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# Reducing Clinical Inertia in Hypertension Treatment: a Pragmatic Randomized Controlled Trial

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## Abstract

Clinical inertia is a major contributor to poor blood pressure (BP) control. We tested the effectiveness of an intervention targeting physician, patient, and office system factors with regard to outcomes of clinical inertia and BP control. We randomized 591 adult primary care patients with elevated BP (mean systolic BP ≥140 or mean diastolic BP ≥90 mm Hg) to intervention or usual care. An outreach coordinator raised patient and provider awareness of unmet BP goals, arranged BP-focused primary care clinic visits, and furnished providers with treatment decision support. The intervention reduced clinical inertia (−29% vs. −11%, $p$=0.001). Nonetheless, ΔBP did not differ between intervention and usual care (−10.1/−4.1 vs. −9.1/−4.5 mm Hg, $p$ = 0.50 and 0.71 for systolic and diastolic BP, respectively). Future primary care-focused interventions might benefit from the use of specific medication titration protocols, treatment adherence support, and more sustained patient follow-up visits.

### Keywords

hypertension; clinical inertia; blood pressure control; randomized controlled trial; pragmatic trial

## BACKGROUND

Hypertension is the most common condition treated in the ambulatory environment.[1,2] While more than 20% of the U.S. population has a diagnosis of hypertension, only 50% of patients with this diagnosis have acceptable blood pressure (BP) control, which leads to tens of thousands of premature deaths from cardiovascular disease annually in the United States.[1] An important contributing factor is clinical inertia, defined as the failure of medical providers to initiate or intensify therapy when treatment goals are unmet.[3–5] Clinical inertia may be present in as many as two-thirds of hypertension clinic visits,[3,6–9] and recent reviews have identified clinical inertia as a key intervention target for improving BP control.[4,10]

Based on the conceptual model of O'Connor, *et al.*, clinical inertia arises from a combination of medical provider, patient, and office system factors.[4] Prior studies suggest

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that addressing these factors simultaneously is the most effective way to overcome clinical inertia.[4,10,11] Nurse-and pharmacist-run care models, for example, focus exclusively on hypertension treatment and use standardized medication titration protocols.[10–13] These approaches simultaneously address provider factors of poor recognition of elevated BP, non-hypertension-related patient concerns, and clinical uncertainty about how to modify therapy; patient factors of poor medication adherence and poor awareness of disease severity; and office system factors related to variable BP measurement methods. Although promising, nurse- and pharmacist-based programs remain uncommon because of inadequate reimbursement, human resource requirements, and logistical complexity.

Because primary care providers (PCPs) continue to have major responsibility for managing hypertension, it is important to improve the effectiveness of traditional clinic visits in real-world settings.[14,15] With this in mind, we designed an intervention that incorporated the following elements: a hypertension registry to track BP control for adult patients in our primary care setting (office system factors); ancillary staff to educate patients and PCPs about suboptimal BP control (office system, patient and provider factors); patient recall for BP-specific clinic visits (office system and patient factors); and treatment decision support for PCPs (provider factors). Disease-specific registries, patient outreach and recall by non-clinician team members, and EHR-based reminders and alerts are key elements of patient-centered medical home practices. We hypothesized that, in comparison with usual care, this type of practice redesign would be associated with improvements in clinical inertia and BP.

## METHODS

### Principal Hypothesis and Primary Outcome

Using a primary care population with elevated BP, we carried out a pragmatic randomized-controlled trial (RCT) to evaluate the hypothesis that, compared with usual care, an intervention targeting physician, patient, and office system factors would result in at least a 5 mm Hg greater improvement in systolic BP.

### Study Setting and Population

This study was carried out within the University of Colorado Hospital primary care system using a diverse patient population that received care in two general internal medicine clinics, four family medicine clinics, and a women's health clinic. All seven clinics shared an electronic health record (EHR, Allscripts Touchworks, version 10, Chicago, IL) and were staffed by approximately 60 PCPs (physicians, nurse practitioners, and physicians' assistants) caring for over 6,000 adults with hypertension.

