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Study Protocol and Statistical Analysis Plan

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Technology Coaching Intervention for Black Women With Hypertension

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Study Protocol

Description of the Study

In the United States, hypertension (HTN) is the leading risk factor for cardiovascular disease and a more significant problem among Black women. About 46.1% of Black women over the age of 20 have HTN compared to White (30.1%) and Hispanic (29.9%) women. Currently, the prevalence of HTN in Black women is highest in the United States and is expected to increase underscoring the relatively ineffective prevention and management efforts for blood pressure (BP) control. Black adults tend to develop HTN earlier in life with greater severity and more organ damage when compared to Whites and uncontrolled HTN increases the risk of heart failure, myocardial infarction, stoke, and kidney disease. Black females experience a substantially higher death rate from HTN at 2.1 times the rate of both White and Hispanic females. Poor execution of evidence based HTN guidelines and clinical inertia among healthcare providers along with patient nonadherence to prescribed treatment contribute to poor BP control. It is well known that antihypertensive medications along with lifestyle modifications have proven efficacy in lowering BP when adhered to consistently. However, for Black adults, the lingering effects of their historical legacy, continued segregated communities, high poverty rates, and unequal medical treatment, place them in a unique position to view healthcare with skepticism that differs from all other racial/ethnic groups. Thus, accepted approaches to HTN management have not been optimally effective in producing sustained BP control for Black women. Since nonadherence occurs in the context of everyday living, strategies are needed that encourage more active individual engagement in health care behaviors and self-care activities, in the physical and social environment where patients can perform them independently. This research study evaluated community-based interventions designed to control hypertension using interactive self-care strategies with coaching and technology.

This study includes a sample of community dwelling Black women with uncontrolled HTN. All participants meeting study eligibility requirements will receive the Chronic Disease Self-Management Program (CDSMP) workshop for 6 weeks. Participants from this pool will be randomized to the treatment and control arm. All study participants will continue to receive usual care for their HTN.

The intervention will be divided into three steps. At Step 1 for 3 months, the treatment arm will receive electronic monitoring (of participants' BP, weight, physical activity, food diary, and medication-taking) with weekly Interactive Technology Enhanced Coaching (ITEC) while the control arm will receive usual care with manual BP measurements monthly. At Step 2 for three months, the treatment arm will receive electronic monitoring with ITEC biweekly, and the control arm will receive electronic monitoring only. At Step 3 for three months, both the treatment arm and the control arm will receive electronic monitoring only.

Information from this study may be used to enhance self-care management, control blood pressure, and increase the quality of life for Black women who are burdened with the adverse effects of HTN and its high disability and mortality rates.

Our sample of n=45 participants per arm (N=90 in total), will be measured (electronic measurements, anthropometric measurements, and data collection tools) at baseline, 3 months, 6

months, and at 9 months post CDSMP. A hierarchical, mixed-effects repeated measures design will be used to analyze the data.

Objective

The specific aims for this study evaluated the effectiveness of an established Chronic Disease Self-Management Program (CDSMP) plus an interactive technology-enhanced coaching (ITEC) intervention on improving 1) BP control, and 2) medication adherence and lifestyle modifications (physical activity, diet, and weight management) compared to the CDSMP and interactive technology (IT) alone.

Design

The proposed project is a two-arm randomized controlled trial (RCT), repeated measures design. We hypothesized that participants who received the CDSMP and ITEC would have lower systolic/diastolic BP and better adherence to antihypertensive medication(s) and lifestyle recommendations post intervention compared to participants receiving the CDSMP and IT alone. Measurements were obtained over 9 months post CDSMP.

Methods

Study Location

The study took place in Charlotte, NC, and surrounding areas. The state of NC lies in the southeastern area of the United States, an area known as the Stroke Belt because of the high incidence of stroke and cardiovascular disease (CVD). The study sample consisted of 90 community-dwelling Black women who had a medical diagnosis of hypertension and meet the study criteria.

