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The Counseling Older Adults to Control Hypertension (COACH) Trial: design and methodology of a group-based lifestyle intervention for hypertensive minority older adults

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Abstract

The disproportionately high prevalence of hypertension and its associated mortality and morbidity in minority older adults is a major public health concern in the United States. Despite compelling evidence supporting the beneficial effects of therapeutic lifestyle changes on blood pressure reduction, these approaches remain largely untested among minority elders in community-based settings. The Counseling Older Adults to Control Hypertension trial is a two-arm randomized controlled trial of 250 African-American and Latino seniors, 60 years and older with uncontrolled hypertension, who attend senior centers. The goal of the trial is to evaluate the effect of a therapeutic lifestyle intervention delivered via group classes and individual motivational interviewing sessions versus health education, on blood pressure reduction. The primary outcome is change in systolic and diastolic blood pressure from baseline to 12 months. The secondary outcomes are blood pressure control at 12 months; changes in levels of physical activity; body weight; and number of daily servings of fruits and vegetables from baseline to 12 months. The intervention group will receive 12 weekly group classes followed by individual motivational interviewing sessions. The health education group will receive an individual counseling session on healthy lifestyle changes and standard hypertension education materials. Findings from this study will provide needed information on the effectiveness of lifestyle interventions delivered in senior

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centers. Such information is crucial in order to develop implementation strategies for translation of evidence-based lifestyle interventions to senior centers, where many minority elders spend their time, making the centers a salient point of dissemination.

Keywords

Hypertension; Minority Elders; Senior Centers; Therapeutic Lifestyle Changes

INTRODUCTION

Poorly controlled hypertension (HTN) is a significant public health concern in the United States, in terms of morbidity, mortality, and economic burden, especially among older minority adults [1-3]. Patient-level barriers to optimal HTN control [4-6] include potentially reversible adverse lifestyle behaviors such as high sodium intake, lack of physical activity, low fruit and vegetable intake. Despite compelling evidence supporting the beneficial effects of therapeutic lifestyle changes (TLC) on blood pressure (BP) reduction from large clinical trials conducted in academic research settings [7-15], there is little evidence to support their effectiveness in community-based settings [16]. The efficacy vs. effectiveness gap is particularly evident among elderly patients, especially minority elders who have abysmally low rates of BP control [3,17]. Thus, beyond the efficacy of TLC on BP reduction, it is equally important to evaluate its generalizability to a broad range of at-risk populations in community settings. The current study will address this gap in the literature by evaluating the effectiveness of an empirically validated lifestyle intervention on BP reduction in community-based senior centers, thus emphasizing its translation to practice.

STUDY OBJECTIVES

The goal of the Counseling Older Adults to Control Hypertension (COACH) trial is to evaluate the effect of a therapeutic lifestyle intervention [delivered via group classes and individual motivational interviewing sessions (MINT-TLC)] versus health education (HE), on BP reduction among 250 African-American and Latino senior-center-attendees aged 60 years and older with uncontrolled HTN. The primary outcome is change in systolic and diastolic BP from baseline to 12 months. The secondary outcomes are BP control at 12 months; changes in levels of physical activity; body weight; and number of daily servings of fruits and vegetables from baseline to 12 months. We hypothesize that seniors randomized to MINT-TLC compared to those in the HE group will exhibit: (1) a greater reduction in systolic and diastolic BP at 12 months; (2) a higher proportion of seniors with adequate BP control at 12 months; and (3) greater levels of physical activity; greater percent change in weight; and increase in intake of fruits and vegetables from baseline to 12 months.

THEORETICAL FRAMEWORK

The Motivational Interviewing [18] (MINT) intervention is informed by Motivational Enhancement Theory [18], which incorporates principles drawn from Self-Determination Theory [19,20], and Self-Efficacy Theory [21]. Figure 1 provides a conceptual model showing the links between the theoretical components, behavior change, and BP reduction. The model depicted shows that the effect of MINT on BP reduction is mediated through enhancement of patients' self-efficacy and increased intrinsic motivation. Thus, patients who undergo MINT will benefit from increased self-efficacy and be more intrinsically motivated to adopt the recommended TLC. The adherence to therapeutic lifestyle behaviors will in turn lead to BP reduction.

