Available online at www.sciencedirect.com

SCIENCE DIRECT

Preventive Medicine 41 (2005) 488–502

Preventive Medicine

www.elsevier.com/locate/ypmed

Outpatient weight management in African-Americans: The Healthy Eating and Lifestyle Program (HELP) study

Shiriki K. Kumanyika, Ph.D., M.P.H., R.D.[a,*], Justine Shults, Ph.D.[a], Jennifer Fassbender, M.S.[a], Melicia C. Whitt, Ph.D.[a,1], Vivian Brake, M.S., R.D.[a], Michael J. Kallan, M.S.[a], Nayyar Iqbal, M.D.[b], Marjorie A. Bowman, M.D., M.P.A.[c]

[a]*Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, 423 Guardian Drive, Philadelphia, PA 19104-6021, USA*

[b]*Division of Endocrinology, Diabetes and Metabolism, Department of Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA 19104-6021, USA*

[c]*Department of Family Practice and Community Medicine, University of Pennsylvania School of Medicine, Philadelphia, PA 19104-6021, USA*

Available online 9 March 2005

Abstract

Background. Effective clinical weight management approaches are needed to reach African-Americans.

Methods. African-Americans recruited through outpatient practices for a culturally-adapted Healthy Eating and Lifestyle Program were offered 10 weekly weight loss classes (Phase 1) with the option of continuing for another 8–18 months (Phase 2) in a randomized comparison of further group counseling or staff-facilitated self-help vs. follow-up clinic visits only.

Results. Of 237 enrollees (91% women; mean age 43.5 years; mean body mass index 38.0 kg/m^2), 167 attended no classes or only the first Phase 1 class, 134 provided Phase 1 follow-up data, 128 were randomized in Phase 2, and 87 provided final follow-up data ("completers"). Mean weight changes for completers were: −1.5 ($P < 0.001$), +0.3 ($P = 0.47$), and −1.2 ($P = 0.04$) kg, respectively, for Phase 1, Phase 2, and overall (baseline to final visit; average 18 months total duration), with no Phase 2 treatment effect ($P = 0.55$). Final study weight was ≥5% below baseline for 25% of completers and was strongly predicted by Phase 1 weight loss.

Conclusions. Weight loss achieved in Phase 1 was maintained even with relatively minimal follow-up contact. Increasing the percent who achieve clinically significant weight loss initially would improve long-term results.

Keywords: African-Americans; Weight loss; Body mass index; Randomized controlled trial; Intervention studies; Outpatients; Cultural characteristics

Introduction

Identifying effective strategies for treating obesity is both a clinical challenge and a public health priority [1,2]. Between 1960 and 2000, obesity prevalence (body mass index [BMI] ≥ 30 kg/m^2) in U.S. adults increased from 11% to 28% in men and from 16% to 34% in women [3] with most of this increase occurring since 1980. The need for effective approaches to obesity treatment is particularly critical for African-American women. For example, 50% of non-Hispanic black women age 20 years and older have class I or greater obesity (BMI ≥ 30 kg/m^2) compared with 28% of non-Hispanic black men and 30% of non-Hispanic white women; 15% of non-Hispanic black women have Class III obesity (BMI ≥ 40 kg/m^2) compared with 3.5% of non-Hispanic black men and 5% of non-Hispanic white women [3]. Both African-American men and women have high rates of risk factors or chronic diseases such as high blood pressure and diabetes that can be potentially ameliorated by weight reduction [4].

* Corresponding author. Fax: +1 215 537 5311.
E-mail address: skumanyi@cceb.med.upenn.edu (S.K. Kumanyika).
[1] Current affiliation: Department of Public Health Sciences, Wake Forest University School of Medicine, Winston, Salem, NC 27157, USA.

0091-7435/$ - see front matter © 2005 Elsevier Inc. All rights reserved.
doi:10.1016/j.ypmed.2004.09.049

Obesity treatment in African-Americans is understudied. The National Heart, Lung, and Blood Institute evidence review published in 1998 [1] identified only one eligible randomized weight loss trial in African-Americans [5]. A 2002 review [6] identified 12 other reports of weight loss programs in African-Americans in clinical or community settings, and a few additional relevant reports have been published subsequently [7–14]. The general impression from these very heterogeneous studies is one of modest success, i.e., weight losses of 1–4 kg over periods lasting from 2 to 17 months, with a variety of adaptations attempted to increase cultural salience and appropriateness.

Subgroup data for African-Americans have also been reported from clinical studies of behavioral obesity treatment [15–17] and randomized controlled trials of the efficacy of lifestyle weight reduction in hypertension prevention and treatment [18–21]. These reports suggest that African-Americans lose less weight, on average, than the White participants in the same study. Nevertheless, the weight losses achieved among African-American intervention participants in these studies are sometimes larger than those observed in studies within African-American samples [6] and sufficient to result in clinically meaningful improvements in blood pressure or glycemic control in African-American as well as White participants. Hence, the systematic intervention approaches used in these efficacy trials provide a potential starting point for obesity treatment with African-Americans in practice settings.

The objective of the Healthy Eating and Lifestyle Program (HELP) was to adapt an efficacious lifestyle weight reduction program for application to African-American adults in a general outpatient population, with cultural appropriateness, feasibility of replication, and inclusiveness of the study population as key considerations [6,22]. A two-phase design was used to determine whether either of two approaches to further counseling would be effective, compared to a usual care condition, for long-term weight management after a relatively brief series of weekly classes. Analyses focused on weight loss after the weekly classes, potential differences in weight change or maintenance according to type of treatment in the second, randomized phase, and possible differences in weight changes during the second phase according to the weight change achieved in the first phase. Changes in cardiovascular disease (CVD) risk factors were also evaluated.

Methods

Study design

The setting was the family practice department of an urban university health system with a large number of African-American patients. In Phase 1, all eligible and interested participants were enrolled in a 10-week group counseling program (HELP). In Phase 2, those who attended the post-Phase 1 data collection visit approximately 3 months after initial enrollment were offered randomization to one of two treatments, with continued semi-annual follow-up clinic visits for up to an additional 18 months (i.e., a possible total enrollment for approximately 21 months). The two treatments, designed to facilitate weight loss maintenance or additional weight loss, were HELP Classes, less frequent (i.e., biweekly, then monthly vs. weekly) group counseling, and Self-HELP, self-directed weight management facilitated by a HELP staff member. The usual care condition, referred to here as "Clinic Visits Only", involved no further study-delivered intervention outside of brief counseling at the semi-annual follow-up clinic visits and advice to seek assistance from their personal physician. There was no untreated control group as such, for ethical reasons and because the obesity treatment literature suggests strongly that an absence of treatment results in no weight loss or in weight gain [1]. The Phase 1 program was expected to facilitate modest weight loss. No specific diet or caloric intake level was specified, except that women and men were advised to consume at least 1200 and 1500 kcal, respectively, per day. Participants were encouraged to set personal goals for gradual behavior change using provided guidance about how to identify and track sources of fat and calories in their usual eating patterns and to make healthful, lower calorie substitutions according to the US Dietary Guidelines and Food Guide Pyramid [23]. Advice to increase physical activity was individually tailored to ability and preferences.

The Phase 2 hypothesis was that continued HELP Classes or Self-HELP, or both, would result in better long-term weight management than Clinic Visits Only, with no a priori assumptions about differences between HELP Classes and Self-HELP. The targeted Phase 2 sample size was 40 participants in each of the three treatments, sufficient for detecting pairwise differences between HELP Classes or Self-HELP and Clinic Visits Only of at least 2.5% weight loss from baseline with type-one error = 0.05 and power = 0.90. To achieve these Phase 2 sample sizes, the Phase 1 recruitment target was set at 250, estimating that about 60% (n = 150) would complete Phase 1 and proceed to Phase 2, allowing for 50 participants per treatment arm with a 1:1:1 randomization and 20% attrition.

All intervention and data collection protocols were approved by the University of Pennsylvania Institutional Review Board. Informed consent was obtained separately for Phases 1 and 2.