Study criteria

Inclusion criteria included 1) self-identified as Black or African American; 2) 18-70 years of age; 3) English speaking; 4) had to live in the study community or surrounding area; 5) systolic blood pressure (BP) greater than or equal to 130 and/or diastolic BP greater than or equal to 80 at screening; 6) prescribed to take one or more antihypertensive medication(s); and 7) smartphone with provider network or Wi-Fi connectivity. Exclusion Criteria included 1) self-report of mental illness that interferes with daily functioning; 2) unable to be physically active; 3) current pregnancy; 4) plans to move from the study community during the project; 5) systolic BP greater than or equal to160 and/or diastolic BP greater than or equal to 100; 6) uncontrolled diabetes (HbA1c >8.5), hemodialysis, history of stroke (within past year with residual effects such as weakness, paralysis, and speech difficulty), cancer treatment (for spread of cancer to other places in the body), or heart attack (within the past year); and 7) concurrent participation in another research study and/or taken any Stanford self-management program.

Recruitment

Women were recruited from Black church congregants that are known to have a high proportion of Black females, from businesses such as hair salons, Black sororities, and community events. Recruitment methods included flyers, announcements on websites using the flyer, presentations, follow-up phone calls, and face-to-face meetings with church leaders, congregants, business owners, sororities, and community members. Those interested in participating in the study were instructed to contact the research staff (PI or trained RAs) who are registered nurses, via telephone or email. The PI or RA conducted either a face to face or telephone screening interview. After an explanation of the study and answering questions, potential participants were (1) screened for inclusion/exclusion; (2) uncontrolled BP (systolic and/or diastolic greater than or equal to 130/80 but less than 160/100 mmHg; interviewees had their BP checked and reported the numbers when called for screening; BP was taken later to confirm eligibility before the consent form was signed and baseline data collected); and (3) ability to participate in physical activity using the Physical Activity Readiness Questionnaire (PAR-Q). Those who were eligible and agree to participate in the study were visited by the PI or RA at their home or another preferred private location. At that time, the participants BP was taken to confirm eligibility for the study. If the BP criteria was met, the participant provided informed consent and baseline data were obtained. If the BP criteria were not met, participants were thanked for their time and told that any collected information during the screening process would be discarded by shredding.

Baseline data

In the privacy of the participant's home or a preferred private location, baseline data were collected and included demographic data (such as age, education, income, and medical history) and manual measurements (such as blood pressure, height, and weight), along with a series of study questionnaires (such as the Hill-Bone Compliance to High Blood Pressure Therapy Scale, Self-Efficacy for Managing Chronic Disease, Healthcare Utilization, and the Self-Care of Hypertension Inventory). To manage data, a secure, web-based application called the Research Electronic Data Capture **(**REDCap) was used to record data via an iPad. The REDCap System provided a secure web-based application using a Cloud provider. If REDCap was not operational, data were collected by paper and pencil and later recorded in REDCap.

Baseline Measures

Screening Questions and Physical Activity Readiness Questionnaire (PAR-Q). Screening questions reflected the eligibility criteria for inclusion and exclusion in the study. The 2017 PAR-Q+ was used as a screening tool to assess possible exercise safety risk before the start of a physical activity program (Warburton et al., 2017). Answers were based on specific health history questions (Warburton, Gledhill, et al., 2011). Sensitivity and specificity of the PAR-Q+ in individuals with and without HTN was 0.90 and 1.0 respectively, and reliability was 0.99 (Warburton, Bredin, et al., 2011).

Demographic Data Tool. The PI developed the Demographic Data Tool to collect standard information not addressed on the other instruments and important in describing the sample. The tool included information such as age, education, income, and medical history.

Baseline and Repeated Measures

Manual Blood Pressure. Using a home BP monitoring procedure (Muntner et al., 2019), participants were seated quietly for at least 5 minutes with their back supported and feet flat on the floor. A manual BP measurement was taken with a Welch Allyn Tycos (DS58) hand aneroid sphygmomanometer in the bare left upper arm while supported at heart level. Three consecutive BP measurements were taken, one minute apart and averaged (Pickering et al., 2005; Whelton et al., 2018). Manual BP measurements were taken at baseline and then at month 3, 6, and 9 to verify readings from the digital Omron oscillometric BP monitor used for the technological data in the study (Abel & DeHaven, 2021). To maintain consistency with the Omron BP recommendation, the left upper arm was used for BP measurements (Omron Healthcare, 2015a).

