Official Title:	Project ALTA: Advancing Long-term Improvements in Hypertension Outcomes through a Team-based Care Approach
NCT Number:	NCT03713515
Study Number:	18-01290
Document Type:	Study Protocol and Statistical Analysis Plan
Date of the Document:	• December 22, 2025

CLINICAL STUDY PROTOCOL

Project ALTA: Advancing Long-term Improvements in Hypertension Outcomes through a Team-based Care Approach

Study Number

s18-01290

Sponsor

NIMHD

Protocol Version

December 19, 2025

version 13

Study Personnel

Principal Investigators

Antoinette Schoenthaler
New York University
Email: Antoinette.Schoenthaler@nyulangone.org

Gbenga Ogedegbe
New York University
Email: olugbenga.ogedegbe@nyumc.org

Investigator

Andrea Troxel
New York University
Email: andrea.troxel@nyumc.org

Key Study Personnel:

Adebayo Ogunlade
New York University
Email: Adebayo.Ogunlade@nyulangone.org

Synopsis

Primary Objective

The primary objective of this study is to refine the practice facilitation (PF) strategies that will be tested in a cluster-randomized trial.

Secondary Objectives (if applicable)

1. To test the hypothesis that the refined PF strategy will result in a higher level of implementation fidelity of ALTA (primary outcome) and improved blood pressure (BP) control and antihypertensive medication adherence (secondary outcomes) at 12 months.
2. To explore potential moderating factors at the practice and individual levels (e.g., organizational capacity to change, evidence-based practice attitudes) that influence implementation of ALTA in a network of 10 safety-net primary care practices in New York.
3. To evaluate the impact of ALTA on the patient-provider relationship (i.e., relationship commitment, patient-provider trust, and patient anxiety in the interaction)
4. To determine whether changes in patient-provider relationship that result from ALTA are associated with changes in medication adherence and BP control (secondary outcomes)

Primary Outcome Variables

The primary outcome is the level of implementation fidelity of ALTA into routine care within the safety-net practices. Implementation fidelity is defined as the degree to which an intervention was delivered, as intended by program developers. We will use a mixed methods approach to assess the five core domains of implementation fidelity.

Secondary and Exploratory Outcome Variables (if applicable)

The secondary outcomes will be measures of clinical effectiveness—BP control and adherence to antihypertensive medications at the pre-intervention (baseline) and post-intervention (12 month) periods.

The tertiary outcomes will be measures of the patient-provider relationship – relationship commitment, patient-provider trust, and patient anxiety in the interaction– at the pre-intervention (baseline) and post-intervention (12 month) periods.

Study Duration

The study duration is 5 years. The pre-implementation phase will be 9 months and the implementation phase will be the remaining 4 years. Sites and participants enrolled in the

implementation phase will participate in the trial for 15 months. The approximate start date for the trial is September 1, 2018. The approximate end date is November 30, 2027.

Study Design

Using a mixed-methods design, the proposed study will be conducted in two phases: 1) A pre-implementation phase (surveys, QI interviews) and 2) an implementation phase.

For the pre-implementation phase, we will use a mixed methods observational research design to refine the PF strategies that will be tested in the implementation phase.

For the implementation phase, we will evaluate, in a stepped-wedge cluster randomized controlled trial, the effect of the PF strategy on the level of implementation fidelity (primary outcome) of ALTA, as well as on clinical outcomes (secondary outcomes) and the patient-provider relationship (tertiary outcomes) as compared to usual care at 12 months.

Study Population

The study population will include practice clinical and nonclinical staff and patients with uncontrolled hypertension (HTN) receiving care in the network of 10 safety-net primary care practices in New York.

Patient Eligibility Criteria

Inclusion Criteria:

• Be fluent in English or Spanish

• Be age 18 years or older

• Receiving care at one of the 10 safety-net primary care practices

• Have uncontrolled HTN documented in the electronic health record (EHR) on at least two visits in the past year (defined as an average BP ≥ 140/90 mmHg)

• Have been prescribed at least one anti-hypertensive medication and be non-adherent to their medications, defined as adherence <80% in the preceding 12 months, as determined by prescription orders obtained from the clinic EHR.

Exclusion Criteria:

• Being deemed unable to comply with the study protocol (either self-selected or by indicating during screening that s/he could not complete all requested tasks)

• Participation in other hypertension-related clinical trials

• Have significant psychiatric comorbidity or reports of substance abuse (as documented in the EHR)

• Plan to discontinue care at the practice within the next 15 months

Clinic and nonclinical staff Eligibility Criteria

Inclusion criteria:

• Primary care provider (MD/DO, NP), Nurse, Medical Assistant, or administrative staff employed at the participating practices and interacts with at least five patients with a diagnosis of hypertension. Exclusion criteria: • Refuse to participate.
Number of Participants Implementation Phase Clinical and nonclinical staff: Surveys and interviews: 204 Patients: Surveys: Randomly selected sample of 70 patients from each of the 10 participating primary care clinics (n=700). We will also be selecting a sample of 300 patients across participating clinics who met the eligibility criteria but did not participate in ALTA to participate as a control group. Interviews: A randomly selected subsample of 30 patients with uncontrolled HTN who participated in ALTA (n=700)

Table of Contents

1 – Introduction

3.3 Introductory Statement

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to ICH GCP guidelines (CRF 21 Part 312), applicable government regulations and Institutional research policies and procedures.

2 – Background

2.1 Background/prevalence of research topic

Despite increasing awareness and treatment of hypertension (HTN) across all racial/ethnic groups, Latinos have the lowest blood pressure (BP) control rates in the US (Latino adults: 34% vs. 43% and 53% in non-Hispanic black and white adults). Among Latino adults in particular, rates of BP control are lower than among non-Hispanic black and white adults (35%, 43%, and 48%, respectively). Importantly, data from the NHLBI-sponsored Hispanic Community Health Study/Study of Latinos showed significant deficits in the treatment and control of HTN, with Latino men from Central American, South American and Dominican ancestry (Latino subgroups largely concentrated in the northeast US) experiencing the lowest rates of BP control (12%, 25% and 27%, respectively) compared to Mexican American men (31%). Similar patterns were seen in Latino women, with the poorest rates of BP control among women of Central American and Cuban descent (32% and 38%, respectively). Overall, these rates are considerably lower than rates of BP control among whites (48%).

These statistics may be explained by the disproportionately poorer adherence to antihypertensive medications among Latinos compared to blacks and whites. Despite the availability of numerous efficacious medications to manage HTN, 33-50% of hypertensive patients have uncontrolled HTN due to poor adherence to antihypertensive medications. The asymptomatic nature of HTN makes non-adherence a greater problem than in other chronic diseases, resulting in high costs due to non-adherence-related hospitalizations, repeat clinic visits, lost productivity, and increased morbidity and mortality. Multiple studies have documented disproportionately poorer medication adherence among Latinos compared to black and white patients.

3 – Rationale/Significance

3.1 Problem Statement

Growing evidence shows that multilevel systems-based interventions (i.e., those in which the patient, healthcare providers, and clinic systems are all recognized) that are designed to bolster optimal medication adherence can produce significant improvements in patients' medication adherence and clinical outcomes. Our Ayudando a Latinos Hipertensos Para Mejorar Adherencia a sus Medicamentos (ALMA) trial, which informs this study significantly improved both BP control (51% vs. 29%, p=.04) and medication adherence (78% vs. 72%, p=.02) compared to enhanced usual care in a sample of Latino patients followed in a safety-net practice. The ALMA intervention was a systems-level approach to improving BP control based on the evidence-based teamlet model and included an office system redesign component (e.g., electronic health record (EHR) embedded templates) and a primary care physician (PCP) support (e.g., telehealth MA coaching) component. Despite their efficacy, systems-level interventions like ALMA often takes up to 17 years to be translated into clinical practice. Implementation strategies are sorely needed to accelerate the translation of evidence-based interventions into routine "real world" safety-net practices, to reduce disparities in BP control in vulnerable populations. However, data are scant regarding which strategies effectively facilitate the translation of efficacious interventions into practice in these settings. Moreover, while a central premise of ALMA is that it will build clinic capacity to deliver equitable, high-quality care to health disparity populations followed in primary care clinics, the program was not designed to evaluate the impact of healthcare technologies on patient-provider relationships. While technology has shown great promise in improving the clinical management of hypertension (HTN), its impact on patient-provider relationships is unclear. Some evidence suggests telehealth could strengthen these relationships through improved access to the care team and remote patient monitoring, but its technical and interpersonal drawbacks may reduce commitment and trust. Addressing these risks is vital for clinics that serve vulnerable populations who may have limited technology access and low digital literacy, and consequently feel disenfranchised from providers using telehealth.

3.2 Purpose of Study/Potential Impact

Practice facilitation (PF)—an implementation strategy that can accelerate the translation of evidence-based systems interventions into routine practice—promises to overcome these barriers.PF involves both a role (a facilitator) and a process for supporting primary care practices to build motivation and capacity at the individual, team, and systems levels to improve organizational performance and health outcomes. Practice facilitators are specially trained individuals who work with primary care practices to help healthcare teams develop the skills they need to adapt and implement evidence-based approaches to their practice environment (e.g., by redesigning workflows to support team-based care).

Despite the growing evidence of PF as effective for the implementation of preventive screenings, its impact on implementing evidence-based systems to support HTN management in safety-net practices remains largely untested. Our study provides a unique

opportunity to fill this evidence-to-practice gap by evaluating the effectiveness of PF as a practical and replicable strategy to implement Advancing Long-term Improvements in Hypertension Outcomes through a Team-based Care Approach (ALTA) in a network of safety-net primary care practices that serve a large population of low-income patients.

ALTA is a health systems approach to improving medication adherence and BP control in primary care practices. It is designed to build practice capacity to address the needs of hypertensive patients by utilizing a team-based approach to delivering HTN care. ALTA includes five key components, which are conducted by existing members of the practice (Table 1): (1) Identify ALTA-eligible patients using hypertension registries. (2) Refer ALTA patients to a clinic Health Coach using the EHR. (3) Coach ALTA patients using a structured counseling tool integrated in the EHR to identify patients' treatment goals; asses their current level of BP control and medication adherence; identify barriers and facilitators to medication adherence; develop patient-centered adherence goals and action plans; and use a structured treatment algorithm to optimize patient antihypertensive medication regimen. (4) Document brief progress notes from the coaching session the EHR to inform other team members of the patient's adherence status, action plans, progress toward goals, and any changes to the antihypertensive medication regimen. (5) Monitor and schedule follow-up sessions with ALTA patients in the EHR.

Table 1. ALTA components

ALTA components	ALTA Activities
Identify and Refer	• EHR registry to identify patients with uncontrolled HTN and non-adherent • EHR-based referral to MA/PCA/RN
Coach	• Structured assessment of medication adherence • Use of MINT to identify facilitators/barriers to adherence and discuss personalized strategies to improve adherence behaviors • Use of structured medication titration algorithm to optimize patient treatment regimen • Use of teach back to ensure patient understanding of treatment plan • Co-creation of culturally relevant goals and action plans
Document	• Structured documentation of coaching sessions in EHR to enable tracking patients' progress over time • EHR Documentation of individualized treatment plan, medication adherence goals, and action plan to guide future sessions and share with primary care provider for clinic visits
Monitor	• Consistent monitoring of patient progress through completion of and tracking follow-up sessions with ALTA patients

3.3.1 Potential Benefits

The intervention is expected to benefit the patients by improving their blood pressure control and adherence to antihypertensive medications, reducing their cardiovascular risk profile, and increasing their role as active participants in the management of their HTN. The intervention is expected to benefit the practices, by changing the usual care practices so that a better quality of treatment for HTN is implemented and potentially maintained, and

generalizes to new patients, as well as to other providers. The knowledge gained from this study will provide key academic, community, and policy stakeholders a practical and replicable strategy for implementing efficacious interventions into routine care that has potential for broad dissemination, ultimately contributing to the reduction of health disparities seen in racial and ethnic minority populations.

3.3.2 Potential Risks

Though we expect the level of risk due to this project to be minimal, potential risks may include the following:

Elevated blood pressure: Since this study focuses on reducing BP, all of the patients are required to have uncontrolled HTN to be eligible to participate. All patients will have a primary care provider as part of this study; however, it is quite conceivable that a patient may have elevated BP readings during the study that will require more aggressive management. The clinical care of any given patient will be entirely handled by the patient's primary care provider, and study participants will be made aware of this at the consent visit. Similarly, any medical problem that arises during study visits will be referred to the patient's provider. If at any study visit, BP is elevated >180 SBP or >110 DBP, the participant will be directed to seek medical attention immediately at the clinic. All such participants will be required to bring to the next study visit a signed document attesting that they sought care. The Program Manager will follow-up with the participant's primary care provider to ensure proper medical follow-up. These data will be reviewed periodically by the DSMB and will be reported to the NYU IRB until the end of Year 5.

Violation of participant privacy and confidentiality: Loss of confidentiality is the greatest potential risk to study subjects. We will obtain written consent from all participants (i.e., practice clinical and nonclinical staff and patients) who participate in surveys, interviews, and/or audiotaped health coaching visits; however, no identifying information will be included on the transcripts of interviews or surveys. As part of the process involved in obtaining written informed or verbal consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their treatment or future interactions with their physician at the practices. Also, if a participant is uncomfortable during a research encounter, they may stop at any time. All survey data entered into the research database will be protected by confidential entry codes. Names will be replaced with identification numbers. All patient data will be de-identified prior to transfer to subcontracts. Locked file cabinets will be used to store materials with identifying information (e.g., patient consent forms). Only members of the research team will have access to patient's personal information file. Study data will be transmitted to Dr. Troxel and the data analyst for data processing using only secure methods (e.g., encrypted email). All electronic audiotaped data will be saved on a secure server housed by NYULH and backed up daily or weekly depending upon the receipt of data. PHI will be confined to a secure server that is not connected to the Internet. All computers are password protected and on a private LAN network. No file and database servers are accessible to the public through the Internet. Prior to inclusion in any data set (internal and external), data will be stripped of all

identifying information. Finally, the web-based surveys will be accessed via a HIPAA compliant application. The data collected for this study will be used strictly for the purposes stated in this grant application and will only be available to relevant research staff. IRB approval will be sought prior to any data collection involving human subjects. Finally, all identifiable patient health information will be obtained and managed in accordance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164.