Phase 1 intervention—10-week Healthy Eating and Lifestyle Program (HELP)

Intervention approach

HELP was adapted from the weekly program used in the Trial of Nonpharmacologic Interventions in the El-

Table 1
Topics of initial 10-week Healthy Eating and Lifestyle Program (HELP) group sessions[a]

Session	Nutrition, behavior, activity content	Interactive and culturally-oriented content[b]
Overall program	Refreshments at each session Weigh in (optional) at each session Group discussion and review at each session Fast food calorie counter Personal physical activity consultation (telephone or in person) Study logo items; door prizes Behavioral strategies	*Study logo and identification as* "*For African-Americans*" Healthy snack/food tasting at each session *Video greetings from African-American principal investigator*
1: Getting started	Overview of program Benefits and importance of making lifestyle changes Why lose weight? Overweight and health in African-Americans Distribution of participant manual Homework: food and activity diary assignment	"*Doing This for Me*" (*Skit*)[c] Stages of change questionnaire and activity: "What would you like to change?" "*A Family Learns to Change*" (*video segment from C.A.R.D.E.S*)[d] "*Your Best Body*" (*booklet for women*)[e]
2: Physical activity and goal setting	Why physical activity? FITT Principle (Frequency, Intensity, Time, Type) Goal setting for lifestyle change Homework: food pantry inventory and morning meal ideas; schedule session with activity consultant; suggest music for exercise session	"*Get up and Move*" (*skit*)[c] "*Energize Yourself: Stay Physically Active*" (*Booklet*)[f] *Historical perspective on diet and physical activity*
3: Starting early—your morning meal	Healthy eating: what does it mean? Healthy eating: the Food Guide Pyramid way Sources of fat, calories, and sodium in morning foods; alternatives S.A.V.E.R. (memory aid and cue): Substitution, Activity Daily, Vegetables and Fruits, Everyday Plan, Reasonable Portions Menu planning for main meals; reading food labels	*Soul food pyramid* (*handout*)[g] *Better breakfasts* (*video segment from SisterTalk*)[h] Exercise demonstration
4: Main meal choices	Label reading Nutrition balance—portion control Sources of fat, calories, and sodium in main meals; alternatives Menu planning for light lunch meals; review picture food cards	Label reading practice
5: Light or lunch meals and snacks and "Be Good to Yourself"	Sources of fat, calories, and sodium in typical food used for cold or light meals Planning healthy snacks and shopping list Emotional eating	*Lunch challenge* (*video segment from SisterTalk*)[h] *Food picture cards* (*from C.A.R.D.E.S*)[d] "*What's in my food?*" (*game*)[i] "*Be Heart Smart: Eat Foods Low in Saturated Fat and Cholesterol*" (*booklet*)[f]
6: Grocery tour	Principles of shopping for healthy eating Field trip to supermarket in African-American neighborhood (near University) Identify recipes to be modified (homework)	In supermarket: "The Label's Right" (parody of "The Price is Right") Tour each aisle, selecting typical purchases and comparing labels
7: Recipe modification; ethnic eating, and developing a support system	Recipe modification Recipe calculation Inventory herbs and spices (homework)	*Healthy eating ethnic food choices* *Heart Healthy Cooking African American Style* (*booklet*)[f]
8: Food preparation; stress management	Tips for cutting calories, fat, and sodium in food preparation How to organize your kitchen; cooking methods Hints for using herbs and spices List your favorite restaurants; bring menus (homework)	Make herb blends to take home
9: Restaurants, take out; social and family eating situations	Making menu choices Strategies for attending social situations Assertiveness in making reasonable requests Common eating triggers and trouble spots Review steps for continuing a healthy eating and lifestyle program after Phase 1	Practice restaurant ordering *Family issues* (*including weight problems in children*)
10: Putting it all together	Review of overall program content Planning and goal setting for continued healthful eating, physical activity, and weight management strategies following the weekly phase	Festive, interactive atmosphere Polaroid photos to take home

[a] Each session lasted approximately 75 min.
[b] African-American-oriented components are italicized.
[c] Source: adapted from printed material or video from the Health Promotion Council of South Eastern Pennsylvania (Philadelphia) (www.hpcpa.org).
[d] Source: see Ref. [26].
[e] Source: National Cancer Institute, NIH, Rockville MD (www.nci.nih.org).
[f] Source: National Heart, Lung, and Blood Institute (www.nhlbi.nih.org).
[g] Source: Hebni Nutrition Associates (www.soulfoodpyramid.org).
[h] Source: see Ref. [27].
[i] Source: see Ref. [28].

derly (TONE) weight loss interventions [21,24]. The TONE programs were based on well-established, theoretically supported behavioral change approaches and adapted for adult learners living in urban communities in both the middle Atlantic and southeastern regions of the United States. To reduce the length and cost of the HELP program relative to the 16-week TONE intervention, which consisted of 12 group and 4 individual counseling sessions, HELP excluded the individual sessions and collapsed the 12 TONE group sessions into 10 weeks.

Table 1 lists the HELP session content for each of the weekly classes and also lists adaptations intended to increase the interactive nature and cultural salience of the program for African-Americans. The TONE meal-by-meal approach to counseling on eating behaviors and the placement of a session on physical activity early in the topic sequence were retained, as was the inclusion of behavioral counseling topics such as self-monitoring, stimulus control, goal setting and planning, overcoming motivational barriers, cognitive restructuring, assertive responding, and relapse prevention and management. The non-prescriptive TONE behavioral change approach was adopted, helping participants build motivation and skills for gradual changes in eating and activity patterns. HELP strongly emphasized overall health improvement and risk factor management in addition to caloric reduction, incorporating content from the TONE combined weight-sodium intervention as well as from the weight-loss-only program. Weigh-ins at class, which were routine in TONE, were optional in HELP and only offered at certain sessions. Food diaries were distributed and self-monitoring was encouraged, but these were not structured aspects of the program. TONE included physical activity during weekly sessions but this was not logistically feasible in HELP. Instead, a personalized physical activity assessment and prescription were offered, conditional on approval of the personal physician.

The cultural adaptations (Table 1) were based on both theoretical and empirical guidance [25], incorporating several techniques or materials from prior studies [26–28]. The "SAVER" acronym (see Table 1, session 3) was created specifically for HELP to simplify and reinforce key principles.

Program setting and implementation

Classes were offered in the family practice department conference room, usually in the early evening. Free parking and convenient public transportation were available. Classes were led by part-time nutrition, exercise, or behavior change specialists, usually working in teams of two and rotating through classes according to topic. Four out of nine counseling staff were African-American. For practical reasons, missed classes were not made up, although reminder calls were made to participants to attend the next session.

Phase 2 interventions—approaches to long-term weight management

HELP classes

Participants assigned to continue in "HELP Classes" were offered six, 1-h classes, twice a month (termed biweekly), followed by monthly classes through the end of follow-up. Classes were led by a subset of the Phase 1 instructors, with new topics, expansion on or review of prior topics, and an even greater focus on group discussion than in Phase 1. Missed classes were followed up with mailings of handouts, and a make-up telephone call was attempted. Counselors occasionally led Saturday morning walks and provided individualized nutrition, physical activity, or behavioral consultations upon request, usually by telephone.

Self-HELP

Participants assigned to "Self-HELP" were given a Self-HELP Kit containing a personalized calendar, a packet describing local resources for healthy eating and physical activity, a personal diary, and a pedometer, and ad hoc telephone support from a HELP outreach worker to facilitate self-directed long-term weight management. The original Self-HELP format was ineffective in engaging participants in the amount of contact intended, i.e., less assistance from staff than in the HELP classes arm, but sufficient staff support to differentiate this arm from the Clinic Visits Only condition. Therefore, during the last two cycles of program implementation and coincident with the resignation of the lay person originally hired to act as the Self-HELP facilitator, the format was changed to provide for structured, staff-initiated contacts, with one of the Phase 1 counselors assuming the facilitator role. All participants in this treatment arm were then invited (some retroactively) to a group orientation meeting to explore ways to approach self-directed weight management, and participant teams were formed to facilitate peer support. Subsequently, the facilitator routinely attempted monthly calls to all participants to review progress and provide coaching on nutrition and physical activity behavior change strategies. She also led several Saturday morning walks; these walks were separate from the walks for those assigned to "HELP-Classes".

Clinic visits only

This treatment was intended to approximate a minimal intervention, usual care condition. The only study contacts were at the semi-annual follow up clinic visits provided to all Phase 2 participants. Participants assigned to this treatment, which was termed the "Personal Physician" arm when communicating with participants, were encouraged to continue with their healthy lifestyle changes and to consult their personal physicians if they had further weight management questions. The physicians of these participants were provided with an information

sheet listing websites with weight management guidelines. No study interventions were provided to these participants or their physicians, and participant interactions with their physicians were not tracked.

Participant enrollment

Recruitment procedures

Inclusion criteria were self-identification as African-American, age 25–70 years, a BMI between 30 and 50 kg/m^2, and a personal physician in the university health system. The "HELP study" was advertised using posters displayed in system hospitals, primary care offices, and examination rooms, and through informational presentations to physicians and staff at the large primary care practices. Intake was through a study "hotline". Those pre-eligible after telephone pre-screening were invited for in-person screening and baseline data collection. The only exclusions were for conditions or circumstances where weight reduction would be contraindicated, inappropriate, or infeasible, or that could confound interpretation of weight loss data, e.g., pregnancy, active treatment for unstable depression or other psychiatric disorders, current use of antipsychotic medications, active chemo- or radiation therapy, alcoholism, eating disorders, or being non-ambulatory. A history of CVD, diabetes, or obesity-related comorbidities was not a basis for exclusion if health status was considered stable and permission of the personal physician was obtained.

Recruitment and implementation were influenced by the availability of staff and classroom and data collection space. There were four recruitment/program cycles: April–May of 2000 (Cohort 1: n = 34), July–September 2000 (Cohort 2: n = 62), October–December 2000 (Cohort 3: n = 50), and January–April 2001 (Cohort 4: n = 91). The average waiting time before the start of Phase 1 classes was 2 months. A counselor attempted a brief telephone consultation with participants waiting to start classes.