MATERIALS AND METHODS

Overview of Study Design

As shown in Figure 2, COACH is a randomized controlled trial (RCT) with two arms: an intervention group (MINT-TLC) and active health education (HE) control group. Eligible seniors with uncontrolled HTN (BP 130/80 mmHg for those with diabetes or renal disease, or BP 135/85 mmHg for all others) are randomly assigned to either MINT-TLC or HE. Seniors randomized to the MINT-TLC group receive 12 weekly group classes [targeted at healthy lifestyle changes, medication adherence and stress management]; followed by individual motivational interviewing (MINT) sessions (monthly for three months and then bimonthly for 6 months). MINT-TLC is designed to help participants adopt healthy lifestyle behaviors and develop skills to maintain these behaviors long-term. Seniors in the HE group receive a single 30-minute individual counseling session on healthy lifestyle changes and print versions of standard hypertension education material. Assessments of primary and secondary outcomes are conducted at Baseline, 3 months (Visit 1), 6 months (Visit 2), 9 months (Visit 3) and 12 months (Visit 4). Study visits range in duration from 20 minutes (Visit 1, Visit 3) to 45 minutes (Baseline, Visit 2, Visit 4).

Study Sites and Participants

The sampling frame is comprised of potentially eligible older adults who attend senior centers (SCs) in New York City (NYC) with a large African American or Latino clientele (as determined by NYC Department for the Aging (DFTA) utilization statistics for each senior center), a daily attendance of at least 100 seniors, and a primarily English speaking population. There are more than 300 such senior centers operating throughout the five boroughs of NYC, and these centers provide an array of services including meals, social engagement activities, social services, and health and wellness programs. Each participating senior center receives a \$1,000.00 honorarium at the end of the recruitment phase to offset the costs of space for study recruitment, follow-up and intervention delivery. In order to be enrolled into this trial, seniors must meet the following inclusion criteria: must be age 60 years or older; self-identify as Black, African American, Latino or Hispanic; have a diagnosis of HTN at the time of screening; be taking at least one antihypertensive medication; have uncontrolled HTN (BP 130/80 mmHg for those with diabetes or renal disease, or BP 135/85 mmHg for all others) at the time of screening, as measured by Watch BP Office Device (Microlife; Golden, CO); and are able to speak and read in English. Seniors are excluded if they have serious cognitive impairment as measured by the Comprehensive Assessment and Referral Evaluation Diagnostic Instrument (CDIAG score 6) [22-23]; severe impairment in vision or hearing; arm circumference too large for reliable BP measurement (i.e. arm circumference greater than 42 cm through October 2010, 52 cm thereafter through the use of an extra large cuff). All participants receive up to \$75.00 over the 12-month study duration as compensation for their time. Participants are required to provide informed consent based on the study approved by the Institutional Review Boards of New York University and Columbia University. The study is monitored by a Data Safety Monitoring Board.

Recruitment Method

The senior centers are recruited through DFTA's Bureau of Community Services, which makes the initial contact with the SC to provide an overview of the study. If the SC's director expresses interest, DFTA then passes the center's contact information to the COACH Project Manager (LF), who then sets up an in-person meeting to go over the project in detail with the director of the senior center. Once a senior center agrees to participate in the study, COACH study staff visit the site, and organize a "kick off day" screening event at the site, during which the study staff introduces the program to seniors, answer their questions about

eligibility and recruit seniors who express interest in the study. COACH study staff visit the senior centers approximately 3 days per week to inform seniors about the study and ascertain their interest in participating in eligibility screening. For each SC recruited into the study, there are two phases – the recruitment and the intervention phase. The first half of the recruitment phase focuses on conducting eligibility screens, while the second half focuses on completing baseline visits for eligible seniors. Once all baseline visits are complete, seniors are randomized and the SC then moves into the intervention phase.

