The Effect of an mHealth self-monitoring intervention (MI-BP) on blood pressure among uncontrolled hypertensive Blacks: A Randomized Controlled Trial

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Abstract

Background: Hypertension (HTN) is one of the most important cardiovascular disease risk factors and affects over 100 million American adults. HTN-related health inequities are abundant in Black communities as Blacks are more likely to utilize the emergency department (ED) for chronic disease-related ambulatory care, which is strongly linked to lower BP control, diminished awareness of HTN, and adverse cardiovascular events. To reduce HTN-related health disparities, we developed MI-BP, a culturally tailed multi-behavior mHealth intervention that targeted behaviors of blood pressure self-monitoring, physical activity, sodium intake, and medication adherence in Blacks with uncontrolled HTN who were recruited from ED and community-based settings.

Objective: We sought to determine the effect of MI-BP on BP, as well as secondary outcomes of physical activity, sodium intake, and medication adherence, compared to enhanced usual care control at one-year follow-up.

Methods: We conducted a one-year, two-group RCT of the MI-BP intervention compared to an enhanced usual care where participants received a blood pressure cuff. Participants were recruited from EDs and other community-based settings in Detroit, MI, where they were screened for initial eligibility and enrolled. Baseline data collection and randomization occurred about 2- and 4-weeks after enrollment to ensure participants had uncontrolled hypertension and were willing to participate. Data collection visits occurred at 13-, 26-, 39-, and 52-weeks. Outcomes of interest included BP (primary outcome), as well as physical activity, sodium intake, and medication adherence (secondary outcomes).

Results: We consented and enrolled 869 participants in this study, yet ultimately randomized 162 participants. At one-year, compared to baseline, both groups demonstrated significant decreases in SBP (MI-BP = 22.5 mmHg decrease in average SBP, $p < .0001$; control group = 24.1 mmHg decrease, $p < .0001$), adjusted for age and sex, with no significant differences between groups (time-by-arm interaction $p = .99$). Similar patterns, where improvements were noted for both groups, yet no differences were found between groups, were demonstrated for diastolic BP, physical activity, sodium intake, and medication adherence. Large dropout rates were observed for both groups (about 60%).

Conclusions: Overall, participants randomized to both the enhanced usual care control and MI-BP conditions experienced significant improvements in blood pressure and other outcomes, however, differences between groups were not detected,

speaking to the general benefit of proactive outreach and engagement focused on cardiometabolic risk reduction in urban dwelling, low-SES Black populations. High rates of dropout were found and are likely to be expected when working in similar populations. Future work is needed to better understand engagement with mHealth interventions, particularly in this population.
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Abstract

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Objective: We sought to determine the effect of MI-BP on BP, as well as secondary outcomes of physical activity, sodium intake, and medication adherence, compared to enhanced usual care control at one-year follow-up.

Methods: We conducted a one-year, two-group RCT of the MI-BP intervention compared to an enhanced usual care where participants ages 25-70 received a BP cuff. Participants were recruited from EDs and other community-based settings in Detroit, MI, where they were screened for initial eligibility and enrolled. Baseline data collection and randomization occurred about 2- and 4-weeks after enrollment to ensure participants had uncontrolled HTN and were willing to participate. Data collection visits occurred at 13-, 26-, 39-, and 52-weeks. Outcomes of interest included BP (primary outcome), as well as physical activity, sodium intake, and medication adherence (secondary outcomes).

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Conclusions: Overall, participants randomized to both the enhanced usual care control and MI-BP conditions experienced significant improvements in BP and other outcomes, however, differences between groups were not detected, speaking to the general benefit of proactive outreach and engagement focused on cardiometabolic risk reduction in urban dwelling, low-SES Black populations. High rates of dropout were found and are likely to be expected when working in similar populations. Future work is needed to better understand engagement with mHealth interventions, particularly in this population.

Trial registration: ClinicalTrials.gov NCT02360293; http://clinicaltrials.gov/ct2/show/NCT02360293.

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Keywords: blood pressure; hypertension; mHealth; mobile phone; smartphone

Introduction

Hypertension (HTN) affects over 100 million American adults and about half of those 20 years of age or older [1]. HTN is also one of the most important cardiovascular disease risk factors and when uncontrolled, it can cause adverse health outcomes such as myocardial infarction, stroke, heart failure and chronic kidney disease [2-6]. Despite the importance of maintaining adequate blood pressure (BP) control, the American Heart Association reported that only about 21.6% of those with HTN have their BP controlled within age-adjusted criteria. Further, 38.8% are unaware of their condition [1]. HTN-related health inequities are abundant in Black communities. Compared to Whites, Blacks have a greater prevalence of HTN, HTN-associated disease severity, and younger age of onset, making uncontrolled HTN a significant problem in this population [7]. Moreover, Blacks are more likely to utilize the emergency department (ED) for chronic disease-related ambulatory care, which is strongly linked to lower BP control, diminished awareness of HTN, and adverse cardiovascular events [8-10].

Although uncontrolled HTN is linked to a host of adverse outcomes, BP can typically be well controlled through lifestyle and behavior changes. Recommendations for managing HTN have been consistent for decades and center on positive health behaviors such as maintaining a healthy weight, reducing daily sodium intake, increasing physical activity, and adhering to prescribed antihypertensive therapies [11]; however, engaging in these behaviors is difficult for many individuals, and this is especially true in Blacks who are less likely than Whites to report adherence to preventive behaviors [1]. With the increasing national conversation focused on health inequities and social determinants of health [12], population-specific interventions are needed to intervene in communities where the burden of HTN is disproportionately high.

Mobile health, also known as mHealth, for chronic disease self-management is increasing in use and based upon this, as well as the high penetration of smartphone ownership among Blacks (currently about 83%)[13], we sought to develop and test an mHealth intervention (MI-BP). The MI-BP intervention was developed with the intention of educating and supporting self-monitoring of multiple health behaviors to reduce BP among Blacks with uncontrolled HTN recruited from urban EDs and community-based settings. Our goal was to determine the effect of MI-BP on the primary outcome of BP and secondary outcomes of physical activity, sodium intake, and medication adherence compared to enhanced usual care control, in a one-year randomized controlled trial (RCT). We hypothesized that:
H1: Mean systolic BP (SBP) would be significantly lower in the MI-BP arm than in the control group after one year.
H2: Measures of physical activity, sodium intake, and medication adherence would be significantly better in the MI-BP arm than in the control arm after one year.

Methods

Overview

This study was a one-year, two-group RCT of the MI-BP intervention compared to enhanced usual care. The methods for this study were approved by institutional review boards at both Wayne State University (WSU) (IRB#: 040416M1F) and the University of Michigan (HUM00114202). The study was overseen by a Data and Safety Monitoring Board (DSMB). Details on the full study protocol were previously published [14], but a summary of those procedures follows.

Clinical Setting and Recruitment

All recruitment occurred in Detroit, Michigan and was primarily conducted at the Detroit Medical Center (DMC) in the emergency departments (EDs) of Detroit Receiving Hospital (DRH) and Sinai-Grace Hospital (SGH). Potentially eligible participants were screened by trained volunteers or by study staff members. Once a potentially eligible participant was identified according to clinical criteria, a research staff member spoke with the treating physician to determine if they were a good candidate for participation. If so, individuals were informed of the study, screened further, and then consented and enrolled if they were interested and met eligibility criteria. Additional recruitment occurred at community events where BP screening was conducted, such as mobile health unit visits, health fairs, and other health-related community events. Procedures for these potential participants were the same, except for not checking with treating physicians to determine whether our staff should proceed with screening and enrollment. All participants provided written, informed consent prior to enrollment.

Eligibility Screening and Consent

Inclusion Criteria

To be eligible to participate in this trial, individuals were required to be Black, between the ages of 25 and 70 years, previously diagnosed with HTN, have a smartphone compatible with the MI-BP intervention, and with uncontrolled BP (SBP>135 mmHg) at triage and on repeat measurement using a BpTRU BPM-200 device (Smiths Medical PM Inc., Waukesha, WI) or Omron HEM 907XL Intellisense (Omron Healthcare, Inc.; Kyoto, Japan) at least 1-hour post triage vitals.

Exclusion Criteria

Individuals were excluded from this trial if they were pregnant; had serious existing medical conditions that may make BP control difficult or necessitate frequent hospitalization (i.e., previous diagnosis of resistant HTN, steroid-dependent asthma or emphysema, cirrhosis or hepatic failure, stage C or D chronic heart failure, stage IV or V chronic kidney disease, and terminal cancer or ongoing active chemotherapeutic or radiation therapy); had a history of other serious medical conditions (e.g., stroke, dementia, myocardial infarction, or known coronary artery disease); or had a history of alcohol or drug abuse as determined by the CAGE-AID (Cut down, Annoyed, Guilty, Eye-opener Adapted to Include Drugs questionnaire [excluded if score was ≥2]).