We created a hypertension registry by querying the EHR to identify primary care patients ages 18–79 years who had elevated BP defined as an average systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg based on the 2–3 most recent clinic visits (whichever was greater) *and* a systolic BP ≥135 mm Hg or diastolic BP ≥85 mm Hg during the most recent clinic visit. The rationale for averaging BP in our study definition of "elevated BP" was to ensure participants met the diagnostic criteria for hypertension.[16] If multiple BP readings were recorded on a single visit, only the final BP reading on that date was extracted. Additional eligibility criteria, designed to identify patients currently receiving care within our system who did not have a recent or near-future primary care clinic visit, included: (1) ≥1 primary care clinic visit in the past 18 months; (2) ≥2 BP readings from separate days in the past 18 months; (3) first PCP visit ≥6 months in the past; and (4) no primary care clinic visit in the past month and none scheduled in the next six weeks. Patients were excluded if they had serious comorbidities (e.g. active cancer diagnosis, hospice care, end-stage renal disease),

diabetes mellitus, BP management by a nephrologist or other sub-specialist, EHR notation of white coat hypertension, or EHR notation to monitor BP at home.

An outreach coordinator spent an average of three minutes per patient reviewing the EHR to exclude patients whose eligibility requirements could not be determined electronically (e.g., those who were deceased, had left the clinic system, or whose hypertension was managed by a sub-specialist). Patients who met final inclusion criteria were randomly assigned in a 1:1 ratio to usual care and intervention groups. Patients were also randomly selected to include 50% with, and 50% without, a formal diagnosis of hypertension. Patients in the latter group had ≥2 elevated BP readings over the prior 18 months, but had not received a formal hypertension diagnosis in the EHR.

## Intervention Description and Implementation

An outreach coordinator (OC) delivered the intervention over a 3-month period. Registry records of intervention group patients were imported into an information management utility developed for this and other preventive and chronic disease outreach interventions.[17,18] The information management utility generated invitation letters that were mailed to patients' homes. Each letter, bearing the name of a patient's PCP on the signature line, explained that the patient's BP was elevated, that BP control is important for preventing cardiovascular disease, and that a BP-focused PCP visit was recommended. Letters referenced "hypertension" only if patients had this diagnosis on their problem list. Patients were invited to call the OC to schedule visits, but if they did not do so within 2 weeks the OC made up to 3 attempts to contact the patient by telephone over the next 2-week period. Patients in the usual care group were merely tracked; they did not receive mail or telephone contact nor did their providers receive any prompts in their EHR task list.

When telephone contact was made, the OC reiterated the letter's message by explaining to patients that recent BP results were elevated and that BP control is important to prevent cardiovascular disease. The OC helped patients schedule a BP-focused PCP appointment, encouraged them to focus on BP during the visit, noted "hypertension" or "elevated BP" as the visit reason in the EHR, and then mailed patients an appointment reminder postcard. Subsequently, the OC sent an electronic prompt to each PCP's patient care task list to be delivered two days prior to patients' BP-focused appointments. These prompts summarized the patient's recent BP readings, strongly encouraged a focus on BP management during the upcoming visit, and included a web address for the 7$^{th}$ Joint National Committee (JNC-7) Guidelines on hypertension diagnosis and treatment.[16] Prompts became part of the EHR, and were visible during BP-focused appointments near the top of a patient's clinic notes. If BP was elevated during the index visit (first post-randomization clinic visit), the OC telephoned patients a second time to facilitate a four-week follow-up BP-focused clinic visit if one had not already been scheduled. The OC made up to 3 attempts to contact the patient by telephone over a 2-week period. Patients were enrolled and tracked between November 3, 2009 and October 8, 2010.