Randomization

After completion of consent procedures and baseline data collection, a list of participant identification numbers is sent weekly to the data management team to be randomized in a 1:1 ratio to either the MINT-TLC or HE group. This project has a hierarchical study design with each senior is nested within a senior center and participants are recruited at different times. Randomization is within the senior center. Patients are informed of the results of randomization by a research assistant (RA) in-person or by phone; at which time, the RA discusses the intervention/counseling session schedule, and answers any additional questions. Given the nature of the intervention, it is impossible to blind the RAs to the assigned condition.

Description of MINT TLC Intervention

The MINT-TLC intervention is based on established clinical practice guidelines for prevention and treatment of HTN [1], which recommend weight loss (if overweight), limiting sodium and alcohol intake, regular physical activity, and eating a low-fat diet that is rich in fruit and vegetables. Seniors attend weekly therapeutic lifestyle group classes for the first 12 weeks (*intensive phase*); followed by 3 individual motivational interview (MINT) sessions that occur monthly over the next three months (*extended phase*); and bi-monthly in the remaining six months (*maintenance phase*). The MINT-TLC sessions are conducted by trained RAs, and are aimed at helping seniors make useful therapeutic lifestyle changes (TLC) and develop skills to maintain these changes over the long-term. See Table 1 for content of the 12 weekly group classes. The methodology, structure and the content of the group classes is patterned after PREMIER and the Trial Of Nonpharmacologic interventions in the Elderly (TONE) [15], two major trials that have tested the efficacy of comprehensive TLC in hypertensive patients. PREMIER is a comprehensive multicomponent lifestyle program, which incorporates the DASH dietary pattern [10].

Monitoring treatment fidelity (intensity and the dose of the intervention)—

Adherence to the MINT-TLC protocol is an important aspect of this study given its intensity. At the trial's inception, the RAs participated in a 3-day training comprising an overview of the behavioral framework of the intervention; the curriculum; and basic group facilitation skills taught through role-plays and didactic instruction. In addition, the RAs participated in a 2-day training on MINT skills including an overview of the basic principles of MINT techniques, development of problem-solving approaches, and practice sessions in the form of role-plays. All MINT sessions are audiotaped and used for two related purposes: (1) to provide feedback and ongoing supervision of the RAs [24], and (2) to provide systematic review for treatment fidelity via a systematic sampling of 30% of the sessions, which will be coded in order to assess adherence to MINT principles using the widely validated Motivational Interviewing Treatment Integrity (MITI) scale [25]. Finally, we record completion of the food diary and homework assignments and attendance of group classes and note the compliance and attrition rates.

Description of the Active Control Health Education (HE) Condition

Seniors in the HE group receive a single 30-minute individual counseling session on healthy lifestyle changes similar to PREMIER [8] and print versions of standard hypertension education material from the National Heart, Lung and Blood Institute [copies of the publications “Your Guide to Lowering Blood Pressure [26]” and “Your Guide to Lowering Your Blood Pressure with DASH [27]”].

Outcomes and Assessments

The primary outcome is change in systolic and diastolic BP from baseline to 12 months. The secondary outcomes are proportion of patients with BP control at 12 months; changes in levels of physical activity; body weight; and number of daily servings of fruits and vegetables from baseline to 12 months. Study assessments for primary and secondary outcomes are completed at eligibility screen, baseline, and every three months thereafter with the final assessment at 12 months. All assessments are performed by trained RAs and include physiological, anthropometric, and self-report measures. Table 2 summarizes the measures according to their timeline.

Physiological Assessments

Blood Pressure: At the eligibility screen and/ or baseline, 3 readings are taken by a trained RA using an automated BP monitor (WatchBP Office Device; Microlife; Golden, CO) with the senior seated comfortably for 5 minutes before measurement, following American Heart Association BP measurement guidelines [28]. The average of the 3 readings is used as the measurement for each visit. Uncontrolled BP is defined as an average BP $\geq 135/85$ mm Hg. The criteria for those with co-morbid diabetes or kidney disease are BP $\geq 130/80$ mm Hg. This procedure is repeated for all follow up visits (3, 6, 9, and 12 months).

Height and Weight: are measured without shoes and with lightweight clothes using a stadiometer and a validated digital scale for weight. All measurements are recorded to the nearest 0.1 cm/ 0.1 kg. These data are used to calculate and assess seniors’ body mass index (BMI). The difference in weight from baseline to 12 months serves as a measure of weight loss. Height is only measured at baseline while weight is measured at baseline, 3 and 12 months.