NYULH employees recruited as research subjects are more vulnerable to undue influence or coercion because of the possibility that they may perceive employment or other benefits as dependent upon their participation in research. In addition, NYULH employees may experience increased risk of invasion of privacy or loss of confidentiality. To minimize these risks, employees who wish to participate will be enrolled by a study team member with no direct supervisory or evaluation responsibilities. At time of enrollment, the study team member will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. No identifiable information will be collected from these employees. Employees will be assigned a unique study number that includes neither contact nor identifying information. No linking list will be kept.

Anxiety: There is a potential risk that participants (i.e., practice clinical and nonclinical staff and patients) may feel uncomfortable or anxious during the audiotaped health coaching sessions, and/or semi-structured interviews. To mitigate this potential challenge, the study staff member who conducts the semi-structured interview will be trained to act professionally and address all participants' concerns. Participants will also be reminded that the tapes are only for research purposes and will not influence their relationship with the practice. Moreover, participants will be reassured that the tapes will be saved in a secure and confidential database that only the study staff will have access to, and that have the right to ask that the tapes be deleted if they feel sensitive information was discussed during the session that they do not want the research team to hear.

4 - Study Objectives

4.1 Hypothesis

The refined PF strategy will result in a higher level of implementation fidelity of ALTA (primary outcome) and improved BP control and antihypertensive medication adherence (secondary outcomes) at 12 months, compared to a self-directed control arm.

4.2 Primary Objective

The primary objective of this study is to refine the practice facilitation (PF) strategies that will be tested in a cluster randomized trial, through a formative evaluation of the barriers and facilitators to implementation of the ALTA intervention based on the Consolidated Framework for Implementation Research and input from a Steering Committee.

4.3 Secondary Objectives (if applicable)

5. To test the hypothesis that the refined PF strategy will result in a higher level of implementation fidelity of ALTA (primary outcome) and improved blood pressure (BP) control and antihypertensive medication adherence (secondary outcomes) at 12 months.
6. To explore potential moderating factors at the practice and individual levels (e.g., organizational capacity to change, evidence-based practice attitudes) that influence implementation of ALTA in a network of 10 safety-net primary care practices in New York.

4.4 Tertiary Objectives

7. To evaluate the impact of ALTA on the patient-provider relationship (i.e., relationship commitment, patient-provider trust, and patient anxiety in the interaction)
8. To determine whether changes in patient-provider relationship that result from ALTA are associated with changes in medication adherence and BP control (secondary outcomes)

5 - Study Design

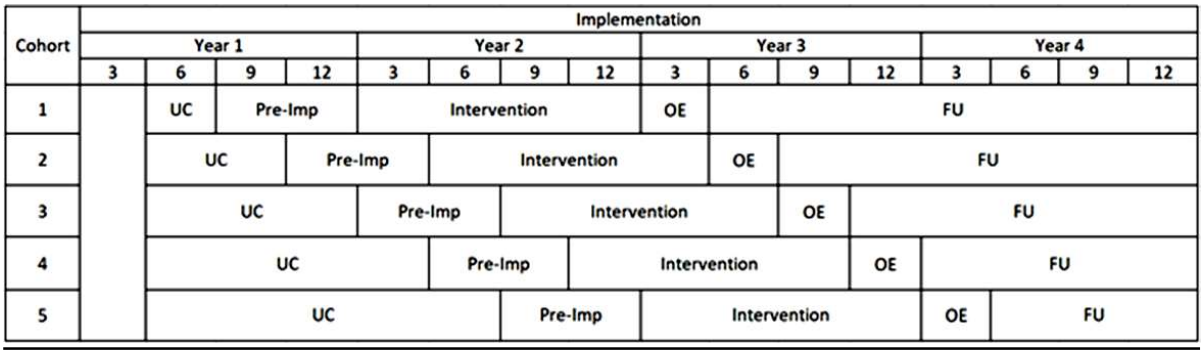
5.1 General Design

Using a stepped-wedge cluster randomized control trial design, this study will evaluate the effect of a tailored PF strategy on the implementation of Advancing Long-term Improvements in Hypertension Outcomes through a Team-based Care Approach (ALTA), our systems-level approach to improving medication adherence and BP control, among patients with uncontrolled HTN receiving care in 10 safety-net practices in New York.

Using a mixed-methods approach, this study will be conducted in two phases: (1) a pre-implementation phase where we will refine the PF strategy, based on the Consolidated Framework for Implementation Research (CFIR) to facilitate implementation of ALTA at the practices and (2) an implementation phase, guided by Proctor's Implementation Outcomes Framework (IOF).The primary aim of the implementation phase is to evaluate, in a stepped-wedge cluster randomized trial, the level of implementation fidelity (e.g., degree to which a program is delivered, as intended) of ALTA because of the tailored PF strategies. The secondary aims are to compare the effects of PF versus usual care (UC) on BP control and medication adherence in 10 safety-net primary care practices and patients with uncontrolled HTN who are non-adherent to their antihypertensive medications. We will also explore the potential moderating factors at the practice and individual levels (e.g., organizational capacity to change, evidence-based practice attitudes) that influence level of implementation fidelity of ALTA at the practices. We will also explore the impact of ALTA on the patient-provider relationship (i.e., relationship commitment, patient-provider trust, and patient anxiety in the interaction), and determine whether any changes to the relationship also affect patients' BP control and medication adherence.

As shown in Figure 1, each participating practice will start with the UC phase and are block-randomized into four waves, with two sites per wave. The UC phase will be followed by the pre-implementation phase of 6 months, during which facilitators will conduct a practice evaluation (e.g., workflow analysis, environmental scan) based on CFIR, refine the PF strategies that will be used in the implementation phase, and train staff in the ALTA model. Following this period, sites will implement ALTA with the assistance of the facilitator for 12 months, with a 3-month follow-up period for outcome assessment.

Figure 1. Stepped wedge design of ALTA implementation



5.1.1 Study Duration (if applicable)

The study duration is 24 months. During the UC phase, patients at the sites will receive standard HTN care delivered by their primary care providers for the first 3 months. The pre-implementation phase will be the following 6 months of the trial to refine the PF strategy that will be used during the implementation phase. The implementation phase will be 12 months and there will be two study visits: consent/baseline and 12-month follow-up.

5.1.2 Number of Study Sites

The study will be conducted at the network of 10 safety-net practices in New York.

5.2.1 Primary Outcome Variables

The primary outcome measure is the level of implementation fidelity of ALTA at the practices. Implementation fidelity is defined as the degree to which an intervention was delivered, as intended by program developers. We will use a mixed methods approach to assess the five core domains of implementation fidelity defined by Proctor's IOF: (1) adherence to the program protocol; (2) dose of the program delivered; (3) quality of program delivery; (4) participant responsiveness; and (5) program differentiation.

5.2.2 Secondary and Tertiary Outcome Variables (if applicable)

Secondary outcomes will be measures of clinical effectiveness—BP control and adherence to antihypertensive medications at the pre-intervention (baseline) and post-intervention (12 month) periods.

BP control, the major secondary outcome, will be defined as SBP <140 and DBP <90 mmHg. BP control will be assessed using the mean of the last two measurements recorded in the EHR during each of the pre-intervention and post-intervention study periods (baseline and 12 months). BP readings will be extracted from patients' EHR by trained RAs. We will use the last two recorded measures to reduce variability associated with multiple BP measurements being taken by different clinic staff. We will also examine the proportion of patients with BP control <130/80 mmHg in exploratory analyses to provide preliminary data on BP control rates of hypertensive patients when considering the new guidelines. We will also explore mean change in systolic and diastolic BP based on the mean of the last two recorded BP readings in the EHR during the pre- and post-intervention periods.

Medication adherence will be assessed via pharmacy refills obtained from prescription orders in the clinic EHR using the proportion of days covered (PDC) metric. The PDC is calculated as the total number of days covered by the medication divided by the number of days between the first fill of the medication in the study period and the end of the study period. Thus, as opposed to other pharmacy refill metrics, the PDC accounts for non-persistence with medications by tracking medications during the study period despite early discontinuation. We will count the days the patient was covered by each of their prescribed antihypertensive medications based on the prescription fill date and days of supply. If prescription fills for the same medication overlap, then we will adjust the prescription start date to be the day after the previous fill has ended. Patients will be considered adherent if

they fill ≥80% of their antihypertensive medications over the 12 months. In addition, we will assess the extent of medication non-adherence and the associated reasons based on the survey developed by Dr. Voils.

Tertiary outcomes will include measures of the patient-provider relationship- relationship commitment, patient-provider trust, patient anxiety in the interaction, patient trust in healthcare, discrimination in medical setting, Health literacy, health intake, and patient trust in medical technology at the pre-intervention (baseline) and post-intervention (12 month) periods.

Relationship commitment: In this study, we operationalize relationship commitment as patients' commitment to maintain care with their PCP when ALTA is introduced into their site. To assess patients' *perceived commitment* to their PCP, we will utilize the self-report measure developed by Berry et al. in a sample of primary care patients. The 5-item measure asks patients to rate their degree of commitment to the relationship with their doctor on a 7-point Likert scale (*strongly disagree* to *strongly agree*). Sample items include: *The relationship with my doctor is…something I am committed to; something I care about; and important to me.* To assess the *behavioral and affective indicators* of relationship commitment we will use natural language processing (NLP) and analyze text of patient-provider interactions that occur in the 12 months prior to ALTA, and over the 12 months ALTA phase. Data will be extracted from the EHR (e.g., clinical notes, messages, and free text) and MyChart to conduct these analyses.

Patient-provider trust: To assess perceived patient-provider trust we will administer the patient and provider measures developed by Thom et al., as they offer the opportunity to measure trust from both sides of the dyad. The 11-item Trust in Physician Scale (TPS) assesses a patient's interpersonal trust in their doctor.[128] Responses are given on a 5-point Likert scale ranging from *totally disagree* to *totally agree.* Sample items include: "*I doubt that my doctor really cares about me as a person" and "If my doctor tells me to do something, then it must be true."* The 12-item Physician Trust in the Patient Scale (PTPS) assesses the provider's perspective of patient behaviors that characterize high and low-trust relationships.[129] The PTPS includes 2 subscales; the first asks about providers' expectations that patients will behave in ways that fulfill their roles in providing accurate and complete histories, asking questions, and adhering to treatment plans. The second subscale includes items about respecting the provider's time and personal boundaries. Like relationship commitment, we will apply text analysis to EHR-derived clinical notes and MyChart secure messages to assess *behavioral indicators* of trust. For example, we will examine patient self-disclosure of problematic behaviors where one could be judged poorly for engaging in that behavior (e.g., non-adherence to medications), and provider's response to the self-disclosure (e.g., use of non-judgmental language vs. admonishing the patient).

Commitment and trustworthiness will be assessed using Patient Trust in Healthcare Practice Scale and Patient Trust in Medical Technology Scale. Patients' commitment in to patient-provider relationship has strong association with trust on their providers. Mutual trust strengthens relationship commitment through increased confidence in the honesty, integrity,

and competence of the partner, and their ability to uphold fidelity (i.e., respect, advocacy) in the interaction.

~~Patient anxiety in the interaction: will be measured using the 6-item State Anxiety Inventory (STAI-6), which has been used to measure state anxiety (anxiety about an event) in patient-provider visits in prior research. Items are rated on a 4-point scale (a*lmost never* to *almost always*) and include: "*I am comfortable; I am at ease" and "I feel nervous."* The STAI-6 is written at a 6th grade reading level and available in Spanish (α=0.86 to 0.95). We will also apply text analysis to the transcribed patient-provider visits to identify the expression of patient anxiety in the interaction.~~

Health literacy will be assessed using the validated Short Assessment of Health Literacy from the PhenX toolkit. The 18-item measure is available in English and Spanish (α=0.89 and 0.80, respectively). Digital and health literacy plays an influential role in how well patients are able to engage with providers, especially through digitally-mediated communications when English is not their first language.

Equity will be assessed using the validated Discrimination in Medical Settings Scale. Power differentials between patient and provider that can be exacerbated due to technology. When relationships are perceived as equitable, individuals are more likely to display behaviors that reinforce relationship commitment, and report that their partner is also engaging in them.

We will be assessing patients experience with technology using the Tech In Take Survey.

5.3 Study Population

The study will be conducted in a network of 10 safety-net primary care practices in New York. The network of practices are recognized leaders in providing high quality, culturally responsive primary care and supportive services that 'move the needle' on health outcomes for low-income residents. Each year, the practices provide care to more than 125,000 patients generating over 800,000 annual visits in underserved communities around the metropolitan New York area. Sixty-eight percent of patients followed in the practices self-identify as Latino (English- or Spanish-speaking). Half of patients (53%) served at the practices have either Medicaid insurance or are uninsured.

Selection rationale: Despite over 30 years of medication adherence research with hypertensive patients, translation of this evidence into practice within safety-net settings has lagged considerably. Our study will contribute to the scientific knowledge about how efficacious implementation strategies such as PF may expedite the translation process for implementing evidence-based systems interventions into safety-net practices to reduce HTN disparities.

5.3.1 Number of Participants

A total of 204 clinical and nonclinical staff will participate in this study, inclusive of surveys and exit interview data. In addition, 70 patients with uncontrolled hypertension (HTN) who receive care in the 10 safety-net practices will randomly be selected to participate in the surveys to assess the patient-provider relationship. Of this sample (n=700), 30 patients will

also be randomly selected to complete an exit interview to explore their satisfaction with the program and its impact on the patient-provider relationship.

An additional 300 patients across the participating safety-net practices will be selected to participate in the control group, to also assess the patient-provider relationship among those who did not participate in ALTA.

5.3.2 Eligibility Criteria/Vulnerable Populations

The study population will include practice clinical and nonclinical NYULH staff and patients with uncontrolled HTN receiving care in the network of 10 safety-net practices in New York.

Patient Eligibility Criteria

Inclusion Criteria:

• Be fluent in English or Spanish

• Be age 18 years or older

• Receiving care at one of the 10 practices

• Have uncontrolled HTN documented in the EHR on at least two visits in the past year (defined as an average BP ≥ 140/90 mmHg)

• Have been prescribed at least one anti-hypertensive medication and be non-adherent to their medications, defined as adherence <80% in the preceding 12 months, as determined by prescription orders obtained from the clinic EHR.