## Determination of Sample Size

Using effect sizes and standard deviations demonstrated in prior hypertension clinical trials,[19] we determined that 200 patients per group would be required for at least 80% power to demonstrate a clinically meaningful group difference in systolic BP of 5 mm Hg using a two-sided t-test and $\alpha$=0.05. A 5 mm Hg difference is associated with a 7% reduction in all-cause mortality at a population level,[16] and has been achieved in other BP interventions.[10,12,20,21] Based on prior experience, we estimated that 50% of patients would be deemed ineligible for inclusion after manual chart review. Thus, to reach a target of at least 400 eligible patients, an initial sample of approximately 800 patients was required. In

assembling an initial cohort, we oversampled African-Americans, Latinos, and patients with greater hypertension severity (average systolic BP ≥160 mm Hg or diastolic BP ≥100 mm Hg) in order to improve the study's external validity for minority populations and patients with stage 2 hypertension.

## Variables

The primary outcome was the between-group difference in ΔBP from baseline to end-of-study. Baseline BP was defined as the average of the 2 to 3 (whichever was greater) most recent BPs recorded at any outpatient clinic visit during an 18-month pre-randomization period. The end-of-study BP was defined as the average of the 1 to 2 (whichever was greater) most recent BPs recorded at any outpatient clinic during a 9-month post-randomization period, excluding the first post-randomization visit (index visit) BP reading if there was at least one additional clinic visit during this period. In the event that there was no additional clinic visit, the index visit BP provided a data point for intention-to-treat analysis.

Secondary outcomes included between-group differences in measures of clinical inertia. Because both medication management and lifestyle counseling are appropriate strategies for controlling BP,[16] we operationally defined constitutive components of clinical inertia to include medication inertia and behavioral inertia. Following other study definitions of clinical inertia,[3,4] we defined *medication inertia* as PCP failure to initiate or intensify medications despite elevated BP. We defined *behavioral inertia* as PCP failure to document behavioral counseling despite elevated BP. Each type of clinical inertia was assessed as a dichotomous, true-false variable for an individual primary care clinic visit. *Combined clinical inertia* was defined as the presence of both medication and behavioral inertia at *every* clinic visit over a defined period of time. For the pre-randomization period, this was calculated on the basis of the last 2 clinic visits prior to randomization. For the post-randomization period, it was based on the first 1–2 clinic visits during the post-randomization period as these were most likely to correspond to the outreach-facilitated visits in the intervention group.

Additional outcomes included between-group differences in the number of primary care clinic visits over the 9-month study period; the average time between randomization and the first post-randomization clinic visit; new hypertension diagnoses on the problem list for previously undiagnosed patients; and types of behavioral counseling. Behavioral counseling included advice documented in the medical record about antihypertensive medication adherence, sodium intake, weight loss, exercise or physical activity, diet, non-steroidal anti-inflammatory medications, and alcohol use.

## Blinding

PCPs were accustomed to electronic reminders and patient outreach protocols used in unrelated clinical programs and were not aware that BP management was subject to evaluation in this specific quality improvement initiative. A research assistant blinded to study group assignment assessed behavioral inertia, medication inertia, hypertension diagnosis, and behavioral counseling through chart abstraction in which all OC-created chart notes were filtered from view in the EHR. BP outcomes, number and frequency of PCP visits, and number of anti-hypertensive medications were determined through electronic queries of the EHR.

## Statistical Analysis

Statistical procedures were carried out using SAS version 9.2 (SAS Institute, Inc., Cary, NC, USA). For bivariate comparisons, we used chi-square tests, as well as Mantel-Haenszel and Fisher's exact test when appropriate for categorical variables. Because BP measurements

and frequency of post-randomization visits were not normally distributed, the non-parametric Wilcoxon test was used to compare pre-randomization BP and post-randomization visits by study group.