Body Mass Index. A portable platform Seca 813 electronic scale was used to measure weight in pounds. Height was measured using a portable Seca 217 stadiometer with measurements to the nearest 0.1 centimeter. Weight and height data were used to calculate the body mass index (BMI) using the metric system formula, weight in kilograms divided by height in meters squared, expressed as: weight (kg) / [height (m)]^2 (*Healthy weight: Body mass index*, 2015).

Waist Circumference. Waist circumference was measured to the nearest 0.1 cm. by using a soft Gulick tape measure to circle around the waist at the top of the iliac crest and slightly above the level of the umbilicus from the "0" end of the tape to the intersection of the waist measurement number. The Gulick tape measure includes a mechanism to ensure consistent tension when measuring. The participant stood in an upright position without sucking the abdomen in while the tape was pulled taut without squeezing into the skin (Frey, 2019, September, 2; "Waist measurement," n.d.).

Hill-Bone Compliance to High Blood Pressure Therapy Scale (Hill-Bone CHBPTS). The Hill-Bone CHBPTS was designed to assess medication compliance/adherence (Kim et al., 2003). The scale is a 14-item assessment tool is a 14-item tool designed to assess medication compliance/adherence. Of the tools three subscales, this study focused on medication taking, 8-items plus one item that addressed prescription refills totaling 9-items. Responses are scored on a 4-point Likert scale from 1 = none of the time to 4 = all of the time. Scores ranged from 9 to 36 and the minimal score indicated perfect adherence. Cronbach's alpha for the Hill-Bone CHBPTS medication compliance subscale was .77, and the total scale was .75 (Kim et al., 2000).

Self-Efficacy for Managing Chronic Disease (SEMCD). The SEMCD is a 6-item scale used to measure perceived ability to manage salient aspects of life with chronic disease such as symptom control, role function, and emotional functioning (Lorig et al., 2001). Responses are scored on a 10-point numeral rating scale (1= not at all confident to 10 = totally confident) with higher values indicating self-efficacy. For the SEMCD, the Cronbach's alpha across eight studies ranged from .88 to .91 (Ritter & Lorig, 2014).

Healthcare Utilization. Healthcare Utilization is a 4-item tool used to measure the number of times a health care service is used. Responses are single item numbers and self-reported by participants. Test-retest reliability for Healthcare Utilization ranges from .76 to .97 (Lorig et al., 1996).

Communication with Healthcare Provider. Communication with Physicians is a 3-item scale used to monitor changes in the key behaviors taught in the CDSMP with items related to prepared questions, understanding treatment, and personal problems. Responses are recorded on a Likert scale (from 0 = never to 5 = always), scored, and averaged. A higher score indicates better communication with providers. Internal consistency reliability for the Communication with Physicians scale is .73 (Lorig et al., 1996).

The Self-Care of Hypertension Inventory (SCHI). The SCHI is a 23-item tool designed to measure self-care intervention effectiveness and self-efficacy in self-care. The SCHI consists of three subscales: self-care maintenance, 11 items; management, 6 items; and confidence, 6 items (Dickson et al., 2016). Each subscale has a differently worded 4-point Likert scale ranging from 0 to 4. Each subscale was scored separately and then transformed to a standardized score that ranges from 0 to 100. Scores of 70 or greater indicate self-care adequacy. Internal consistency reliabilities for the SCHI three subscales are .83 for maintenance; .78 for management; and .94 for confidence (Silveira et al., in press).

Chronic Disease Self-Management Program (CDSMP)

After collecting baseline data, all participants were enrolled in a 6-week Chronic Disease Self-Management Program (CDSMP) that was held in a classroom at a local church. The CDSMP focused on disease management skills related to decision making, problem-solving, and action planning with topics for healthy living (such as assessing nutritious foods, improving physical activity, managing excess weight, reducing stress, adhering to medications, communicating with providers, and dealing with depression). Participants received a copy of the book entitled, *Living a Healthy Life with Chronic Conditions*, 4th Ed. with reading assignments to prepare for weekly sessions.

As a standardized curriculum, fidelity was maintained through the use of trained leaders who followed teaching materials without modifications to provide consistent and specific interventions to all participants. The CDSMP was conducted by two trained people - a nurse and a layperson (peer) with the hypertension diagnosis, who served as a role model to participants and was able to address non-medical concerns. The PI was a registered nurse who completed the CDSMP training along with the layperson who had the hypertension diagnosis. The trained layperson received an incentive/fee for working with the PI to conduct the CDSMP classes. The layperson was not a member of the research team.