Randomization to Phase 2

Participants completing Phase 1 and consenting to continue in Phase 2 were randomly assigned to one of the three treatments via a permuted block randomization scheme in a 1:1:1 ratio. The study coordinator used sealed envelopes prepared and monitored by the study statistician to identify randomization assignment. A packet explaining the treatment assignment was given to each participant, and the primary care physician was notified of his or her patient's randomization assignment. All participants received a seasonal study newsletter, small gifts as incentives, and a copy of "Children Should Know Their Grandparents" (©Association of Black Cardiologists, Atlanta GA), a video designed to motivate lifestyle changes for CVD risk reduction among African-Americans.

Data collection procedures

Questionnaires and measurements

Participants completed questionnaires on demographic, medical history, weight history, and other health and behavior information. The same trained observer, the study coordinator, took weight, height, and blood pressure measurements, and collected the questionnaire data at all visits using standardized protocols. This observer was not involved in any intervention activities or interim reviews of study data, but it was not feasible to mask her to treatment assignment during Phase 2. Height was measured to the nearest inch, with shoes removed, using a portable stadiometer (SECA Road Rod; Hanover, MD). Participants were weighed in light clothing using a portable Electronic Digital BWB-627A TANITA Scale (Tokyo, Japan). Waist was measured using a 60-in. retractable pliable tape. Seated blood pressure was measured using a mercury sphygmomanometer (Baumanometer® Desk Model (W.A. Baum Co., Inc.), according to the American Heart Association guidelines [29]. For blood samples, participants were instructed to fast for at least 12 h and to take their usual medications, except anti-diabetic medications prior to a scheduled phlebotomy appointment at the General Clinical Research Center laboratory. The fasting blood samples were analyzed at the Core Laboratory of the General Clinical Research Center for determination of total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG), and glucose.

Clinic visits

The baseline visit included an explanation of both study phases, informed consent for Phase 1, and measurements and questionnaires to determine final eligibility and baseline data. A 10–15 min consultation with a HELP study physician was also included to confirm eligibility and discuss motivation for participation. Participants were also asked to provide a medical evaluation form completed by their personal physician.

Follow-up clinic visits followed the same format as the baseline clinic visit. The Phase 1 follow-up clinic visit, which also included randomization procedures, served as the Phase 2 baseline visit. During Phase 2, follow-up clinic visits were scheduled every 6 months after randomization. Due to administrative truncation of follow-up in the latter recruitment cohorts, the number of semi-annual follow-up clinic visits during Phase 2 varied according to enrollment date. There were three Phase 2 follow-up clinic visits for Cohorts 1 and 2 (at approximately 6, 12 [no blood collection], and 18 months [final visit] after randomization), but only two Phase 2 follow-up clinic visits for Cohorts 3 and 4 (approximately 6 [no blood collection] and 12 months [final visit] after randomization).

At each follow up clinic visit, the study coordinator and study physician provided verbal feedback on progress and

ascertained interim changes in health status. Laboratory results and weight, waist, and blood pressure measurements were then sent to the participant's personal physician. To decrease the potential for bias in outcome ascertainment, intervention staff were not involved in clinic visits or data collection. Token incentives, but no monetary compensation, were provided for attendance at clinic visits. The final visit included an overall review of changes in weight, waist, blood pressure, and available laboratory results. The study coordinator gave each participant a close out packet consisting of a study logo tote bag and a personalized calendar with tips and tools for planning to continue healthful eating and physical activity and weight management, and requested completion of an anonymous participant feedback form.

Process monitoring and evaluation

Attendance was taken at all group sessions. Attempted and completed telephone calls were tracked for the Phase 2 Self-HELP condition. Participant feedback was elicited with an anonymous questionnaire given at the final Phase 2 clinic visit. Staff feedback was ascertained through written weekly reports and at a de-briefing meeting at the end of Phase 1.

Data management and statistical methods

Data were recorded and entered using scannable forms. Editing was done using range checks and logic algorithms. Questionable entries were checked against paper forms. Statistical analyses were done with Stata 8.0 [30]. Hypothesis tests were two-sided, with a P value < 0.05 as the criterion for statistical significance and 95% confidence intervals to estimate precision of group means. Primary analyses involved assessment of weight change, i.e., whether Phase 1 resulted in significant weight loss, whether the ability to improve or maintain weight loss differed according to Phase 2 treatment, and whether the weight change in Phase 2 was dependent upon the Phase 1 weight change. All other analyses, e.g., subgroup analyses of weight change by cohort, were considered secondary and exploratory. Weight change (kg) was assessed in several ways, including post–pre differences, and percent weight change as both a continuous and categorical variable, with a loss of $\geq$5% pre-specified as of clinical significance [31]. Analysis results did not differ according to the weight change variable used; as a result, our findings are presented primarily in terms of weight differences (kg) and the distribution of percent weight change. Tertiles of Phase 1 weight loss were created to analyze associations between Phase 1 and Phase 2 outcomes.

The primary study hypotheses were expressed in terms of the baseline and final visit within each phase, i.e., from baseline to the follow-up clinic visit after Phase 1, and from the beginning of Phase 2 (using the Phase 1 follow-up clinic visit as the baseline) to the last possible Phase 2 visit. We assessed the potential influence of recruitment cohort differences in the duration of Phase 2 using both graphical analyses and multivariate modeling.

Descriptive analyses included calculation of means, medians, and standard deviations of continuous study outcomes and patient characteristics, and frequency distributions of categorical variables. When required, the assumption of normality was assessed via graphical checks and the Shapiro–Wilk test. Bivariate analyses included application of analysis of variance (ANOVA) for testing the equality of means across $\geq$2 groups, the Student's t test for comparisons of means between two groups, and Chi-square tests when variables to be compared were categorical. The non-parametric analogues of these tests (Kruskall–Wallis and the Shapiro–Wilk rank sum test, respectively) were also used to assess the sensitivity of results to possible departures from normality in the variable under consideration. The Student's paired t test was used to test the within subject equality of weight and other clinical variables at baseline vs. follow-up during each phase of the study and overall. The linear association between variables was assessed with Pearson's correlation or the non-parametric analogue (Spearman).

Multivariate analyses were conducted to further investigate potentially important relationships identified in the bivariate analyses. For example, a linear regression model to assess whether the rate of weight change differed among cohorts included indicator variables for cohort, time of follow-up, and time $\times$ cohort interaction terms. Logistic regression was used to explore associations between binary outcomes and potential correlates. The assumptions of the regression models were explored via appropriate graphical checks and tests of hypothesis. The correlation between covariates was also assessed.

In addition to analyses that only used data for completers, we conducted secondary analyses based on quasi-least squares (QLS) [32] to use all available data on each subject, i.e., for completers, these analyses included data for interim Phase 2 visits and for those who did not attend the final clinic visit, data for any clinic visits that they did attend. QLS allows for a variable number of measurements per subject and is appropriate for analysis of measurements that are unequally spaced in time. The QLS findings were confirmatory of the primary analyses and are, therefore, not presented.

Results

Recruitment and retention

Participant flow from initial contact through study completion is shown in Fig. 1. Many of those who called the study hotline were not successfully contacted and prescreened, did not wish to continue after the initial call, or did not come for their baseline screening appointment. Of