To determine study group differences in ΔBP and Δcombined clinical inertia, we performed intention-to-treat analyses using restricted maximum likelihood (REML) for a repeated measures model with incomplete data (SAS PROC MIXED). As this analysis assumes that the occurrence of missing follow-up data depends only on observed data (i.e., pre-randomization values), we also performed a sensitivity analysis using the method proposed by Little.[22] The estimates from the sensitivity analysis were virtually identical to the REML results, providing assurance that the missing data were missing at random (data not shown). Moderation analyses also assessed the effect of key demographic covariates (age, gender), and key clinical covariates (pre-randomization BP medications [≥1 vs. 0], pre-randomization diagnosis of hypertension [yes/no], and pre-randomization hypertension stage [2 vs. 1, JNC-7 criteria]). Because many participants' race and ethnicity were recorded as "unknown", we could not perform moderation analyses using race.

### Human Participants

This intervention was designed and carried out as a quality improvement program that relied on standard methods for creating patient registries and providing patient outreach. The Colorado Multiple Institutional Review Board approved publication of results following the removal of protected health information. Because there were no patient exclusions based on informed consent requirements, the study population was representative of the clinic population.

## RESULTS

### Sample

A sample of 591 individuals met eligibility criteria and study group was randomly assigned. Figure 1 depicts the study flow per Consolidated Standards of Reporting Trials (CONSORT) recommendations for pragmatic RCTs.[15] Table 1 summarizes participant characteristics. At baseline, there were no group differences in BP or sociodemographic characteristics. Intervention group participants had more pre-randomization clinic visits than usual care group participants ($p = 0.05$).

### Primary Outcome: Blood Pressure

There was no significant difference in ΔBP in intervention vs. usual care groups (−10.1/−4.1 vs. −9.1/−4.5 mm Hg, $p = 0.50$ and 0.71 for systolic and diastolic BP, respectively, Figure 2). There was also no difference in the percentage of patients achieving BP goal by the end of study (42.7% vs. 37.4%, respectively, $p = 0.27$). Finally, there were no group differences in ΔBP in separate moderation analyses that adjusted for key demographic (age, gender) and clinical characteristics (hypertension diagnosis, hypertension stage, and pre-randomization hypertensive medications), respectively (data not shown).

### Secondary Outcomes

Compared with usual care, the intervention group's combined clinical inertia improved by an additional 18.6% (95% CI, 7.4 to 29.7 percentage points; mean scores of −29.3% vs. −10.7% in intervention and usual care, respectively, $p = 0.001$, Figure 3). In terms of constitutive components of inertia, the intervention group's behavioral inertia improved by an additional 16.2% (95% CI, 4.5 to 27.9 percentage points; mean scores of −32.2 vs. −16.0% in intervention and usual care, respectively, $p = 0.007$) and medication inertia improved by an additional 15.5% (95% CI, 3.5 to 27.4 percentage points; mean scores of

−29.3 vs. −13.8% in intervention and usual care, respectively, $p = 0.01$), as compared with usual care. The improvement in medication inertia was related primarily to up-titrating medications, however, as there was no significant difference in the number of end-of-study anti-hypertensive medications in intervention and usual care (63% vs. 58% with ≥1 medication, $p = 0.25$).

The intervention was associated with improved primary care visit frequency and timeliness. In the 9-month study period, there were 2.5 visits in the intervention group as compared to 1.8 visits in the usual care group ($P < 0.0001$). In addition, almost two-thirds (65%) of intervention group participants completed their first post-randomization visit within nine weeks, whereas just over one-third (39%) of the usual care group did so ($p = 0.02$). Among patients with undiagnosed hypertension at study entry, a new diagnosis of hypertension was added to the problem list for 26% of participants in the intervention group compared with 16% in the usual care group ($p = 0.03$).

The most commonly documented behavioral counseling elements were advice to exercise (16.1% intervention vs. 7.2% usual care, $p = 0.0007$), restrict sodium intake (13.4% intervention vs. 6.1% usual care, $p = 0.003$), modify diet (11.1% intervention vs. 4.1% usual care, $p = 0.001$), lose weight (6.7% intervention vs. 2.4% usual care, $p = 0.01$), and take antihypertensive medications as prescribed (4.4% intervention vs. 2.4% usual care, $p = 0.18$).