Exclusion Criteria:

• Being deemed unable to comply with the study protocol (either self-selected or by indicating during screening that s/he could not complete all requested tasks)

• Participation in other hypertension-related clinical trials

• Have significant psychiatric comorbidity or reports of substance abuse (as documented in the EHR)

• Plan to discontinue care at the practice within the next 15 months

Clinic and nonclinical staff Eligibility Criteria

Inclusion criteria:

• Primary care provider (MD/DO, NP), Nurse, Medical Assistant, or administrative staff employed at the participating practices and interacts with at least five patients with a diagnosis of HTN.

Exclusion criteria:

• Refuse to participate.

Control group eligibility criteria

Inclusion criteria:

• Patients who fit the inclusion criteria of the intervention group

Exclusion criteria:

• The same exclusion criteria of the intervention group will be applied to the control group

• Patients who refuse to participate in the evaluation

As ALTA grows and becomes standard-of-care, we anticipate that some patients may crossover from the control group to intervention group. The opposite will not occur because that is considered a withdrawal from the study. Our sample size for the control group can remain dynamic in that fashion, and we will recruit until the end of the evaluation period.

Vulnerable Populations

This study targets employees which are considered a vulnerable population given the additional risks of coercion and undue influence that are inherent in research studies conducted in the workplace. Targeting this population is essential to understand the practices' ability and attitudes toward implementing evidence-based interventions such as ALTA and refine strategies to help them succeed, including on-site coaching, expert consultation, data tracking and feedback, electronic health record (EHR) support, and shared learning collaboratives that are tailored to practices' needs.

NYULH employees recruited as research subjects are more vulnerable to undue influence or coercion because of the possibility that they may perceive employment or other benefits as dependent upon their participation in research. In addition, NYULH employees may experience increased risk of invasion of privacy or loss of confidentiality. To minimize these risks, a study team member with no direct supervisory or evaluation responsibilities will enroll employees who wish to participate. At time of enrollment, the study team member will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. All identifying information for employees will be kept strictly confidential following the data security provisions outlined in this protocol.

6 - Methods

6.1 Description of PF implementation strategy

6.1.1 *Usual Care (UC) Phase*

During the UC phase, patients at the sites will receive standard HTN care delivered by their primary care providers. In addition, patients and their providers will receive standard printed HTN treatment guidelines. ALTA will not be implemented at the practices during this period. During this time, bilingual RAs will recruit eligible patients into the study and collect the baseline measures at the patient, staff, and practice-levels.

6.1.2 Pre-implementation phase

Immediately following the UC phase and prior to implementation of ALTA, all practices will participate in the pre-implementation phase for a period of 6 months. During the first 3 months, facilitators will utilize qualitative interviews, validated surveys, and environmental scans to conduct a practice capacity assessment at each practice. To conduct the interviews, facilitators will use a CFIR-guided semi-structured QI interview protocol to help identify barriers and facilitators to the implementation of ALTA. This QI data will facilitate the creation of tools and training needed to support the implementation of ALTA at the sites. In accordance with CFIR, the interview guide will explore the: 1) inner practice setting (e.g., leadership support, organizational capacity); 2) external environment (e.g., patient needs and resources, external resources and incentives), 3) staff characteristics (e.g., self-efficacy, knowledge and beliefs about patient-centered counseling), and 4) intervention characteristics (e.g., complexity).

This phase will be comprised of establishing a Steering Committee who will provide oversight and feedback over the course of the trial as well as conducting an environmental scan at each of the participating practices. Both are described below.

Steering committee (SC): We will assemble a SC comprising one Medical Director, two trained ALTA MAs, one Patient Service Coordinator, one PCP, and two patient advocates recruited across the 10 practices to inform all phases of the project. The SC will: 1) help to maximize the fit of ALTA to the practices by incorporating leadership, organizational, and community knowledge; 2) involve patients and Medical Directors in refinement of the PF strategy to enhance practice capacity; and 3) help to monitor study progress, project timelines, and milestones to enhance buy-in, and implementation of ALTA at the practices. The SC will meet monthly in Year 1 and quarterly in Years 2—5. Our experience with SCs has demonstrated that the most effective way to address inherent challenges to ensuring sustained cooperation across different stakeholder groups is to implement a variety of communication strategies (e.g., WebEx meetings and weekly email updates to all partners between meetings). Besides these strategies, participating SC members will receive a $250 honorarium for their participation.

Environmental scan: An environmental scan is a structured needs assessment that combines observational and survey data collection methodologies to develop a robust understanding of the internal conditions and external factors that affect an organization. In

this study, the environmental scan will serve the dual purpose of: (1) developing a practice assessment to guide the refinement of the PF strategies that will be tested in the implementation phase and (2) giving the facilitators an opportunity to form relationships with practice staff and develop a shared understanding of project roles and responsibilities. To conduct the scan, facilitators will combine the CFIR observational tool with a structured workflow analysis and survey questions that assess staffs' perceptions about the practice culture, beliefs about organizational change, and self-efficacy to conduct health coaching sessions. Together, these data will be used to develop a robust understanding of the facilitators and barriers to implementation of ALTA at the practices. The facilitators will use a CFIR observational tool at the practices to conduct joint observations at four practices to establish inter-rater reliability. Once the facilitators achieve an acceptable level of agreement (Krippendorff's alpha >0.80), they will independently complete the observational tool at the remaining six practices. Observations will be completed in-person or virtually, as possible and permitted by the practices, to accommodate to the current COVID-19 situation. There will be no data collection with patients and clinical and nonclinical staff during this phase of the study.

During the second 3-month period of the pre-implementation phase, the study team will synthesize data collected from the QI interviews and environmental scan and present the findings to the Stakeholder Committee. The Committee, in partnership with the study team, will use this data to develop a refined PF strategy tailored to the practice context and designed to overcome the challenges to implementation of ALTA into routine practice in the implementation phase. During this period, the study team will also hold a Kick-off Event at the practices that will include didactic and interactive sessions on topics such as: the ALTA model components; best practices for implementing team-based models of care; defining roles and responsibilities in interdisciplinary care teams; developing effective interdisciplinary and patient-centered communication skills; and a discussion of the implementation and evaluation process. All clinical and non-clinical staff as well as site leadership will be encouraged to attend the Kick-off Event.

6.1.3 Description of Implementation phase

PF condition: Our PF strategy is designed to stimulate specific, actionable steps that the practices can undertake to build an internal foundation that supports the implementation of ALTA in primary care practices as routine care. This requires practice redesign with external support from the facilitators who will work with each practice for a period of 12 months. PF consists of building trusting relationships, fostering collaborative team-based problem solving, building effective communication, leveraging data and health information technology to drive improvement, establishing and sharing common goals between the facilitator and those engaged in making the change, and developing change management methods, such as Plan Do Study Act [PDSA]) to test, spread and sustain changes in the practice. A quality improvement and implementation manual informed by these tasks will be developed by the study team to drive delivery of the PF strategy and implementation of ALTA. Practice facilitators will assist practices in the following tasks:

- Setting practice change and performance goals

- Training staff on methods to help them develop robust quality improvement strategies for practice redesign (e.g. workflow mapping)
- Developing methods to identify and track patient progress through the EHR (e.g., developing registries)
- Helping practices strategize on how to implement ALTA-related practice changes (e.g., retraining MAs to serve as health coaches)
- Training MAs on the ALTA counseling script for use with patients during health coaching sessions
- Identifying best practices for integrating ALTA into the clinic workflow and spread them to other practices
- Assisting teams in testing system changes and interpreting outcomes based on the PDSA cycle

  Helping practices integrate all of the practice redesign work occurring at the site into a cohesive whole

Our PF strategy will combine one-on-one onsite tailored facilitation with opportunities for shared learning across practices through peer-to-peer collaborative calls. We will leverage our marketing and communications office at NYULH to assist in creating a project website in the first year of the study. The website will have all the project materials and will host an interactive "Ask an Expert" forum. Each MA champion and site coordinator will create a profile and password to log into the website to access the “Ask an Expert” resource.

Each facilitator will be responsible for five practices and will conduct a minimum of 13 site visits over the 12-month implementation period. These design decisions (number of site visits, ratio of facilitators to practices) are based on a systematic review of PF research and our experience implementing similar studies.

6.1.4 Selection of Instruments/Outcome Measures

Primary Outcome

Implementation fidelity is defined as the degree to which an intervention was delivered, as intended by program developers. We will use a mixed methods approach to assess the five core domains of implementation fidelity defined by Proctor's IOF:(1) adherence to the program protocol; (2) dose of the program delivered; (3) quality of program delivery; (4) participant responsiveness; and (5) program differentiation. The table details evaluation goals for each domain, and the method and timing of assessment.

Table. Domains of Implementation Fidelity, Methods and Timing of Assessment

DOMAIN	GOAL	METHOD AND TIMING OF ASSESSMENT
Adherence	To measure the extent to which ALTA has been implemented, as per protocol	Monthly Facilitator narrative reports and checklists that will provide a cumulative overview of all implementation activities including which components of ALTA were implemented, what did and didn’t work and approaches to adaptation of components to the practice context. Utilization patterns of MA case notes sent to and accessed by physician
Dose	To measure the extent to which patients were exposed to ALTA	Web-based software tool (salesforce.com) that Facilitators will use to document, on a weekly basis, the number, frequency and duration of sessions with the MA

Quality	To measure the skillfulness of the staff delivering the program components. This includes qualities related to skills communication and technical abilities	Bimonthly review of attendance logs that document registration and attendance of care teams (e.g., PCPs, MA) at the collaborative calls, kick off sessions, exposure to training and expert consultations by the Facilitators. Attendance logs of CHW at staff meetings. Trained study staff will evaluate a random sample of 10% of audiotaped sessions/calls with MAs using our previously developed Health Coaching Evaluation Checklist[8,118] Structured data collection tool embedded in the EHR that will be used to rate the quality of data entry in HTN management and community referral templates (e.g., documentation of patient goal and action plan using SMART framework, # of referrals made and completed)
Responsiveness	To measure the level of patient and staff engagement with and acceptance of ALTA	Self-administered survey at 12-months to assess patient and clinic staff (e.g., MA, PCP) satisfaction with ALTA and acceptability of the practice changes. The staff survey will be adapted from the 28-item practice redesign satisfaction survey developed by Lewis et al. (α = .87). The patient survey will be assessed with the well-validated Experience of Care and Health Outcomes (ECHO) survey measures. We will also include items specific to ALTA to these surveys. Semi-structured interviews at 12 months with a random sample of 30 staff and 30 patients across that will inquire about topics such as: satisfaction with ALTA, challenges with using/receiving care in the ALTA model, and factors that affected their ability to engage with the different components of ALTA (e.g., availability of MAs at pre and post-visit time points)
Differentiation	To measure the unique features of ALTA that are distinguishable from other programs at the SIPs	Web-based software tool that Facilitators will use to document all the initiatives that are occurring at the practices during the study, the goals of the initiatives, the specific components and related activities of each initiative, the staff involved, and the target patient populations

Our qualitative measure of implementation fidelity will be comprised of practice facilitator narrative reports (to assess program adherence), audiotaped health coaching sessions (to assess implementation quality) and semi-structured interviews with clinic staff/providers and patients (to assess participant responsiveness). In addition, each of the five core domains of implementation fidelity defined by Proctor's IOF will be assessed using a structured tool developed for this study and defined in the following manner:

Level of implementation adherence will be evaluated quantitatively as the degree to which the components of ALTA (e.g., identify, refer, coach, document, monitor) were implemented as intended, using data from checklists completed by the facilitators as well as extracted from the EHR. Each intervention component will be rated on a 3-point scale: 1=The component was not implemented, as per protocol; 2=The component was partially implemented; and 3=The component was fully implemented and/or modified with permission, as per protocol. We will calculate adherence as the number of components fully implemented (ratings of 3) divided by the total number of possible components (N=8). Practices will be considered adherent to the protocol if components were implemented completely and/or they were completed with an adaption that did not affect the programs core components and was approved by the study team. Facilitators will also complete monthly narrative reports that summarize all adaptations made to the components and what did/did not work for each practice context. We will also measure adherence through the Health Coaching Evaluation Checklist. The checklist will be used to count the parts of the standardized counseling script that were covered by the MAs at each health coaching session.

Implementation dose will be evaluated as the extent to which patients were exposed to ALTA. We will collect data on utilization patterns of the different ALTA components including the mean number of: ALTA-eligible patients identified in the registry and referred to a Health Coach; health coaching sessions completed with ALTA patients; entries in the EHR-embedded coaching script; progress notes documented in the EHR and shared with the care team; and follow-up sessions that are scheduled and/or completed. System files will be extracted quarterly and will contain date and time stamps as well as user logins for the tools used.

Implementation quality of each ALTA component will be evaluated as the quality and content of data entry in the HTN registry, EHR-embedded coaching script, progress notes, and follow-up scheduling. Facilitators will rate the completeness of this form using a 3-point rating scale (1, poor; 2, adequate; 3, high). A random 10% sample of counseling sessions by the clinic Health Coaches will also be audiotaped and evaluated using the Health Coaching Evaluation Checklist, as we have done in our previous trials. A fidelity score will be calculated as the percentage of topics completed and how well they were delivered (1: poor skill performance, 2: adequate skill performance, 3: exemplary skill performance).

Participant responsiveness will be evaluated as patient and practice staff/provider satisfaction with ALTA and acceptability of practice changes with validated measures (i.e., ECHO survey for patients and a modified survey for staff/providers). In addition, qualitative interviews will be conducted with a random sample of clinic staff (n=30) and patients (n=30) across the practices to assess satisfaction with the intervention.

Program differentiation will be evaluated as the unique features of ALTA that are distinguishable from other programs at the sites. Throughout the study, facilitators will catalogue all initiatives that are occurring at the practices (as observed during site visits and/or reported by the practice leadership). This will be used to quantify the degree of overlap between the ALTA components and other quality improvement initiatives at the sites (1: no overlap, 2: some overlap], 3: significant overlap) as well as isolate the unique features of ALTA that distinguish it from those initiatives.

Secondary Outcomes

Workbench report will be requested from DataCore to include data from patients that have been diagnosed with hypertension and receiving care from the 10 safety-net practices. The workbench report will include PDC scores, demographics, B/P readings, medication list, and Voils medication adherence scores.

The ALTA workflow was built in Epic in coloration with MCIT. Therefore, we want to evaluate how the end-users (MAs, RNs, MDs, and PSAs) use the template built to enhance hypertension care at their sites. The data from the workbench report will be de-identified and analyzed in aggregate form to explore the primary outcome of Project ALTA.