Study Procedures

Baseline Data Collection Visit

After consent and enrollment, participants were scheduled for a return visit 1-2 weeks later for baseline data collection at a nearby university building. Transportation to all study visits, via taxi or ride-sharing service, was offered to anyone requiring transportation assistance. At the baseline visit, secondary BP screening was conducted to ensure we were only retaining participants with persistent uncontrolled HTN in the study. At this time, participants who had a SBP < 130 mm Hg were deemed ineligible and excluded from the study. Next, baseline data were collected. To control response fatigue in the baseline data collection survey, we created 6 different permutations, each with a different order of instruments, which were also balanced within blocks. At this time, participants were also given a prescription for antihypertensive

therapy. If needed, referrals to primary care were made by study physicians. In the event a participant was already taking antihypertensive medications prescribed through a pre-existing relationship with a primary care provider (PCP), we contacted their PCP to inform them of our algorithm-based approach to antihypertensive therapy and coordinated with them when medication adjustments were indicated.

Medication Titration and Randomization Visit

Two weeks post-baseline, participants were assessed for medication titration, the process of adjusting antihypertensive medication dosages to ensure appropriate and optimal treatment. At this time, participants were randomized into 1 of the 2 study arms in the trial. In total, it took approximately 4 weeks for an enrolled participant to be randomized in the study. This month-long de facto wash-out period was designed to ensure that we were truly reaching individuals with uncontrolled HTN, and were not just temporarily presenting with elevated BP in the ED. Moreover, our previous experiences conducting work in this setting demonstrated high levels of attrition between ED recruitment and initial follow-up. Delaying randomization also helped to ensure identification of individuals who did not intend to fully participate at the outset, increasing the likelihood of randomized participant retention. Trial randomization was stratified by sex in blocks of equal size. Study staff responsible for arm allocation were blinded to block size to prevent contamination. After randomization, all study materials, including any equipment and/or materials, were distributed to the participants according to the treatment arm. A second titration visit was conducted six weeks after randomization, and the need for titration was assessed at each subsequent follow-up visit.

Quarterly Follow-Up Visits

Data collection assessments were conducted at weeks 0, 13, 26, 39, and 52, using a consistent set of study measures. In addition to survey measures, patients were instructed to bring their HTN medications with them so pill counts could be conducted. As EHR data were not available to our study team, all medication data, including prescribed medication names and doses were self-reported and/or captured from pill bottles. We also monitored for any potentially harmful renal or metabolic issues at weeks baseline, 26, and 52 and adjusted medications accordingly. To measure sodium intake (a secondary outcome measure of interest), at weeks 0, 26, and 52, participants were given supplies to collect 24-hour urine for sodium measurement. Study staff collected these specimens directly from the participants at their home to improve adherence. All medication titration and study follow-up visits were free; however, participants were responsible for the cost of medications, PCP visits, or copays, as applicable. Participants received financial incentives to participate in this study, with each visit individually incentivized, and could earn up to $275 over the course of one year.

Impact of COVID-19 on Study Procedures

In March 2020, the MI-BP trial was closed to new enrollments and in-person data collection due to the COVID-19 pandemic. This necessitated protocol changes in the following weeks and months in an effort to maximize data collection from participants who were enrolled in the study pre-pandemic. To summarize these changes, we pivoted to remote data collection for follow-up assessments via phone or videoconference. This meant that home monitored BPs, using study-issued cuffs, served as the final outcome measures for participants completing their trial participation between March 2020 and April 2021. Additionally, since all in-person

participant interaction had been suspended, all lab measures were discontinued during the COVID era and survey-based assessments were conducted verbally by phone or video conference out of concern for literacy levels among participants. We also removed several instruments from interim follow-up assessments in weeks 13 and 39. Finally, anthropometric assessments, including weight, height, and waist circumference measurements were self-reported by participants using their own home scales and tape measures. Given the increased reliance on home-based, self-reported data, the chance for missing data from follow-up assessments was greater.

Trial Arms

Participants in this trial were randomized equally to one of the two treatment arms, which included an enhanced usual care control arm, as well as the MI-BP intervention arm.

Enhanced Usual Care (Control Arm)

Participants in the enhanced usual care group were given a prescription for antihypertensive medications, printed educational materials on HTN, and a BP monitor for daily use. Participants assigned to the enhanced usual care control group received no further intervention; however, they were asked to take part in all study-specific follow-up visits. The decision to provide home BP cuffs to control participants, above and beyond true usual care, was made to reflect the fact that home BP monitoring is widely accepted as a guideline-based standard of care for individuals being treated for HTN[6], making it appropriate to include in the usual care arm. We acknowledge this active control represents a departure from true usual care; however, it does represent an ideal usual care scenario based on current HTN management guidelines.

MI-BP (Treatment Arm)

Participants randomized to receive the MI-BP intervention were given a prescription for antihypertensive medication, a Bluetooth-enabled pedometer (Fitbit Zip), a BP cuff, and access to the MI-BP mobile app. Participants were asked to use the MI-BP mobile app and related peripheral devices for 12 months.

MI-BP Intervention

MI-BP is a comprehensive, multicomponent intervention that targeted multiple behaviors for managing HTN via smartphone app, including BP self-monitoring, physical activity tracking, sodium intake tracking, goal setting, educational and motivational messaging, and medication adherence reminders. The MI-BP application was developed by Vibrent Health (Fairfax, VA), a digital health company. Vibrent Health designed the app, online portal, and server platforms necessary to support this trial. The MI-BP app was previously described in detail but is summarized here [14].

BP Monitoring

To support BP self-monitoring, participants who could utilize a standard BP cuff (suitable for an arm circumference between 23 and 45 cm) were provided with a Bluetooth-enabled BP cuff (A&D UA-651BLE) that could sync to the MI-BP app. The MI-BP app showed different visualizations of BP over time, including both graph and log form. In the event that a participant required a larger cuff size (between 42 and 60 cm), we provided an extra-large arm monitor (LifeSource A&D UA-789), which was not Bluetooth-enabled and required manual data

entry. Participants were instructed to measure and sync (or manually enter) their BP to the MI-BP app, at home using a commonly accepted home BP monitoring protocol, for a minimum of at least 3 days per week; however, daily self-monitoring and syncing were encouraged. If participants self-monitored a SBP reading of greater than 180 mmHg or less than 100 mmHg, or a DBP reading of greater than 110 mmHg, they were instructed by the study staff at baseline, as well as by automated notifications within the app at the time of the elevated reading, to check their BP again. If still elevated after 3 days, participants were instructed to call the study staff. Participants were also instructed to report to the ED and to follow up afterwards with a call to the research staff if they were experiencing symptoms of dizziness, chest pain, severe headache, visual changes, or numbness or weakness in the face or extremities.

Physical Activity Monitoring and Tracking

To support physical activity self-monitoring, participants were provided with a Fitbit Zip pedometer that could sync to the MI-BP app, which showed different visualizations (graph and log form) of physical activity data over time. Participants were instructed to wear their Fitbit daily and to sync the device at least once per week.

Sodium Intake Monitoring and Tracking

To support sodium intake monitoring, the MI-BP app used a logging approach that encouraged participants to identify their intake of high-sodium foods, using a checklist-type log available within the MI-BP app. The checklist comprised 7 categories, with 3 to 8 items per category, and represented the most common high-sodium foods that contribute to high-sodium diets. Although we encouraged users to track their intake of high-sodium foods daily, users were minimally instructed to engage in highly focused, 3-day consecutive bouts of logging that were prompted within the MI-BP app.

Goal Setting

Participants received weekly step-count goals that were displayed in the MI-BP app and were also delivered via push notification. Based on previous work from our team [15-19], step-count goals were gradually incremented and were based on an average of 7 consecutive days of data, during which at least 5 of the days needed to be considered valid. A valid day was defined as more than 200 steps/day. As we gradually incremented weekly goals, calculated goals never exceeded 600 additional steps over the previous goal. This gradual increment in weekly step-count goals was made in an effort to reduce potential adverse events.