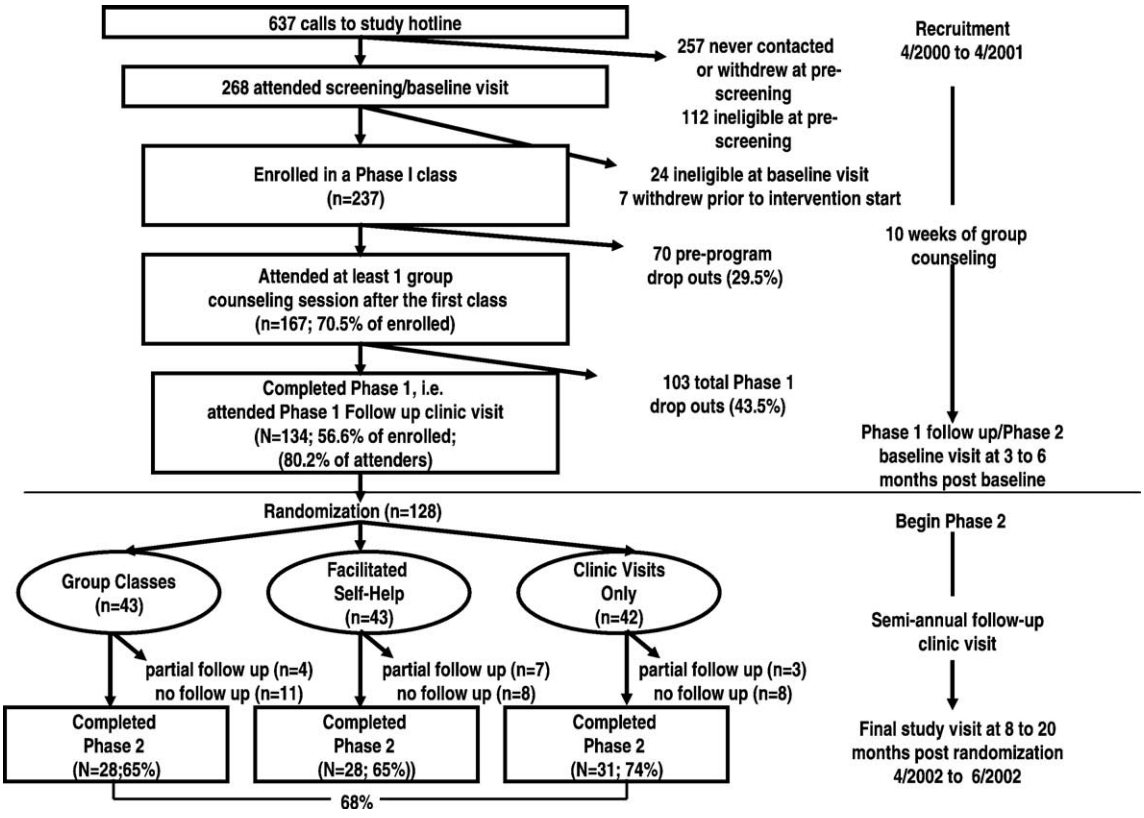

Fig. 1. Retention and drop out of study participants in the initial and randomized phases of the HELP study.

the 380 remaining, 36% (n = 136) did not meet the study inclusion criteria and seven who were eligible after screening withdrew before classes began. Reasons for ineligibility were: BMI out of range (33 too low, 33 too high, 1 not specified); personal physician outside of the university health system (n = 20) or no health insurance (n = 1); medical or medication exclusions (n = 11); age (n = 6); pregnancy (n = 2); not African-American or not English speaking (n = 2); not specified (n = 27).

As shown in Fig. 1, 30% (n = 70) of those enrolled were considered Phase 1 "drop-outs", defined as attending no classes or only the first class; 80% of the remainder completed the follow up visit after Phase 1 (n = 134), and 96% (n = 128) of these were randomized to Phase 2. In Phase 2, attendance at interim follow-up was 60% and 36%, respectively, at 6 and 12 months post-randomization for Cohorts 1 and 2 (combined) and 70% at 6 months post-randomization for Cohorts 3 and 4 (combined). The percent of randomized participants attending the last possible follow-up clinic visit was 68% and was similar across treatment arms (Fig. 1). Of the 41 randomized participants without a final visit, 14 attended at least one interim visit during Phase 2 (termed "partial" follow-up).

Duration of follow up

Average time between the baseline and the Phase 1 follow-up visits was approximately 4 months for Cohorts 1–3 and 5 months for Cohort 4. Phase 2 duration (i.e., post-randomization) by cohort was 17–19 months (mean 18.1) for Cohort 1, 14–19 months (mean 17.4) for Cohort 2, 12–13 months (mean 12.4) for Cohort 3, and 8–11 months (mean 9.9) for Cohort 4 ($P < 0.0001$ for difference across cohorts). For the 87 participants who completed Phase 2, the mean (SD) duration of follow-up for Phases 1 and 2 combined (termed "overall" follow-up) was 17.8 (3.2) months; range 13.2–24.4 months. Mean (SD) overall duration was 21.9 (0.6), 21.7 (1.1), 16.7 (0.8), and 14.9 (1.2) months, respectively, for Cohorts 1 through 4.

Participant characteristics

Table 2 shows participant characteristics at the time of initial enrollment in the study for the total sample and separately for those who did or did not attend follow-up (completers and non-completers, respectively), for both study phases. The only cohort difference identified was for education: significantly more participants in Cohort 1 (95%) had >12 years of education compared to Cohorts 2, 3, and 4 (65%, 60%, and 50% of respectively; P = 0.01) (not shown). Compared to those initially enrolled, participants randomized to Phase 2 were significantly older, better educated, more likely to be employed in a professional or managerial occupation, and more likely to complete the baseline laboratory visit (see Table 2). When these variables were entered into a logistic regression model, only pro-

Table 2
Characteristics of completers and non-completers[a] of HELP study Phases 1 and 2 at the time of enrollment in Phase 1

Variable	Phase 1			Phase 2		
	All	Non-completers	Completers	All	Non-completers	Completers
N	237	103	134	128	41	87
Female (%)	89.9	89.3	90.3	90.6	97.6	87.4[b]
Age (years) (mean ± SD)	43.4 ± 10.5	40.9 ± 10.7	45.2 ± 10.0**	45.4 ± 10.2	43.1 ± 10.9	46.5 ± 9.7[b]
Education >12 years (%)	63.5	49.2	70.6**	70.2	70.3	70.2
Professional occupation (%)	50.5	37.1	57.1**	56.2	48.6	59.5
Married (%)	39.7	34.7	43.6	44.1	41.5	45.3
Children <18 years (%)	58.7	63.4	55.2	54.7	56.1	54.0
Current smoker (%)	16.8	19.8	14.5	14.4	20.0	11.8
Current drinker (%)	29.0	31.5	27.4	26.9	22.2	29.2
Self-rated health (%)						
Excellent or Very good	19.7	16.0	22.4	21.9	19.5	23.0
Good	54.3	54.0	54.4	54.7	56.1	54.0
Fair or poor	26.1	30.0	23.1	23.4	24.4	23.0
Positive medical history (%)						
Cardiovascular disease	23.8	23.5	24.1	23.6	22.0	24.4
Respiratory problems	23.0	26.5	20.3	19.7	26.8	16.3
High blood pressure	39.7	39.2	40.2	40.5	45.0	38.4
Diabetes	14.5	17.6	12.1	12.7	9.8	14.1
Musculoskeletal problems	48.9	52.5	46.1	46.0	41.5	48.2
Obesity-related comorbidity[c]	75.5	76.7	74.6	75.0	70.7	77.0
Weight (kg) (mean ± SD)	102.7 ± 17.2	103.6 ± 17.4	102.0 ± 17.0	99.9 ± 16.9	98.8 ± 13.2	100.4 ± 18.5
BMI (kg/^{2}) (mean ± SD)	38.0 ± 5.3	38.0 ± 5.3	37.9 ± 5.4	37.0 ± 5.5	37.2 ± 5.2	36.9 ± 5.7
Waist circumference (cm)	111.9 ± 12.6	112.9 ± 12.5	111.1 ± 12.6	108.6 ± 13.1	109.3 ± 12.3	108.2 ± 13.5
Age first overweight by 10+ lb (years) (mean ± SD)	24.1 ± 11.3	23.7 ± 9.8	24.4 ± 12.5	24.7 ± 12.6	21.7 ± 12.1	26.2 ± 12.6[b]
Expected weight loss in first 3 months (mean ± SD)	28.2 ± 14.4	26.9 ± 14.2	29.2 ± 14.6	28.9 ± 14.3	30.8 ± 13.0	28.0 ± 14.9
No. of prior weight loss programs (mean ± SD)	1.4 ± 1.7	1.1 ± 1.4	1.6 ± 1.9[b]	1.6 ± 1.9	1.6 ± 1.7	1.6 ± 2.0
Completed baseline labs (%)	74.7	51.5	92.5***	92.2	92.7	92.0
No. of Phase 1 sessions attended (mean ± SD)	4.4 ± 3.6	1.3 ± 2.0	6.9 ± 2.4***	7.0 ± 2.3	6.3 ± 2.4	7.3 ± 2.3[b]
Weight change (kg) (mean ± SD) in Phase 1	–	–	−1.7 ± 3.7	−1.7 ± 3.7	−2.1 ± 4.0	−1.5 ± 3.5
Percent losing ≥5% of baseline weight in Phase 1			14.2%	14.8%		12.6%

[a] Completers and non-completers (came to or did not come to the final visit data collection visit for the phase).
[b] $P < 0.10$.
[c] Reported history of high blood pressure, gallbladder disease, gout or elevated uric acid, obstructive sleep apnea, breathing problems, stroke, angina, heart disease, arthritis, joint pain, diabetes mellitus, hypercholesterolemia or high cholesterol.
** $P < 0.01$.
*** $P < 0.001$.

fessional occupation and having baseline laboratory values remained in the final model for completion vs. non-completion of Phase 1. For those continuing in Phase 2, no differences in baseline characteristics by treatment group were identified either at the time of randomization or for those who completed their final study visit; hence, data in Table 2 are not presented by treatment group. Phase 2 drop out was not associated with any of the baseline variables shown in Table 2.

Feasibility, intervention attendance, and participation

The Phase 1 and Phase 2 intervention programs were generally implemented as intended. Timely provision of individual exercise prescriptions was limited by lateness in receiving medical clearance for some participants, combined with difficulty in reaching participants by phone to discuss their exercise preferences and options.

