

Effectiveness of a Tailored Behavioral Intervention to Improve Hypertension Control

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The study by Friedberg et al, “Effectiveness of a tailored behavioral intervention to improve hypertension control,” addresses a vital and well-recognized health issue.¹ Specifically, the burden of uncontrolled hypertension is substantial, despite a near doubling in hypertension control from 27% in 1988 to 1994 to 53% in 2009 to 2010.² Yet in 2010, hypertension-related disease contributed to >10 million years of life lost from ischemic heart disease, stroke, hypertensive heart disease, chronic kidney disease, other cardiovascular and circulatory diseases.³ Treatment and control of hypertension reduce fatal and nonfatal cardiovascular events, especially when combined with effective hypercholesterolemia management.⁴ In addition to the health toll, the economic burden of cardiovascular diseases in 2010 was ≈\$445 billion with a projected increase to roughly \$1.1 trillion in 2030.⁵ A disproportionate share of the increase is likely to occur among individuals ≥65 years.

Million Hearts estimated that 1 000 000 cardiovascular events could be prevented in the United States in a 5-year period from 2013 to 2017, with hypertension control a featured component of the success plan.⁶ Effective, affordable, and highly scalable interventions that can significantly improve hypertension control are important.

In the study by Friedberg et al,¹ the effects of 2 different monthly telephone-based interventions for 6 months were compared with usual care (UC). They found that a monthly 30-minute telephonic intervention delivered by well-trained psychologists, and which accounted for the patients stage of readiness to change (stage-based intervention [SBI]), improved hypertension control compared with UC (64.6% versus 45.8%; $P=0.001$). In contrast, a monthly telephonic health education intervention (HEI) using the same well-trained individuals, which was not adapted to the patient’s stage of readiness to change, did not significantly improve hypertension compared with UC (54.3% versus 45.8%; $P=0.108$). Both interventions aimed to increase physical activity, improve nutrition, and enhance adherence. SBI improved nutrition alone, whereas HEI did not significantly improve any of the 3 measures.

The authors provide context for their findings in the Perspectives section: “Healthcare is moving toward providing patient-centered care through the medical home model, with counseling regarding diet, physical activity, and medication adherence being provided by phone by a nonphysician. Moreover, because this trial did not involve in-person contact, it has the potential to increase scalability and reduce costs. In addition, The methods and findings from this study could be used to develop a toolkit that would allow a hospital or clinic to deliver the SBI by different disciplines.”¹

This commentary recognizes the important positive findings and attempts to provide contextual perspective about broader dissemination of SBI specifically and interventions to engage patients in self-care more broadly.

Intention-to-Treat Versus On-Treatment Analysis

In general, clinical studies are designed, powered, and analyzed using the intention-to-treat rather than on-treatment principle. Table 1 provides the on-treatment analysis and the originally planned intention-to-treat analysis⁷ with 2 different assumptions: all dropouts and lost to follow-up were (i) uncontrolled or (ii) had the same control as UC at 6 months. Not unexpectedly, hypertension control rates with SBI (and HEI) decline relative to UC when dropouts are included.

Improve the SBI Intervention and Measurement Tools

The original sample size estimate assumed 69% control at 6 months with an intention-to-treat design versus the projected intention-to-treat control rate of 57% to 62% using 2 different assumptions (Table 1). The discrepancy between projected and actual improvements in hypertension control suggests that there may be opportunities to optimize SBI to attain more of the anticipated benefit. Specifically, SBI improved nutritional congruence with a Dietary Approaches to Stop Hypertension (DASH)-type eating plan, but did not alter physical activity or medication adherence. Alternatively, the instruments used to assess physical activity and medication adherence may not be adequate for reliably detecting small but clinically important changes.

Additional Data

Additional data would be helpful in supporting broader dissemination of telephonic counseling-based interventions as summarized in Table 2. For example, the study was conducted on military veterans in Veterans Administration clinics. The overwhelming majority of patients were men with a mean age of ≈66 years. On a positive note, the men were diverse from a race/ethnicity perspective with fewer than half white and more than half black and Hispanic. Moreover, patients in the age

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Table 1. Hypertension Control at Baseline and After 6 Months in the 3 Study Groups

Variable (Group)	Stage-Matched	Usual Care	Health Education
Participants, N	176 _{int} /156 _{ot}	177 _{int} /159 _{ot}	180 _{int} /170 _{ot}
BP control baseline, %	42.6	44.6	40.6
BP control 6 months, %			
On-treatment (reported)	64.6	45.8	54.3
ITT–0%	57.4	41.2	51.1
ITT–UC%	62.5	45.8	53.9

ITT–0%, BP control assuming all participants who dropped and were lost to follow-up had uncontrolled hypertension. ITT–UC%, BP control assuming all participants who dropped out and were lost to follow-up had hypertension control similar to UC on-treatment at 6 months. BP indicates blood pressure; ITT, intention-to-treat; and OT, on treatment.

group studied are projected to contribute most to the increased cost for cardiovascular care by 2030.⁵