Goal setting for sodium intake goal setting was also conducted every two to four weeks after an intensive, one-week baseline self-monitoring period that was used to calculate the initial goal for each participant. Sodium intake goals were displayed within the app and were also sent via push notification. Participants were instructed to log their intake of high-sodium foods for a 3-day period approximately 2 weeks after receiving their initial sodium goal that limited the number of high sodium foods consumed. When sodium goals were met during a logging period, a new lower sodium intake goal was issued, and participants were asked to log their high-sodium foods 4-weeks later. If the goal was not met, participants were asked to try again in 2 weeks. Additional details on our sodium logging and goal setting protocols have been published previously [14].

Messaging

MI-BP provided users with 4 different types of messages, which were sent via push notification and in-app messaging. These included educational messaging focused on HTN, physical activity, sodium, tips for behavior change and overcoming barriers to behavior change; motivational messaging; tailored messaging, including tips for overcoming specific-self-reported barriers to behavior changes and daily medication reminders, as well as tailored feedback responsive to whether participants were meeting their set goals; and customizable daily medication reminders. In addition to the customizable daily medication reminders, MI-BP sent about 7 messages per week. Message content, frequency, and timing were varied and tailored wherever possible, to maximize user engagement.

Measures

We collected a variety of different measures throughout this study. Full details of our study measures have been published previously [14]; however, those discussed in this paper are described here. Data were collected at baseline, medication titration visits at weeks 2 and 8, as well as planned follow-up assessments at weeks 13, 26, 39, and 52. Although most measures were collected at all time points, some were collected less frequently due to participant burden and cost of administration. The primary outcome measure of BP was measured in clinic (or at home during the COVID era) and was assessed at every study visit by a trained study staff member using a BpTRU BPM-200 (Smiths Medical PM Inc, Waukesha, WI) or Omron HEM 907XL Intellisense (Omron Healthcare, Inc.; Kyoto, Japan) BP monitoring device. Secondary outcome measures included the following: physical activity as measured by the International Physical Activity Questionnaire (iPAQ) [20]; sodium intake as measured by the Block Sodium Screener (BSS)[21], as well as a 24-hour urine sodium test; self-reported medication adherence using the Adherence to Refills and Medication Scale (ARMS-14) [22]; self-efficacy for changing targeted behaviors, including physical activity via the Exercise Self-Efficacy Scale (ESES) [23], medication adherence via the Medication Adherence Self-Efficacy Scale (MASES) [24], and diet using an investigator-developed 11-item instrument assessing confidence in reducing sodium consumption, avoiding high-fat foods, avoiding sugar-sweetened beverages, and improving vegetable and legume intake. In addition to instruments assessing physical activity, sodium intake, and in-clinic measured BP, we also analyzed related study data from MI-BP treatment arm participants collected in-app.

Statistical Analysis

Sample Size

As stated in our study protocol [14], our sample size was initially developed with two co-primary outcomes: SBP measured continuously and SBP control (defined as either above or below the SBP target of 130 mmHg), which is a more conservative measure. After experiencing sustained challenges with recruitment, the more conservative dichotomous BP control measure was dropped as a co-primary outcome. This necessitated a recalculation in sample size, based solely on continuously measured SBP, where we estimated a 10 and 17 mmHg point drop in SBP in the usual care and MI-BP arms, respectively, at the end of the trial. A constant between-subject standard deviation of 10 mm Hg was assumed, along with an intra-subject correlation of 0.5. With 121 subjects per arm, these estimates would allow us to detect a group-by-time interaction with power > 95% at 5% level of significance. Allowing for 20% attrition, we sought to recruit 152 participants per study arm, for a total of 304 participants.

Analysis Plan

Descriptive statistics were calculated for demographic variables and baseline measures. To ensure balance across study arms, these measures were compared using t-tests, Wilcoxon rank-sum tests, or chi-square tests, as appropriate. Linear mixed models (LMM) were employed to investigate differences in change of the outcomes between study arms, with time, study arm, and their interaction as primary covariates. For all outcomes, time was entered as a categorical covariate. The models were further adjusted for age and sex. For the BP outcomes (SBP and DBP), a second set of models were explored, where time was entered as a linear term in order to capture the rate of change in the outcomes. All models included a random intercept to account for intra-subject correlation. Square root transformations were employed to IPAQ-SF and BSS, and a log transformation was applied to ARMS-14 before running the LMM to better meet model assumptions.

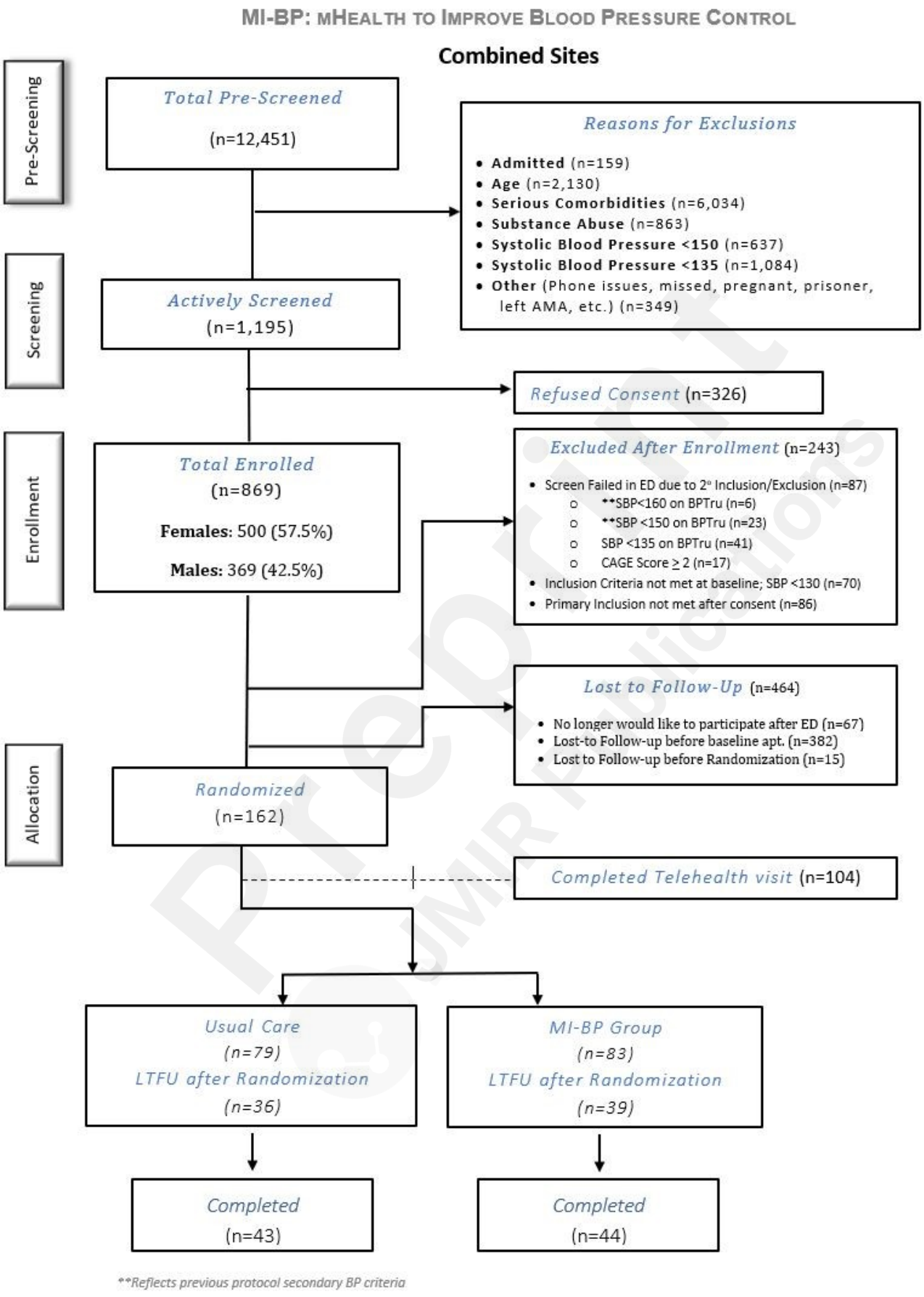
To investigate whether dropout was associated with any covariates, a time to dropout analysis was carried out using a Cox regression model. Since this study was partially conducted during the COVID-19 pandemic, we wanted to consider the impact of COVID-19 on dropout. Towards that end, we defined a new variable “COVID group” for each individual, at each time point. If the event time (e.g. week 13) of individual assessments were before 3:00pm March 16, 2020, we considered these records as ‘before COVID-19’. Otherwise, we consider records as ‘During COVID-19’ records. Thus, COVID group was modeled as a time-dependent covariate in the Cox model. All statistical analysis were carried out in SAS 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Trial Recruitment

In total, we prescreened 12,451 individuals, predominantly in ED settings (12,089 in ED, 169 from community events, and 193 from mobile health units), of which 1,195 (9.6%; 1,195/12,451) were preliminarily eligible for participation. Of those, 869 (72.7%; 869/1,195) were consented and enrolled in this study. The majority of enrolled participants were either excluded after enrollment (prior to randomization for failing secondary screening in ED, not meeting inclusion criteria at baseline, or not meeting primary inclusion criteria after consent (28.0%; 243/869), lost to follow-up prior to randomization (47.9%; 416/869), or were scheduled for baseline or randomization visits, but were halted due to the COVID-19 pandemic (5.5%; 48/869). See Figure 1 for the CONSORT diagram of participant flow through the trial. Due to the COVID-19 pandemic, in March 2020, ED recruitment for the trial was suspended precluding new enrollments from the ED. While we were able to eventually transition to community-based recruitment using mobile units under an IRB approved protocol amendment within nine months of this, screening was severely reduced, and no new randomizations occurred. These considerations, combined with the challenge of keeping participants engaged using remote follow-up promoted a decision by the study team, made in concern with our data safety and monitoring board, to end recruitment for this study in January 2022. Ultimately, we randomized 162 participants to the MI-BP trial.