As part of the ongoing Quality Improvement evaluation process, the study team will use the data from the workbench report to:

- Identify missed opportunities (patients who were eligible but were not enrolled in the program) and generate ideas for improvement with the sites (e.g., discuss these missed opportunities in daily huddles). Data will be presented to sites in an aggregated form.
- Collaborate with MCIT to refine the Epic workflows based on-site feedback and data from the workbench reports (e.g., smartest for MDs to place the MyChart Home Blood Pressure monitoring not firing)
- Complete PDSA (Plan-Do-Study-Act) cycles with the ALTA QI Champions at the sites to develop shared goals for improving ALTA implementation.

Since the data needed to provide performance feedback to the sites is in Epic, exported data will be password protected and stored in a study folder shared drive. Only study team members will have access to the data.

BP control, the major secondary outcome, will be defined as SBP <140 and DBP <90 mmHg. BP control will be assessed using the mean of the last two measurements recorded in the EHR during each of the pre-intervention and post-intervention study periods (baseline and 12 months). BP readings will be extracted from patients' EHR by trained RAs. We will use the last two recorded measures to reduce variability associated with multiple BP measurements being taken by different clinic staff. We will also examine the proportion of patients with BP control <130/80 mmHg in exploratory analyses to provide preliminary data on BP control rates of hypertensive patients when considering the new guidelines. We will also explore mean change in systolic and diastolic BP based on the mean of the last two recorded BP readings in the EHR during the pre- and post-intervention periods.

Medication adherence will be assessed via pharmacy refills obtained from prescription orders in the clinic EHR using the proportion of days covered (PDC) metric. The PDC is calculated as the total number of days covered by the medication divided by the number of days between the first fill of the medication in the study period and the end of the study period. Thus, as opposed to other pharmacy refill metrics, the PDC accounts for non-persistence with medications by tracking medications during the study period despite early discontinuation. We will count the days the patient was covered by each of their prescribed antihypertensive medications based on the prescription fill date and days of supply. If prescription fills for the same medication overlap, then we will adjust the prescription start date to be the day after the previous fill has ended. Patients will be considered adherent if they fill ≥80% of their antihypertensive medications over the 12 months.

Tertiary Outcomes

Relationship commitment: To assess patients' *perceived commitment* to their PCP, we will utilize the self-report measure developed by Berry et al. in a sample of primary care patients. The 5-item measure asks patients to rate their degree of commitment to the relationship with their doctor on a 7-point Likert scale (*strongly disagree* to *strongly agree*). Sample items include: *The relationship with my doctor is…something I am committed to; something I care about; and important to me.* This measure will be administered to patients at baseline and 12 months.

To assess the *behavioral and affective indicators* of relationship commitment we will use NLP and analyze text of patient-provider interactions that

Table 1. Exemplars of behavioral and effective indicators of relationship commitment

Part of the clinical interaction	Examples of relationship commitment behaviors and affect	Measurement strategy
Initiating the session	Patient and PCP creates a warm and friendly environment; collaboratively identify reason for visit and negotiate agenda	Sentiment analysis to identify affective behaviors (warmth, cheerfulness, and attentiveness) [108]
Gathering information	PCP use of questions to explore a patient's problem and creates opportunities for patients to express concerns and ask questions; looks for potential barriers to communication (e.g., language, anxiety). Patient provides a complete medical history and information on current behaviors and condition from their perspective	Lexicon dictionaries (e.g., Linguistic Inquiry and Word Count [LIWC]) to identify interrogatives - e.g., asking questions[105]
Explanation and planning (shared decision-making)	PCP gives succinct, jargon-free information and checks patient understanding; actively involves patient in decision making process, and respects patient's decision Patient communicates their level of understanding and ask PCP to clarify information; adds perspective on treatment plans and agrees on what is feasible	LIWC to identify presence of assent words, absence of interaction qualities that inhibit openness, i.e. negative affect, anxiety, use of tentative words.[105]
Closing the session	PCP provides a summary of the discussion, verifies plan, and clarifies future expectations. Patient agrees on plan; clarifies what s/he should do between visits	To identify lexicons associated with closing rituals of speech acts with LIWC, and DAMSL.[106,107]

occur in the 12 months prior to ALTA, and over the 12 months ALTA phase. Data will be extracted from the EHR (e.g., clinical notes and free text) and MyChart secure messages to conduct these analyses. Table 1 provides examples of how we will examine patients' and providers' commitment to one another, and the associated measurement strategy, as they occur across different parts of the clinical interaction.

Patient-provider trust: To assess perceived patient-provider trust we will administer patient and provider measures developed by Thom et al. at the baseline and 12-month visit.

Patient: The 11-item Trust in Physician Scale (TPS) assesses a patient's interpersonal trust in their doctor. Responses are given on a 5-point Likert scale ranging from *totally disagree* to *totally agree.* Sample items include: "*I doubt that my doctor really cares about me as a person" and "If my doctor tells me to do something, then it must be true."* The TPS has high internal validity (α=0.89) and adequate test-retest reliability in a primary care sample. Prior research has found that TPS scores are associated with continuity of care, medication adherence, and satisfaction with care.

Provider: The 12-item Physician Trust in the Patient Scale (PTPS) assesses the provider's perspective of patient behaviors that characterize high and low-trust relationships. The PTPS includes 2 subscales; the first asks about providers' expectations that patients will behave in ways that fulfill their roles in providing accurate and complete histories, asking questions, and adhering to treatment plans. The second subscale includes items about respecting the provider's time and personal boundaries. The PTPS has high internal reliability (α=0.93), and convergent and discriminant validity. Prior research has found an association between low PTPS scores and patient non-adherence. To examine mutual trust, we will dichotomize scores on the TPS and PTPS into high and low trust values and compare the level of congruence between patients' and providers' score as: fully congruent, partially congruent, and incongruent. Like relationship commitment, we will apply text analysis to EHR-derived clinical notes and MyChart secure messages to assess *behavioral indicators* of trust. For example, we will examine patient self-disclosure of problematic behaviors where one could be judged poorly for engaging in that behavior (e.g., non-adherence to medications), and provider's response to the self-disclosure (e.g., use of non-judgmental language vs. admonishing the patient).

Moderator Variables

For the secondary aim 2, we will evaluate the potential moderating roles of practice- and individual-level factors on ALTA implementation at the practices. We will administer measures at baseline and 12 months (Table 2). All measures will be administered to clinical and nonclinical staff and administrative leadership at the practices. Based on our prior work, we expect a response rate of 70% across practices. Individuals will receive an incentive for timely completion of the surveys (n=204).

Practice-level measures

Organizational change process capability is a validated tool specifically applicable to primary care practice. The survey is divided into three domains that correspond to the three domains

of the Ingersoll definition of capacity to manage change: (1) history of change; (2) plans for continuous organizational refinement; and (3) ability to initiate and sustain change.

Implementation leadership will be assessed with the 12-item Implementation Leadership Scale (ILS), which has excellent reliability, and convergent and discriminant validity. The ILS is comprised of four subscales—Proactive Leadership (α=.95), Knowledgeable Leadership (α=.96), Supportive Leadership (α=.95), and Perseverant Leadership (α=.96)—and a total score (α=.98).

Adaptive reserve is defined as a practice's ability to make and sustain change and includes measures of facilitative leadership, relationship infrastructure and culture of learning. Adaptive reserve will be assessed with the 23-item scale developed for the National Demonstration Project Model of the Patient-Centered Medical Home (α = .86) that is scored on a 5-point Likert scale (strongly disagree, disagree, neutral, agree, strongly agree). The final result is scaled in a 0-1.0 scale with 1.0 being a perfect score.

Individual-level measures

Evidence-based practice attitude scale is a measure with four subscales that assess attitudes toward implementation of evidence-based practices (EBP) as a function of perceived appeal of EBP, requirements to use EBP, provider openness, and perceived divergence between EBP and usual care. Total scores (α=.76) represent global attitudes toward adoption of EBP.

Organizational change recipients' beliefs scale is a tool that evaluates: a) the degree of buy-in among change recipients (the MAs); b) deficiencies in specific beliefs that can adversely impact the success of organizational change; and c) planning and executing actions to enhance buy-in among organizational change recipients. Items are scored on a 5-point Likert scale. The Cronbach α ranges from .70 to .94.

MA counseling self-efficacy will be assessed with an adapted version of the Counselor Self-Efficacy Scale, which assesses counselor's level of confidence for performing client-centered skills and addressing client concerns (α=.98)

Practice culture assessment (PCA) is a scale that assesses provider and staff perceptions of practice culture thought to be important to practice functioning and successful implementation of quality improvement projects. The three subscales are: 1) work culture (e.g., how team members collaborate to ensure high-quality care); 2) change culture (e.g., quality of collaborative problem resolution and change management); and 3) chaos (e.g., level of practice instability, disruption, and disorganization).

Implementation climate will be assessed with the Implementation Climate Scale (ICS) that measures shared perceptions of the policies, practices, procedures, and behaviors that are expected, supported, and rewarded to facilitate effective EBP implementation (α=.91). The six subscales of EBP Implementation Climate are: Focus on EBP (α=.91), Educational Support for EBP (α=.84), Recognition for EBP (α=.88), Rewards for EBP (α=.81), Selection for EBP (α=.89), and Selection for Openness (α=.91).

Practice and participant characteristics

Practice characteristics: At baseline, we will collect data on the number of full-time equivalent staff, insurance payer mix, clinic volume, practice structure, patient demographics, staff composition (e.g., number of nurses, MAs), use of health information technology, current quality improvement initiatives, and other current or planned programs at each practice. We will also collect EHR data on the number and type of providers seen by patients enrolled in ALTA and provider turnover rate (i.e., stopped having patient encounters on the site for at least 12 months).

Clinical and nonclinical Staff characteristics: At baseline, we will collect data on education level, race/ethnicity, age, sex, primary language spoken, time working at the practice, patient load, previous trainings in chronic disease management, patient-centered communication and quality improvement methods, and job satisfaction and stress.

Patient sociodemographic and clinical characteristics: At baseline, we will collect sociodemographic data such as patient age, sex, place of birth, acculturation, primary and preferred language, insurance status, duration of HTN, number and classes of prescribed HTN medications, doses and frequencies of ingestion, and medical comorbidity. At 12 months, we will collect data on changes in doses of HTN medications, frequency of clinic visits, and the use of other medications that affect BP (e.g., NSAIDS, hormone replacement therapy).

Observational measure: The CFIR observational tool was developed to document observations during a site visit, organized by the five domains of the CFIR model. Trained practice facilitators will use the CFIR observational tool during the pre-implementation phase to assess all 10 practices on the current state of its inner practice context (e.g., workflows, communication channels) and external environment (e.g., awareness of patient needs and preferences, connections to outside organizations).

Table 2. Study measures

Domain	Measures	Data Source	Timing of Administration
Baseline Measures			
Practice characteristics Patient characteristics Staff Characteristics	• Practice characteristics extraction form • Socio-demographic form	• EHR	Baseline
Practice-level moderators	• Implementation Climate Scale • Implementation Leadership Scale • Evidence-Based Practice Attitude Scale • Change Process Capability Questionnaire (and 12 mos.) • Adaptive reserve (and 12 mos.)	• Clinical and nonclinical staff survey	Baseline
Pre-implementation Phase Measures			
Internal practice and external context	• CFIR Observational Tool • Workflow analysis • CFIR interview • Organizational Change Recipients' Beliefs Scale • Counselor Self-Efficacy Scale • Practice Culture Assessment	• Practice facilitator environmental scan • Key informant interviews with 30 clinical and nonclinical staff across 5 intervention practices • Clinical and nonclinical staff survey	Pre-implementation phase (post randomization)
Primary Study Measures			
Implementation fidelity (primary outcome)	• Adherence to the ALTA protocol • Dose of ALTA components delivered • Quality of delivery • Participant responsiveness • Program differentiation	• Web-based PF tracking system and narrative reports • Training/collaborative call attendance logs • Audiotaped health coaching sessions • Quality of data entry in EHR templates	Ongoing

		• Key informant interviews with practice staff • Clinic staff and patient satisfaction surveys (12 months only)	
Blood pressure (BP; secondary outcome)	• Attainment of BP control	• EHR	Baseline and 12 months
Adherence to antihypertensive medications (secondary outcome)	• Proportion of days covered metric based on pharmacy refill data • EHR	• EHR • Voils Adherence Measure	Baseline and 12 months
Patient-provider relationship	• Perceived strength of relationship commitment • Level of mutual trust between patients and providers • Level of patient anxiety in the interaction	• EHR • MyChart • Survey	Baseline and 12 months (survey) Ongoing (EHR and MyChart)
Semi-structured interviews			
Exit interview	• Moderator's guide that inquiries about satisfaction and recommendations for improvements as well as impacts of ALTA on the patient-provider relationship	• Interviews with 30 clinical and nonclinical staff across all sites • Interviews with 30 patients across all sites	12 months

An outcomes assessment is completed at the Implementation Phase Study Visit at 12-months, including surveys about satisfaction with the intervention and implementation process at each site. A set of questions measuring potential ripple effects and capacity for sustainability will be assessed at this time at FGP practices as part of the 12-month Online Survey, and is described below. We are completing these questions at FGP practices only to understand sustainability considerations within these practices. Questions take less than 10 minutes to complete.