Self-report Measures

Eligibility Screening: The eligibility screening includes items that assess ten domains of eligibility including: (1) Age; (2) HTN diagnosis; (3) Race/Ethnicity; (4) Blood pressure; (5) Cognition; (6) Vision; (7) Hearing; (8) Literacy; (9) English Fluency; (10) Participation in other HTN studies.

Cognition: is assessed using the Comprehensive Assessment and Referral Evaluation (CARE) dementia diagnostic scale (CDIAG) [22,23]. This instrument was selected because it has been found to perform in a culture-fair manner [29] with better specificity among ethnically diverse groups, in comparison with other cognitive screens [30].

Antihypertensive Medications: are assessed using an instrument we developed for similar studies [31,32]. Dosage and timing of medications are administered at all study visits.

Demographics: This instrument is used to collect socio-demographic data that will allow us to properly describe the cohort and examine effects of these factors on BP control. Variables include age, marital status, education level, race/ethnicity, household income, employment status, and health insurance status.

Physical Activity is assessed with two instruments: the Yale Physical Activity Scale (YPAS) [33] and the International Physical Activity Questionnaire (IPAQ) [34]. The YPAS evaluates the amount of physical activity engaged in during “the past week”. The measure has two sections, and scores provide eight indices of physical activity. Section one contains three checklists (work, recreation, exercise), and section two includes categorical responses to assess participation in three dimensions (vigorous activity, low intensity walking, and general moving around). It estimates total weekly physical activity by asking participants to indicate the number of hours per day spent in various types of physical activity. An index of total time in physical activities is created by summing time spent in all activities in the YPAS checklist. An energy expenditure summary index is created by multiplying the amount of time spent in each activity by an intensity code, and then summing for all activities. Indices for five specific activity dimensions are created by multiplying the frequency score by the duration score, and then multiplying by a final weighting factor for vigorous activity questions, leisurely walking, moving, standing and sitting questions. A final total activity dimension score is created by summing across the five individual indices. The IPAQ is a seven-item measure that evaluates the amount of physical activity engaged in during the last seven days. It was developed to assess health-related vigorous and moderate-intensity physical activity as well as sedentary behaviors in adults over a one week period. It estimates total weekly physical activity by asking participants to indicate the number of hours and minutes per day spent in various types of physical activity. The amount of time spent in each activity is multiplied by the average metabolic equivalent (METs, or kcal/kg/hr) of each category and summed to calculate energy expenditure as kcal/kg/minutes/week. The IPAQ’s reliability and validity has been well established in diverse populations, including multiple age groups.

Dietary Intake is assessed using a 36 item measure developed by Resnicow and colleagues and validated in a large sample of African American adults [35]. Participants are asked to indicate the number of times that they ate each item in the last seven days and the amount of food (1/2 cup, 1 cup). Portion size is fixed to that of a medium serving.

Medication Adherence to prescribed antihypertensive medications is assessed with the widely used and well-validated 8-item scale developed by Morisky [36,37]. The measure has acceptable reliability in the development sample ($\alpha = 0.83$), and correlated well with the previously validated 4-item version [36] ($r = 0.64$, $p < .05$). The measure was found to be able to correctly categorize BP control status in 80% of cases [37]. Data on medication adherence will allow us to assess the potential effect of adherence on BP control.

Comorbid Medical Conditions are assessed with the Charlson Comorbidity Index (CCI) [38], in order to adjust for the confounding effects of comorbidity on BP and their non-uniform prognostic impact. The CCI is a weighted index for prospectively classifying comorbid conditions, which takes into account the number and seriousness of comorbid diseases.

Self Reported Health Status is assessed with the EuroQol (EQ-5D) [39], which measures an individual’s health state in multiple domains including mobility, self-care, activities, pain/discomfort, anxiety/depression, and asks patients to rate their overall health state using a visual analog scale. This measure will be used to assess patient’s self reported quality of life in relation to BP control.