## DISCUSSION

Clinical inertia arises from factors such as a lack of provider awareness of in-clinic BP readings; a failure to formally diagnose hypertension; postponement of BP treatment intensification when BP is close to but nonetheless above goal levels; patient and provider reticence to add more medication; an overreliance on lifestyle strategies rather than pharmacotherapy; an assumption that in-clinic BP readings may represent a “white coat” phenomenon; and medical concerns that compete with BP for attention during time-limited clinic visits.[4–6,23–28] In this study, we evaluated a population-based BP management program designed to mitigate patient, provider, and office system influences on clinical inertia. Specifically, we attempted to raise patient and provider awareness of unmet BP goals, recalled patients for BP-focused clinic visits, and furnished medical providers with EHR prompts prior to BP-focused clinic visits that included a web address for treatment decision support. Compared with usual care, the intervention resulted in almost one additional primary care visit (2.5 vs. 1.8 visits) and in reduced measures of clinical inertia (−29% vs. −11%). Nonetheless, although BP appeared to improve in both study groups, most likely reflecting regression toward the mean, the intervention did not result in superior BP control compared with usual care. Regression toward the mean is common when a population characteristic, like BP, is selected on the basis of extreme values and then re-measured over time.

Although improved clinical inertia has been associated with improved BP in other trials,[12,13,29,30], there are several possible reasons we did not observe this result here. First, a majority of hypertensive patients require 2 or more anti-hypertensive classes to achieve BP control.[16] In this study, however, there was relatively little initiation of new medication. Also, while dose intensification took place, and was the major reason for improved medication inertia measures, the intensification may not have been sufficiently aggressive. It is quite possible that these weaknesses could have been mitigated if we had provided PCPs with specific medication treatment protocols like those employed in nurse- and pharmacist-based hypertension programs.[10–13] An EHR-based point-of-care decision support tool might have been particularly helpful for this purpose.

Because medication adjustments and behavioral counseling require follow-up clinic visits to assess BP responses, and because there were only 0.7 greater visits in the intervention group, patient follow-up may have been insufficient to achieve a beneficial effect on BP. By helping providers to focus on inadequate BP management over at least two clinic visits, we envisioned that providers would proactively and autonomously maintain this focus over a longer period until BPs were controlled. Unfortunately, this did not happen. Other BP interventions have incorporated more persistent and prolonged follow-up between providers and patients.[11–13] Although it is unclear how intense and sustained this activity needs to be, treatment goals are typically reached more quickly as a result of multiple, frequent encounters.[31]

We also suspect that poor medication adherence might have undercut any potential intervention benefit. U.S. rates of non-adherence to anti-hypertensive medications are 20%–50%,[32–34] and adherence tends to be poorer in populations with poorly-controlled BP.[34] Our intervention did not assess adherence nor incorporate strategies to help patients and providers minimize the widespread problem of poor adherence. In other studies, promising strategies have included simplifying medication regimens and motivational strategies ranging from medication reminder charts to culturally appropriate storytelling.[14,21,33]

Finally, “best practices” can increase the accuracy of BP measurements including, for example, ensuring that proper cuff sizes are employed and that patients are seated for ≥5 minutes before BPs are assessed.[16] Although medical assistants in our clinics have been trained to follow proper BP measurement techniques,[35] fidelity to these techniques is likely variable. This was not an efficacy trial that incorporated strict protocols for assessing outcomes in an ideal or controlled setting, but was instead an evaluation of a “real world” clinical practice. It is more likely that BPs are erroneously high than low when proper measurement techniques are not followed, and repeated measurement produces regression towards the mean. In this study, the magnitude of such a phenomenon might have blunted a possible intervention effect. Greater attention to standardizing BP measurement would be important for future interventions.