- Ripple effects are unanticipated impacts to organizations or stakeholders that may result from evidence-based intervention implementation. A working group created a survey to measure the ripple effects of the program on practice staff and practice sites. The survey is adapted from a compilation of possible ripple effect categories identified and described in the literature (Pullmann et al 2022). It consists of 10 questions measuring potential unintentional impacts of the program on the delivery of other programs, job satisfaction, staff roles and relationships, accuracy of data, health equity, resources, delivery of health care, and culture. Questions will be answered on a 5-point bidirectional likert scale, with response options ranging from 'strong negative' to 'strong positive'. The survey will be administered to practice providers and staff at FGP practices at End of Study with the Exit Interviews and will follow the same protocol. Surveys will be sent via email and completed via REDCap. No identifying information will be collected. Risk to participants for completion of the survey is minimal with a slight risk to subject confidentiality. The deidentified data will be sent to the Research Coordinating Center and Data Safety Monitoring Board every September.
- Clinical Sustainability Assessment Tool - Clinical sustainability capacity is defined as the ability of an organization to maintain structured clinical care practices over time and to evolve and adapt these practices in response to new information. This tool 27-item tool is an assessment of current capacity for sustainability across a range of specific organizational and contextual factors. Responses will identify sustainability strengths and challenges that can be used to guide sustainability action planning for clinical practice.
- Exit Interview Guide for FGPs- to understand the satisfaction with the intervention and implementation at each site as well as areas for improvement

6.1.5 Intervention Administration

Practice facilitator staffing and training: We will leverage the existing network of trained practice facilitators in our Department at NYULH to hire two facilitators. Our facilitators are health professionals with a minimum of a master's degrees (e.g. MPH) who have clinical and managerial experience and have been working in primary care settings as a facilitator over the past two years. Our facilitators were previously trained at the University of Buffalo Practice Facilitator Training program. This training program was designed and developed by national experts who drew upon the AHRQ Practice Facilitation Handbook. This is a 92-hour course with 13 weekly 1.5-hour live online classes plus a 40-hour fieldwork practicum (shadowing an experienced facilitator) and 26 hours of reflective learning. The training includes 21 modules that cover the full range of topics for trainees to achieve the four core competencies of practice facilitators: data use to drive improvement, interpersonal skills, Health IT optimization, and quality improvement and change management methods. In the first year of the project, we will add curriculum components to meet the specific goals of this study (e.g. education on the updated HTN guidelines) as well as training tailored to the specific intervention components, including system changes that we propose to implement, and data extraction from EHRs. They will also receive trainings on human subjects research and data safety. In subsequent years of the project, they will receive booster trainings on the curriculum components, as needed. The training combines didactic sessions with case-based learning using "standardized practice" exercises and will also be incorporated into the fieldwork experience.

Practice facilitator supervision: Drs. Schoenthaler and Ogedegbe will serve as facilitation managers where they will provide the day-to-day oversight of the facilitators. Drs. Schoenthaler and Ogedegbe will meet weekly with Facilitators at the start of the week to review the schedule, anticipated challenges, the need for additional expertise or assistance from IT or other project staff, and to review the previous weeks tracking reports (Table 5). These meetings are meant to assist facilitators to 1) develop and maintain facilitative relationships, 1) maintain effective boundaries to allow the practice to build capacity, 3) acquire the content knowledge needed for the particular PF intervention, 4) monitor their panel of practices' progress through the stages of the intervention model and implementation of change concepts, 5) troubleshoot problems, and 6) review the structured weekly activity reports and monthly narrative reports

6.1.6 Reaction Management

In the event that any of the participants (patients and clinical and nonclinical staff) experience anxiety as a result of participating in the pre-implementation and/or implementation phases of this trial, we will provide a list of mental health services that are offered at no or low-cost through the NYU Brooklyn network of participating practices. If immediate attention is warranted, the clinic social worker and/or psychologist will be contacted.

6.2.1 Efficacy

The efficacy of the intervention will be assessed via the secondary outcomes, improved BP control and antihypertensive medication adherence, at 12 months. BP control will be assessed using the mean of the last two measurements recorded in the EHR during each of

the pre-intervention and post-intervention study periods (baseline and 12 months). Medication adherence will be assessed via pharmacy refills obtained from prescription orders in the clinic EHR using the proportion of days covered (PDC) metric over the course of the 12-month study.

6.2.2 Safety/Pregnancy-related policy

Patients who are pregnant or planning to become pregnant in the next 12 months are excluded from participation in this trial.

6.2.2.1 Adverse Events Definition and Reporting

The Principal Investigator (PI) will be responsible for quality control including reviewing and reporting adverse events. The plan will comprise the following elements:

- Adverse events will be reported to the IRB.
- A detailed plan to address serious events that may arise during study visits, such as blood pressure values that indicate a hypertensive emergency, is in place. Critical blood pressure values are defined as: 180/100 mm Hg or higher. In the event that the RA encounters such readings at any point in the study visit process, the following protocol will be triggered: (1) Let the participant know that these values are very high and recommend follow-up with his/her primary care provider; (2) Alert the study PI and contact the Project Manager to inform that such a reading has occurred; (3) Document all cases on Adverse Event Form. The Project PI and key personnel will meet every 6 months to review adverse events reports, participant complaints, if any, and dropout rates. Data will be provided at those meetings by the investigators on key variables that may indicate harm, including changes in blood pressure and cardiovascular risk profile.
- Any unexpected adverse reactions that are associated with the research and that are fatal or life threatening will be reported to the IRB within 24 hours of discovery. Any unexpected adverse events associated with the study that are moderate to severe in nature, but not life threatening, will be reported to the IRB in 5 days.
- Summaries of adverse events reports will be made to NIMHD in the yearly progress or report or, at the end of year 5, in the final report, unless the nature of a particular event is such that it bears immediate reporting to NIMHD.
- If a serious adverse event occurs as a result of the study, consideration will be given to stopping the study early. In the event of early stopping of the study, the IRB will be promptly notified.

6.2.3 Pharmacokinetics (if applicable)

Not applicable

6.2.4 Biomarkers (if applicable)

Not applicable

6.3.1 Study Schedule

The duration of the pre-implementation phase is 6 months. During this time, we will collect observational data through the environmental scan, and data on practice characteristics via the EMR.

The duration of the implementation phase is 12 months. The intervention includes site visits by a practice facilitator. It is estimated that facilitators will conduct a minimum of 13 sites visits over the 12 month intervention period. In addition to the site visits, patients and clinical and non-clinical staff will participate in two study visits over the course of 12 months: baseline and 12 months

The estimated time for each study visit is outlined below:

Patients:

QI improvement interviews at 3 and 6 months: 15 min

Consent/Baseline visit: 30 minutes

Final study visit (survey and exit interviews) at 12 months: 75 minutes

Staff:

Consent: 10 minutes

Baseline: 20 minutes

Final study visit at 12 months: 60 minutes

The study visits are not linked. Staff will be consented at both baseline and final study visit.

6.3.2 Informed Consent

Both patients and clinical/nonclinical staff will provide informed consent to participate in this study. The New York University IRB will approve the protocol and consent.

Clinical/nonclinical staff Survey Consenting Process: Due to COVID-19 regulations, staff will complete the consent form and the baseline surveys remotely via RedCap. A RedCap link will be sent to a general email distribution list with information about the study and staff interested in participating will click on the link, provide informed consent and complete the baseline, and/or the 12-month surveys anonymously.

After clicking on the link, potential participants will read the 'consent statement' which includes PI name, brief study purpose, details on voluntary participation, ability to stop at any time without explanation and further, that such action will in no way affect their relationship with the primary care practice, confidentiality (anonymous survey), risks/benefits, etc. The email will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. They will then be given the option of whether they choose to participate. If they choose to participate, they will proceed to the survey, otherwise, participants will terminate the survey.

All participants will have the capacity to give consent. Comprehension will be assumed when participants read and accept the terms of consent statement prior to initiating the survey. Debriefing procedures will not be necessary.

For the clinical/nonclinical staff only clicking on the “proceed to the survey” button, will be the subject’s documentation of consent to participate in the study. Staff will be consented at both baseline and final study visit and consent/surveys will not be linked as the surveys are anonymous.

Clinical/nonclinical staff Exit Interview Consenting Process: A random sample of 30 clinical/nonclinical across all 10 practices will complete an exit interview where they will be queried about their experiences with ALTA and the PF intervention (if applicable) over the past 12 months and recommendations for improvements. This visit should take 30 minutes.

Participation is voluntarily and those interested in participating will be encouraged to sign and date a consent form. The interviews will be completed in-person or virtually to accommodate to the current COVID-19 situation. The interview method (face-to-face face vs. virtual) will be determined at the discretion and preference of the participants, while following practices and NYU institutional regulations for COVID-19. Invitation to participate will be random. A RedCap link will be sent to a general email distribution list with information about the exit interview and staff interested in participating will click on the link to provide informed consent. An RA will then proceed to arrange a meeting with staff to review the consent form and answer questions staff may have. Audio recording will be obtained and after the interview is recorded it will be transcribed and identifier removed to protect the subject.

Patients: Patient consent will be conducted during an in-person meeting with a RA in a private place at the practice. During the meeting the RA will give a fuller description of the study to the participant in clear, easy to-understand language, emphasizing the points made during the initial telephone call/letter/Epic invitation. All patients will be told that their responses are anonymous and confidential, that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such action will in no way affect their future interactions with their PCP. If the patient remains interested in participating, they will be provided with a copy of the consent form to read; if the patient asks for help or evidences a problem in reading the consent due to literacy issues, the RA will read and explain the consent him/her. Patients will be asked to repeat back to the salient points of the consent form to make sure that they understand the study they are agreeing to participate in. Patients who exhibit any cognitive deficits will not be eligible to participate in this study. If the patient desires to participate, s/he will sign, and the RA will co-sign. Participants will receive a copy of the signed informed consent. A second copy will be stored in a secure, locked filing cabinet in a dedicated room. We are also submitting a waiver of documentation consent in order to obtain verbal consent as an option for patients. We are requesting verbal consent to assist participants who are uncomfortable using redcap on their phones the opportunity to verbally consent. As we continue using traditional recruitment methods virtually (i.e., calling patients), we’ve repeatedly encountered challenges with obtaining electronic consent from older patients. While we guide them through the process of opening and submitting the REDCap form, many have expressed frustration with the technology. Adding a verbal consent option would significantly reduce this barrier and improve patients’ willingness to complete brief virtual surveys.

We are providing the options for both written and verbal informed consent. The consent form will be reviewed with all patients by a research assistant and patients can choose to provide consent in written form or verbal form and the study team will document as such in REDCap. In anticipation of crossover from the control to the intervention group, we are using a single consent form for the evaluation.

Due to COVID-19 and to keep the safety of both our research team and research subjects, we are slightly modifying our consenting strategy to maintain our original plan of doing in-person consenting strategies as well as to permanently include collecting virtual consent (e.g., via telephone, using RedCap), as follows. Once the participant agrees to participate in the study, a trained RA will schedule a time with eligible interested participants to go over the written consent via telephone. RAs will email or mail a copy of the consent to participants in preparation for the telephone consent. After going over the written consent via telephone, RAs will also send the consent via an IRB approved RedCap link where the participant has the opportunity to read the consent and sign it electronically as well as to confirm that they read and understood the consent. Once the participant has signed the consent form, the RA will print out the signature page, sign it and mail it back to the participant. A copy of the signed consent form will be kept securely on file in the participant's study folder. Alternatively, participants will have the option to use finger signature in RedCap and mail the signed page of the consent back to the RA. The RA will then sign and mail the consent back to the participant. A copy of the signed consent will be kept securely on file in the participant's study folder. RAs will also document on RedCap the time and date of the telephone consent and note that the consent process was done via telephone.

The RAs on the project will have previous experience working on intervention trials and as part of this work have obtained informed consent from demographically divers e participants. Further, the RAs will be experienced with consenting Spanish-speaking participants. If the participants speak Spanish, they will receive an IRB approved Spanish translated Consent form. The Spanish consent form will be explained by a Spanish-speaking RA. A modification will be submitted that contains only translated research materials, including the informed consent documents.

6.3.3 Screening

Trained RAs will be responsible for screening potentially eligible participants from the practices. Once a potentially eligible patient is identified for this study, they will be screened using a standardized form that outlines the study's inclusion and exclusion criteria. Study staff will obtain verbal consent prior to beginning the eligibility screening. Only participants that meet all eligibility criteria will provide written informed consent.

6.3.4 Recruitment, Enrollment and Retention

Practice clinical and non-clinical staff will be recruited through study team attendance at the monthly staff meetings, email communications that describe the project including the overarching goals and what is expected of participants, and in-person or virtual meetings with the practices.

We will recruit approximately 500 patients across the practices who meet the following eligibility criteria (described above). Several strategies will be used to maximize the number

of eligible patient participants recruited per practice as described below. Signed informed consent will be obtained from participants who meet the study eligibility criteria.

Since this is a clinic wide initiative, we are broadening our eligibility criteria to include patients of all race and ethnicities, and not be exclusive to Latinx patients (this is also reflected in the change to our project name). We will still recruit a random sample of 70 patients per clinic that receive care in the 10 safety-net practices to participate in the surveys to assess our tertiary outcomes. Of this sample, 30 will be randomly selected to participate in an exit interview. Patients will be randomly selected from a list of patients who receive care in the clinics and have been exposed to the ALTA project. The same recruitment strategies will be employed to recruit 300 patients who receive care in the clinics and met eligibility for ALTA but did not ultimately participate in the project. All patients will provide written informed consent prior to participating in the study.

Method 1: Recruiting Using EHRs through EPIC: We will use EPIC to identify potentially eligible patients seen in the practices, based on DRG codes indicating presence of hypertension. Each month we will create a roster of potentially eligible patients through a review of the EHR-embedded HTN registry for each treating physician in the practice. Primary care providers will be asked to review the list of their eligible patients, and then asked permission to enroll the patients in this study. Lists of patients deemed appropriate (i.e., "yes") by the physician will be generated. Following permission from practice treating physicians to recruit their patients to the study, patients will be approached and screened using the following process: (a) A letter signed by the treating physician and Dr. Schoenthaler will be sent to the treating physician's patients notifying them of the study, and informing that an NYULH clinical staff person will contact them to explore their willingness to consider participation, or that their patients can call directly to the study staff to ask about the study. (b) Study staff will call patients who agree to be contacted, describe the study and, if the patient expresses an interest, conduct preliminary screening by telephone. Verbal consent is obtained by study staff prior to eligibility screening. (c) For potentially eligible patients with active MyChart accounts that have agreed to be contacted for research and indicate yes under the “recruiting ok?” option on EPIC, study staff will send the already IRB approved email script via Epic. The patient will receive the message via MyChart and it will automatically be noted on their EHR as an encounter message. (d) Written informed consent will be obtained with subsequent in-person or virtual visit for eligible participants to accommodate to the current COVID-19 situation. The consenting method (face-to-face face vs. virtual) will be determined at the discretion and preference of the participants at the time of the telephone screening, while following practices and NYU institutional regulations for COVID-19. An IRB-approved waiver of authorization will be obtained prior to searching the EHR.

Method 2: Participant self-referral through EPIC EHR MyChart alerts: We will provide the NYULH Epic Research Integration team with a list of potentially eligible patients provided to us by NYULH DataCore services through an IRB-approved waiver of authorization. The Epic team will create weekly reports on upcoming appointments from this potentially eligible patient's list, and will send these patients an alert notification two weeks prior to these

appointments. These alerts will inform patients to check MyChart electronic record for a new message. A modification will be submitted with the alert text prior to starting the study.