Hypertension Control Versus Reduction in Blood Pressure as the Main Focus

The benefit of an intervention to lower blood pressure (BP) on cardiovascular outcomes is likely related more to reduction in BP than in achieving a somewhat arbitrary control goal, for example, <140/<90.⁸ Although the study was not powered to compare SBI and HEI, SBI lowered systolic BP a mean of 4.7 mmHg and HEI, 5.4 mmHg.¹ Moreover, nonsignificant group differences may have favored BP control in SBI compared with HEI. Prevalent diabetes mellitus was 40.3% (N=71) in SBI versus 46.7% (N=84, if total N=180) in the HEI and 45.2% in UC (N=80, assuming total N=177 [Figure

Table 2. Additional Information That Would be Helpful in Supporting Widespread Dissemination of a Structured Behavioral Intervention or Health Education for Improving BP Control

1	Confirmatory dissemination and implementation studies in a diverse group of clinics and patients representative of primary care that confirm initial findings
2	Determine optimal frequency (weekly, biweekly, monthly, bimonthly) and duration in months of SBI and HEI
3	Determine whether BP responses are maintained longer term and whether maintenance intervention is required, and, if so, the frequency of the maintenance intervention
4	Determine which behaviors are most affected by SBI and HEI: lifestyle (eg, nutrition, physical activity) and medication adherence
5	Identify baseline patient characteristics that predict response or lack thereof to SBI, HEI
6	Patient and staff preferences for in-office vs telephonic intervention in primary care sites with and without a patient-centered medical home
7	Active comparisons of SBI, HEI (counselor-based) vs lower-cost technology-based interventions, eg, (i) interactive voice-response; (ii) application(app)-based; (iii) blood pressure self-monitoring with facilitated relay and clinical support to improve adherence behaviors and blood pressure control
8	Cost effectiveness of office-based vs telephonic intervention

BP indicates blood pressure; HEI, health education intervention; and SBI, stage-based intervention.

1]). Thus, fewer individuals in SBI required a BP <130/<80 than in HEI and UC groups to attain control. Second, the SD of systolic BP seemed larger in HEI than SBI (17.8 versus 11.8 mmHg) and mean systolic BP was slightly higher (137.2 versus 136.0). These data suggest that more individuals in HEI were farther from goal than in SBI, which could also have contributed to a lesser control with HEI, despite a slightly greater mean reduction of systolic BP.

Comparative Effectiveness Research

The reported study was not powered to compare SBI and HEI. Comparative effectiveness research is preferred in deciding which interventions to implement clinically. Moreover, in studies to address patient preferences, patient-centered care, and patient-centered medical home, it is important to include patients and their healthcare team in the design, conduct, and interpretation of the research, as well as the dissemination and implementation of findings.

Guidelines in Effect When a Study Is Designed and Conducted Versus When a Study Is Analyzed and Published

In this case, the BP goal for patients with diabetes mellitus was raised from <130/<80 mmHg at the time of study design and conduct to <140/<90 mmHg at the time of publication. Moreover, there is a controversy over whether the current goal BP for adults ≥60 years without diabetes mellitus or chronic kidney disease should be <150/<90 versus <140/<90 mmHg. When designing future studies, it may be worthwhile to prespecify a secondary analysis that conforms to criteria for patient inclusion and treatment goals on the conclusion of the investigation. Prespecified analytic criterion should include adjustment for nonsignificant differences, which are likely to affect clinical implementation, for example, group differences in age, race/ethnicity, sex, and comorbid health conditions.

Cost Effectiveness

The authors suggest telephone counseling is more cost-effective than clinic counseling without data. In a previous pilot study, 6 months of telephone (30 minutes each session) for 10 patients cost \$316 versus \$410 for clinic counseling (40 minutes each session) for 10 patients with both at an interval of every 3 weeks (\$9/hour for a social worker).⁹ Clinic counseling increased diastolic BP control from 1 to 5 of 10 patients, whereas the telephone counseling increased control from 5 to 8 in 10 patients. The cost per patient controlled was \$102 for office-based and \$105 for telephone-based counseling.

Future Improvement in Hypertension Control

Friedberg et al noted that much of the improvement in hypertension control likely reflects changes in healthcare delivery rather than patient engagement. In fact, patients with hypertension have become more obese, and their diets have either not improved or improved minimally during time. Better hypertension control seems to largely reflect greater patient awareness of hypertension and a greater proportion on anti-hypertensive pharmacotherapy. Among patients on treatment,

a progressively higher proportion is receiving ≥ 3 different antihypertensive medication classes.¹⁰ As a healthcare system, we may be moving toward the limits of what can be achieved pharmacologically without engaging patients more actively in their own health care.¹ A behavioral intervention matched to the patient's stage of readiness to change is intellectually appealing and seems to significantly lower BP and improve hypertension control. Further studies to provide additional information as indicated in Table 2 could lead to clinically effective and patient-centered approaches that move us toward the Health People 2020 goal of controlling 88% of treated patients with hypertension and 61.2% of all adults with hypertension in the United States.

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