Beyond identifying possible ways of improving hypertension treatment where PCPs maintain exclusive responsibility for medication management, our results suggest that a more fine-grained approach to measuring clinical inertia might be useful in future studies. For example, the reduction in behavioral inertia that we observed (an outcome rarely assessed in other studies) might actually reflect clinicians’ sometimes misplaced emphasis on lifestyle counseling over medication management. Alternatively, lifestyle counseling in lieu of medication intensification may reflect patient or provider resistance to starting additional medications. Thus, we propose that medication inertia should be subdivided into two types: inertia to adding medications and inertia to escalating medication doses. In a population-based program, both are important but the former is probably more important for reaching BP goals.

## Study Limitations and Strengths

This study has several potential limitations. The academic setting, patient population, and use of a specific type of EHR might limit generalizability. A spillover effect of increased provider vigilance with regard to BP in the control group was possible because randomization took place at the patient rather than clinical practice level; however, if present it is unlikely to have been significant because providers were unaware of a formal quality improvement evaluation plan, the total number of enrolled patients per provider was small, the duration of patient outreach was only a few months, and the frequency of BP-focused clinic visits in the intervention group was low. Adherence measures were not included, limiting our ability to determine whether poor medication adherence affected intervention

effectiveness. We included patients with elevated BPs who met criteria for a hypertension diagnosis, but half had not yet been formally diagnosed. However, patients with and without a formal hypertension diagnosis might require different management strategies as patients in the latter group require more education and time to accept their diagnosis.

Despite these limitations, the study had a number of unique strengths. It employed a pragmatic trial approach in which a large and diverse cohort of patients was enrolled in a real world setting without exclusions based on informed consent requirements. Also, the intervention incorporated multiple strategies to address the types of patient, provider, and office system factors identified as important in systematic reviews.[4,10]

## CONCLUSIONS

There is still little evidence about how the care of hypertensive patients can be better organized and delivered by PCPs.[10] Our multifaceted intervention emphasized appointment scheduling for a specific purpose and the timely provision of information and advice to both PCPs and patients. While these efforts clearly affected the behavior of both parties and reduced clinical inertia as traditionally measured, they did not result in improved BP control. This is counter-intuitive and is therefore worth noting for future interventions. Despite the negative result, and viewed from an orientation of clinical effectiveness (rather than efficacy), a useful lesson is that measurements of clinical inertia should reflect aspects of treatment intensification that are most likely to be associated with improvements in BP control. One possibility is to differentiate between inertia to adding new medications, on the one hand, and inertia to titrating doses of existing medications, on the other. Another lesson to be drawn is that future success will likely require alteration or augmentation of some elements of our intervention. Compelling options might include the use of specific medication protocols for PCPs; more sustained patient outreach to address unmet BP goals; greater attention to measuring and overcoming poor medication adherence; and the implementation of “best practices” related to measuring BP.