Attendance at Phase 1 classes declined from 89% at the first class to around 60% by week 5, stabilizing at 47–54% through week 10 (not counting drop outs), with individual attendance averaging 6–7 of the 10 sessions. Thirteen percent attended only 1 or 2 classes, 35% attended 3–6 classes, 41% attended 7–9 classes, and 11% attended all classes. None of the baseline characteristics in Table 2 predicted attendance level in either the 167 attendees or the 134 who completed the Phase 1 follow-up visit.

In Phase 2, average group session attendance in the HELP Classes arm was 40% of expected for the six bi-weekly sessions and 31% of expected during the more

extended period of monthly contact, with no clear trend over time. There was higher attendance in Cohort 4 (47–71% attended biweekly sessions and 71% attended monthly sessions compared to 22–46% biweekly and 10–20% monthly attendance in Cohorts 1–3). In Self-HELP, the facilitator completed 35–55% of monthly telephone calls, with no apparent difference by recruitment cohort. The median percent participation (group sessions attended and/or protocol telephone contacts completed divided by contacts offered × 100) for individuals assigned to either HELP classes or Self-HELP was 38%. Median rate of contact (group sessions attended and/or protocol telephone contacts completed divided by total months in Phase 2, without considering the actual timing of the contacts during this period) was 0.4 for participants in both HELP classes and Self-HELP. A few statistically significant associations of Phase 2 participation with baseline characteristics were observed, but with no clear pattern (data not given).

Weight change

Phase 1

Phase 1 weight change was similar for those who completed Phase 1 (n = 134), were randomized to Phase 2 (n = 128), or completed Phase 2 (n = 87) (see last two rows in Table 2). Therefore, for ease of comparison across both phases, data for changes in weight and clinical variables are reported only for the 87 who completed Phase 2 unless otherwise noted. Participation in Phase 1 was associated with modest average weight loss overall (mean [95% confidence intervals] −1.5 kg [−2.3,−0.1], P = 0.04; range −18.8 to +4.6 kg), with slightly more than half (n = 46, or 53%) losing 1 kg or more, and 15% losing at least 4.5 kg (see Table 3). Fourteen percent lost 5% or more of their baseline weight.

Phase 2

Neither HELP Classes nor Self-HELP was superior to Clinic Visits Only with respect to weight loss or maintenance during Phase 2 (n = 87) (Table 4). Pre–post differences within treatment group were negligible: 0.02 (P = 0.98), 1.1 (P = 0.12), and 0.04 (P = 0.96 kg), respectively, for HELP Classes, Self-HELP, and Clinic Visits Only, and not significantly different across treatments (P = 0.55). Pre–post changes were also not significant in data pooled across treatments (0.3 kg, P = 0.47) (Table 4). However, the range of weight change was −9.6 to +13.4 kg and, as shown in Table 3, substantial proportions either lost or gained at least 1 kg.

Weight change data were plotted to examine potential effects of the longer duration of Phase 2 for Cohorts 1 and 2 (17–18 months) compared to Cohorts 3 and 4 (10–12 months) (Fig. 2). This plot, using data pooled across treatment arms, shows weight change from initial enrollment and includes all participants who came to the Phase 1 follow up clinic visit (n = 134). The data extend to the end of follow up only for the 87 who completed their final study visit (n = 32 in the Cohorts 1 and 2 data and n = 55 in the Cohorts 3 and 4 data). The impression from Fig. 2 is that in Phase 2–which begins 3–6 months after baseline–relatively

Table 3
Weight and other clinical variables at baseline, Phase 1, and Phase 2 follow up, and change from baseline for HELP Phase 2 completers (n = 87)

Variable[a]	Phase 1			Phase 2		Entire study period
	Baseline	Phase 1 follow up	Change during Phase 1	Final visit	Change during Phase 2	Final visit minus baseline
Weight (kg)	102.0 ± 18.5	100.4 ± 18.5	−1.5 ± 3.5***	100.8 ± 19.4	0.3 ± 4.4	−1.2 ± 5.2*
Distribution of weight change[b]						
Lost ≥4.5 kg (10 lb)	–	–	13 (15)	–	12 (14)	23 (26)
Lost 1 to 4.49 kg[b]	–	–	33 (38)	–	19 (22)	20 (23)
±0.99 kg of baseline[b]	–	–	21 (24)	–	19 (23)	13 (15)
Gained 1 to 4.49 kg[b]	–	–	19 (22)	–	24 (27)	19 (22)
Gained ≥4.5 kg[b]	–	–	1 (1)	–	13 (15)	12 (14)
BMI	37.5 ± 5.5	36.9 ± 5.7	−0.7 ± 1.6***	37.1 ± 5.9	0.2 ± 1.9	−0.5 ± 1.9*
Waist	110.6 ± 12.8	108.2 ± 13.5	−2.6 ± 7.1**	108.6 ± 14.8	1.0 ± 7.8	−1.7 ± 5.9**
Systolic BP (mm Hg)	123.7 ± 15.1	119.5 ± 15.1	−4.2 ± 11.5**	117.2 ± 13.1	−2.6 ± 11.7*	−6.5 ± 11.0***
Diastolic BP (mm Hg)	79.9 ± 8.5	77.8 ± 9.2	−2.0 ± 7.9*	75.3 ± 7.9	−2.7 ± 7.6**	−4.9 ± 6.8***
Total cholesterol (mg/100 ml)	190.0 ± 35.8	187.9 ± 37.3	1.9 ± 23.4	190.0 ± 35.9	3.5 ± 28.8	3.0 ± 22.3
HDL cholesterol (mg/100 ml)	49.4 ± 12.4	49.5 ± 11.2	−0.3 ± 5.9	51.7 ± 13.1	2.2 ± 8.0*	2.5 ± 6.5**
LDL-cholesterol (mg/100 ml)	120.4 ± 31.1	117.1 ± 31.2	−3.9 ± 20.0	118.4 ± 29.6	2.9 ± 25.2	0.6 ± 20.8
TC/HDL ratio	4.0 ± 1.1	3.9 ± 0.9	−0.1 ± 0.6	3.8 ± 1.0	−0.04 ± 0.5	−0.1 ± 0.6[c]
Triglycerides (mg/100 ml)	97.6 ± 58.4	98.8 ± 56.8	2.4 ± 33.4	90.2 ± 43.4	8.4 ± 35.7[c]	−4.5 ± 45.3
Blood glucose	101.3 ± 31.8	100.6 ± 40.7	−2.4 ± 20.4	95.9 ± 36.4	−2.7 ± 29.2	−3.8 ± 27.2

[a] Mean (SD) unless otherwise noted.
[b] n (%).
[c] $P < 0.10$.
* $P < 0.05$.
** $P < 0.01$.
*** $P < 0.001$.

Table 4
Changes in weight (kg) during Phase 2 and overall by Phase 2 treatment assignment for HELP Phase 2 completers (n = 87)

Randomization group				All
Variable[a]	HELP classes	Self-HELP	Clinic visits only	
n	28	28	31	87
Phase 2				
Weight at randomization	103.3 (18.7)	98.5 (16.8)	99.5 (19.9)	100.4 (18.5)
Weight at final visit	103.3 (19.0)	99.6 (18.6)	99.5 (20.7)	100.8 (19.4)
Change (95% CI)[b]	0.02 (−1.7,1.8)	1.1 (−0.3,2.5)	−0.04 (−1.9,1.8)	0.3 (−0.6, 1.3)
Overall				
Baseline weight[c]	104.1 (18.1)	100.9 (17.4)	100.9 (19.9)	102.0 (18.5)
Weight at final visit	103.3 (19.0)	99.6 (18.6)	99.5 (20.7)	100.8 (19.4)
Change (95% CI)	−0.8 (−2.5,0.9)	−1.3(3.4,0.9)	−1.4 (−3.5,0.7)	−1.2 (2.3,−0.1)*

[a] Mean (SD) unless otherwise noted.
[b] CI = confidence interval.
[c] At enrollment in Phase 1.
* P = 0.038 for change from baseline.

more Cohort 3 and 4 participants were able to continue losing or to maintain weight loss during Phase 2 compared to Cohorts 1 and 2. Consistent with this impression, mean Phase 2 weight change was 2.3 [−0.5, 5.1] kg for Cohort 1; 2.0 [−0.4, 4.4] kg for Cohort 2, i.e., an increase, but for Cohorts 3 and 4 weight decreased or did not change (respectively −1.8 [−3.5, −0.1] and −0.2 [1.5, 1.1]) (P for analysis of variance across cohorts = 0.02; n = 87). However, associated regression analyses did not indicate significant differences in the rate of weight change between the two sets of cohorts either during Phase 2 (P = 0.83) or overall (P = 0.71). Similar results were obtained using a longitudinal quasi-least squares analysis that used information for all 101 participants with any follow-up in Phase 2.