We will provide a NYULH Epic Research Integration team with an IRB-approved patient-facing script to be posted in the Epic electronic health record patient portal (MyChart) with a brief study description and encouragement to discuss the study with their treating physician on their next appointment. After this encounter, the Epic Research Integration team will send a second alert to potential participants after their medical appointment for them to check MyChart for another IRB-approved message reminding patients to contact study staff for any questions or to express their interest to participate. At this point, study recruitment proceeds as per protocol: (a) study staff describe the study and, if the patient expresses an interest, conduct preliminary screening by telephone. Verbal consent is obtained by study staff prior to eligibility screening. (b) Written informed consent will be obtained with subsequent in-person or virtual visit for eligible participants to accommodate to the current COVID-19 situation. A modification will be submitted with the alert text prior to starting the study.

Method 3: Self-referral from advertisements placed in the practices: IRB-approved fliers and brochures containing an overview of the study will be created and displayed in the clinical practice setting for those who may be interested. Interested patients will be provided with the phone number of the study staff that they may call to obtain additional information about the study. Those participants contacting the study office will be provided a brief description of the goals of the study and what their participation would entail. Those who remain interested will be screened to assure that they meet eligibility criteria and schedule an informed consent in-person or virtual visit. We will contact the patients' healthcare provider/agent to determine if their patient is fit to participate in the study. A modification will be submitted with flyers prior to starting the study.

Method 4: Physician referral: During the provision of routine ambulatory care, physicians will identify potentially eligible participants and ask about their interest in a study that proposes to examine how patient and providers talk about taking medications. Interested patients will be advised to contact the study by telephone to discuss possible enrollment. Interested patients will be provided with the phone number of the investigators that they may call to obtain additional information about the study. Those participants contacting the study office will be provided a brief description of the goals of the study and what their participation would entail. Those who remain interested will be screened to assure that they meet eligibility criteria and will be scheduled to complete the informed consent in-person or virtual visit.

Method 5: The study team will also conduct in-service in-person or virtual visits with the study sites prior to patient enrollment and every 3 months thereafter to explain the study rationale, its significance and procedures. At this time, clinic staff will be given a postcard (either digital or paper copy) that lists eligibility criteria and contact information for the RAs. During these in-person or virtual visits, personnel from each site with access to hypertension registries (nurses or staff participating in ALTA) will be assigned, with help from leadership,

to send a monthly roster list with potential eligible participants scheduled to see their PCP in the following month.

We will use several strategies to retain practices and participants while they are enrolled in the trial. These include: (1) Signed memorandum of understanding (MOU): We have found that this formal agreement ensures that the sites understand the purpose of the study and their roles and responsibilities for participation, which increases the likelihood of retention. The MOU also highlights the benefits of participating in the project. All sites will be asked to sign this agreement as part of the recruitment and enrollment process. (2) Identify a practice champion or key contact to act as a liaison: This is also crucially important to ensure fidelity to the implementation of the ALTA intervention into the clinic workflow. (3) Offer monetary incentives for participation. For patients, this includes offering appropriate incentives, time to complete study visits, periodic phone calls, and transportation to the sites (total incentive: $70: $25 for each of the two study visits (baseline and 12 months; $20 for the exit interview, if selected). Staff will be offered an incentive of $50 for completion of the two study visits (baseline and 12 months) and an additional $25 for the interview, if selected). (4) Maintain communication: For patients, following consent, we will request the names, addresses, and telephone numbers of two friends or relatives, so we can contact patients in the event of a missed appointment. This approach has been a helpful strategy in prior trials. We will implement additional strategies that have led to successful retention of racial/ethnic minority patients in clinical trials such as: provision of a toll-free study telephone number; flexible scheduling; and continuity of study staff to maintain a personal connection to the study. For clinical/nonclinical staff, we will maintain contact through an emailed newsletter for these sites that provides updates about national and statewide health care initiatives but does not discuss intervention-related information. We will also remind staff of the protocol at the monthly meetings.

In addition to these recruitment strategies, a subsample of individuals will be selected to be randomized to one of three Clinical and Translational Science Institute (CTSI) recruitment approaches to complete the eligibility screener and to enroll:

- Proactive outreach by mail or telephone – We will reach out to potential participants proactively by mail and phone. Potential participants will receive two mailings, followed by four telephone calls.
- Proactive outreach through EHR – We will reach out proactively through MyChart to potential participants. Potential participants will receive a message every 2 weeks for a total of four messages.
- Unsolicited text messages – Using an approach we have used previously [1] [2], we will send unsolicited text messages, using TelASK software, mentioning the study and offering the opportunity to enroll. Texts will be sent by a study team member using a study iPhone. As required by the Federal Communications Commission, these messages will be preceded by a message from the health system, telling

[1] Krebs P, Sherman SE, Wilson H, et al. Text2Connect: a health system approach to engage tobacco users in quitline cessation services via text messaging. *Transl Behav Med.* 2020;10(1):292-301.
[2] Abroms LC, Wu KC, Krishnan N, et al. A Pilot Randomized Controlled Trial of Text Messaging to Increase Tobacco Treatment Reach in the Emergency Department. *Nicotine Tob Res.* 2021;23(9):1597-1601.

people how to opt out of further messages. If the person does not opt out, they will then receive four text messages over a 2-week period. Text message distribution will be automated using TelASK workflows software where data are timestamped and continuously synchronized with a secure HIPPA compliant server.

- Interactive Voice Response – We will reach out to potential participants via phone call with a pre-recorded automated message briefly explaining our research study. Patients will have the option to learn more, leave a call back number for a research assistant or decline participation in the study. Potential participants will receive an automated call every 2 weeks for a total of four calls. These calls will be made using TelASK healthcare services. Participants who respond will be transferred to a research assistant who would then facilitate enrollment.

TelASK is a personalized automated telephone follow-up software that will assist with patient engagement and recruitment for our multiple recruitment strategies. TelASK will work with external vendors such as Lumen (www.lumen.com) for phone calls and Synch (www.synch.com) for SMS text messaging to recruit participants. The only information shared with TelASK will be the participant's name, phone number, and PCP's name. They will assist with the text messaging and interactive voice response (IVR) component of our recruitment strategies.

A convenience sample of individuals who are randomized will be selected to include endorsement from the potential participant's physician. For the letter, EHR message and text message, this would mean it would have signature from the study team and from the person's own physician. For the IVR method, we will include a recorded audio message from a select group of the patient's physicians endorsing the study. All messages would be IRB approved. We will create a stratified recruitment pool that is deliberately balanced with respect to age, sex, race and ethnicity. We will aim to enroll a total of 300 participants using the recruitment strategies mentioned above.

6.3.5 On Study Visits

Clinical/Nonclinical staff Consent/Baseline Visit: A trained RA will send an email with RedCap link containing consent to all clinical/nonclinical staff via a general email distribution list. After clicking on the link, potential participants will read the 'consent statement' which includes PI name, brief study purpose, details on voluntary participation, ability to stop at any time without explanation and further, that such action will in no way affect their relationship with the primary care practice, confidentiality (anonymous survey), risks/benefits, etc. The email will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. They will then be given the option of whether they choose to participate. If they choose to participate, they will proceed to the survey, otherwise, participants will terminate the survey. Following informed consent, clinical/nonclinical staff will complete baseline measures of demographics, implementation climate, organizational capacity to change, individual attitudes toward evidence-based practices, and provider trust. These measures should take 20 minutes.

Quality Improvement (QI) interviews:

After completion of the baseline visit and during the second 3-month period of the pre-implementation phase, the study team will complete an environmental scan comprised of QI interviews. We will recruit approximately 10 clinical (e.g., primary care providers, nurses, medical assistants) and 5 non-clinical staff per practice to complete the study measures on the implementation of ALTA and complete a baseline semi-structured interview. Additionally, a random sample of 30 clinical/nonclinical staff across the practices will be asked to complete a semi-structured interview. This sample size is based on our previous studies using similar data collection methods. Each interview will have a maximum duration of 15 minutes. We will use a CFIR-guided semi-structured interview protocol to help identify barriers and facilitators to the implementation of ALTA in Phase 2. In accordance with CFIR, we will develop an interview guide that will explore the following domains: 1) inner practice setting (e.g., leadership support, organizational capacity); 2) external environment (e.g., patient needs and resources, external resources and incentives), 3) MA characteristics (e.g., self-efficacy, knowledge and beliefs about patient-centered counseling), and 4) intervention characteristics (e.g., complexity). The interview will be completed in-person or virtually to accommodate to the current COVID-19 situation. The interview method (face-to-face face vs. virtual) will be determined at the discretion and preference of the participants, while following practices and NYU institutional regulations for COVID-19.

The Stakeholder Committee, in partnership with the study team, will use this data to develop a refined PF strategy tailored to the practice context and designed to overcome the challenges to implementation of ALTA into routine practice in the implementation phase. During this period, the study team will also hold a Kick-off Event at the practices that will include didactic and interactive sessions on topics such as: the ALTA model components; best practices for implementing team-based models of care; defining roles and responsibilities in interdisciplinary care teams; developing effective interdisciplinary and patient-centered communication skills; and a discussion of the implementation and evaluation process. All clinical and non-clinical staff as well as site leadership will be encouraged to attend the Kick-off Event.

As part of the implementation QI Interviews, patients who have been invited to participate in the program by their physicians and decline participation will be asked to complete questions regarding the reason for declining participation, as follows:

Patients who decline participation:

- Patients who refuse participation will be invited to complete an interview at checkout before leaving the clinic on the day when the program was offered to them, and they declined.
- The interview is voluntary and anonymous, and no private information (name, MRN, email, SS, dates, or other identifiable information will be collected).
- We are aiming to complete the interview with 60 patients across all participating sites.

Procedures to complete the interview with patients who decline participation:

- Study staff will be at the sites 2-3 times per week in the afternoon. When the research staff is at the sites, any patient who declines participation will be approached at check out and will be asked if they are interested in voluntarily answering a questionnaire about reasons for declining participation and ideas for improving the program. We will

continue to invite patients to voluntarily answer the anonymous interview until we reach 60 patients.

- Patients will be asked the following main questions:

1. What are some ways that we could support you to manage your high blood pressure?
2. In what ways might the ALTA program help you better manage your high blood pressure?
3. What are your main reasons for declining participation in the ALTA program?
4. Based on conversation today, is there anything we can do to change the ALTA program to make you more likely to sign up at your next clinic visit?

- Patients will be explained that a) participation is voluntary and won't affect their care received at the clinic, b) no identifiable information will be collected (name, MRN, email, SS, dates, or other identifiable information will be collected), and c) the answers will be used to improve the existing blood pressure program being offered at the clinic.
- Patients will be given hard copies of the questions and will be asked if staff can read those questions to them or if they prefer to answer the questions by themselves. A RedCap survey will be available to patients who opt to answer the questions by themselves. For patients who agree to answer the questions on site with assistance from staff, the patient will be taken to a private space at the clinic where the questions can be read to them.
- Patients will be asked if they need assistance administering the questions in their preferred language. The interpreter line will be used to assist patients who need interpretation, following current practices and policies at the sites.
- Study staff will assist clinical and non-clinical staff at the sites (e.g., RNs, CHWs, PCPs, NTV volunteering at the sites) complete the interviews with patients during clinical visits, 2-3 times per week in the afternoons. We will leverage existing resources at the sites for the interview and survey completion. For example, it is the standard of care coordination at the participating sites that CHWs conduct follow-up calls with patients to assist them with MyChart enrollment. Therefore CHWs, or NVTs already approved to work at the practices could be well suited to complete the interviews as part of their ongoing patient outreach.

Upon completing the interviews, study staff will meet with site leadership to review the information obtained and discuss changes needed to the program to increase patient participation. The analysis of the interviews will only be used to inform patient-driven modifications to the program to improve patient acceptance rates.

6.3.6 End of Study and Follow Up

Patient Consent at baseline: During this visit, trained RAs will use a standardized form to screen patients based on the study's inclusion and exclusion criteria. Verbal consent will be obtained prior to beginning the eligibility screening. Only patients that meet all eligibility criteria will then complete the consent procedures, during which a trained RAs will describe the study in easy-to-understand language. If the patient remains interested, the RA will obtain written informed consent in the patient's preferred language (English or Spanish). The patient will then complete a demographic questionnaire, validated surveys on patient trust, relationship commitment and anxiety, and have their medical chart reviewed by a trained RA. This visit should take 15 minutes.

Final study visit at 12-Months (post randomization): At 12 months, trained RAs will repeat the chart review procedures for consenting patients, in accordance with IRB and

HIPAA regulations. Patients will also complete the same measures on patient trust, relationship commitment and anxiety. In addition, we will conduct semi-structured interviews with a random sample of 30 patients with uncontrolled HTN about their experiences with ALTA over the past 12 months and its impact on the patient-provider relationship, as well as recommendations for improvements. This visit will take approximately 60 minutes.

Clinical/nonclinical staff 12 month visit survey: Clinical/nonclinical will be asked to complete measures regarding implementation leadership and climate, counseling self-efficacy, organizational capacity to change, individual attitudes toward evidence-based practices, the degree of buy-in among the change recipients, and provider trust. A trained RA will send an email with RedCap link containing consent to all clinical/nonclinical staff via a general email distribution list. After clicking on the link, potential participants will read the 'consent statement' which includes PI name, brief study purpose, details on voluntary participation, ability to stop at any time without explanation and further, that such action will in no way affect their relationship with the primary care practice, confidentiality (anonymous survey), risks/benefits, etc. The email will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation. They will then be given the option of whether they choose to participate. If they choose to participate, they will proceed to the survey, otherwise, participants will terminate the survey.

Please note that the baseline and 12-month surveys are not linked. Staff will be consented at both baseline and final study visit.

Clinical/Nonclinical staff Consent Exit Interviews: In addition, a random sample of 30 clinical/nonclinical across all 10 practices will complete an exit interview where they will be queried about their experiences with ALTA and the PF intervention (if applicable) over the past 12 months, its impact on the patient-provider relationship, and recommendations for improvements. This visit should take 30 minutes.

