HIGHLIGHTS:

- **PROGRAM:** Hypertension Control Program in Argentina (HCPIA), a multicomponent program to improve blood pressure control among low-income patients with hypertension. The program includes a community health worker-led, home-based component; a physician training component; and a text messaging component.

- **EVALUATION METHOD:** A well-conducted randomized controlled trial (RCT) in which 18 community health care centers in Argentina were randomly assigned to a treatment versus control group.

- **KEY FINDINGS:** 18 months after random assignment, 73% of HCPIA patients had controlled hypertension (i.e., a blood pressure reading under 140/90 mm Hg) versus 52% of control group patients. This difference was statistically significant.

- **OTHER:** The program was evaluated in a middle-income country (Argentina), with a sample of low-income, uninsured patients who receive free medications and health care as part of a national public system. Whether the results would generalize to the United States or other settings is yet unknown; replication trials in such settings are needed to find out.

I. **Evidence rating:**  **SUGGESTIVE TIER**

The standard for Suggestive Tier is:

*Programs that have been evaluated in one or more well-conducted RCTs (or studies that closely approximate random assignment) and found to produce sizable positive effects, but whose evidence is limited by only short-term follow-up, effects that fall short of statistical significance, or other factors. Such evidence suggests the program may be an especially strong candidate for further research, but does not yet provide confidence that the program would produce important effects if implemented in new settings.*
II. Description of the Program:

The Hypertension Control Program in Argentina (HCPIA) is an 18-month multicomponent program to improve blood pressure control among low-income, uninsured patients with hypertension. The program includes (i) a community health worker-led, home-based component, in which health workers coach patients on lifestyle modifications to reduce blood pressure, home blood pressure monitoring, and medication adherence during monthly or bi-monthly home visits; (ii) physician training and certification in blood pressure management; and (iii) weekly, personalized text messages sent to patients to encourage medication adherence and health behavioral change. The average cost of the program is approximately $115 per patient.

III. Evidence of Effectiveness:

Overview of Study Design:

The study sample was composed of 18 primary health care centers located in poor urban areas of Argentina, that were affiliated with a national public system that provides free medications and health care to low-income, uninsured patients. The centers were randomly assigned either to a treatment group that delivered HCPIA or to a control group that did not. The treatment and control centers then used identical, objective procedures to recruit patients into the study. Specifically, the centers sought to enroll all patients who had uncontrolled high blood pressure (i.e., systolic blood pressure above 140 and/or diastolic blood pressure above 90 measured on at least two separate screenings); were 21 years or older; had a spouse with or without hypertension or adult family members with hypertension living in the same household who were willing to participate in the study; and had consented to study participation at the time of eligibility screening. These procedures resulted in a sample of 743 patients with hypertension at the treatment centers and 689 patients with hypertension at the control centers. Patients’ blood pressure was measured by nurses who were not involved in the delivery of the program at baseline, 6, 12, and 18 months after patient enrollment in the study.

Key Findings:

Over the 18-month follow-up period, patients in the HCPIA group experienced significantly greater reductions in systolic blood pressure than patients in the control group (the average difference was 5.8 mm Hg) and significantly greater reductions in diastolic blood pressure (the average difference was 4.6 mm Hg). In addition, at the 18-month follow-up, a much higher proportion of the HCPIA

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1 Control group clinics did not receive any of the components of the program. Their patients were encouraged to visit a clinic every month after initiating blood pressure medication, or every 3-6 months if they had controlled blood pressure.

2 The study sample for the primary analysis only included family members with uncontrolled high blood pressure.

3 The reductions in systolic and diastolic blood pressure were the study’s two primary, pre-specified outcome measures.
group had controlled blood pressure (i.e., below 140/90 mm Hg\(^4\)) than the control group -- 73% versus 52%, respectively. The study reported that all of the above effects were highly statistically significant (p<0.01); however, as noted below, the study’s analysis methods may have led to an overstatement of the statistical significance.

**Discussion of Study Quality:**

Based on our review, we believe this was a well-conducted RCT. Patients were recruited into the study sample using identical, objective procedures at the HCPIA and control centers. Patients in the two groups were largely similar in their pre-program characteristics (e.g., demographics and medical history). The study had low sample attrition; at the 18-month follow-up, outcome data were obtained for 95% of patients in the study’s primary analysis sample. The study appropriately obtained and analyzed outcomes for all members of the HCPIA group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis). The study measured an outcome – incidence of high blood pressure – that has been shown in numerous studies to be a strong causal factor in cardiovascular diseases, such as heart attack and stroke, and is therefore of high policy importance.

The study had a few limitations. First, while the study appropriately sought to adjust for the fact that health care centers, rather than individual patients, were randomly assigned, it did so using an analysis method – generalized estimating equations (GEE) – that is only appropriate for RCTs that randomize 40 or more centers (Murray et. al., 2004). Since this study randomized only 18 centers, the use of GEE likely resulted in an overstatement of the findings’ statistical significance. Second, the study only measured outcomes over the 18-month program period, so it is not yet known whether the effects endure after patients complete the program. Third, the study was conducted in a middle-income country (Argentina) with a sample of low-income, uninsured patients who receive free medications and health care as part of a national public system. Whether the results would generalize to the United States or other settings is yet unknown; replication trials in such settings are needed to find out.

**IV. References:**


\(^4\) This definition of controlled hypertension was pre-specified in the study’s protocol.