Life Stressors occurring in the past year are assessed with nine items that examine areas such as loss of job/retirement; major intra-family conflict; marital separation/divorce; major personal illness/injury experienced in the past year. “No” responses are assigned a score of

“0” and “Yes” responses are assigned a score of “1”. Total scores can range from 0 to 9, with higher scores indicating a greater level of life stressors experience within the past year.

Depression is assessed with the European Depression scale (EURO-D) [40,41], a widely used reliable scale has been utilized to detect probable cases of depression in older populations. It is derived primarily from the Geriatric Mental State interview, and includes 12 items: depressive affect, pessimism, wishing death, guilt, sleep, interest, irritability, appetite, fatigue, concentration, enjoyment and tearfulness.

Health Literacy will be assessed with the Rapid Estimate of Adult Literacy in Medicine (REALM) [42], a commonly used health literacy instrument, which consists of 3 separate lists of 22 words each. Participants are asked to read the words aloud, and are given 1 point for each word that is pronounced correctly. Total score ranges from 0 to 66 points. Health literacy data will further characterize our sample, and may be used as a covariate in analyses.

Recruitment

In order to meet our recruitment goal (see power calculations below) approximately 491 seniors were screened for eligibility with 56% (N = 275) satisfying the eligibility criteria. Of those, 251 agreed to participate.

ANALYSIS

Sample Size and Power Analysis

Randomization was of attendees within senior centers, with equal numbers assigned to the intervention and usual care groups. Senior centers are the clustering units; the number of centers (clusters) is 10. The average cluster size is 23.2 (S.D.=12.6) with a range from 10 to 45. The intracluster correlation coefficient was posited to be low (0.02 or less). Power calculations were based on examinations of the least detectable differences under a variety of scenarios. The original set of calculations assumed that because of random assignment, there is no need to adjust for covariates. Change (from baseline) in endpoint means at 12 months was examined [43]. The nature of the MINT-TLC intervention has been shown in some studies to yield heterogeneous variances; thus power was calculated, adjusting for unreliability of blood pressure measures with and without heterogeneous variances [44].

Based on estimates from other clinical trials in uncontrolled hypertensive patients [8,11,15,45], it was estimated that the cross-sectional standard deviations (SD) of systolic/diastolic BP at baseline would be between 9 and 15 mm Hg. However, the observed standard deviations ranged from 14 to 18, with an average of about 16.5 for SBP; for DPB, the range of SDs was from 5.48 to 9.63 in the literature, but was observed to range from 10 to 11, with an average of about 10.7. The observed mean differences were posited to be from 3 to 8 for SBP and from 2 to 6 for DBP. The original assumptions were as follows: $\alpha = .05$ for a two-tailed test; $1 - \beta = .80$ and above; $\mu_1 - \mu_2 = 3-8$ -units for SBP and 2-6 for DBP; $\sigma^2 = (5-20)^2$ for SBP and $(5-15)^2$ for DBP; R (reliability) = .90. Calculations were performed for SBP with heterogeneous variances over time ranging from a difference of 1 to 3 SD units, and with correlations between baseline and endpoint ranging from .5 to .7. Original calculations accounted for attrition and considered only three waves of data over one year. Assuming an SD of 12 or less, with $\alpha = .5$ or higher, power was estimated at 0.80 or greater to detect endpoint differences of 5 points, with sample sizes of 100 per group (see Figure 3, panel a). With regard to diastolic blood pressure, it was found that differences of four to six points could be detected, assuming that SDs range from 8 to 15. For example, as shown in the graph, power is greater than .80 ($\alpha = .05$ for a two-tailed test), assuming $\mu_1 - \mu_2 = 5$ -units of SBP, and $\sigma^2 = (5-10)^2$. As reviewed above, based on the results from previous

studies regarding effect sizes and standard deviations, this was a plausible scenario at the time of proposal development. Because some of the assumptions above did not hold, power calculations were performed again after baseline data were collected based on actual observed values for this study. This exercise presents a case study in the degree of convergence between power calculations performed based on assumptions and based on observed data.