Figure 1: CONSORT Diagram showing participant recruitment and retention



Participant Characteristics

Of the 162 participants randomized within this trial (79 to usual care, 83 to the MI-BP

intervention), participants were predominantly female (60%; 97/162) and were on average 48.3 years of age (range 29-68, SD=9.3). As race was an inclusion criterion, 100% of our participants were Black. Participants were characterized by being single (53% 86/162), employed (60%; 97/162), with having high school or less education (56%; 90/162) and an average household income of <$25,000 (59%; 73/123). Please see Table 1 for participant characteristics, as well as summary baseline measures stratified by study arm.

Table 1. Participant Characteristics and Baseline Measures by Study Arm

Participant Characteristics and Baseline Measures	Overall^ N=162	Intervention^ N= 83	Control^ N = 79	*p*-value*
Site				0.4487
COM	17 (10.49%)	10 (12.05%)	7 (8.86%)	
DRH	83 (51.23%)	45 (54.22%)	38 (48.10%)	
SGH	62 (38.27%)	28 (33.73%)	34 (43.04%)	
Gender				0.8230
Female	97 (59.88%)	49 (59.04%)	48 (60.76%)	
Male	65 (40.12%)	34 (40.96%)	31 (39.24%)	
Age	48.33 (9.28)	48.47 (8.97)	48.18 (9.64)	0.8416
Height (cm)	170.92 (10.16)	170.82 (10.85)	171.03 (9.46)	0.9533
Weight (kg)	101.80 (26.48)	100.95 (26.49)	102.67 (26.60)	0.8181
Waist circumference (mm)	1125.66 (203.53)	1102.4 (215.93)	1150.69 (188.83)	0.2888
Heart Rate (beats per minute)	78.09 (13.73)	78.59 (13.23)	77.56 (14.30)	0.6335
Marital Status				0.8065
Single/Never been married	86 (53.09%)	42 (50.60%)	44 (55.70%)	
Married/Cohabitating	33 (20.37%)	18 (21.69%)	15 (18.99%)	
Divorced/Widowed/Separated	43 (26.54%)	23 (27.71%)	20 (25.32%)	
Education				0.8589
less than college	90 (55.56%)	47 (56.63%)	43 (54.43%)	
Some College	40 (24.69%)	19 (22.89%)	21 (26.58%)	
a college/technical degree	32 (19.75%)	17 (20.48%)	15 (18.99%)	
Insurance				0.8015
Private Health Insurance	48 (29.63%)	24 (28.92%)	24 (30.38%)	
Medicare	12 (7.41%	7 (8.43%)	5 (6.33%)	
Medicaid/Medicare and Medicaid	74 (45.68%)	40 (48.19%)	34 (43.04%)	
No Insurance	27 (16.67%)	12 (14.46%)	15 (18.99%)	
Unknown/Refused	1 (0.62%)	0 (0%)	1 (1.27%)	
Employment Status				0.3347
Currently Employed	97 (59.88%)	53 (63.86%)	44 (55.70%)	
Others	64 (39.51%)	30 (36.14%)	34 (43.04%)	
Unknown/Refused	1 (0.62%)	0 (0%)	1 (1.27%)	
Annual household income (before taxes)				0.4169
< $10,000	45 (27.78%)	24 (28.92%)	21 (26.58%)	

$10,000 - $24,999	28 (17.28%)	16 (19.28%)	12 (15.19%)	
$25,000 - $49,999	36 (22.22%)	21 (25.30%)	15 (18.99%)	
$50,000 and over	14 (8.64%)	11 (13.25%)	3 (3.80%)	
Unknown/Refused/Missing	39 (24.07%)	11 (13.25%)	28 (35.44%)	
Health Literacy (measured by REALM-SF)				0.4345
0 (3rd grade and below)	4 (2.47%)	1 (1.2%)	3 (3.80%)	
1-3 (4th-6th grade)	13 (8.02%)	5 (6.02%)	8 (10.13%)	
4-6 (7th-8h grade)	49 (30.25%)	24 (28.92%)	25 (31.65%)	
7 (high school)	95 (58.64%)	53 (63.86%)	42 (53.17%)	
Missing	1 (0.62%)	0 (0%)	1 (1.27%)	
HELM Knowledge	8.38 (2.37)	8.62 (2.27)	8.11 (2.47)	0.1919
Patient Activation (measured by PAM)	64.00 (12.67)	64.50 (13.50)	63.48 (11.81)	0.6028
SF12 PCS (Physical Component Summary)	42.05 (11.88)	42.23 (11.26)	41.86 (12.57)	0.9837
SF12 MCS (Mental Component Summary)	48.85 (11.75)	50.18 (11.07)	47.46 (12.34)	0.1842

COM: community, DRH: Detroit Receiving Hospital, SGH: Sinai-Grace Hospital

^ Mean (Standard Deviation) for continuous variables and N (%) for categorical variables.

* Descriptive statistics were calculated for demographic variables and baseline measures and compared across the study arms using t-tests, Wilcoxon rank-sum tests, or chi-square tests, as appropriate.

Effect of MI-BP on Outcomes

Blood Pressure

For our primary outcome of SBP, sex and age adjusted average baseline SBP was comparable between groups (MI-BP group mean = 153.92 mmHg, enhanced usual care group mean = 153.96 mmHg, p=.99). Both groups saw a mostly steady and similar decline in SBP over the 12-month intervention (unadjusted means in Figure 2a). Table 2 shows a model-based assessment of pairwise differences in adjusted mean SBP for each study arm. At week 52, compared to baseline, the MI-BP group exhibited a 22.5 mmHg decrease (se = 3.35 mmHg, p < .0001) and the control group a 24.12 mmHg decrease (se = 3.25mmHg, p < .0001) in average estimated SBP adjusted for age and sex. The average declines are not significantly different between groups (time-by-arm interaction p = .99). Regression model with a linear time term estimated the rate of decline in the MI-BP group to be .3 mmHg/week (se = .05mmHg/week, p <.0001) and .34 mmHg/week (se = .05mmHg/week, p < .0001) in the control group, adjusted for age and sex. Again, these rates are not significantly different between groups (interaction p = .6) (Appendix Table B1).

