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Design of the Rural LEAP Randomized Trial: An Evaluation of Extended-Care Programs for Weight Management Delivered via Group or Individual Telephone Counseling

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Abstract

Obesity is a major contributor to the greater prevalence of chronic disease morbidity and mortality observed in rural versus nonrural areas of the U.S. Nonetheless, little research attention has been given to modifying this important driver of rural/urban disparities in health outcomes. Although lifestyle treatments produce weight reductions of sufficient magnitude to improve health, the existing research is limited with respect to the long-term maintenance of treatment effects and the dissemination of services to underserved populations. Recent studies have demonstrated the feasibility of delivering lifestyle programs through the infrastructure of the U.S. Cooperative Extension Service (CES), which has more than 2,900 offices nationwide and whose mission includes nutrition education and health promotion. In addition, several randomized trials have shown that supplementing lifestyle treatment with extended-care programs consisting of either face-to-face sessions or individual telephone counseling can improve the maintenance of weight loss. However, both options entail relatively high costs that inhibit adoption in rural communities. The delivery of extended care via group-based telephone intervention may represent a promising, cost-effective alternative that is well suited to rural residents who tend to be isolated, have heightened concerns about privacy, and report lower quality of life. The Rural Lifestyle Eating and Activity Program (Rural LEAP) is a randomized trial, conducted via CES offices in rural communities, targeted to adults with obesity (n=528), and designed to evaluate the effectiveness and cost-effectiveness of extended-care programs delivered via group or individual telephone counseling compared to an education control condition on long-term changes in body weight.

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Disclosure statement

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Obesity; obesity management; weight loss; rural health services; cost-benefit analysis

1. Introduction

Obesity disproportionately affects Americans living in rural areas and contributes to higher prevalences of chronic diseases and all-cause mortality observed in rural versus nonrural communities [1–6]. In rural areas, the convergent effects of poverty, low educational attainment, limited access to preventive health services, and cultural factors regarding diet and exercise contribute to higher rates of obesity and associated diseases [7–13].

Weight loss can reverse many of the adverse consequences linked to obesity [14]. According to national guidelines [15] and literature reviews [16–20], the most effective means of achieving weight reductions at the individual level is comprehensive lifestyle treatment. Participants in lifestyle interventions are taught behavioral strategies (e.g., goal setting and selfmonitoring) to modify their eating and physical activity patterns so as to produce a negative energy balance and weight loss. Comprehensive lifestyle treatment routinely results in weight losses of 5–10% [16–20]. Reductions of this magnitude can produce beneficial effects on hypertension, glucose intolerance, and hyperlipidemia, and can prevent the onset of type 2 diabetes [15,21–23].

The limited availability of obesity treatment options in rural communities prevents many residents from engaging in weight-control efforts [24]. With a nationwide network of more than 2,900 offices and a mission that includes nutrition education and health promotion, the Cooperative Extension Service (CES) [25,26] has the potential to play an important role in providing treatment for obesity in rural communities.

While lifestyle interventions can produce clinically meaningful weight reductions, the long-term maintenance of those losses remains a challenge. Without follow-up care, participants commonly regain one-third to one-half of their initial weight loss within one year [18,27–31]. Providing extended care via face-to-face sessions improves long-term outcomes [28,32], but is time- and cost-intensive [29,33,34], thereby limiting adoption in low-resources settings. Delivering extended care via telephone counseling may decrease the burdens associated with face-to-face treatment while producing equivalent weight-loss outcomes [35].

Most studies supporting phone-based interventions (e.g., [31,35]) have utilized *individual* telephone counseling, which requires a significant amount of provider time and consequently poses a major barrier to widespread implementation. Group-based phone counseling may overcome this challenge, but evidence of its effectiveness is limited. Befort and colleagues [36] found that group phone counseling produced weight losses equivalent to individual phone counseling, but at lower costs, and in a subsequent trial [37] showed that

extended care delivered via group phone counseling improved weight-loss maintenance compared with a newsletter control group. In an efficacy study conducted largely with urban participants, Donnelly et al. [38] found equivalent outcomes for lifestyle treatment delivered via face-to-face sessions versus group conference call counseling. However, the impact of extended-care interventions delivered via group- versus individual telephone counseling in less resourced, rural areas remains unknown.

The Rural Lifestyle Eating and Activity Program (Rural LEAP) is a randomized trial designed to evaluate the comparative effectiveness and cost efficiency of three methods of delivering extended-care counseling for weight-loss maintenance in rural communities. The intervention is delivered through the infrastructure of the CES, and the primary outcome is weight change over the course of 18 months following initial treatment.