Overall weight change (Phases 1 and 2 combined)

Overall, pre–post weight changes from initial enrollment to the final visit were not significant within treatment groups: −0.8 (P = 0.35), −1.3 (P = 0.23), and −1.4 (P = 0.17) kg, respectively, for HELP Classes, Self-HELP, and Clinic Visits Only, and were not significantly different across treatments (P = 0.90) (Table 4). The overall pre–post weight change in pooled data was statistically significant (−1.2 kg, P = 0.038), with a range of individual weight loss of −14.6 kg to +10.3 kg, and 25% losing ≥5% of their baseline weight. As shown in Table 3, the percent of participants with an overall weight loss of at least 4.5 kg (10 lb) was greater at the end of Phase 2 (26%) than after Phase 1 (15%). However, the proportion with a gain of 4.5 kg or more was also higher after Phase 2 (14%) than at the end of Phase 1 (1%).

Association of Phase 2 weight change with Phase 1 weight change

We created tertiles of Phase 1 weight change for participants who completed Phase 2 and examined the Phase 2 and overall weight change both graphically (see Fig. 3) and in regression models. Boundaries for the first, second, and

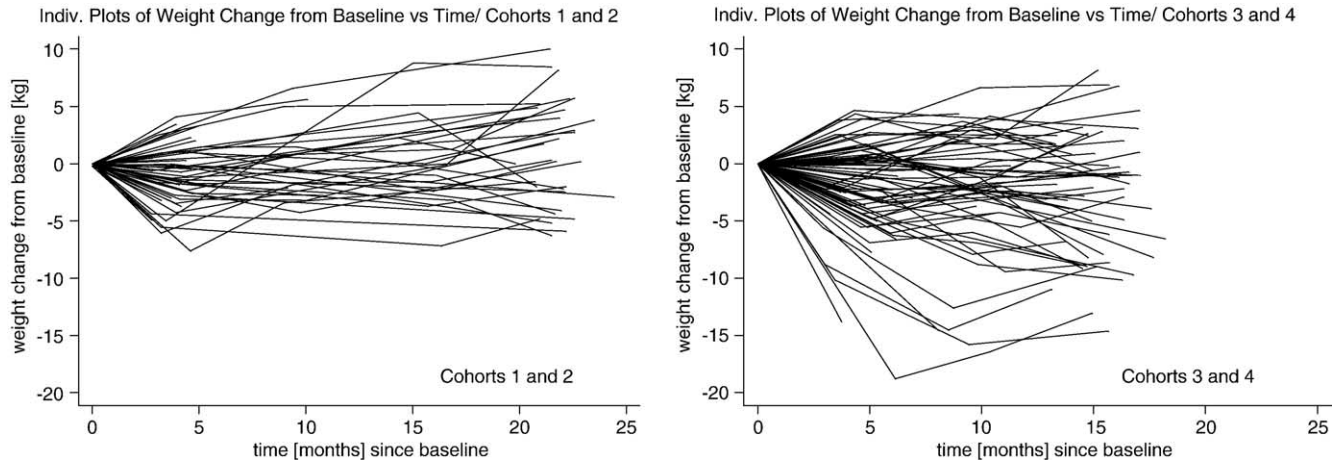

Fig. 2. Weight change from initial enrollment as a function of time on study using all available data for participants with at least one follow-up clinic visit (maximum n = 134), by recruitment cohort. Later recruitment cohorts (3 and 4) had shorter time on study due to administrative censoring.

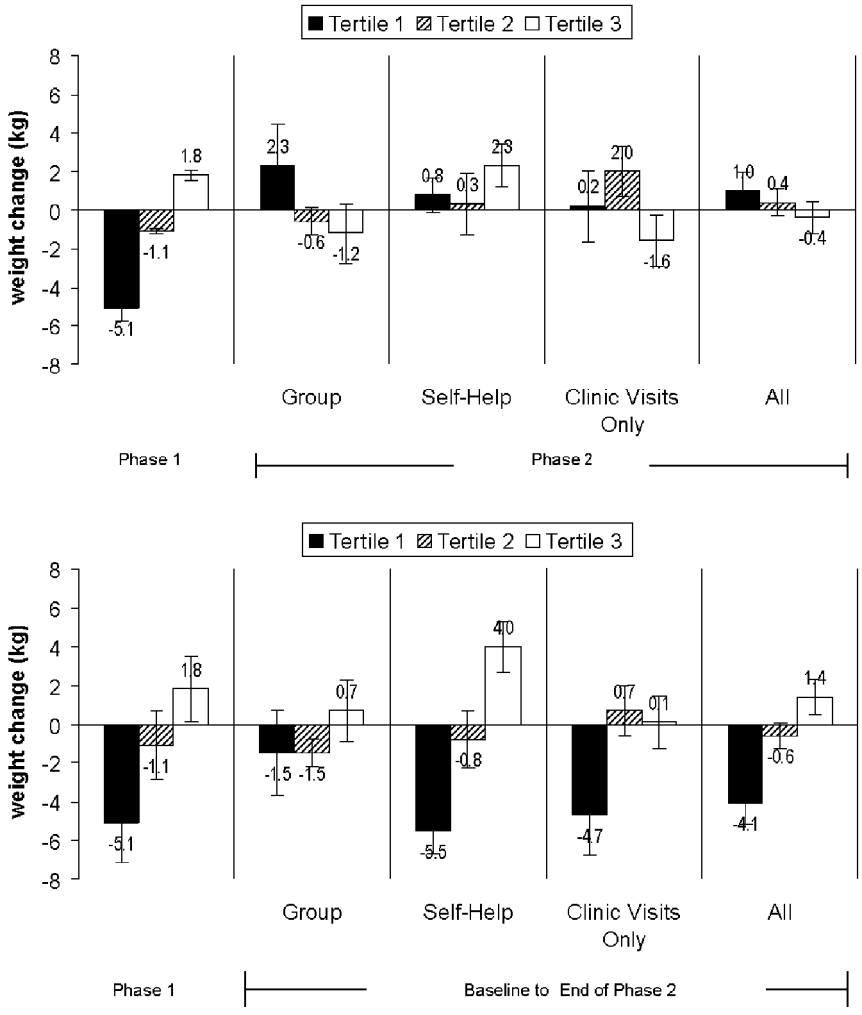

Fig. 3. Tertiles of Phase 1 weight change, Phase 2 weight change, and overall weight change, by tertile of Phase 1 weight loss, within treatment group and pooled. All data are for subgroup mean ± SE.

third tertiles were, respectively, −18.8 to −2.5 kg, −2.4 to 0.1 kg, and 0.2 to 4.6 kg. The Phase 2 data in Fig. 3 (top) suggest that treatment assignment modified the association of tertile of Phase 1 weight change with weight change during Phase 2: relatively greater weight gain or regain in the first tertile for those assigned to HELP Classes and in the third tertile for those assigned to Self-HELP. Only the interaction between HELP Classes and tertile 1 was supported ($P = 0.05$) in the exploratory regression analyses and only in the model for Cohorts 1 and 2 (combined).

The strong association of tertile of Phase 1 weight change with overall weight change from baseline to the end of Phase 2 is also shown in Fig. 3 (bottom). This observation was supported by a regression model with all completers that included terms for tertiles of Phase 1 weight loss, treatment assignment, and treatment by tertile interactions. The main effect of being in the first tertile of Phase 1 weight loss was −4.6 kg ($P = 0.002$). Neither the interaction of HELP Classes by tertile 1 nor that for Self-HELP by tertile 3 was statistically significant (both $P = 0.10$).

Baseline predictors of weight change (n = 87)

Only one of the baseline variables in Table 2 was associated with Phase 1 weight loss: married participants lost more weight than unmarried participants (−2.5 vs. −0.7 kg, respectively, $P = 0.03$). Phase 2 weight change was inversely correlated with age when first overweight (Pearson's $r = -0.27$ $P = 0.02$), suggesting that participants with a more recent onset of overweight had a more favorable pattern of weight change during Phase 2. Having a history of CVD was also associated with Phase 2 weight change in those with vs. without a history of CVD (respectively, −1.4 and +0.9 kg, $P = 0.04$). Among those assigned to HELP Classes or Self-HELP, neither percent participation nor rate of participation was associated with Phase 2 weight change. The association of age at first overweight was also present in the overall weight data for Phases 1 and 2 combined ($r = -0.23$, $P = 0.05$). The number of prior weight loss programs was associated with overall weight loss ($r = -0.23$, $P = 0.03$).

Changes in other clinical variables

Waist circumference, BMI, and systolic and diastolic blood pressure decreased significantly at the Phase 1 follow-up visit and a further significant decrease in blood pressure was observed during Phase 2 (Table 3). All of these variables decreased significantly from baseline to the end of Phase 2. Lipids and blood glucose did not change appreciably during Phase 1 but mean HDL-C increased by 2.2 and 2.5 mg/100 ml ($P < 0.05$ and <0.01), respectively, during Phase 2 and from baseline to the end of Phase 2. Improvements in total and LDL-cholesterol after Phase 1 were correlated with the number of Phase 1 classes attended (not shown) (Pearson's $r = -0.22$, $P = 0.02$, and -0.21, $P = 0.03$, respectively).