Participants attended weekly 2½-hour classes for six weeks. The group size was uniform per the CDSMP recommendation for 10-16 participants per session with six classes scheduled to accommodate the 90 participants. In addition to class activities, participants made specific action plans each week that were consistent with the study aims. For example, a physical activity action plan may specifically address, “what” (this week, I will walk), “how much” (around the block),

"when" (before lunch), and "how often" (three times). All participants continued to receive usual care for HTN throughout the study period.

Technology

After completing the CDSMP sessions, study participants were randomly assigned to either the treatment (ITEC) or the control arm (IT).

The technology component of the study was linked to Fitbit Plus, a cloud-based collaborative care platform that was designed to store and track data. The PI was trained in the Fitbit Plus platform, synchronizing data collection devices, instructing participants in the use of equipment, monitoring participant data, and interactive coaching messages. In the privacy of their homes, or another preferred location, each study participant received individualized instruction (about 45 to 90 minutes) to Fitbit Plus and all study tools accommodating various technological skills.

Study equipment included three wireless tools (Omron BP monitor, Fitbit activity tracker, and Fitbit weight scale) and five apps (Omron Connect, Fitbit, MyFitnessPal, Apple Health if iPhone user or Google Fit if android user, and Fitbit Plus). Apps were installed and tools synchronized to the participant's smartphone. Apple Health and Google Fit allowed Fitbit Plus to import app data from Fitbit, MyFitnessPal, and Omron. Participant action plans were set up in Fitbit Plus to correspond to the study aims. As participants wore their Fitbit activity tracker, took their BP, stepped onto the weight scale, or entered food intake, their measurement data were transmitted in real time via Wi-Fi and Bluetooth Smart technology to the Fitbit Plus dashboard. In the dashboard, participants could view their data along with the PI. Two exceptions were the manual BP recording for Android users and the manual self-reported medication-taking for all participants, as described under Fitbit Plus Measures. The PI monitored all study participant data during a two-week trial period to allow participants an opportunity to adapt to using the wireless tools and apps. Once the orientation period was over, data were monitored via the Fitbit Plus platform for study purposes.

Fitbit Plus Technology Measures

Wireless Blood Pressure Monitor. The Omron 10 wireless Bluetooth home BP monitor (Model BP786N) is clinically validated for accuracy according to international guidelines (*Omron: Why validation is important*, 2019). Participants were trained to measure their BP two times per day (morning and night) after they had been seated for at least five minutes with feet flat on the floor and back supported. The easy-wrap ComFit cuff (fits standard to large arms, 9 to 17 inches in circumference) was placed directly on the bare skin of the left upper arm ½ inch above the elbow with the air tube on the inside of the arm and aligned with the middle finger (Omron Healthcare, 2015b). Three consecutive BP measures were automatically taken with the left arm supported at heart level with one minute between measurements (Whelton et al., 2017). Omron home BP monitors are designed for use on the left arm because validation during clinical studies used the left arm (*FAQs: Blood Pressure Monitors*, 2020). All BP readings were recorded, analyzed, automatically averaged, and synchronized to the Omron Connect app on smartphones. However, real-time tracking in the Fitbit Plus dashboard only occurred for iPhone users. Because Android phones did not automatically transmit Omron BP data to Fitbit Plus,

Android users manually recorded their daily BP measurements in Fitbit Plus and emailed BP recordings weekly from the Omron app generated spreadsheet to the PI to ensure accuracy of BP entries. This study examined changes in BP over time.

Medication Adherence. All medications were physically inspected by the PI during baseline data collection. Only prescribed anti-hypertensive medication names, dosages, and time frequencies were recorded in the Fitbit Plus dashboard and updated if changes occurred during the study. In the Fitbit Plus app, each participant manually checked each time they took their BP medicine. The Fitbit Plus dashboard recorded medication-taking and tracked self-reported adherence. This study examined changes in the calculated value of average adherence based on the participant's self-report (Lagasse, 2018, September 19).