2. Methods

2.1. Overview

The study consists of three distinct phases: (1) Phase I, a non-randomized 4-month weight-loss phase (Months 1 through 4) during which all participants received the same face-to-face group lifestyle intervention for weight loss; (2) Phase II, a 12-month extended-care phase (Months 5 through 16) during which participants receive additional treatment according to randomized assignment to group-based (GRP) phone counseling, individual-based (IND) phone counseling, or an education control (CTRL) group; and (3) Phase III, a 6-month no-contact follow-up period (Months 17 through 22).

2.2. Participants

The study was approved by the Institutional Review Board of the University of Florida. Participants included 528 adults, 21–75 years of age, with body mass indices (BMI) of 30–45 kg/m^2. Eligible participants were free of uncontrolled diabetes and hypertension and had no active manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease. Exclusion criteria included the use of medications known to affect body weight, musculoskeletal conditions that precluded walking for 30 minutes, and weight loss > 4.5 kg in the preceding 6 months. Psychosocial contraindications included clinically significant depression and substance abuse.

2.3. Recruitment and Screening

Study announcements were mailed to residential addresses within 14 rural counties in northern Florida [39]. All 14 counties were designated in whole or in part as “Health Professional Shortage Areas” [40]. In response to the mailings and other outreach activities (e.g., presentations at churches and community events), 851 adults completed a preliminary telephone screening and met basic eligibility criteria for study participation. An in-person screening visit was then conducted at a local CES site during which the study was described and informed consent was obtained. At the screening visit, a medical history was collected, and a study nurse measured the potential participant’s height, weight, and resting blood pressure, and a fasting blood sample was drawn and analyzed for metabolic and lipid profiles. Following review of the screening visit results, 220 individuals were excluded, 103

individuals declined to participate, and the remaining 528 were enrolled into Phase I of the study (see Figure 1).

Baseline characteristics of Phase I participants, those not randomized to Phase II, and participants randomized to Phase II are shown in Table 1. The study sample was composed largely of middle-aged, White, non-Hispanic women, with a high school diploma or GED as their highest level of education, and a mean BMI in the Class II obesity range [41]. Approximately half of participants had an annual household income less than $50,000. Chi-square tests were conducted for differences in the categorical demographic variables between participants not randomized to Phase II and those randomized to Phase II. The only variable that was significant was Obesity Class, X^2 (2, n = 528) = 6.49, p = .04 (unadjusted for multiple comparisons), with a larger of percentage of individuals with Class III obesity among those not randomized to Phase II.

2.4. CES Offices and Interventionists

The initial weight-loss intervention in the current trial is delivered on site via CES sites in 14 rural counties in northern Florida. All 14 counties have a centrally-located site available for the intervention. Interventionists are CES Family and Consumer Sciences Agents or individuals with a bachelor's or master's degree in nutrition, exercise science, or psychology. Fifty percent of the counties employed local CES Agents with the remaining sites employing other qualified individuals to conduct the intervention. All interventionists were provided with training in lifestyle treatment and nutrition education that included two 8-hour workshops held semi-annually, plus case management reviews with a clinical health psychologist (MGP) or registered dietitian (MNS), each with extensive experience overseeing behavioral interventions for obesity. The case management reviews are conducted weekly during Months 1 through 4, biweekly during Months 5 through 10, and monthly during Months 11 through 16. Interventions sessions are audio-taped and random reviews are carried out to ensure treatment fidelity. Corrective feedback is provided during training, case management reviews, or individually with the interventionists.

2.5. Phase I Lifestyle Intervention

Phase I consisted of 16 weekly face-to-face group sessions conducted at local CES offices. Each group consisted of 4–16 participants, and each session lasted approximately 90 minutes. Intervention content was derived from the Diabetes Prevention Program (DPP) [42,43]. Modifications to the DPP approach included group rather than individual counseling [44] and home-based rather than center-based physical activity [45]. The DPP intervention was further modified to address weight-management challenges experienced by individuals living in rural areas (i.e., lack of places to exercise, traditions of high-fat Southern cooking, absence of social support for weight loss, etc.). Similar to the DPP, the Rural LEAP intervention was guided by social-cognitive and self-regulation theories [46–48] and incorporated key behavioral modification strategies including goal setting, self-monitoring of dietary intake and physical activity, stimulus control, cognitive restructuring, and problem solving [33]. Utilization of problem-solving skills, in particular, was emphasized as a way to address the specific challenges experienced by adults living in rural

communities [49,50]. Topics and objectives for the 16 Phase I and 18 Phase II weight-loss treatment modules are presented in Table 2.