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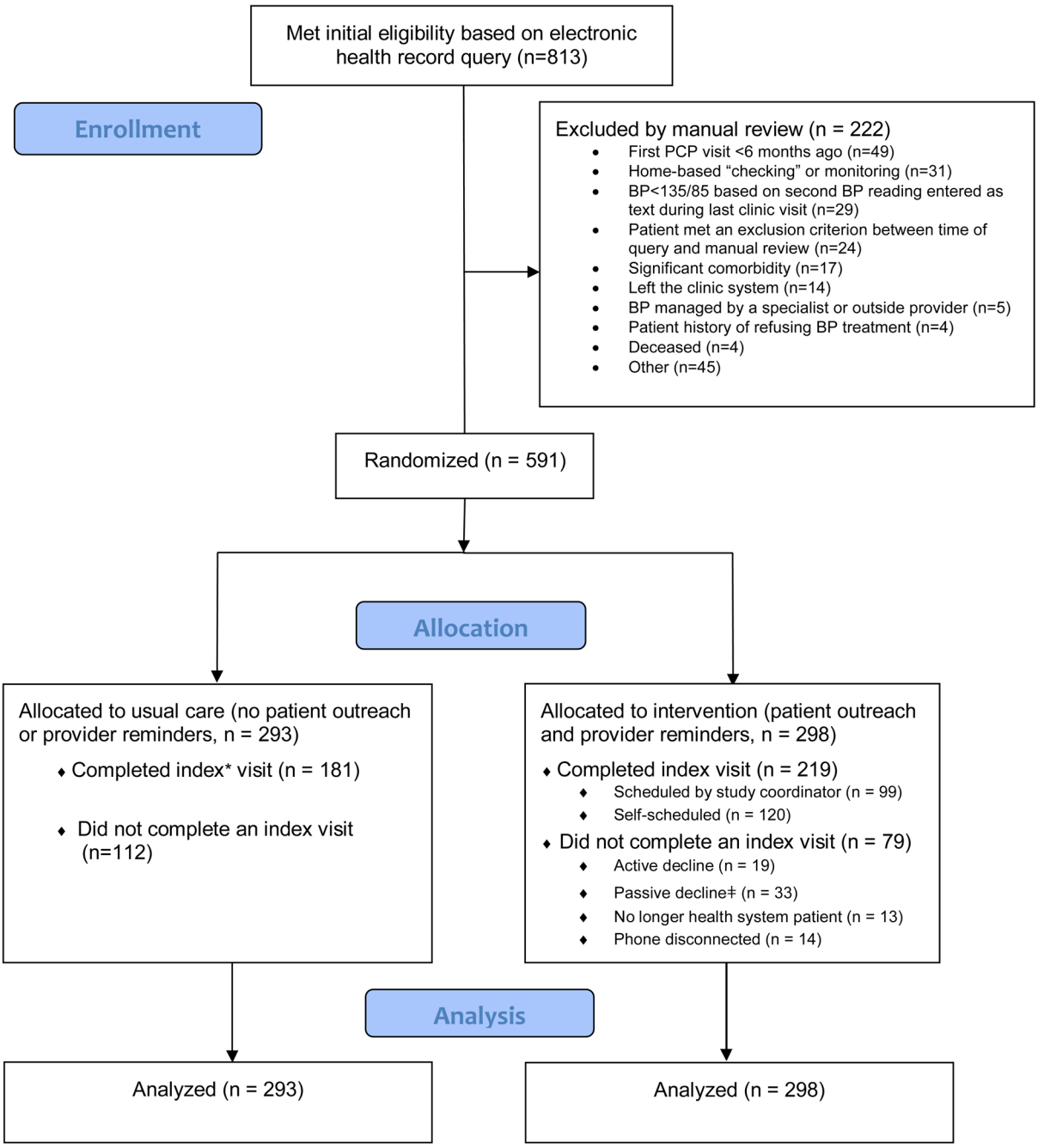


**Figure 1.**
Study Flow Diagram
*The index visit is defined as the first post-randomization PCP clinic visit;
‡Passive decline refers to patients who did not respond to a full cycle of outreach (one letter and three phone calls) and to those who either cancelled or no-showed to their appointments.