Repeated measures analysis of covariance (ANCOVA) model examining average change over one year—Because of the observed large cluster sizes and variances and because repeated measures were collected at five points in time (0, 3, 6, 9 and 12 months), power was re-estimated. The observed data showed that the groups were somewhat unbalanced at baseline (usual care 139.4 (16.4) and intervention 136.7 (16.3)). Thus, an ANCOVA model was used in the new set of power calculations. As is well known, ANCOVA models result in increased power, e.g., [46]

Systolic Blood Pressure: The following parameter estimates are based on observed data: $R = 0.90$ (reliability), $g = 2$ (groups); $\sigma^2 = 16.5$ (pooled: 14.0 at screen, 16.4 at baseline, 17.5 at 3 months, 17.6 at 6 months, 16.4 at 9 months, 16.6 at 12 months). The average cluster size was 23; the intraclass correlation was $ICC = 0.01$, and the resulting variance inflation factor (VIF) was estimated as 1.22. The observed estimate of ρ (0.5) is the average correlation between baseline and follow-up assessments. The following effect sizes were examined: $\delta = 3, 3.5, 4$ (average SBP point reduction over one year in the intervention group), $d = \delta / \sigma$ (where δ is the point reduction per year and d is Cohen's d). $T_n = 5$ time points (baseline, 3 month, 6 month, 9 month, 12 month), and the following formula was used based on [47,48].

$$n^* = \frac{2 \left(\sigma_T^2 + \sigma_e^2 \right) \left(z_{\alpha/2} + z_\beta \right)^2 \left(1 - \frac{1 + (T_n - 1)\rho}{T_n} \right) (1 + (T_n - 1)\rho)}{T_n \delta^2};$$

adjusting for reliability: $m = \frac{n^{**} \nu_{if}}{R}$

As shown in Figure 3, panel b, and Table 3, based on an n of 120 per group, under intent-to-treat, the detectable effect size is an adjusted mean endpoint difference in SBP between intervention and usual care of about 3- 4 points, given $\alpha = 0.05$ and $1 - \beta = 0.80$.

Diastolic Blood Pressure: The same observed estimates for cluster size, reliability and the average correlation over the five waves of data was used for these analyses. Additionally, the estimates of the pooled variance were as follows: $\sigma^2 = 10.7$ (pooled: 11.1 at screen, 9.8 at baseline, 11.2 at 3 months, 10.2 at 6 months, 11.4 at 9 months, 10.6 at 12 months). The following effect sizes were examined: $\delta = 3.5$ to 3.8 (DBP point reduction per year in intervention group), $d = \delta / \sigma$ (where δ is average point reduction over one year and d is Cohen's d). As shown, with about 120 per group, effect sizes as low as 2.21 can be detected. (See figure 4 and table 4).

Analysis of the Primary Aim

Analyses will be performed under an intent-to-treat design; therefore all participants, including those who drop out of the study will be invited back for assessment evaluations. Methods for analyses of treatment effects in pre-post clinical trials, in the context of missing data, have recently been compared in the statistical literature [49-55]. As is well known [55], complete case analysis and last observation carried forward are not optimal methods. Traditional ANCOVA models require stringent assumptions, e.g., homogeneous variances,

and the accompanying software results in exclusion of subjects with missing data. Alternative mixed modeling software (SAS, PROC MIXED), used to compute full-information maximum likelihood (FIML) estimates, permits modeling of such assumptions, and the inclusion in the analysis of participants who do not complete the follow-up assessment (on an intent-to-treat basis). Thus, an ANCOVA model, using SAS PROC MIXED will be used to allow for more flexible modeling of assumptions, treatment of missing observations and inclusion of all subjects with at least one wave of data. Based on prior analytic experience with the outcome variables, it is not expected that transformations will be necessary. The post-treatment values of continuous outcomes will be modeled as functions of baseline values, treatment and the interaction of baseline and treatment.

Prior to analyses, baseline values of all variables from each arm will be examined; however, no p values will be provided, and covariates (other than baseline values) are not proposed for inclusion in the main analyses of treatment effects. Examination of baseline differences on key variables between completers and those lost-to-follow-up will be conducted in order to inform about the nature of the missing data. Methods of examining missing data, e.g., propensity scores, EM algorithm and multiple imputation sensitivity analyses will be considered if necessary. However, thus far missing data are minimal, and may not require modeling. Participation in the program sessions is good, and the majority of respondents attended all sessions. However, if necessary, secondary analyses will be conducted in order to investigate the impact of differential participation, stratifying the participants in the MINT-TLC condition based on their degree of participation and examining differences between strata on the outcome measures at follow-up.