The goals of the initial lifestyle intervention were to decrease caloric intake in a nutritionally sound manner [51–53] so as to produce a weight loss of approximately 0.4–0.9 kg per week and to increase home-based walking to 210 minutes per week [54]. Initial caloric intake goals were determined by the participant's baseline weight (e.g., 1200 kcal/day for participants weighing ≤ 113.6 kg; 1500 kcal/day for those weighing > 113.6 kg). Participants were instructed to keep daily logs of their food and drink intake, including the types and amounts of foods consumed along with corresponding caloric values, using either written logs or online programs/applications (e.g., MyFitnessPal® or Lose It!®). Participants were also instructed to keep daily records of their steps using a pedometer or activity monitor. To support these self-monitoring efforts, participants were provided, at no cost, with a *Calorie King* reference book [55,56], blank food logs, measuring cups, a food scale, and a clip-on pedometer. As a substitute for the use of a pedometer, participants were permitted to self-monitor physical activity via self-purchased electronic tracking devices (e.g., Fitbit®, Garmin®, or Apple Watch®).

Participants were encouraged to work toward meeting their daily caloric intake goals by selecting lower-calorie food options, decreasing consumption of "fast food," decreasing or eliminating sugar-sweetened beverages, increasing consumption of fruits, vegetables, and whole grains, and using lower-fat methods of preparing foods. Weight-loss treatment modules included instruction on the USDA's *MyPlate* to emphasize choosing whole grains, fruits, vegetables, lean meat, and low-fat dairy products [51].

Walking was the primary form of prescribed physical activity. During week 2, each participant's steps were monitored over 7 days, and then participants were encouraged to gradually increase their planned daily walking time by 5–10 minutes (i.e., 500–1000 steps) each week as tolerated until they reached an average of 30 minutes/day (3000 steps) above their baseline level. Participants who achieved this objective were encouraged to further increase their steps toward an ultimate goal of 60 min/day of walking for exercise (i.e., 6000 steps above baseline).

2.6. Phase II Randomization and Extended-Care Lifestyle Intervention

To maximize participation in the randomized and follow-up phases (II and III) of the trial, only those individuals who attended fewer than 50% of the Phase I sessions were excluded from advancing to Phase II randomized assignments. All other participants, regardless of initial weight loss achieved, were randomly assigned to one of the three Phase II conditions (GRP, IND, or CTRL). Randomization was completed by the study statistician (MJD) using the random number generator in R statistical computing software [57]. County size, county, Phase I group, and session time were balanced during randomization. Interventionists notified participants of their Phase II group assignment during the last Phase I session. The primary objectives of Phase II (Months 5–16) are to sustain the lifestyle changes accomplished in Phase I so as to maintain lost weight and to make further adjustments in energy balance to produce additional weight loss during "campaigns" conducted in Months 8–9 and Months 13–14.

The mode of extended-care contacts differs by condition during Phase II, but the schedule of contacts is consistent across the conditions. Intervention contact across all three conditions occurs bi-weekly during Month 5 through 10 and monthly during Months 11 through 16. At each of the scheduled contact points, participants in all three conditions receive a weight-loss treatment module delivered via e-mail or U.S. mail with information and recommended behavioral activities targeted at maintaining lost weight. All participants are also provided with a supply of blank self-monitoring logs and pre-paid mailers for returning completed dietary logs to the interventionists.

2.6.1. GRP condition—Participants randomized to the GRP condition call into a teleconference line for 60-minute group sessions with the interventionist and other members from their Phase I group. The calls include three primary components: (1) a group "check-in" during which participants report progress toward goals and problems experienced since the previous session coupled with group problem solving of one or two complex issues to address barriers to progress [49]; (2) group discussion of the treatment module with the interventionist explaining new objectives and suggesting behavioral strategies to achieve those objectives; and (3) structured individual goal setting with respect to each participant's plans for diet and/or physical activity changes to be accomplished prior to the next session. To maximize the time efficiency of the group session, all participants are asked to identify their calorie and step goals *prior* to the call.

The group problem-solving activities facilitated by the interventionist during the extended-care sessions incorporates the use of an evidence-based, five-step model [49,50] including: (1) orientation (i.e., developing an appropriate coping perspective -- "Problems are a normal part of managing your weight, but they can be dealt with effectively."); (2) definition (i.e., specifying the problem and goal behaviors - "What is the particular problem facing you right now? What is your goal in this situation?"); (3) generation of alternatives (i.e., brainstorming potential solutions - "The greater the range of possible solutions you consider, the greater your chances of developing an effective solution."); (4) decision making (i.e., anticipating the probable outcomes of different options - "What are the likely short- and long-term consequences of each of your options?"; and (5) implementation and evaluation (i.e., trying out a plan and evaluating its effectiveness - "What solution plan are you going to try and how will you know if it works?").