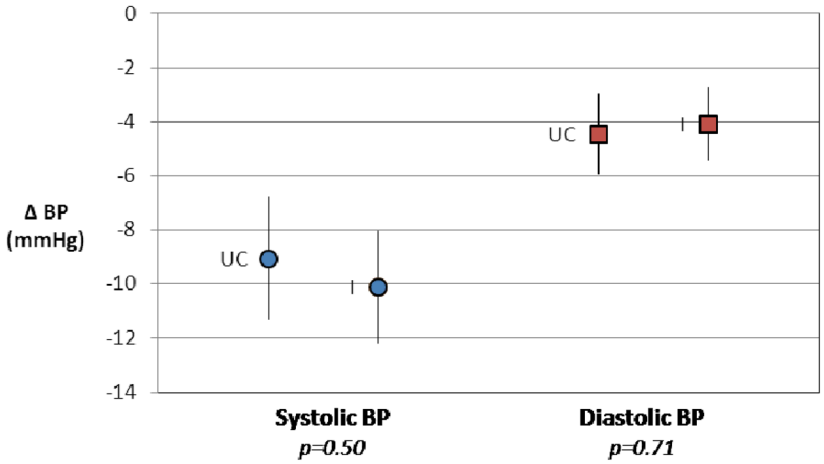


**Figure 2.**
Blood pressure outcomes
Point estimates with 95% confidence intervals. UC=usual care; I=intervention

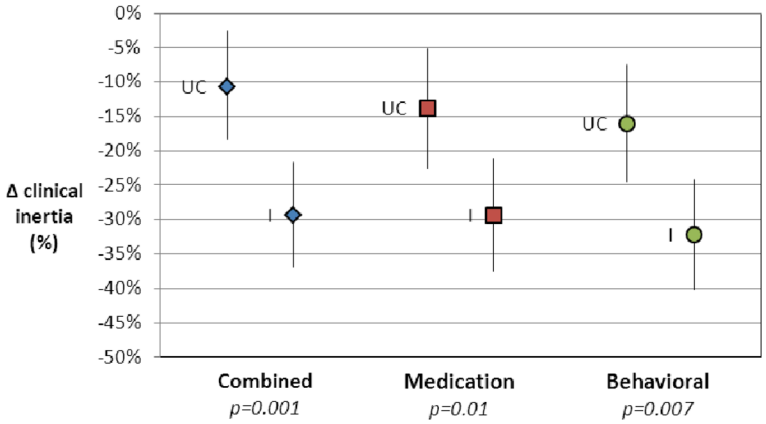


**Figure 3.**
Clinical inertia outcomes
Point estimates with 95% confidence intervals. UC=usual care; I=intervention

## Table 1

Participant Characteristics (n=591)

| Characteristic | Usual Care N=293 (%) | Intervention N=298 (%) | *p* value |
|---|---|---|---|
| **Demographic Characteristics** | | | |
| Sex | | | |
| Female | 52.2 | 57.1 | 0.24 |
| Age category | | | |
| <45 | 23.9 | 24.8 | |
| 45–54 | 23.6 | 18.8 | |
| 55–64 | 27.3 | 28.5 | |
| 65–79 | 25.3 | 27.9 | 0.75 |
| Race | | | |
| Non-LatinoWhite | 31.4 | 37.9 | |
| Black | 23.9 | 22.5 | |
| Latino | 7.5 | 10.7 | |
| Other/Unknown | 37.3 | 28.9 | 0.10 |
| Marital status | | | |
| Single | 35.5 | 34.9 | |
| Married / Partnered | 62.8 | 61.7 | |
| Unknown | 1.7 | 3.4 | 0.44 |
| Insurance status | | | |
| Commercial | 52.2 | 48.3 | |
| Medicaid / Indigent | 9.6 | 10.4 | |
| Medicare | 27.7 | 26.9 | |
| Tricare | 10.6 | 14.4 | 0.51 |
| **Clinical characteristics** | | | |
| Hypertension diagnosed | | | |
| No | 46.8 | 47.0 | |
| Yes | 53.2 | 53.0 | 0.96 |
| Hypertension stage | | | |
| 1 | 70.7 | 68.8 | |
| 2 | 29.4 | 31.2 | 0.62 |
| eGFR | | | |
| <=60 | 5.5 | 7.4 | |
| >60 | 76.5 | 76.5 | |
| Missing | 18.1 | 16.1 | 0.55 |

| **Characteristic** | **Usual Care N=293 (%)** | **Intervention N=298 (%)** | ***p* value** |
|---|---|---|---|
| Number of pre-randomization anti- hypertensive medications | | | |
| None known | 55.6 | 52.7 | |
| 1 | 19.1 | 21.5 | |
| >=2 | 25.3 | 25.8 | 0.61 |
| Number of PCP visits in 18 month pre-randomization phase | | | |
| 1–2 | 28.0 | 21.8 | |
| 3–4 | 38.9 | 38.9 | |
| 5 or more | 33.1 | 39.3 | 0.05 |

Abbreviations: GFR, glomerular filtration rate; PCP, primary care provider