Analysis of the Secondary Aims

The hypothesis that there will be greater improvements in lifestyle behaviors that are targeted by the MINT-TLC intervention will be tested in a similar manner to that described above. Separate analyses will be performed for *a*) the summary measure of physical activity, and *b*) the summary measure of 7-day intake of fruits and vegetables.

Analytic Issues

As shown here, assumptions regarding power calculations are based on best guesses informed by the literature and prior experience and evidence of investigators; however, these assumptions may be incorrect. For this study, the original power calculations assumed a lower than observed pooled variance for both SBP (a pooled SD of 12 or less vs. 16.5 observed) and DBP (pooled SD of 10 or less posited and 10.7 observed). On the other hand, the original analyses posited heterogeneous variances, which were not observed. Finally, it was assumed that there would be no imbalance between groups in baseline scores. Some slight imbalance was observed, however. The original power calculation ($1 - \beta = 0.80$; $\alpha = 0.05$, two tailed test), showed that 100 per group would yield effect sizes of a 5 point endpoint difference for SBP. Using the observed data, an ANCOVA model was required, and showed that 100 subjects would permit detection of an effect size of about 4 for SBP and 2.4 for DBP. As expected, despite the higher observed standard deviations that typically result in reduced power, ANCOVA models were most powerful. The ANCOVA model provides information about the average change across waves over one year, while a slope analysis examines the overall (cumulative) change over the year. Generally, a slope analysis, e.g., [56] would have conferred more power because of the additional information provided by modeling time as continuous and considering the variance of time; however, the five waves of data are all within a one year period, thus limiting the advantage of examining the rate of change. In fact the detectable effect sizes, given equivalent sample sizes for the analyses of rates of change are twice that of the ANCOVA model examining average change. Thus the optimal analyses are ANCOVA modeling of the repeated observations.

DISCUSSION

Conclusions: Implementation and Lessons Learned

Study implementation began in January 2009 with a two month pilot phase to familiarize study staff with senior center culture (e.g. time of highest utilization; monthly schedule of activities), and to test and refine (1) the recruitment protocol, (2) length and content for seniors. Piloting took place with 30 seniors from one senior center. Based upon pilot testing, the study team made modifications to the recruitment and assessment protocol and class content. The recruitment protocol was refined to include additional techniques to boost visibility of the project (e.g. raffles during lunch for small low-cost prizes [approximately \$1.00 each]; sponsorship of a breakfast or lunch [approximately \$1.50 per person]). The assessment protocol was shortened to prevent participant fatigue. The class content was refined to clarify concepts, simplify forms used weekly to track health behaviors (e.g. medication use, physical activity, goal-setting and implementation).

Study implementation continued with recruitment of additional sites beginning in March, 2009 and the continued enrolment of participants at our first study site. During this phase, additional refinements took place based upon lessons learned in every day implementation. Recruitment techniques were modified with (1) staggered enrolment of sites, (2) reduction of days at senior centers (down from five to three) to accommodate senior center activities schedule and utilize staff time efficiently, and (3) implementation of techniques to target visibility among male seniors (e.g. sponsorship of a game of billiards or cards). Retention strategies were modified to include an “RA leader” at each site who is primarily responsible for contacting and scheduling participants for assessments in order to promote continuity of staff across study visits; mailings of class calendars, birthday and holiday cards; study promotional items with study logo (e.g. pens) distributed during recruitment, and additional items (e.g. pill boxes, bags) distributed to both MINT-TLC participants during MINT-TLC classes and HE participants at the end of their participation in the trial. The intervention was further refined by (1) increasing flexibility of class times to accommodate SC preference and schedule, (2) modifying the interventionist guide to increase utilization of the “elicit-provide-elicit” framework [18] of health behavior education, (3) simplifying of forms for tracking health behaviors, (4) offering the option of completing MINT-TLC session 8 “Grocery Store Tour” for study participants with limited mobility and those who preferred not to travel to a local grocery store. We also mailed session packets to participants when they missed MINT-TLC classes and provided make-up sessions after every 4 classes. As noted in Table 2, Session 8 provides an opportunity to examine food labels in a “real-world” setting and discuss consistency with the DASH eating plan, senior preferences, and potential modifications to improve health. To this end, food labels of products most often used by seniors (based on self-report) were gathered and organized to replicate a grocery store layout at the senior center. Emphasis was placed on gathering food labels of DASH-consistent (e.g. low fat milk and cheese) and DASH-inconsistent (e.g. high sodium) food products to facilitate discussion.