Figure 2. Unadjusted mean trajectories for SBP and DBP by study arm

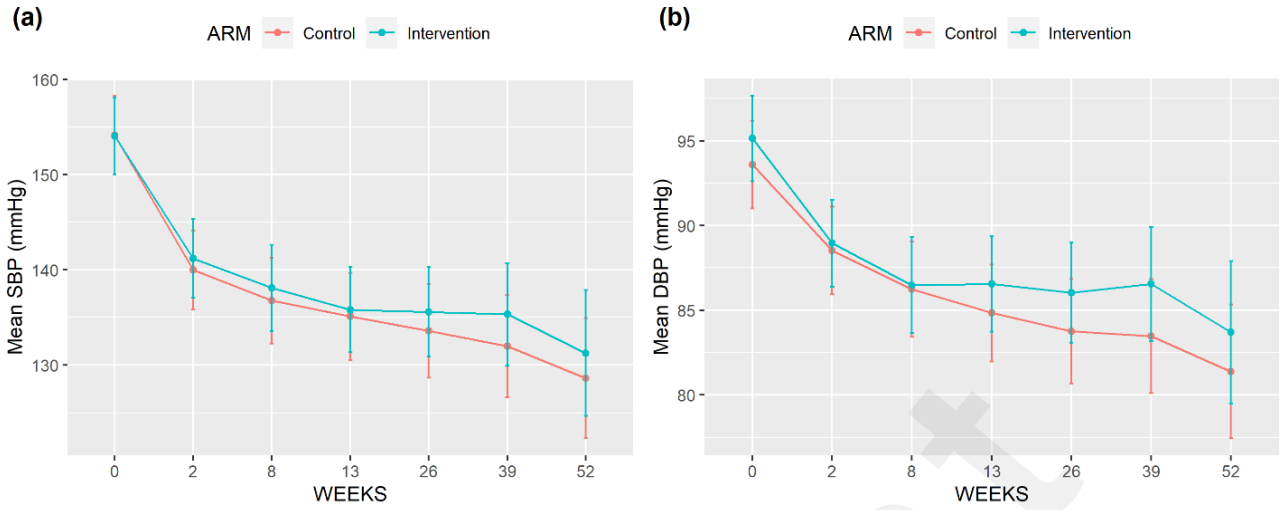


Table 2: Estimated pairwise mean differences and standard error across time for SBP by Study Arm

Comparison	Intervention			Control		
	Mean Difference (time2-time1)	Standard Error	P-value	Mean Difference (time2-time1)	Standard Error	P-value
0-weeks vs. 2-weeks	-12.8394	2.4156	<.0001	-14.1392	2.4466	<.0001
0-weeks vs. 8-weeks	-15.3359	2.5677	<.0001	-16.7350	2.5790	<.0001
0-weeks vs. 13-weeks	-17.9052	2.5566	<.0001	-18.6283	2.6044	<.0001
0-weeks vs. 26-weeks	-17.4752	2.6346	<.0001	-19.2175	2.7335	<.0001
0-weeks vs. 39-weeks	-17.3283	2.8752	<.0001	-21.2452	2.8972	<.0001
0-weeks vs. 52-weeks	-22.5007	3.3471	<.0001	-24.1173	3.2502	<.0001
2-weeks vs. 8-weeks	-2.4966	2.5852	0.3345	-2.5958	2.5790	0.3145
2-weeks vs. 13-weeks	-5.0658	2.5742	0.0495	-4.4891	2.6044	0.0852
2-weeks vs. 26-weeks	-4.6358	2.6520	0.0809	-5.0782	2.7335	0.0636
2-weeks vs. 39-weeks	-4.4890	2.8882	0.1206	-7.1060	2.8972	0.0144
2-weeks vs. 52-weeks	-9.6613	3.3583	0.0041	-9.9781	3.2502	0.0022
8-weeks vs. 13-weeks	-2.5692	2.6855	0.3390	-1.8934	2.6886	0.4815
8-weeks vs. 26-weeks	-2.1393	2.7702	0.4402	-2.4825	2.8147	0.3781
8-weeks vs. 39-weeks	-1.9924	2.9898	0.5054	-4.5102	2.9664	0.1289
8-weeks vs. 52-weeks	-7.1647	3.4428	0.0378	-7.3823	3.3121	0.0261
13-weeks vs. 26-weeks	0.4300	2.7428	0.8755	-0.5891	2.8296	0.8351
13-weeks vs. 39-weeks	0.5768	2.9774	0.8464	-2.6169	2.9850	0.3810
13-weeks vs. 52-weeks	-4.5955	3.4361	0.1815	-5.4890	3.3253	0.0993
26-weeks vs. 39-weeks	0.1469	3.0223	0.9613	-2.0278	3.0707	0.5092
26-weeks vs. 52-weeks	-5.0255	3.4733	0.1484	-4.8999	3.3983	0.1498
39-weeks vs. 52-weeks	-5.1723	3.6255	0.1541	-2.8721	3.5034	0.4126

DBP exhibited a very similar pattern as SBP (Figure 2b) with MI-BP and the control arms

experiencing significant reductions in DBP from baseline to 52 weeks with a 10.20 mmHg (se=1.82 mmHg; p<0.0001) and 11.44 mmHg (se=1.75 mmHg; p<0.0001) estimated average decrease, respectively (Table 3). However, no significant differences were found between these differences (time-by-arm interaction p = .79). Model based rates of decline were observed in the MI-BP (estimate = .13mmHg/week, se = .03mmHg/week, p < .0001) as well as the control group (estimate = .17mmHg/week, se = .03mmHg/week, p < .0001). (Appendix Table B1). Again, none of these changes were statistically significantly different between groups (p=.21).

Table 3: Estimated pairwise mean differences and standard error across time for DBP by Study Arm

Comparison	Intervention			Control		
	Mean Difference (time2-time1)	Standard Error	P-value	Mean Difference (time2-time1)	Standard Error	P-value
0-weeks vs. 2-weeks	-6.2249	1.2940	<.0001	-5.0759	1.3099	0.0001
0-weeks vs. 8-weeks	-7.9787	1.3772	<.0001	-6.8315	1.3829	<.0001
0-weeks vs. 13-weeks	-8.0509	1.3713	<.0001	-8.1532	1.3967	<.0001
0-weeks vs. 26-weeks	-8.2251	1.4136	<.0001	-8.8694	1.4665	<.0001
0-weeks vs. 39-weeks	-7.5165	1.5436	<.0001	-9.5521	1.5551	<.0001
0-weeks vs. 52-weeks	-10.1987	1.8209	<.0001	-11.4393	1.7453	<.0001
2-weeks vs. 8-weeks	-1.7538	1.3861	0.2062	-1.7555	1.3829	0.2047
2-weeks vs. 13-weeks	-1.8261	1.3803	0.1863	-3.0772	1.3967	0.0279
2-weeks vs. 26-weeks	-2.0003	1.4225	0.1601	-3.7935	1.4665	0.0099
2-weeks vs. 39-weeks	-1.2916	1.5500	0.4050	-4.4762	1.5551	0.0041
2-weeks vs. 52-weeks	-3.9738	1.8263	0.0299	-6.3634	1.7453	0.0003
8-weeks vs. 13-weeks	-0.0723	1.4389	0.9600	-1.3217	1.4403	0.3591
8-weeks vs. 26-weeks	-0.2465	1.4854	0.8683	-2.0380	1.5087	0.1772
8-weeks vs. 39-weeks	0.4622	1.6035	0.7732	-2.7206	1.5904	0.0876
8-weeks vs. 52-weeks	-2.2200	1.8703	0.2357	-4.6078	1.7768	0.0097
13-weeks vs. 26-weeks	-0.1742	1.4698	0.9057	-0.7163	1.5164	0.6368
13-weeks vs. 39-weeks	0.5345	1.5967	0.7379	-1.3989	1.6003	0.3823
13-weeks vs. 52-weeks	-2.1477	1.8669	0.2504	-3.2861	1.7837	0.0659
26-weeks vs. 39-weeks	0.7087	1.6201	0.6619	-0.6827	1.6455	0.6784
26-weeks vs. 52-weeks	-1.9735	1.8858	0.2957	-2.5699	1.8219	0.1588
39-weeks vs. 52-weeks	-2.6822	1.9658	0.1729	-1.8872	1.8775	0.3152

Physical Activity

Slight Improvements in physical activity over the course of the trial were found for both the MI-BP and enhanced usual care control groups, as measured by the iPAQ-SF, although the improvements were not statistically significant in general. In the MI-BP group, the age and sex adjusted average IPAQ-SF (after square root transformation) increased by 10.25 MET-min per week (se = 6.37 MET-min per week, p = .11) at 52-weeks, while the increase was 10.57 MET-min per week (se = 5.87 MET-min per week, p = .07) (Appendix Table B2). Both groups exhibit fluctuations in the change pattern, where the up-and-down behavior is more prominent in the MI-BP arm (Appendix A1). There is, however, no significant differences in the change pattern across the groups (time-by-group interaction p-value = .93).

Sodium Intake

Appendix A2 demonstrates that mean sodium intake measured by the BSS declines fairly steadily in the MI-BP arm, whereas in the enhanced usual care group there is a fluctuating pattern in the mean trajectories. Both arms, however, experienced significant improvements when comparing baseline with the 52-week values. In the MI-BP group the average decrease in the adjusted (square-root transformed) BSS is .357 (se = .19, p-value = .06), while the average decrease in the control arm is .60 (se = .18, p-value = .001) (Appendix Table B3). No significant time-by-group interaction was observed (p=.19).

