatment assignments, time, sex indicator, race and ethnicity indicator, high baseline blood pressure indicator, clinical network indicator, insurance type indicator, and mean blood pressure (systolic or diastolic, depending on the model's outcome) in the baseline period.

dressed would have exposed participants to adverse consequences given the clear connection between food insecurity and other poor health outcomes.[2,5]

One unexpected finding was that the difference in blood pressure between the food subsidy and food box arms at 12 months was numerically different from the estimates at 6 months. The reasons for this are unclear. The study did occur during a period of high food price inflation, and so the real value of the subsidy may have eroded over time. Alternatively because the 95% CI for the 12-month period did con-

Figure 3. Food Insecurity Results




The mean food security score, with standard error bars, by treatment at baseline, 6-month, 12-month, and 18-month time points. Results are from generalized estimating equation models with an autoregressive correlation structure for repeated observations within individuals and including the following covariates as fixed effects: food dimension assignment, lifestyle dimension assignment, duration dimension assignment, all 2-way and 3-way interaction terms for treatment assignments, time, sex indicator, race and ethnicity indicator, high baseline blood pressure indicator, clinical network indicator, insurance type indicator, and baseline food security score.

tain the point estimates for the other time points, it may simply have been chance variation.

This study has several implications, although we caution that these are presently speculative and future research should investigate these ideas more fully. First, low adherence is a likely explanation for the lifestyle counseling intervention's lack of benefit, especially since similar programs have been proven effective in studies that specifically recruited people interested in lifestyle intervention.[16-19,25-27] Participants in this food insecurity–focused study may have been, on average, less interested in lifestyle intervention than those recruited specifically because of interest in lifestyle intervention. Second, the lack of difference between the 12- and 6-month arms may be related to the episodic nature of food insecurity; approximately 50% of individuals who experience food insecurity in 1 year do not experience it the next year.[58] As such, 6 months of support during a "rough patch" may be sufficient to mitigate some consequences of food insecurity while the individual works to change their circumstances. Of course, the finding that there was no difference on average does not necessarily mean that no individual would have done better with longer vs shorter intervention. Thus, in implementing a food insecurity intervention, it may make sense to reassess individual needs at 6 months to evaluate whether an individual is likely to benefit from further support rather than ending support at 6 months for all individuals.

### Limitations

The findings of this randomized comparative effectiveness trial should be interpreted considering several limitations. First, though the study was adequately powered to test hypotheses along 1 dimension of intervention, it was underpowered to detect interactions between multiple dimensions. However, because our analytic approach allowed for interactions, even if not statistically significant, we do not believe that this affects interpretation of the results that compare single dimensions. Second, this was a pragmatic trial with a sample that faced many barriers to participating in research. The lack of engagement with lifestyle counseling likely reflects competing demands that can limit engagement in lifestyle interventions. This is an important finding in its own right, and one that should be considered when implementing interventions outside of a research context. Prior studies using this intervention that involved individuals who enrolled in research with the explicit intent to improve their diet achieved a higher level of adherence and improved health outcomes.[16-19,25-27] Though there was loss to follow-up, it was within the level of attrition we expected, and we used an appropriate missing data strategy to help mitigate its impact on analyses.

## Conclusions

This pragmatic comparative effectiveness trial of food insecurity interventions to improve blood pressure found that a food subsidy led to lower blood pressure than a food box. There was little difference between being offered and not being offered lifestyle counseling or between having 6 vs 12 months of intervention. Both food insecurity and hypertension are important threats to health. This study suggests how these issues might be jointly addressed to improve population health.

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*Supervision:* Berkowitz, Wertman, Pignone, Qaqish, Turner, Lumpkin, DeWalt.

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Editor's Note

HEALTH EQUITY

# Simple Solutions for Complex Problems

Raegan W. Durant, MD, MPH

Related article page 1423

**Food insecurity remains** a consistent challenge to many individuals, particularly those in low-income households.[1] In addition to directly compromising nutrition, food insecurity can also portend poor outcomes for chronic diseases such as hypertension and diabetes, among others.[1] To mitigate the deleterious effects of food insecurity, multiple intervention approaches, ranging from patient education to actual delivery of meals, have been previously tested.

In this issue of *JAMA Internal Medicine*, an article by Berkowitz et al[2] focuses on a factorial randomized clinical trial testing a monthly $40 food voucher vs monthly $115 home-delivered meals vs community health worker–delivered lifestyle support, with each of those intervention durations being tested for 6 months vs 12 months. The authors found that participants in the food voucher arm had moderately lower systolic blood pressure compared to those in the home-delivered food box arm at 6 months (132.8 vs 135.3 mm Hg; difference, −2.5 mm Hg; 95% CI, −4.1 to −0.9; $P = .003$). While this blood pressure difference seems moderate, at a population level, a reduction of this magnitude can substantially reduce the risk of cardiovascular disease, stroke, and mortality across a population.[3] Neither the community health worker support intervention nor varying the duration of any of the 3 interventions made a difference in any of the outcomes. Intermediate food insecurity outcomes were also similar across multiple intervention arms.

The findings of Berkowitz et al[2] exemplify that more simple interventions for social determinants can achieve better or equivalent results than more complex solutions. In this context, population health managers or others overseeing care delivery may be prompted to pursue a straightforward cash subsidy compared to the more logistically challenging home delivery of prepared meals. In many instances, the absence of supporting infrastructure (eg, food delivery vehicles), regulatory constraints of spending related to health care, or sustainability concerns may foreclose the possibility of more complex approaches. Simplicity may be a particularly important value in efforts to address multifaceted social determinants of health such as food insecurity, housing insecurity, and neighborhood and built environment.

Of note, the similar changes in food insecurity, across both the food voucher and the home-delivered meals arms, also suggest that alternative mechanisms, aside from improving food insecurity, accounted for the difference in blood pressure. The authors suggest that the food voucher may have provided recipients with greater flexibility to purchase healthy food that is more aligned with their own dietary preferences. This flexibility may contribute to greater patient activation for individuals engaging in their own health care (eg, using a food voucher to select their own healthy foods). The active task of purchasing one's own food may also motivate broader lifestyle change for individuals (such as increasing activity, getting out and about, interactions with others in stores and in the community) compared to the more passive receipt of a prepared meal at home. Facilitating individuals' abilities to play active roles in making lifestyle changes may also be a benefit of simpler focused interventions. Broader, downstream multifaceted approaches may inadvertently deprive individuals of opportunities to make changes for themselves. Conversely, more focused upstream interventions may both improve outcomes and leave room for individuals to participate more actively in modifying their health behaviors.

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