Participation is voluntarily and those interested in participating will be encouraged to sign and date the consent form. The exit interviews will be completed in-person or virtually to accommodate to the current COVID-19 situation. The interview method (face-to-face face vs. virtual) will be determined at the discretion and preference of the participants, while following practices and NYU institutional regulations for COVID-19. Invitation to participate will be random. If staff expresses interest in participating, he/she will receive a RedCap link to the consent form. An RA will then proceed to arrange a meeting with staff to review the consent form and answer questions staff may have. Audio recording will be obtained and after the interview is recorded it will be transcribed and identifier removed to protect the subject.

6.3.7 Removal of Subjects

Subjects may withdraw voluntarily at any time for any reason.

Participants may also be withdrawn from the study for certain reasons. Some possible reasons for withdrawing a subject from the study would be worsening health or other conditions that might make it harmful for continued participation (as determined by their

primary care physician). In addition, participants may be withdrawn if they fail to comply with the study protocol, keep appointments or follow directions.

6.4.1 Statistical Design

The proposed project will evaluate, in a stepped-wedge cluster randomized controlled trial, the effect of the PF strategy on level of implementation fidelity (primary outcome) of ALTA, as well as on clinical outcomes (secondary outcomes), as compared to usual care at 12 months. Implementation fidelity will be assessed through a process evaluation using a mixed methods approach based on five core dimensions of implementation fidelity, as defined by Proctor's Implementation Outcomes Framework (described below). Clinical outcome measures include blood pressure (BP) control (defined as <140/90 mmHg) and medication adherence (assessed using the proportion of days covered [PDC] via pharmacy records). We will also examine change in systolic and diastolic blood pressure (SBP, DBP) as well as an alternate definition of BP control (<130/80 mmHg as per the new hypertension guidelines) in exploratory analyses.

6.4.2 Sample Size Considerations

Power calculations are based on the clinical outcome of BP control using our prior work implementing the ALTA model in a community-based clinic. In the former trial, we found a significant improvement in attainment of BP control at 6 months among patients randomized to the intervention group compared to the UC group (51% vs. 29%, p=.03). We expect a similar group difference of a 20% increase in BP control between the implementation and UC phases in the current study. Calculations of achieved power were estimated with a stepped-wedge design using Power Analysis and Sample Size (PASS) software program. The power calculations show that we can recruit 10 sites and 700 patients and have at least 80% power to detect a more conservative 15% difference in BP control between the UC and implementation phases for intraclass correlation coefficients (ICCs) ranging from 0.01 to 0.05. Using our original estimate of a 20% difference in BP control, we would have over 90% power to detect a difference between the UC and implementation phases with 10 sites and 700 patients.

6.4.3.1 Primary Analyses

General procedures for analysis of our primary outcome: We will use a mixed methods approach to assess the five core dimensions of implementation fidelity, as defined by Proctor's IOF: (1) adherence to the program protocol; (2) dose of the program delivered; (3) quality of program delivery; (4) participant responsiveness; and (5) program differentiation.

Our qualitative analysis of implementation fidelity will be comprised of practice facilitator narrative reports (to assess program adherence), audiotaped health coaching sessions (to assess implementation quality) and semi-structured interviews with clinic staff/providers and patients (to assess participant responsiveness). Transcriptions of the narrative reports and interviews will be coded using Atlas.ti, software designed for qualitative coding. The coding scheme will be developed by the Data Management and Analysis Subcommittee to focus on key dimensions identified both a priori (i.e., from the interview protocols) and those that emerge during site visits and interviews. The study team members coding the transcripts will

be rigorously trained on both the coding scheme and on the use of Atlas.ti. Initial coding by the coders will be reviewed by either Dr. Schoenthaler or Rosal and any corrections to the coding will be made and/or additional coder training. Following this period, two coders will independently code at least 10 interviews. At this point we will establish the inter-rater reliability and if it is inadequate (Krippendorff's alpha <0.80) the Data Management and Analysis Subcommittee will work collaboratively to refine and/or clarify the coding scheme and provide additional coder training. Double coding will continue until adequate inter-rater reliability is achieved. Coding the data will allow us to fully describe the themes and the prevalence of specific themes and sub-themes. Following the procedures in our previous trials (e.g., ALMA trial), we will audiotape and archive MA-led health coaching sessions, of which 10% will be coded using the Health Coaching Evaluation Checklist. The checklist assesses the degree to which the MAs are correctly using their coaching techniques and are achieving the desired impact with patients. We will apply the same coding methods as the narrative reports and interviews. Briefly, two members of the study team will be rigorously trained by the Data Management and Analysis Subcommittee to apply the checklist to the tapes, and supervised by Dr. Schoenthaler. The coders will listen to the audiotapes twice, the first review will be done to get a sense of the session flow and MA counseling style; the second to code the interaction. We will establish in inter-rater reliability after the two coders independently code at least 10 tapes, and double coding will continue until adequate inter-rater reliability is achieved (Krippendorff's alpha >0.80).

Level of implementation adherence will be evaluated quantitatively as the degree to which the components of ALTA (e.g., identify, refer, coach, document, monitor) were implemented as intended, using data from checklists completed by the facilitators as well as extracted from the EHR. Each intervention component will be rated on a 3-point scale: 1=The component was not implemented, as per protocol; 2=The component was partially implemented; and 3=The component was fully implemented and/or modified with permission, as per protocol. We will calculate adherence as the number of components fully implemented (ratings of 3) divided by the total number of possible components (N=8). Practices will be considered adherent to the protocol if components were implemented completely and/or they were completed with an adaption that did not affect the programs core components and was approved by the study team. Facilitators will also complete monthly narrative reports that summarize all adaptations made to the components and what did/did not work for each practice context. We will also measure adherence through the Health Coaching Evaluation Checklist. The checklist will be used to count the parts of the standardized counseling script that were covered by the MAs at each health coaching session.

Part 2.

- Level of Implementation dose will be evaluated as the extent to which patients were exposed to ALTA. We will collect data on utilization patterns of the different ALTA components including the mean number of: ALTA-eligible patients identified in the registry and referred to a Health Coach; health coaching sessions completed with ALTA patients; entries in the EHR-embedded coaching script; progress notes

documented in the EHR and shared with the care team; and follow-up sessions that are scheduled and/or completed. System files will be extracted quarterly and will contain date and time stamps as well as user logins for the tools used. We will also calculate the average program dose, which is defined as all the number of times the MA-led health coaching sessions occurred during the implementation phase divided by the total number of patient encounters at the clinic during that same period of time (i.e., 12 months). To compare average dose across the practices, we will use a least square means analysis of variance (ANOVA) model with weighting by the number of patients seen in each practice within the specified time period.

- Level of Implementation quality of each ALTA component will be evaluated as the quality and content of data entry in the HTN registry, EHR-embedded coaching script, progress notes, and follow-up scheduling. Facilitators will rate the completeness of this form using a 3-point rating scale (1, poor; 2, adequate; 3, high). A random 10% sample of counseling sessions by the clinic Health Coaches will also be audiotaped and evaluated using the Health Coaching Evaluation Checklist, as we have done in our previous trials. A fidelity score will be calculated as the percentage of topics completed and how well they were delivered (1: poor skill performance, 2: adequate skill performance, 3: exemplary skill performance).
- Level of responsiveness will be evaluated as patient and clinic staff/provider satisfaction with ALTA and acceptability for practice changes with validated measures (i.e., ECHO survey for patients and a modified survey developed by Lewis et al. for staff/providers). For both staff/provider and patient measures, we will calculate means and standard deviations for each scale across respondents within the practice. In addition, qualitative interviews will be conducted with a random sample of clinic staff (n=30) and patients (n=30) across the practices to assess satisfaction with the intervention. To compare responses across the practices, we will use a least square means ANOVA model with weighting by the number of respondents in each practice.
- Level of program differentiation will be evaluated as the unique features of ALTA that are distinguishable from other programs at the sites. Throughout the study, facilitators will catalogue all initiatives that are occurring at the practices (as observed during site visits and/or reported by the practice leadership). This will be used to quantify the degree of overlap between the ALTA components and other quality improvement initiatives at the sites (1: no overlap, 2: some overlap], 3: significant overlap as well as isolate the unique features of ALTA that distinguish it from those initiatives.

Following the NIH Best Practices for mixed methods research, we will construct a joint display that integrates the qualitative themes with the quantitative data to create a composite measure of implementation fidelity based on the five dimensions outlined above. Should the data be divergent, we will assign higher credence to the qualitative data because it provides richer explanation about participants' behaviors. We will also explore the association between implementation fidelity and the clinical outcomes. This analysis will be accomplished with a multilevel MANOVA (unstructured covariance matrix across two time points: baseline and 12 months). The analysis will have one within person factor — Time (baseline and 12-month coded naturally as months (0 and 12)) and one primary between-

patient factor (Randomization Group dummy coded as 0 = UC and 1 = PF). We will use the composite measure of implementation fidelity to predict changes in BP control and medication adherence at 12 months. We will use a 3-level analytic model to accounting for nesting in the data (observations nested within subjects nested within practices). Multilevel modeling software (SAS, Version 9, PROC MIXED) will be used to compute full information maximum likelihood (FIML) estimates of the model parameters. The PROC MIXED procedure will use an error structure that allows for the possibility of group differences in (a) the error variances at 12 months; and (b) the serial correlations of the baseline with the 12 month outcomes. The primary test is the treatment X time interaction, and the resulting F-test will provide the primary "intent to treat" test of the hypothesis. If this is statistically significant at the two tailed α=.05 level, for ease of interpretation, we will estimate and report the magnitude of the treatment effect, with 95% CI for fidelity. Covariates will be included as necessary in adjusted analyses. All tests will be 2-sided, 0.05 level tests.

6.4.3.2 Secondary Objectives Analyses

The effect of PF on BP Control

Our main clinical outcome is the proportion of patients with adequate BP control (<140/90 mmHg) at 12 months in the implementation vs. UC phase. BP control will be treated as a dichotomous outcome variable in this analysis; any patients with missing follow-up BP data will be assumed to have inadequate BP control. To examine the difference in BP control rates between the implementation and UC phases, we will utilize a generalized linear mixed model (GLMM) to assess the PF effect. A Poisson regression model will be used to predict BP control specifying a fixed effect for time, a fixed effect for treatment and a time by treatment interaction. Random effects will be specified for person and practice to account for the clustered nature of the dataset (observations within person and people within practices). As a sensitivity analysis, we will also assess an alternate definition of BP control (< 130/80 mmHg) indicated by the new hypertension guidelines. In exploratory analyses, will examine the intervention effect on BP reduction at 12 months, treated as a continuous variable. An additional sensitivity analysis will be conducted using GLMM to evaluate the effect of PF on BP reduction. We will test the treatment X time interactions in a random effects linear regression model to determine the time-specific differences BP reduction attributable to PF at the end of the implementation phase.

Randomization of the stepped-wedge design should obviate the need for adjustment, but in the case of imbalanced in baseline covariates; these will be included as necessary in adjusted analyses. All tests will be two-sided with alpha=0.05 for comparison between the implementation and UC phases. Maximum likelihood estimation of mixed-effects models will be used to account for missing data; in the context of a mixed-effects model, this is equivalent to an assumption of data that are missing at random (MAR); we will conduct sensitivity analyses assessing this assumption. We will also compare participants with and without missing values with respect to baseline and practice characteristics. If differential patterns emerge, we will consider the use of multiple imputation and/or inverse probability weighting to adjust for missing data. Analyses will be conducted using Stata, SAS, and R.

Associations between rates of BP control and implementation fidelity will be evaluated using structural equation modeling methods. We will estimate a path model using maximum likelihood estimation to investigate relationships between BP control and implementation fidelity. Implementation fidelity will be identified as individual and simultaneous predictors of BP control. Practice-, staff-, and patient-level variables, which may influence level of implementation fidelity, will also be included in the model. In addition to the direct effects of each variable, the indirect effects from each variable to BP control via mediator variables will be estimated as the product of component direct effects and tested using bootstrapped 95% confidence intervals. Structural equation modeling analyses will be conducted using R and fit indices will be evaluated to ensure model fit.

The effect of PF on medication adherence

We will estimate similar models as BP control with PDC, calculated from available pharmacy records, as the outcome. A GLMM model using maximum likelihood estimation will be utilized to estimate the effect of PF on medication adherence with fixed effects specified for treatment phase, time, and the treatment by time interaction. We will apply any necessary transformations to the PDC outcome to improve the approximation to normality, and explore alternative regression strategies, such as rank regression and/or beta regression.

The effect of practice and individual-level moderators on implementation fidelity of ALTA

Using validated surveys (described above), we will explore potential practice-, staff- and patient-level moderators, assessing interactions between the PF strategy, level of implementation fidelity and modifiers. Potential moderators of the association between PF and implementation fidelity of ALTA will be evaluated using structural equation modeling methods. We will determine potential moderators by examining the PF x moderator interaction effects. Fit indices will be evaluated for all models to ensure adequate model fit.

6.4.3.3. Tertiary Outcomes

We will use Generalized Linear Mixed Model to analyze the effect of ALTA on differences in relationship commitment (primary outcome) and patient-provider trust (secondary outcome). A Poisson regression model will be used specifying a fixed effect for time, a fixed effect for treatment,a time by treatment interaction, and a control group indicator. Only patients that declined participation in ALTA for the entire evaluation period will be included in the control group for the final analyses. Patients that crossover from the control group to intervention group and continue to participate in the evaluation will be counted towards the intervention group sample. Since they are asked the same questions, it does not impact the analyses. Random effects will be specified for person and clinic to account for the clustered nature of the dataset (observations within person and people within clinics). Relationship commitment will be defined as a continuous variable while patient-provider trust will be categorized as ordinal. Randomization of the stepped wedge design should obviate the need for adjustment, but in the case of imbalance in baseline covariates, these will be included as necessary in adjusted analyses. Sex will be accounted for as a covariate and examined as a potential moderator. All tests will be two-sided with alpha=0.05 for comparison between the ALTA and UC phases.