Medication Adherence

Both treatment groups experienced significant improvements (reduction) in medication adherence as measured by the ARMS-14 over one year (Appendix A3). Average estimated decrease at 52 weeks compared to baseline in log-transformed ARMS-14 in MI-BP group was 0.20 (se = .04, p-value < .0001) while the corresponding decrease in the control arm was .15 (se = .04, p-value = .0002) (Appendix Table B4). No significant difference in the pattern of change was observed (time-by-group interaction p-value = .30).

Self-Efficacy

Self-efficacies were measured in four different ways, related to attitude and habits of exercise, medication adherence, and eating habits. Appendix A4(a) and Appendix A4(b) show that the trajectories of Exercise Self-efficacy as measured by 2 subscales (Sticking to It and Making Time for Exercise) are similar within each study arm. However, in neither arm did the average scores improve significantly. In MI-BP the average estimated increase in the Sticking to It subscale at week 52 from baseline was 0.11 (se = .20, p-value =.59), while the corresponding increase in the control arm was .01 (se = .18, p-value = .94). For the Making Time for Exercise subscale, the adjusted mean increase was .09 (se = .22, p-value = .69) for MI-BP and .11 (se = .21, p-value = .58) for the control arm, respectively (Appendix Tables B5 and B6). As with other outcomes, no significant time-by-group interactions were found (p-values = .88 and .94 for Sticking to It and Making Time for Exercise, respectively).

For Medication Adherence Self-Efficacy (MASES), statistically significant improvements were observed for both arms as the trajectories seemed to follow similar patterns (Appendix A4(c)). The increase in estimated average MASES in MI-BP arm was .38 (se = .16, p-value = .02) and the corresponding increase in the control arm was (average = .37, se = .15, p-value = .01) (Appendix Table B7). No significant time-by-arm interaction was observed suggesting no differences in the pattern of change between groups (overall time-by-group interaction p = 0.47).

The Self-Efficacy for Eating Behaviors (SEEB) showed worse values compared to baseline (estimated mean = 43.95) within the intervention group at week 52 as the estimated mean reduced from a baseline value of 43.95 to 40.04 at week 52 (estimated mean reduction = 3.9, se = 1.47, p = .008). By contrast, in the control arm, the score increased slightly from baseline (mean = 41.64) to week 52 (mean = 43.69) although this improvement was not statistically significant (estimated mean improvement = 2.05, se = 1.4, p = .14 [Appendix Table B8]). This was the only outcome for which significant time-by-group interaction was observed (p=.0035), albeit in the unintended direction.

Trial Retention

Over the course of the 12-month RCT, we saw steady rates of participant dropout over time, and only 67 participants (33 in intervention and 34 and control) remained at the end of the one-year study (retention rate = 41.4%; 67/162). The greatest rates of dropout occurred early in the trial between the Week 2 and Week 8 visits, followed by the time periods later in the trial between the Week 26 and Week 39 visits, and between the Week 39 and Week 52 visits.

Dropout Analysis and Effect of COVID-19

Steady dropout was observed in both treatment arms over the study period, cumulating to 60% and 58% dropout in MI-BP and control arms, respectively, at the end of study. These dropout patterns were very similar in both study arms (Figure 3). In the time-to-dropout analysis, marital status and COVID group turned out to be statistically significant at the 5% level, with the post COVID-19 phase demonstrating a strong propensity (Table 4) for dropout (HR = 2.12, se=.23, p-value = .001).

Figure 3. Dropout history over the course of trial by study arm

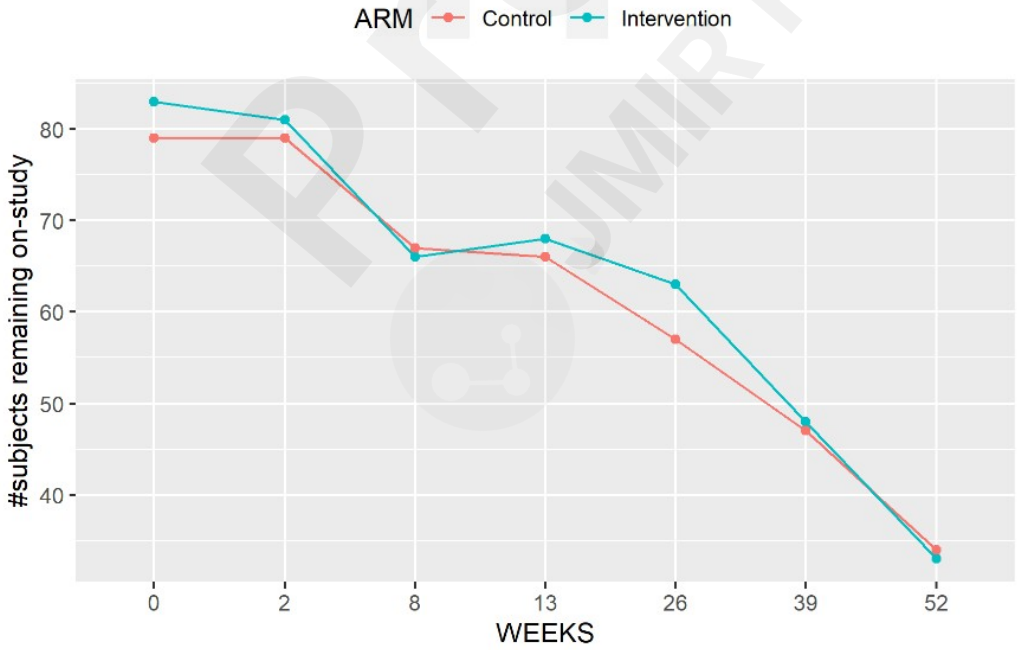


Table 4. Time to dropout results based on Cox regression model

Variables	Hazard Ratio	95% CI	P-value
Covid Group (Ref: Before Covid)	2.120	(1.353, 3.322)	0.001

Age	0.983	(0.959, 1.008)	0.180
Marital Status (Ref: Divorced/Widowed/Separated)			
Married/Cohabitating	1.998	(1.049, 3.802)	0.035
Single/Never been married	1.820	(1.021, 3.247)	0.042
Gender (Ref: Male)	0.912	(0.604, 1.379)	0.664

Adverse Events

Adverse Events (AEs) for this trial were all determined to be cardiovascular in nature. Fifteen AEs of SBP>180 were reported. All were determined to be unrelated to the study and all were reported to both the WSU Institutional Review Board and to the study Data Safety and Monitoring Board (DSMB). In addition, during the course of this trial, three serious adverse events (SAEs) were reported by research participants. All three SAEs were determined to be unexpected and unrelated to the MI-BP interventions and all three patients recovered with treatment. SAEs reported in this trial included two instances of non-ST-elevation myocardial infarction and one instance of cerebral visual impairment. All SAEs were reported to both the WSU Institutional Review Board and the study DSMB.

Discussion

Results from this study suggest that compared to our enhanced usual care control, the MI-BP intervention did not have any significant effects on participants in this study, including the primary outcome measure of BP, nor on the secondary outcome measures of physical activity, sodium intake, and medication adherence. Even though the trial was underpowered to detect differences due to stopping recruitment early because of the COVID-19 pandemic, trends to suggest that MI-BP had an effect on these outcomes compared to enhanced usual care control were not evident. However, it is important to note that, despite a high overall dropout rate, participants in both groups experienced significant reductions in SBP, DBP, and sodium intake, as well as significant increases in physical activity and medication adherence, from baseline to one year. This speaks to the general benefit of proactive outreach and engagement focused on cardiometabolic risk reduction in urban dwelling, low-SES Black populations.

Our findings are similar to recent work by Pletcher et al.[25], which found no benefit in terms of SBP reduction for BP self-monitoring using a connected smartphone app compared to standard BP self-monitoring over six months. As in our trial, Pletcher et al. found that at six months, both intervention and control arms experienced comparable and significant decreases in SBP (−10.8 (18) mm Hg vs −10.6 (18) mm Hg in enhanced vs standard groups) (See Appendix A4.d), with no significant differences between group, in a sample of 2,101 patients with uncontrolled BP. While our findings and those of Pletcher et al. stand in contrast to other work suggesting benefit of mHealth apps to reduce BP [14], it should be noted that the evidence base for app-supported self-monitoring of BP is often plagued by short duration and follow-up, small sample sizes, and inconsistent comparison groups, which undermines the quality of research in this area. Moreover, it is important to remember that our control group was not assigned to usual care alone; rather, we utilized an active control condition, where control group participants received a home BP monitor in addition to antihypertensive medications and standard educational materials. This may have led to greater reduction in BP than may have been experienced with standard usual care alone.