Physical Activity tracker. Fitbit Inspire HR (Diaz et al., 2015; *Fitbit Inspire and Inspire HR*, 2019) is a physical activity tracker and accelerometer that measures steps, distance, calories burned, and active minutes. The Fitbit was worn on the non-dominant wrist to monitor physical activity during waking hours. Steps in the Fitbit app were synchronized to the Fitbit Plus dashboard. The outcome of interest for this study was changes in the number of steps.

MyFitnessPal Food Diary. MyFitnessPal app is used with smartphones to log food intake using a comprehensive food database (Van Horn et al., 2016). MyFitnessPal calculates calories, macronutrients (such as carbohydrates, fats, proteins), and micronutrients (such as vitamins, and minerals) from the food intake. Caloric and sodium intake were synchronized to the Fitbit Plus dashboard. Because sodium is known to increase BP, it was monitored to provide insight to the participant's dietary patterns. Participants were instructed to log their food intake immediately after eating. The outcome of interest in this study was changes in caloric intake.

Weight Scale. The Fitbit Aria 2 weight scale (Wi-Fi Smart Scale) was used to measure weight, BMI, and body fat percentage. Participants were instructed to weigh every morning after emptying their bladder. Weight measurements were synchronized via the Fitbit app to the Fitbit Plus dashboard. This study examined changes in body weight.

Fitbit Monitoring

With smart monitoring of connected devices in Fitbit Plus, data were tracked, analyzed, and transparently displayed to provide opportunities for participants to better understand their condition and self-manage by being actively engaged in their own care. In the CDSMP, all participants were taught to write action plans and report if they were successful, partially successful, or not successful in achieving their plan based on participant self-tracking of their data. Fitbit Plus allowed real-time adherence tracking. If participants were adhering to their action plan, study measures displayed a green color indicating a positive trend and if they were not adhering, measures would display a red color indicating a negative trend, alerting the PI to communicate with participants and encourage active engagement in their self-care.

Only the treatment arm action plans were monitored with individualized coaching messages (ITEC) via secure text messaging in the Fitbit Plus dashboard with real-time participant feedback. Coaching messages focused on helping participant's problem-solve barriers to goal

achievement with relevant dialogue to encourage BP control, medication adherence, and lifestyle modifications (physical activity, caloric intake, and weight management). The PI sent tailored ITEC messages via Fitbit Plus to treatment arm participants weekly for months 1-3, biweekly for months 4-6, and no ITEC messages for months 7-9 (to assess for sustainability).

During months 1-3, the control arm received usual care only, along with monthly manual BP and weight measures. After that time, the control arm was given the same wireless tools and apps as the treatment arm. In addition, they received individualized instruction equivalent to the treatment arm and practiced using the tools during a two-week trial period. For months 4-9, the control arm was monitored with IT via Fitbit Plus with no coaching. Fitbit Plus was used only to track participants for comparative data with the treatment arm. The control participants were not contacted between data collection periods, except to send reminders if they were not participating in daily measures.

All baseline manual measurements and study questionnaires were repeated at 3, 6, and 9 months. All other data were collected through the Fitbit Plus Platform via wireless tools. Personal contact every three months for about 30 minutes provided a human element to the Fitbit Plus technology component and allowed the PI to troubleshoot any problem areas or equipment issues.

Gift cards were given to participants for time expended for baseline assessment ($20) and repeated measures at 3- ($30), 6- ($40), and 9-months ($60) totaling $150.

If study participants completed all parts of the research study, then as a completion bonus, they were allowed to keep all measurement tools including the blood pressure monitor, Fitbit, and weight scale, along with the CDSMP book at the conclusion of the study. After Fitbit Plus access ended, participants were able to continue to monitor themselves through the corresponding apps on their smartphone. For those study participants who do not complete the study, the blood pressure monitor, Fitbit, weight scale, and book were returned to the PI when they exited the study.

At the completion of the study, Fitbit Plus transmitted a copy of all collected data at the request of the PI. Both the PI and study participants instructed Fitbit Plus to delete all study participant data when the study ended.

A summary of the overall results of the project in ‘lay’ language was shared with participants in their preferred format (such as email, letter, or in-person) while ensuring confidentiality of individual responses after the study has ended.