Participant and staff feedback

Participant feedback forms were obtained from 95% (83 of 87) of Phase 2 completers. All aspects of the study experience were well received. Attending Phase 1 classes, receiving an organized manual of information, and the nutrition component of the program were rated "very useful" (the highest rating) by 95%. Most other Phase 1 components were rated "very useful" by 80–90%, with fewer (66–71%) giving the highest rating to the physical activity component, the deck of food cards, and watching videos in class. In answer to specific questions about the possibility of having continued with weekly classes in Phase 2, 82% would have wanted this option: 40% for 3 months but the remainder for either 6 or 12 months. Only 53% of participants indicated that the incentives provided helped to keep them coming back to the study.

Staff felt that the general program format and content were effective. Suggestions to improve the program included a more even balance between the nutrition, exercise, and behavior components, more hands-on experiences such as field trips and demonstrations, and a stronger physical activity component (e.g., not only more sessions but also better facilities and equipment). Staff also noted that the reading level of the materials might have been too low for some of the participants.

Discussion

HELP was scaled down, from a more extensive intervention, for feasibility in an outpatient setting and was culturally adapted for African-American adults. Study participants were African-Americans typical of those who might self-refer or be referred for a weight loss program in an urban university hospital setting. All were clinically obese (BMI $\geq$ 30) with many in the class II or class III obesity range, and most had been diagnosed with at least one obesity-related comorbidity. We observed a modest average weight loss after the 10-week program in Phase 1 that was relatively well maintained regardless of the Phase 2 treatment assignment. About one-quarter of program completers achieved a clinically significant weight loss over an overall average of 18 months duration. About half lost between 1 and 15 kg.

The 1.5–1.7 kg weight loss observed in Phase 1 is consistent with expectations for this type of non-prescriptive lifestyle change program, which does not specify a particular diet or caloric intake level and emphasizes gradually shaping behavior toward a lower caloric intake. A similar amount of weight loss has been reported (or can be estimated from data reported) at about 3 months for African-American participants in the weight loss intervention arms of TONE and similar trials [5,18–21,33]. Weight change at 3 months among the African-American controls in these trials was negligible, e.g., −0.1 to +0.3 kg, suggesting that the HELP Phase 1 weight loss can be taken at face value.

The Phase 2 results were surprising. We had expected that participants assigned to at least one of the two interventions tested would have either significant additional weight loss or significantly better weight loss maintenance compared to those assigned to Clinic Visits Only. This expectation was based on the fact that many studies observe continued weight loss through the first 6 months before a plateau occurs [1] and also on a TONE finding which suggested that some African-American participants who were not initially successful in losing weight did begin to lose weight during the phase of biweekly and monthly contact [21]. We have no clear explanation for why the considerable additional contact provided in the Phase 2 active interventions was not more effective. This result could be due to constraints imposed by the setting, design, and staffing. For example, offering the HELP Phase 2 classes at only one time per week, regardless of participant scheduling preferences, could have decreased participation. For the Self-HELP condition, the low response to the initial approach to facilitation could have limited overall effectiveness in the first two cohorts. The discontinuity and delay between Phase 1 and the randomized Phase 2 are other possible negative influences. For example, results might have differed if Phase 2 interventions had retained the Phase 1 class groups, to take advantage of supportive relationships that might have developed in these classes, or had begun immediately after the end of the Phase 1 classes.

Another possibility is that the contact frequency during Phase 2 was not adequate to promote further weight loss in either HELP Classes or Self-HELP. The U.S. Preventive Services Task Force (USPSTF) evidence review [34,35] supported the potential utility of "high intensity" counseling interventions, defined as more than 1 face-to-face counseling session (individual or group) per month for at least the first 3 months, to promote weight loss and recommended that such programs be offered in conjunction with maintenance programs. By this definition, the HELP Phase 1

program was a high-intensity intervention. However, monthly contact, the predominant mode in HELP Phase 2 and the level that we considered feasible as potentially sustainable in usual practice, constitutes only medium level intervention in the USPSTF classification, and there was insufficient evidence that monthly contact is adequate to produce sustained weight loss.

The USPSTF did not define the type of maintenance intervention recommended. Semi-annual follow up clinic visits, as provided to all HELP Phase 2 participants, might be sufficient. Outside of any assistance obtained from their personal physicians (which was not tracked), these semi-annual visits were the only Phase 2 contact for participants in the Clinic Visits Only arm, who had no weight regain on average over 8–19 months. The usual observation in weight control programs is gradual weight regain once the active intervention is withdrawn, and secular trends of gradual weight gain in usual care participants given no active intervention [1,34,35]. African-American participants in the TOHP II weight loss intervention had lost 2.3 kg by 6 months (a loss of 2.7 after adjustment for a 0.4 kg weight gain in usual care), but regained 2.1 kg (1.8 kg after adjustment for a further gain of 0.3 kg in usual care) between 6 and 18 months of follow-up, to a level that was only 0.2 below baseline weight (−0.9 kg after adjustment for weight gain in usual care) at 18 months [20]. Our results, showing relatively little regain, were more similar to those in TONE: negligible and statistically insignificant weight change between 6 months and the last on-study measurement about 19 months later (mean −0.3 kg or +0.7 kg after adjustment for usual care), and a final weight loss of 3.2 kg (2.0 kg after adjustment for usual care) below baseline [21]. The rate of weight regain after intensive intervention has been positively correlated with the rate of initial weight loss, supporting the advisability of initial interventions that promote gradual rather than rapid weight loss [1]. Our finding that Phase 1 weight loss was the strongest and only significant predictor of final weight loss could, therefore, reflect the sustainability of gradual weight changes made by the subset of Phase 1 participants who were successful in losing a modest amount of weight.

Taken together, our findings are encouraging with respect to feasibility, acceptability, maintenance of initial effect, and associated positive changes in blood pressure and lipids. Nevertheless, the overall 1.2 kg weight loss is less than the expected 3–5 kg benefit noted in the USPSTF guidelines [34] and is clinically unimpressive in a population weighing an average of 103 kg upon enrollment. We believe that efforts to improve HELP outcomes should focus specifically on increasing the proportion who lose weight in Phase 1, i.e., achieving some weight loss in all participants rather than simply increasing the average weight loss by any means. Only about half of participants lost weight even in the best-case scenario confined to study completers, but the weight loss for this subset was substantial.

Being married, having later onset obesity, and having more prior weight loss program experience were the only baseline variables that appeared to predict better weight loss, and these were not strong relationships. This makes it difficult to identify non-responders at the outset for special consideration or even referral to other types of programs. A stronger focus on proven behavioral change strategies such as self-monitoring of food intake and physical activity and regular weighing at intervention sessions [1,35] may also be helpful. These strategies were encouraged in HELP Phase 1 but not required. Offering make up sessions to those who miss classes does not seem indicated given the potential expense and the lack of observed association of weight loss with attendance. Offering more than 10 weeks of initial classes might be of benefit but would also increase costs.

We identified some potentially relevant published studies that tested logical strategies to improve weight loss in African-Americans or in clinical settings but found no new insights about how to improve the program. Mayer-Davis et al. [12] found no benefit of adding formal evaluation for continuous quality improvement in a behavioral weight loss pilot program with a predominantly African-American sample of adults with Type 2 diabetes. Raghuwanshi et al. [13] found no benefit of charging fees or imposing specific attendance requirements to improve outcomes of a very low calorie diet program. Yeh et al. [36] evaluated a highly-structured skill building intervention (SBI) based on the Pressure System Model, among middle income white women, that included group education, experiential learning in supermarkets, and an individualized home visit. Their hypothesis that long-term results would be superior to the more costly individualized counseling-based intervention (CBI) was not supported: weight changes were: −1.7, −0.77, and −0.59 kg from baseline, respectively, at 6, 12, and 24 months in the SBI group compared with −3.99, −1.81, and −1.09 kg at these times in the CBI group.

Given the paucity of weight loss studies in high-risk ethnic minority populations and the need for translation from efficacy to effectiveness [22, 35], several strengths of this study can be identified: the focus on African-Americans, basing the core intervention program on an approach previously found to be efficacious, the apparent acceptability of the program to the participants, our inclusiveness with respect to age, BMI range, and presence of comorbidities, and an implementation model that was sensitive to the realities and constraints of a typical practice setting. The randomized design of Phase 2 is a strength in one respect, although the resulting artificial discontinuity between Phases 1 and 2 is problematic for interpretation.

With respect to limitations, the possible suboptimal implementation of the Phase 1 physical activity component and of the Phase 2 active intervention conditions may lead to an understatement of the potential for program effectiveness. The less than complete follow-up for data collection is also a limitation. Even though identifiable differences be-

tween completers and non-completers were minimal in Phase 1 and absent in Phase 2, differential drop out based on motivation or feasibility cannot be fully assessed from the data available. On the other hand, retention of 80% of Phase 1 attenders and 68% of randomized participants in Phase 2, without payments to participants for visit completion, was better than in many published reports of clinical studies or among African-Americans in any setting [6,36,37].