Maximum likelihood estimation of mixed-effects models will be used to account for missing data; this is equivalent to an assumption of data missing at random. We will conduct sensitivity analyses assessing this assumption. We will also compare participants with and without missing values in baseline and site characteristics, as well as intervention vs control group status; if differential patterns emerge, we will consider using multiple imputation and/or inverse probability weighting to adjust for missing data. For our behavioral measures of commitment and trust derived from text analysis, we will use Python with a dedicated suite of libraries for sentiment analysis and emotion detection. The text processing libraries will be used to complete the pre-processing steps including tokenization, stemming, and lemmatization. Tokenization is the process of separating text into smaller units, i.e., words, characters, or subwords. Stemming and lemmatization will be done to reduce inflectional forms and derive the common base form [e.g., am, are, is → be]. Next, each document (clinical notes, transcripts, secure messages) will be represented as vectors using word embeddings. Distributional semantics models (e.g., continuous Bag-of-Words, Skip-gram, Global vectors) will be used to represent each word as a vector while preserving the contextual information of the word before the training phase. Resources such as lexicons (e.g., LIWC, EmoLex) will be used for feature extraction representing presence or absence of emotion words, and words associated with opening or closing rituals of a conversation. Next, multiple supervised and unsupervised algorithms (e.g., attention-based neural models, transformers architecture) will be trained on the dataset and an optimized model will be established via several rounds of experiments and rigorous evaluations. Once the best fitting model is established, it will be used to train on clinical notes data before and after ALTA implementation. Patient and providers' sentiment will be compared to establish how the relationship has changed through ALTA participation. we will use GLMM to analyze the effect of ALTA on the tertiary outcomes of patient state anxiety, SBP, DBP, and PDC. Since each individual outcome is of interest, testing will be 2-sided with a Type I error rate of 0.05 and no adjustment for multiple testing.

Analysis of Exit Interviews: Following best practices in qualitative analyses, we will use a grounded theory approach to analyze interviews with our key stakeholders, starting with a stratified sample informed by our contextual factors and proceeding until we reach theoretical saturation. Guided by our research questions, we will let the data itself drive our investigation and identification of emergent themes within the data through immersion in interview transcripts and a team-based approach to qualitative coding. After training, team members will independently review transcripts to identify initial in vivo open codes incorporating respondents' language. The team will then meet to discuss the codes and collectively develop a codebook. The codebook will be applied and iteratively refined during additional transcript reviews by the coders. We will progress to axial coding to relate categories and properties, and selective coding to derive core concepts, iteratively modifying codes throughout based on group consensus to increase validity. At each stage of analysis, we will convene meetings to discuss, define and refine emergent concepts and ensure appropriate application of codes throughout data sources. Emergent themes will be identified based on coded data and consensus forming discussions. Codes specifying elements related to our contextual factors, guided by our conceptual framework will also be

applied to transcripts; for example, we will look for themes related to modes of communication, characteristics of the patients, providers, and of the sites that may affect our outcomes. We will also triangulate across the qualitative and quantitative data using a mixed methods matrix approach to compare transcripts with data analyzed via NLP to identify both common themes and divergence across findings, providing valuable evidence of the validity of NLP-measured sentiments to assess commitment and trust. The team will use Dedoose software that allows for the integration of quantitative data with qualitative data.

6.4.3.4 Safety/Pregnancy-related policy

Patients who are pregnant or planning to become pregnant in the next 12 months are excluded from this trial.

6.4.3.5 Analysis of Subject Characteristics

Baseline characteristics and outcomes will be summarized descriptively and graphically; we will summarize continuous variables with means, standard deviations, medians, and ranges, and will summarize categorical variables with frequency distributions. We will document any observed reasons for missing data during data collection.

6.4.3.6 Interim Analysis (if applicable)

Not applicable

6.4.3.7 Health economic evaluation

Not applicable

6.4.3.8 Other

Not applicable

6.4.4 Subsets and Covariates

Not applicable

6.4.5 Handling of Missing Data

Rules for missing values will be discussed in appropriate places in the analysis plan below. In general, all available data will be included in data listings and tabulations. Population denominators will be displayed in column headers. Individual denominators will be displayed for each summary to indicate the number of missing values. Patients who withdraw from the study or are lost to follow-up will still be included in the denominators for any proportions where data are available.

7 - Trial Administration

7.1 Ethical Considerations

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki.

To mitigate any breaches in security or privacy as it relates to the collection of data and/or intervention delivery, we will enact the following safeguards:

First, all study staff will be required to be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure the confidentiality in order to obtain Institutional Review Board (IRB) approval from NYULH. Second, no identifying information will be included on the transcripts of interviews or surveys. As part of the process involved in obtaining written informed consent, all participants will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their treatment or future interactions with their physician at the practices. Also, if a participant is uncomfortable during a research encounter, they may stop at any time. All survey data entered into the research database will be protected by confidential entry codes. Names will be replaced with identification numbers. All patient data will be de-identified prior to transfer to subcontracts. Locked file cabinets will be used to store materials with identifying information (e.g., patient consent forms). Only members of the research team will have access to patient's personal information file. Study data will be transmitted to Dr. Troxel and the data analyst for data processing using only secure methods (e.g., encrypted email). All electronic audiotaped data will be saved on a secure server housed by NYULH and backed up daily or weekly depending upon the receipt of data. PHI will be confined to a secure server that is not connected to the Internet. All computers are password protected and on a private LAN network. No file and database servers are accessible to the public through the Internet. Prior to inclusion in any data set (internal and external), data will be stripped of all identifying information. Finally, the web-based surveys will be accessed via a HIPAA compliant application. The data collected for this study will be used strictly for the purposes stated in this grant application and will only be available to relevant research staff at NYULH and University of Massachusetts. IRB approval will be sought prior to any data collection involving human subjects. Finally, all identifiable patient health information will be obtained and managed in accordance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164.

As part of their participation in this study, patients and providers will receive a small amount of payment to reimburse them for their time and effort. The payment is needed to reimburse patients and providers for the additional travel to the practices for study visits and additional time to participate.

7.2 Institutional Review Board (IRB) Review

This study will be overseen by the NYU School of Medicine Institutional Review Board. All research staff will have completed and passed IRB and HIPAA training and will be thoroughly trained in appropriate consent procedures and the need to maintain strict

confidentiality. All research protocols will be reviewed and approved by the IRB prior to gaining access to protected health information and subject recruitment.

7.3 Subject Confidentiality

As part of the process involved in obtaining written informed consent, all patients/staff will be reminded that their responses are confidential and that they may refuse to participate in the project or withdraw at any time without explanation, and further, that such an action will in no way affect their future interactions with the practice. To minimize the increased risk of invasion of privacy or loss of confidentiality for NYULH employees, a study team member with no direct supervisory or evaluation responsibilities will enroll these participants (send the survey link). The informed consent form send in the electronic link will emphasize that participation is voluntary and refusal to participate will not affect employment or job performance evaluation.

To ensure confidentiality, data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a locked drawer. Only members of the research team will have access to the participants' personal information file. All computers containing confidential data will meet security requirements established by the HIPAA Security Rules, and established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems. Specifically, all electronic interview data will be saved on a secure server housed by NYULH and backed up daily or weekly depending upon the receipt of data. PHI will be confined to a secure server that is not connected to the Internet. All computers will be password protected and on a private LAN network. No file and database servers are accessible to the public through the Internet. Prior to inclusion in any data set (internal and external), data will be stripped of all identifying information.

7.4 Deviations/Unanticipated Problems

If any protocol changes are needed, the Principal Investigators will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB will be promptly informed of the change following implementation (within 10 working days).

7.5 Data Quality Assurance

In accordance with procedures for Good Clinical Practice, the PI will be responsible for data quality control including reviewing protocol compliance, data collection and verification. Data will be reviewed monthly.

Since assessment data is all entered electronically, accuracy and completeness of the data is maximized through alerts and pop-ups if the data is inconsistent, out of range, or not entered. The data entry procedures include a secure intra-net log-in that is password protected and data entry will have data quality checks with the electronic data system. Outcome measure data that involve questionnaire responses are collected in the secure REDCap. Safety data are collected in a separate database related to each participant.

At the outset of the study, an investigator meetings will be held to introduce investigators and study personnel to the study protocol, data collection forms, procedures and regulatory requirements. During the course of the study, the program coordinator will make routine site visits to review protocol compliance, compare data collection forms with individual subject's original source documents, assess test material accountability and ensure that the study is being conducted according to the pertinent regulatory requirements. The review of the subject's medical records will be performed in a manner to ensure that subject confidentiality is maintained.

7.5.1 Data Collection

Data collected in the study are divided into four categories: (1) observational, (2) outcomes, (3) moderators, and (4) semi-structured interview. The measures table above (Table 2) provides information on the measure to assess each variable and timing of administration. All measures will be obtained by a trained RA and/or practice facilitator using a standardized procedure.

Data collection forms will be identified only with IDs; relating of ID code to names will require information kept under lock and key and supervised by a designated high-level staff member. None of the analyses will permit individual identification. Only ID numbers will be used for communication with the RAs in the event of data anomalies. The clinical/research barrier will remain intact, in that it will not be necessary for the data-processing staff to know the identity of the participants.

7.5.1.1 Access to Source

It is assumed that all PHI will be collected after informed consent; as a result certain PHI (e.g., date of birth) that are necessary for analyses may be entered as part of the data set. Certain rules obtain for handling PHI: a) copies of hard copy data will be hand-delivered in a sealed envelope marked confidential (e.g., via messenger or directly by the RA) or sent via FEDEX; b) non-encrypted electronic data, e.g., lab values will be accessed using a project-specific password or uploaded to the NYU secure server; c) prior to electronic submission or upload to the NYU server, all data containing PHI will be encrypted using PGP or Silver Key encryption software (e.g., assessment data). PGP and Silver Key ensure data safety by requiring digital keys for decryption; d) a security code will be required for access to fax transmissions. This secure fax machine is housed in a locked area. All project related fax transmissions will contain a confidentiality notice.

7.5.1.2 Data Storage/Security

Hard copy data and log sheets are kept in a locked storage area behind a locked, alarmed door. Electronic data will be backed up daily or weekly depending upon the frequency of receipt/ entry. The backup disks will be stored in a fireproof safe in a different location. All computers are password protected and are on a private LAN network. There are no servers that are accessible to the public through the Internet. A hardware-based firewall separation protects against hackers and unauthorized access to all electronic data not maintained on the server, providing protection against viruses, worms and Trojan horses transmitted over the Internet. The firewall contains anti-virus software (McAffee Anti Virus) to protect the

network from threats of viruses contained in email attachments. Through "push-technology" this anti-virus software is automatically updated for all virus definitions and other updates. Secure internet communication is established through a VPN tunnel which is configured through the firewall.

7.6 Study Records

Study records will include all regulatory documents, protocols, consents forms, data collection forms, subject medical records, surveys, and transcripts from audio-taped interviews and observational forms.

7.6.1 Retention of Records

In acordance with 45 CFR 164.530(j)(1) of HIPAA, research records including signed consent forms that contain the HIPAA authorization will be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later. In addition, we will maintain records of IRB activities for at least three years after completion of the research (45 CFR 46.115(b)).

7.7 Study Monitoring

The Data Safety Monitoring Board (DSMB) will be responsible for monitoring the study. The purpose of the DSMB is to ensure the safety of participants and the validity and integrity of the data. Personnel involved in the monitoring activities will include:

• The co-Principal Investigators

• Designated medical monitor (a physician in our program who will provide consultation on medical risks and who will review adverse events)

• Internal Committee (PI and the Co-Investigator on the present proposal)

• DSMB (see details below)

• Institutional Review Board

The DSMB will be made up of professionals in the field who are willing to participate, and who have no conflict with serving on such a Board. We shall include the following:

• A behavioral scientist (PhD) with expertise in the conduct of clinical trials targeting medication adherence

• Two professionals with substantive expertise in the area of hypertension/blood pressure control and practice facilitation, one a physician, one a Ph.D.

• A biostatistician with expertise in clinical trials

The DSMB will perform the following activities:

• Review the research protocol and plans for data and safety monitoring.

• Evaluate the progress of the interventional trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome.

• Monitors will also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study. For example, if there is a systematic trend showing decreasing, rather than improving medication adherence or patient communication, in the II vs. the control condition.

• Make recommendations to the IC, IRB, and investigators concerning continuation or conclusion of the trial(s).

• Protect the confidentiality of the trial data and the results of monitoring.

7.8 Data Safety Monitoring Plan

The Data and Safety Monitoring Plan will comprise the following elements:

• Reporting of adverse events to the IRB and to the NIH: Adverse events will be reported to the New York University IRB, as well as to the Chair of the DSMB. The DSMB has the authority to halt the trial if it perceives that harm is occurring due to the intervention. Summaries of adverse events reports will be made to NIH in the yearly progress or report or, at the end of Year 5, in the final report, unless the nature of a particular event is such that it bears immediate reporting to the NIH.

• As of December 31, 2023 (end of Year 5), we will no longer continue DSMB meetings or DSMB reports. We will continue with evaluating Project ALTA. Therefore, a DSMB will no longer be necessary. Study monitoring will continue to be completed by the PI.

• A detailed plan to address serious events that may arise such as blood pressure readings that indicate a hypertensive emergency that occur during the study. The plan will include a step-by-step algorithm to deal with such events.

• The DSMB will meet with the PIs, and the co-Investigator every 6 months to review adverse events reports, senior complaints, if any, and dropout rates. Data will be provided at those meetings by the investigators on key variables that may indicate harm, including changes in cardiovascular risk profile, and medical comorbidity. The DSMB biostatistician will evaluate the confidentiality and integrity of the database, and the procedures for recording and storing confidential files. The DSMB will also review the elements of the plan to deal with emergencies.

7.9 Study Modification

The study may be modified or discontinued at any time by the IRB, NIMHD, or other government agencies as part of their duties to ensure that research subjects are protected. If any protocol changes are needed, the PIs will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval unless necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB will be promptly informed of the change following implementation (within 10 working days).

7.10 Study Discontinuation

The study may be discontinued at any time by the IRB, NIMHD, or other government agencies as part of their duties to ensure that research subjects are protected. If a serious

adverse event occurs as a result of the study, consideration will be given to stopping the study early. In the event of early stopping of the study, the IRB will be promptly notified.

7.11 Study Completion

The estimated completion date of this study is 06/30/2023. At that time, a progress report will be submitted to the IRB and the record will remain open for analysis of study data. Once all research-related interactions with participants are completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished, the study will be closed with the IRB.

7.12 Conflict of Interest Policy

All study team members will complete a financial disclosure form. In the event a conflict that requires disclosure or management is identified, the PI will provide to the IRB in writing with a summary of conflict and the conflict management plan.

7.13 Funding Source

This project will be funded by the NIH/NIMHD.

7.14 Publication Plan

Publication of the results of this trial will be governed by the policies and procedures developed by the PIs and study team. Any presentation, abstract, or manuscript will be made available for review by NIMHD prior to submission.