The high dropout rate (58.6%) among enrolled and randomized participants warrants further mention. While this dropout rate is higher than other studies that involved similar digital interventions for monitoring and controlling BP and/or study populations [26-28], high dropout rates in studies that deployed digital health interventions are quite common in the mHealth domain and range upwards of 80% attrition, with about 49% attrition in observational studies and 40% attrition in RCTs. In his seminal piece, Eysenbach described The Law of Attrition for eHealth interventions, which describes the phenomenon of participants dropping out of a research trial prior to completion, or stopping their usage of the trial intervention before the study is over [29]. This phenomenon has been described time and time again in the digital health literature and has been specifically evident for mHealth interventions focused on physical activity [30, 31], diet [32], and medication adherence (all targeted behaviors in the MI-BP intervention) [33]. Recent studies demonstrated that a higher dropout rate is even more common for digital health intervention studies involving Black participants[34]. For instance, Jonassaint and colleagues suggested that it may be important to develop a digital intervention system that is culturally tailored to historically marginalized groups. However, our intervention was culturally tailored to the Black community, suggesting room for other explanations for the high dropout rate. We did include a washout period to screen out individuals who did not truly have uncontrolled HTN and identify those who were not fully vested in trial participation, but neither of these is a culture specific approach. Michaud and colleagues [35] have suggested that a high incentive program may be effective in decreasing the attrition rate for digital health interventions for increasing physical activity for Black women. Although we incorporated a distributed incentive system, which rewarded participants for each visit completion, this was not sufficient to prevent the high dropout rates that echoed those in similar digital intervention studies. It should be mentioned that particularly when working within historically excluded and under-resourced communities, the notion of providing higher incentives to encourage participation is a hotly contested topic, as some believe that it may be considered coercive; however, study incentives are meant to acknowledge participant burden, such as loss of time and differentially incentivizing study participants based on level of advantage introduces its own host of ethical conundrums.

Our findings, coupled with the high dropout rates found in similar studies, suggest that these types of mHealth behavior change interventions may not be a complete solution that can promote behavior change and improve health outcomes in this population. Rather, mHealth may have the greatest potential as part of a suite of approaches available to healthcare professionals and patients. It is clear that mHealth solutions are here to stay, but the goal of future research should be to identify the use cases and implementation strategies and factors that contribute to the optimization. Moreover, the expectation of high dropout rates for mHealth interventions, especially when working in challenging populations with considerable barriers caused by social determinants of health, should be assumed and addressed at the outset. This is important as underpowered samples compromise the quality of research studies and the evidence base; however, review panels for different funding mechanisms often look unfavorably on proposed research studies that anticipate very high dropout rates. This may cause researchers to intentionally underestimate attrition, which may compromise the research study as a whole.

Limitations

As with all research, this study was not without limitations. Perhaps the largest limitation was the undeniable negative impact of the COVID-19 pandemic which caused us to stop study recruitment early and likely had significant effects on trial participation for those who were

already randomized in the study. Combined with a high dropout rate, early study termination led to an underpowered study, which may have caused us to be unable to find significant differences between groups. That said, data trends across our participants suggest that both groups experienced significant improvement in both primary and secondary outcomes and if there really was a benefit of the MI-BP intervention, it was likely much smaller than our initially projected effect size. Given the absence of a signal suggesting differential improvements, future efforts would be better served simply focusing on scalable outreach and engagement programs that facilitate better care of Black patients with uncontrolled HTN.

We should also note that although we consented and enrolled 869 individuals in the ED and other community-based settings, 53% (464/869) were considered lost to follow-up prior to randomization. Most of this loss to follow-up occurred before the baseline visit (Fig 1). Although we cannot say for certain why there was such tremendous loss to follow-up prior to randomization, our de facto wash-out period helped to remove individuals who were not fully committed to participation in the trial. Given the large loss to follow-up prior to randomization, we most certainly have some degree of selection bias in our randomized sample. In addition to our loss to follow-up prior to randomization, as discussed, we also experienced high drop out rates in our trial arms, which serves as a potential threat to the validity and generalizability of our findings. We also note that our quarterly follow-up assessments may have helped some participants stay engaged with the intervention and trial, masking even further attrition that may have been experienced without frequent contact. As suggested previously, very high rates of attrition are not uncommon in mHealth studies and our trial was no exception. More research on how to best engage participants in these types of interventions and trials is desperately needed as the mechanisms that drive engagement are poorly understood. Moreover, our work is met with additional challenges as we are positioned in a community where social determinants of health play an enormous role in the daily lives of our participants. These additional challenges are sure to contribute to our high attrition rates. While attrition may serve as a threat to the validity of our findings, it is important to remember that this is often the reality of working within populations of individuals who experience health inequity. Rather than shy away from work in this area due to methodological and statistical concerns, we must continue to conduct research with populations of individuals with great need in order to address inequities.

Conclusion

Although we did not find increased improvement in outcomes for participants using MI-BP, compared to enhanced usual care control, we are encouraged to see that proactive outreach in a sample of uncontrolled hypertensive Blacks recruited from EDs and other community-based settings had a significant effect in improving HTN-related outcomes, regardless of treatment group. Given that mHealth approaches for chronic disease self-management are becoming more commonplace, continued work is needed to understand how to better engage and retain users, as well as how to better position these types of interventions within a suite of treatment options available to patients. Moreover, participant dropout in mHealth interventions remains high in many studies, including ours, and this phenomenon must be further explored before optimal mHealth use can be achieved.

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Conflicts of Interest

None declared.

Abbreviations

Hypertension (HTN)
emergency department (ED)
blood pressure (BP)
randomized controlled trial (RCT)
systolic BP (SBP)
Diastolic BP (DBP)
Wayne State University (WSU)
Data and Safety Monitoring Board (DSMB)
Detroit Medical Center (DMC)
Detroit Receiving Hospital (DRH)
Sinai-Grace Hospital (SGH)
Cut down, Annoyed, Guilty, Eye-opener Adapted to Include Drugs questionnaire (CAGE-AID)
Primary Care Provider (PCP)
International Physical Activity Questionnaire (iPAQ)
Block Sodium Screener (BSS)
Adherence to Refills and Medication Scale (ARMS-14)
Exercise Self-Efficacy Scale (ESES)
Medication Adherence Self-Efficacy Scale (MASES)
Linear Mixed Models (LMM)
Self-Efficacy for Eating Behaviors (SEEB)
Adverse Events (AEs)
Serious Adverse Events (SAEs)