An additional limitation is the inability to partition results based on the specific study components. For example, cultural adaptations were included–including advertising the program to and delivering it within an African-American-only sample–but we are unable to assess the extent to which these adaptations actually influenced outcomes. We did not assess potential effects of ethnicity of the intervention staff, although this would be difficult to separate from other staff characteristics. We assessed satisfaction with clinic monitoring and counseling visits, but did not separately assess the perceived benefit of the physician counseling component of these visits. Given the expense and logistical issues involved in arranging time for the physician visit, it would have been useful to know whether this aspect could be eliminated (e.g., replaced with brief counseling by another health professional) without influencing initial weight loss or subsequent maintenance.

The translation of lifestyle interventions from efficacy studies for effectiveness in routine clinical settings is influenced by logistics, financial and staffing resources, as well as participant ethnic and socioeconomic status diversity, clinical characteristics, and motivations [22]. If viewed as a "glass half-full", the HELP program has the potential for producing clinically significant, sustainable weight loss in a substantial proportion of participants with a level of resource inputs that might be feasible for usual practice settings. Cost analyses of this program have not been done, but the resources needed can be estimated approximately as follows: 10 classes of 15 each delivered by a team of two nutrition and physical activity behavior change specialists consulting at about $35 per hour, allowing a 4-h period to prepare and deliver a 90-min class = $187 per person for the Phase 1 program. The additional cost of 6 individual 30-min assessment and counseling visits (months 0, 3, 6, 12, 18, and 24) at $35 per hour of counselor time would add $105, for a total 2-year direct cost of $292 or less than $146 per person per year. Considering the extreme high costs of obesity [38] to our health care system, the investment of resources at this level would seem worthwhile, particularly if the proportion of responders can be improved based on the insights obtained here.

Acknowledgments

This study was funded by a grant from the American Heart Association National Center (#9970068N). Partial support was also provided by a General Clinical Research Center Grant from the National Institutes of Health/ National Center for Research Resources (# M01 RR00040) and by the Penn-Cheyney EXPORT Center for Inner City Health (National Institutes of Health/National Center for Minority Health and Health Disparities, grant # P60MD000209).

References

[1] Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults—The Evidence Report. National Institutes of Health. Obes Res 1998;6(Suppl 2):51S–209S.
[2] U.S. Department of Health and Human Services. The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville (MD): U.S. Department of Health and Human Services; 2001.
[3] Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults, 1999–2000. JAMA 2002;288 1723–7.
[4] Must A, Spadano J, Coakley EH, Field AE, Colditz G, Dietz WH. The disease burden associated with overweight and obesity. JAMA 1999; 282:1523–9.
[5] Agurs-Collins TD, Kumanyika SK, Ten Have TR, Adams-Campbell LL. A randomized controlled trial of weight reduction and exercise for diabetes management in older African-American subjects. Diabetes Care 1997;20:1503–11.
[6] Kumanyika SK. Obesity Treatment in Minorities. In: Wadden TA, Stunkard AJ, editors. Handbook of Obesity Treatment. New York: Guilford Press; 2002. p. 416–46.
[7] Ard JD, Rosati R, Oddone EZ. Culturally-sensitive weight loss program produces significant reduction in weight, blood pressure, and cholesterol in eight weeks. J Natl Med Assoc 2000;92:515–23.
[8] Karanja N, Stevens VJ, Hollis JF, Kumanyika SK. Steps to soulful living (steps): a weight loss program for African-American women. Ethn Dis 2002;12:363–71.
[9] Yanek LR, Becker DM, Moy TF, Gittelsohn J, Koffman DM. Project Joy: faith based cardiovascular health promotion for African American women. Public Health Rep 2001;116:68–81.
[10] Oexmann MJ, Thomas JC, Taylor KB, et al. Short-term impact of a church-based approach to lifestyle change on cardiovascular risk in African Americans. Ethn Dis 2000;10:17–23.
[11] Oexmann MJ, Egan BM. Efficacy of a church-based intervention on cardiovascular risk reduction. Ethn Dis 2001;11:817–22.
[12] Mayer-Davis EJ, D'Antonio A, Martin M, Wandersman A, Parra-Medina D, Schulz R. Pilot study of strategies for effective weight management in type 2 diabetes: Pounds Off with Empowerment (POWER). Fam Commun Health 2001;24:27–35.
[13] Raghuwanshi M, Kirschner M, Xenachis C, Ediale K, Amir J. Treatment of morbid obesity in inner-city women. Obes Res 2001;9:342–7.
[14] Walcott-McQuigg JA, Chen SP, Davis K, Stevenson E, Choi A, Wangsrikhun S. Weight loss and weight loss maintenance in African-American women. J Natl Med Assoc 2002;94:686–94.
[15] Darga L, Holden JH, Olson SM, Lucas CP. Comparison of cardiovascular risk factors in obese blacks and whites. Obes Res 1994; 2:239–45.
[16] Wing RR, Anglin K. Effectiveness of a behavioral weight control program for blacks and whites with NIDDM. Diabetes Care 1996;19: 409–13.
[17] Yanovski SZ, Gormally JF, Leser MS, Gwirtsman JY. Binge eating disorder affects outcome of comprehensive very low calorie diet treatment. Obes Res 1994;2:205–12.
[18] Kumanyika SK, Obarzanek E, Stevens VJ, Hebert PR, Whelton PK, Kumanyaka SK. Weight-loss experience of black and white partic-

ipants in NHLBI-sponsored clinical trials. Am J Clin Nutr 1991;53: 1631S–8S.
[19] Wylie-Rosett J, Wylie-Rosett J, Wassertheil-Smoller S, et al. Trial of antihypertensive intervention and management: greater efficacy with weight reduction than with a sodium–potassium intervention. J Am Diet Assoc 1993;93:408–15.
[20] Stevens VJ, Obarzanek E, Cook NR, et al. Weight loss and blood pressure changes over a three to four year follow up. Results of the trials of hypertension prevention—phase II. Ann Intern Med 2001;134:1–11.
[21] Kumanyika SK, Espeland MA, Bahnson JL, et al. Ethnic comparison of weight loss in the trial of nonpharmacologic interventions in the elderly. Obes Res 2002;10:96–106.
[22] Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. Am J Public Health 2003;93: 1261–7.
[23] Nutrition and Your Health: Dietary Guidelines for Americans. Washington DC: U.S. Departments of Agriculture and Health and Human Services; Fifth Edition Home and Garden Bulletin No. 232; 2000.
[24] Appel LJ, Espeland M, Whelton PK, et al. Trial of nonpharmacologic intervention in the elderly (TONE). Design and rationale of a blood pressure control trial. Ann Epidemiol 1995;5:119–29.
[25] Kumanyika SK, Morssink CB. Cultural appropriateness of weight management programs. In: Dalton S, editor. Overweight and Weight Management. Gaithersberg, MD: Aspen; 1997. p. 69–106.
[26] Kumanyika SK, Adams-Campbell L, Van Horn B, et al. Outcomes of a cardiovascular nutrition counseling program in African-Americans with elevated blood pressure or cholesterol level. J Am Diet Assoc 1999;99:1380–91.
[27] Gans KM, Kumanyika SK, Lovell HJ, et al. The development of SisterTalk. A cable TV-delivered weight control program for black women. Prev Med 2003;37:654–67.
[28] Tomey K, Kumanyika S, Odoms A, James V. What's in My Food? game with food picture cards. GEM No. 310. J Nutr Educ 1999;31:360A.
[29] Perloff DGC, Flack J, Frohlich ED, Hill M, McDonald M, Morgenstern BZ. Human blood pressure determination by sphygmomanometry. Circulation 1993;88:2460–70.
[30] StataCorp. Stata Statistical Software: Release 8.0. College Station, TX: StataCorp LP; 2003.
[31] Thomas Paul R, editor. for the committee to develop criteria for evaluating the outcomes of approaches to prevent and treat obesity. Weighing the options. Criteria for evaluating weight-management programs. Washington (DC): National Academy Press; 1995.
[32] Shults J, Chaganty NR. Analysis of serially correlated data using quasi-least squares. Biometrics 1998;54:1622–30.
[33] Kumanyika SK. The impact of obesity on hypertension management in African Americans. J Health Care Poor Underserved 1997;8(3): 365–78.
[34] U.S. Preventive Services Task Force. Screening for obesity in adults. Recommendation and rationale. Ann Intern Med 2003;139: 930–2.
[35] McTigue KM, Harris R, Hemphill B, Lux L, Sutton S, Bunton AJ, et al. Screening and interventions for obesity in adults. Summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003;139:933–49.
[36] Yeh M-C, Rodriquez E, Nawaz H, Gonzalez M, Nakamoto D, Katz DL. Technical skills for weight loss: 2 year follow-up results of a randomized trial. Int J Obes 2003;27:1500–6.
[37] Bronner Y, Boyington JE. Developing weight loss interventions for African-American women: elements of successful models. J Natl Med Assoc 2002;94:224–35.
[38] Finkelstein EA, Fiebelkorn IC, Wang G. State-level estimates of annual medical expenditures attributable to obesity. Obes Res 2004 (Jan);12(1):18–24.