

IIR 04-170 A Behavioral Intervention to Improve Hypertension Control

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BACKGROUND/RATIONALE:

High blood pressure (BP) is the most common chronic condition among patients. It greatly increases their risk for cardiovascular disease (CVD) and kidney failure. Diet, exercise and medications are primary therapy with the target BP being < 140/90 mm Hg. Though the effectiveness of hypertension control (Systolic BP [SBP] < 140 mm Hg and diastolic BP [DBP] <90 mm Hg) in preventing CVD is well established, a significant gap exists between ideal control rates and what is actually achieved. Insufficient treatment adherence contributes to poor BP control, and clinicians are faced with the difficult challenge of motivating their patients to exercise, diet, and take drugs as prescribed. Despite the relative ease and low cost of treating high BP, and despite being prescribed treatment, many patients remain nonadherent and have uncontrolled hypertension. This proposal is a direct consequence of a HSR&D career development project targeted at optimizing hypertension control in patients and builds on previous research that demonstrates the feasibility of this approach. We propose a randomized controlled trial (RCT) at 2 Medical Centers to evaluate the effect of a telephone-delivered Transtheoretical stage-matched intervention to improve hypertension control in patients with uncontrolled BP. The study addresses three important priority areas: 1) Telemedicine, 2) Patient-Centered Care, and 3) Implementation of clinical practice guidelines while targeting a chronic condition of enormous importance, hypertension.

OBJECTIVE(S):

The specific aims of the study are: 1) To determine whether a stage-matched intervention (SMI) will lower BP at 6 months compared to usual care (UC) or a health education intervention (HE1) in patients with uncontrolled hypertension 2) To evaluate whether the SMI is effective in improving adherence to exercise, diet, or medications at 6 months in participants who receive the SMI compared to participants who receive UC or HEI 3) To assess whether patients randomized to the SMI achieve sustained benefit to significantly lower BP and improve adherence 6 months after intervention completion (i.e., 12 months after randomization) compared to those on UC or HEI. 4) To examine the effect of SMI on patient's health-related quality of life, satisfaction, and acceptability. 5) To determine the cost-effectiveness of the SMI

METHODS:

Patients with uncontrolled hypertension (n=528) will be randomized equally to 3 groups: 1) The Stage-Matched Intervention (SMI) will use the Transtheoretical model (TTM) as the overall study framework (constructs: stages

of change, decisional balance, and self-efficacy), while also incorporating key aspects of Bandura's social cognitive theory, behavioral self-management and the skills model of adherence. Delivery of the behavioral intervention will be by phone. Patients in this group will receive TTM stage-matched counseling for exercise, diet, and medications via monthly telephone counseling sessions based on current stage. A counselor will assess each participant's current stage for each behavior and use a previously developed and tested computerized system to deliver the appropriate standardized SMI. The SMI will be based on the processes of change tailored to each patient's responses to the stage of change, decisional balance and self-efficacy. 2) The Health Education Intervention (HEI) group receives monthly telephone calls by a counselor during which they will receive education about hypertension management, and 3) The Usual Care (UC) group participates in all the in-person visits but does not receive monthly calls. The randomized participants will be followed for a total of 12 months. There will be an initial 6-month active intervention phase following which the intervention will be stopped and patients will be followed for another 6 months to assess sustainability of the intervention. Participants will make in-person visits at baseline and at 3, 6, and 12 months. BP, the primary outcome, will be measured from several BP readings (at least 5 mm apart), and analyzed as categorical (<140/90 or not) or continuous. Secondary outcomes include adherence to diet, exercise and medications; quality of life; satisfaction; acceptability; cost and cost-effectiveness. In order to preserve the benefits of randomization and guard against bias, the study will be analyzed using longitudinal data analysis methods using an "intention to treat" strategy.

FINDINGS/RESULTS:

This study has started enrolling patients but there are no findings to report as yet

IMPACT:

This project builds on previous research to test the effect of SMI in lowering BP by improving adherence to antihypertensive therapy (medication, exercise, and diet). It may provide the scientific rationale, not only for using such interventions to improve BP control, but also for other conditions where sustained adherence is a problem. This could be an efficient and cost-effective way to enhance treatment adherence and improve outcomes- among patients living at a distance. This research may also influence future health behavior studies in patients to achieve better clinical outcomes.

PUBLICATIONS:

None at this time.