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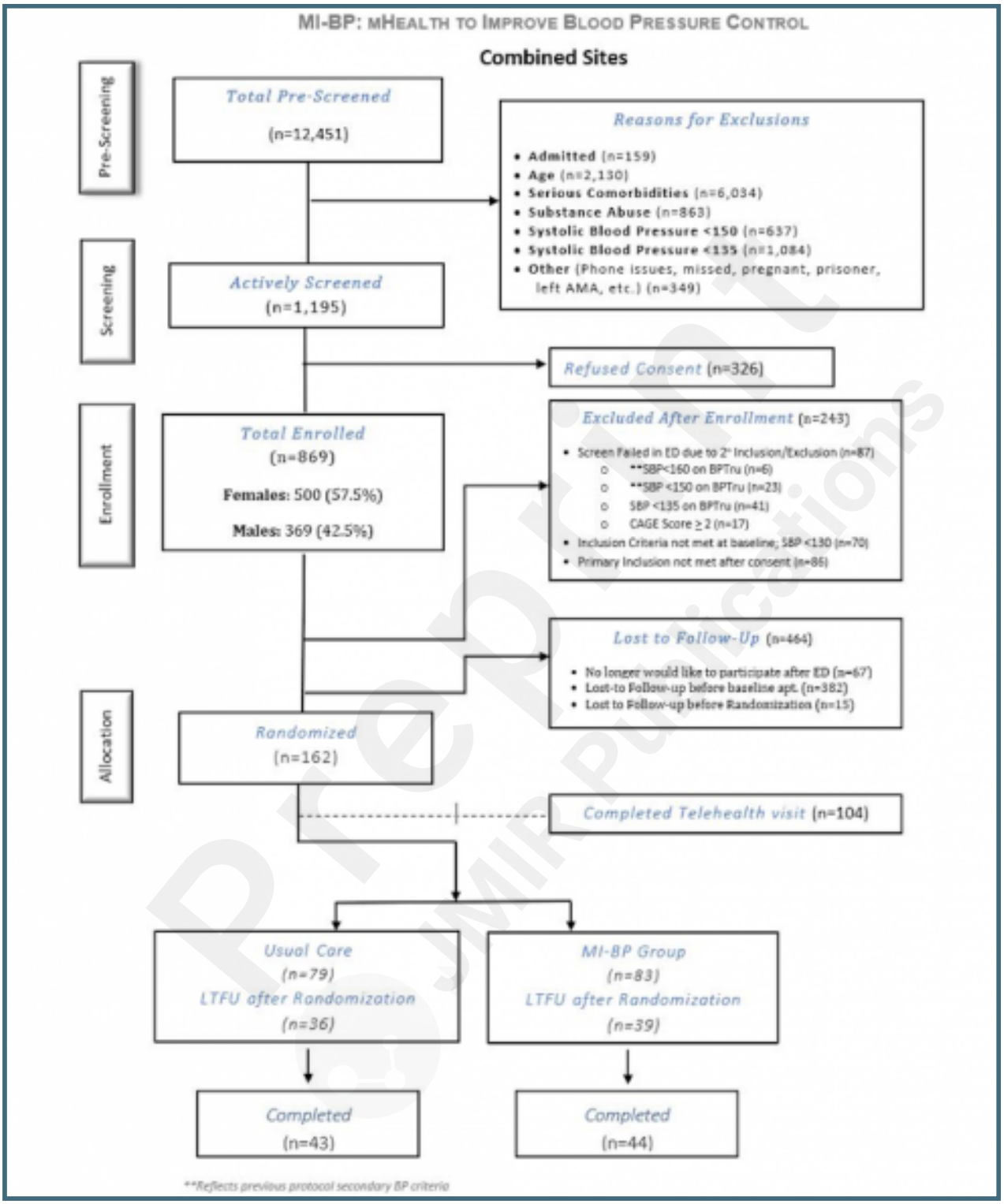
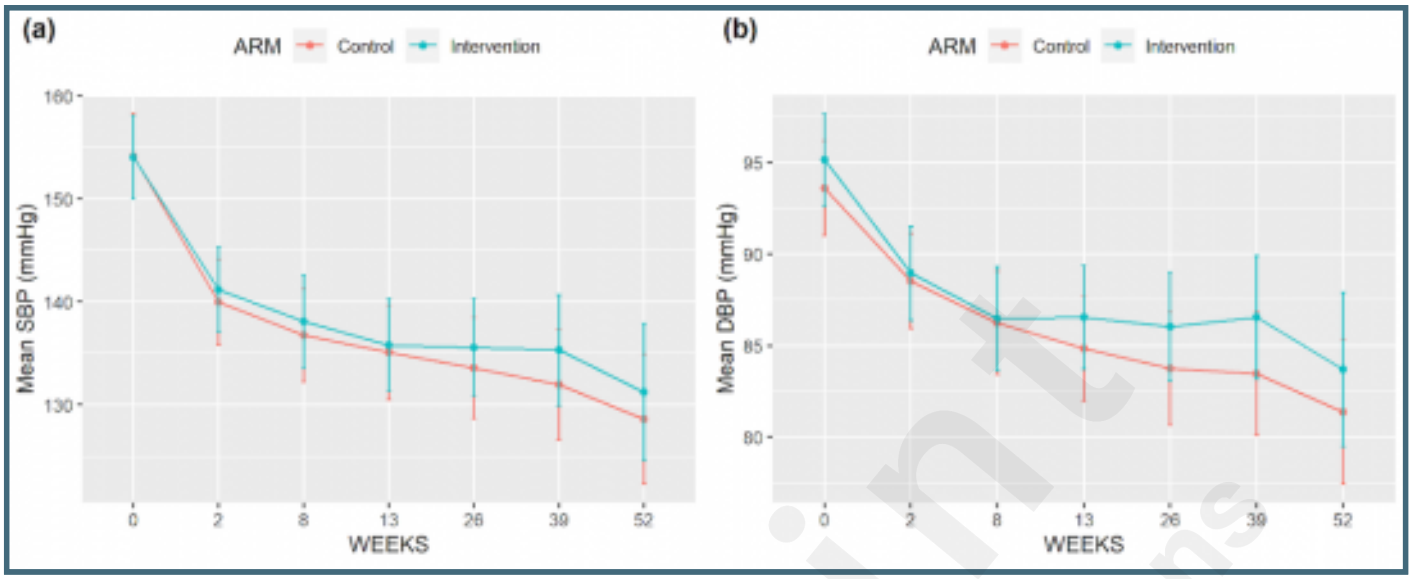
Supplementary Files

Figures

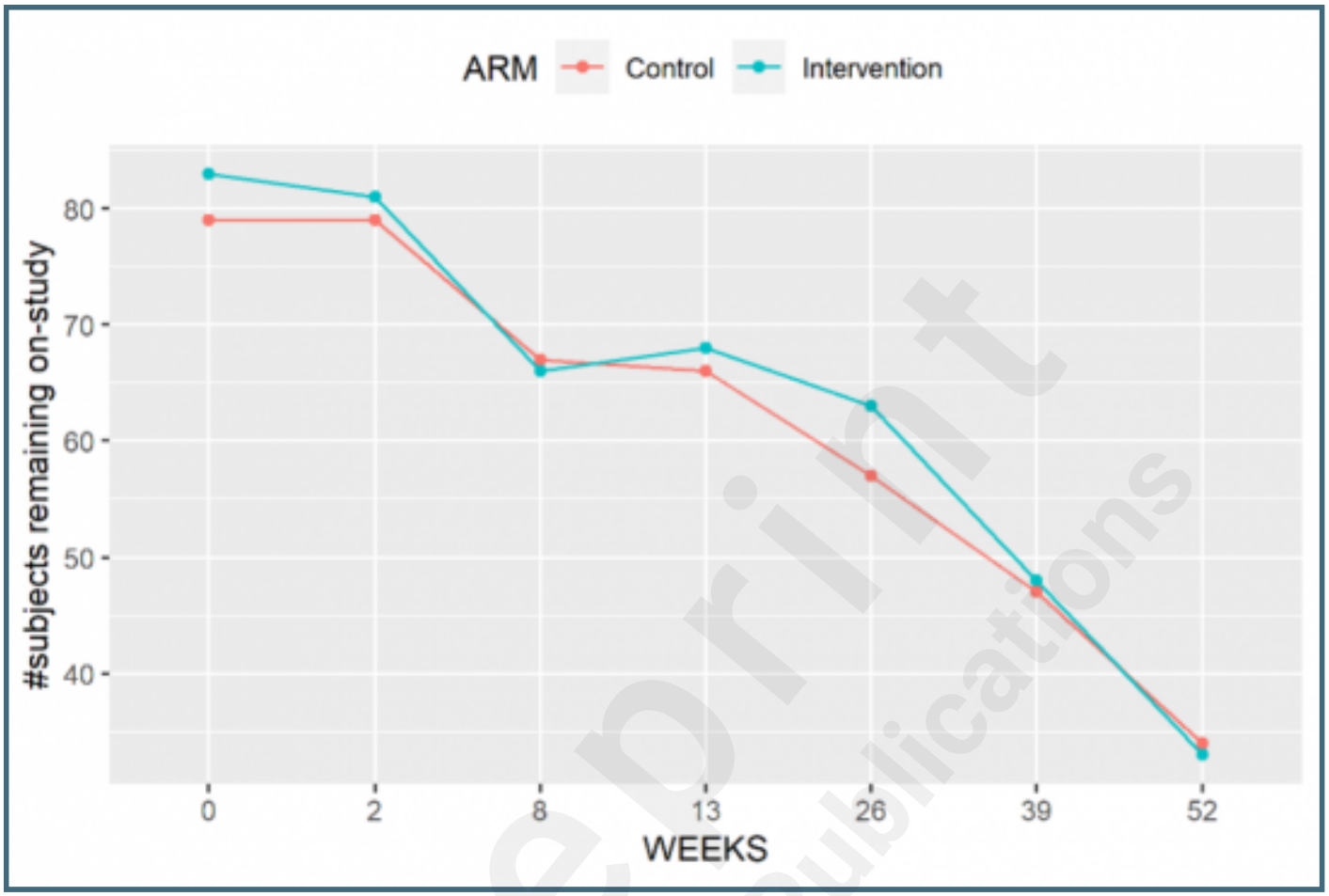
CONSORT Diagram showing participant recruitment and retention.



Unadjusted mean trajectories for SBP and DBP by study arm..



Dropout history over the course of trial by study arm.



Multimedia Appendixes

Supplementary Figures.
URL: http://asset.jmir.pub/assets/8570f2a52323b00f82bb4b82ff86d211.docx

Supplementary Tables.
URL: http://asset.jmir.pub/assets/f9420c3b7dac7b05ea6c9ab56a2186f9.docx