TRIAL STATUS

The COACH trial began in February 2009. To date, we have finished enrollment with a total of 251 seniors recruited from 12 senior centers from all five Boroughs of NYC. Data collection is currently ongoing.

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Figure 1.
Conceptual model of the effects of Motivational Interviewing and its mediators

Figure 2.
COACH study design

Figure 3.

Panel A shows the original power calculations incorporating heterogeneous variances and BP correlations over time. (s =standard deviation). Panel B shows the revised power calculations using ANCOVA: SBP average point reduction over one year (sample size, m per group, power=0.80, r =observed average correlation over time):

Figure 4. Revised power calculations with observed data for DBP using an ANCOVA model: Sample size m per group (power=0.80).

Table 1**MINT-TLC Weekly Session Content**

SESSION	CONTENT
1	Introduction to COACH, lifestyle changes, and hypertension
2	Medication facts and importance of adherence
3	Overview of DASH eating plan; Serving sizes; Goal setting
4	Food labels; Physical activity; Goal setting
5	Portion control; Sodium and salt
6	Fruits and Vegetables; Medication adherence; Finding time for physical activity
7	Whole grains; Meal planning and grocery shopping tips; Social support
8	Grocery store tour: Field trip to neighborhood supermarket to evaluate food labels
9	Dairy; Stress & health
10	Meats/Fish/Poultry; Eating triggers including holiday/social eating
11	Nuts/Seeds/Dried beans; Smoking
12	Fats/Oils/Sweets; Alcohol; Planning for lasting change

Table 2**Measures**

MEASURES	ES	BL	V1	V2	V3	V4
PHYSIOLOGICAL						
Blood pressure measurements	X	X	X	X	X	X
Height measurement		X				
Weight measurement		X		X		X
SELF-REPORT						
Eligibility Screener, including CARE DIAG	X					
Medications		X	X	X	X	X
Demographics		X		X		
Physical Activity (YPAS and IPAQ)		X		X		X
Diet (36-item fruit and vegetable frequency questionnaire)		X		X		X
Medication adherence (Morisky Questionnaire)		X		X		X
Medical Comorbidity (Charlson Comorbidity Index)		X		X		X
EQ-5D (Self-perceived Health and Quality of Life Utility assessment)		X		X		X
Life Stressors		X		X		X
EURO-D (Depression)		X		X		X
Rapid Estimate of Adult Literacy in Medicine (REALM) Questionnaire		X		X		X

Note: ES = Eligibility Screen Visit; BL = Baseline Visit; V1 = Visit 1, 3 Month Visit; V2 = Visit 2, 6 Month Visit; V3 = Visit 3, 9 Month Visit; V4 = Visit 4, 12 Month Visit.

Table 3

Detectable effect sizes for SBP

Intervention group reduction per year	=3 (d=0.18)	=3.5 (d=0.21)	=4 (d=0.24)
r=0.5	155	114	87
SBP average point reduction over one year and Cohen's d (power=0.80)			
m per group	100	110	120
R=0.5	=3.73 (d=0.23)	=3.56 (d=0.22)	=3.4 (d=0.21)

Table 4

Detectable effect sizes for DBP

Intervention group reduction per year	=2 (d=0.19)	=2.5 (d=0.24)	=3 (d=0.28)
r=0.5	146	94	65
DBP average point reduction over one year and Cohen's d (power=0.80)			
m per group	100	110	120
R=0.5	=2.42 (d=0.23)	=2.31 (d=0.22)	=2.21 (d=0.21)