Data safety and Monitoring

The Data Safety and Monitoring Plan (DSMP) ensured the safety of research participants and protection of the integrity and confidentiality of the clinical trial study data. Because this is a small study with low risk, the PI, mentor, and biostatistician provided oversight of this study. The DSMP was reviewed monthly (and more frequently as needed). Progress reports, including participant recruitment, retention/attrition, and adverse events (AEs), were addressed at each of

the monthly reviews. All AEs identified were reported to the Institutional Review Board (IRB) and to the National Heart, Lung, and Blood Institute (NHLBI) as applicable.

Statistical Analysis Plan

Sample size and power. All participants meeting study eligibility requirements received the CDSMP classes for 6 weeks. Participants from this pool were randomized to the treatment arm (with ITEC and electronic devices such as the home BP monitoring, weight scale, and physical activity tracker), and the control arm, with IT monitoring only. Our sample of n=45 participants per arm (N=90 in total), measured at baseline, and at 3-, 6-, and 9-months post CDSMP, has approximately 80% power (assuming 5 dropouts per arm) to detect an effect size of ~0.205 or greater at the α=0.05 level of statistical significance, given a realistic range of simulated unstructured covariance matrices. Assuming an 11% rate of attrition, the enrollment target was set at 90 for both arms, which would yield a final sample of 80 participants, or 40 per arm.

Statistical analysis. A hierarchical, mixed-effects repeated measures design was used to analyze the primary and secondary outcomes of interest. This model, which allows for heterogeneous variances across time points, is preferred over a simple univariate model that requires compound symmetry (i.e., the correlation between a measurement at time Ti and any other measurement within the same patients at Tj, is equal for all i and j). A mixed-effects model is more efficient for handling missing at random (MAR) data than, for example, a generalized estimating equations (GEE) repeated measures approach, which requires the more restrictive assumption that missing data are missing completely at random (MCAR). We performed a sensitivity analysis using both a GEE model and sequential application of the EM algorithm to impute missing data. Data from participants (n=7) who dropped out of the study before their first post-CDSMP visit were not included in the analysis. However, baseline information for these participants were compared with participants who continued in the study.

When appropriate a constrained longitudinal data analysis (cLDA) model was used, assuming the same baseline mean for treatment and referent arms with missing baseline data. The cLDA model examines treatment differences over time. Coffman et al. (2016) cite the cLDA as the method of choice for longitudinal RCTs because it yields robust estimates of treatment effect differences under reasonable missing data assumptions.

Both models are valid for repeated measures if data are missing at random (MAR). Little's test was used to determine if variables were missing completely at random (MCAR) while significant covariate-dependent missing values were identified by regressing a dichotomous indicator variable for missingness against key models factors. (Li, 2013) That is, if the missing values were non-randomly associated with the latter variables of interest, the mechanism was deemed to be missing at random (MAR). A sampling of observed vs. non-unobserved items were subjectively scrutinized for signs of a 'missing not at random (MNAR)' pattern for the data. Overall, no relevant violation of the MAR assumption was evident in our analyses.

Descriptive statistics were used to summarize demographic data (such as marital status, education, and income) of study participants.

An independent (unpaired) samples t-test was used to determine the difference between the means of the treatment and referent groups. The dependent (paired) sample t-test was used to determine the mean differences between variables (systolic and diastolic BP and weight/BMI) for treatment and referent group participants from baseline (post-CDSMP) to month 3, from month 3 to 6, and from month 6 to 9. Time frames were allotted to further participant engagement in self-management.

The use of a two-sample t-test versus non-parametric methods for nonnormally distributed data has been debated in the literature (le Cessie et al., 2020). In general, the former is reasonable robust to departures from normality, providing that the sample sizes are sufficiently large, and the underlying variances are finite (with no extreme outliers) (Lumley et al., 2002)

All data collection tools (except the Hill-Bone CHBPTS medication subscale) were converted to a 100-point scale to enable comparison. Questionnaire scores were analyzed for changes across several time points using a mixed-effects repeated measures model for both groups. In comparison to a repeated measures ANOVA test, the mixed model tends to yield valid estimates of treatment effects even when the missing values are not completely missing at random (Detry & Ma, 2016). Rounding was based upon significant digits rather than a fixed number of decimal places (i.e., Goldilocks method) (Efird, 2021). Data were analyzed using SAS - v 9.4 (Cary, NC).

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