2.6.2. IND condition—Participants randomized to the IND condition call into a teleconference line at a predetermined appointment time for a one-on-one, 10- to 20-minute session with the interventionist. Participants are contacted to schedule make-up calls in the event of time conflicts or missed calls. Aside from the difference in call length and the absence of other group members, IND calls include the same structure, components, and problem-solving focus of the GRP calls.

2.6.3. CTRL condition—Participants in the CTRL group receive a series of 18 written educational weight-loss treatment modules delivered via e-mail or U.S. mail delivered on the same schedule as the GRP and IND contacts during Phase II. The modules include the identical content used in the GRP and IND conditions. The CTRL condition does not

include any scheduled phone or in-person interactions with the interventionists or other participants.

2.7. Measures

2.7.1. Assessment visits—Study personnel masked to participant randomization conduct in-person assessment visits at baseline and at Months 4, 10, 16, and 22. Assessment visits are conducted at the same local CES site for all time points. Self-reported medical history and a list of medications are updated at each assessment visit.

2.7.2. Anthropometrics—At baseline, height is measured using a stadiometer (ShorrBoard®), with participant shoes removed. At baseline and subsequent assessment visits, weight is measured with a calibrated digital scale (Tanita BWB-800S), with participants in light indoor clothing, pockets emptied, and shoes removed.

2.7.3. Fasting blood samples—Fasting blood samples are obtained by the study nurse at baseline and at Months 4 and 22 and analyzed for metabolic and lipid profiles by Quest Diagnostics®.

2.7.4. Resting blood pressure and heart rate—Blood pressure and heart rate are measured at baseline and Months 4 and 22. Measurements are taken while the participant is seated with feet resting on the floor for five minutes in a quiet room free of distractions. Resting systolic and diastolic blood pressure are taken three times, two minutes apart, using a Dinamap® Automated Vital Signs Monitor with appropriate cuff size; the second and third readings are entered and averaged in the study database.

2.7.5. 400 Meter Walk Test—The 400 Meter Walk Test [58], a standardized measure of physical fitness commonly used to assess individuals with chronic health conditions, is completed at baseline, and at Months 4 and 22 to assess fitness.

2.7.6. Participant questionnaires—The following questionnaires are completed by the participants at baseline and at Months 4, 10, 16, and 22.

2.7.6.1. Paffenbarger Physical Activity Questionnaire: Self-reported physical activity is collected via the Paffenbarger Physical Activity Questionnaire [59], which includes questions on distance walked, flights of stairs climbed, and time spent in other sports, recreational, or fitness activities during a typical day or week.

2.7.6.2. Medical Outcomes Study 36-Item Short Form Health Survey (SF-36): The SF-36 [60] is a quality-of-life measure that assesses the following domains: (a) physical functioning; (b) role limitations due to physical health; (c) bodily pain; (d) general health; (e) vitality; (f) social functioning; (g) role limitations due to emotional problems; and (h) mental health [61].

2.7.6.3. Social Problem-Solving Inventory-Revised (SPSI-R): The SPSI-R [62–64] is a 52-item questionnaire that evaluates positive versus negative problem orientation and problem-solving style.

2.7.6.4. Social Provisions Scale: The 24-item Social Provisions Scale [65,66] measures perceived support from others in one's social network.

2.7.6.5. Cost Analysis Questionnaire: The cost analysis questionnaire [35] assesses direct and indirect costs of lifestyle interventions.

2.7.6.6. Health Thermometer: The Health Thermometer is a visual analog scale [67] that measures health-related quality of life on a scale of 0 to 100 with 0 indicating the "worst imaginable health state" to 100 indicating the "best imaginable health state."

2.7.6.7. Program Satisfaction and Group Leader Evaluation Forms: Participant ratings of program satisfaction, the usefulness of specific treatment strategies (e.g., self-monitoring, cognitive restructuring, etc.), and the effectiveness of interventionists are completed at Months 4, 10, 16, and 22.

2.8. Participant Retention Strategies

Participants receive payments on a study-provided credit card of $50 upon completion of the Month 4 visit, $20 upon the completion of the Month 10 and Month 16 visits, and $75 upon completion of the Month 22 visit. Participants also receive $10 as travel reimbursement for each of the in-person sessions attended during Phase I.

2.9. Data Management and Statistical Analyses

2.9.1. Data management—Data are stored in a database via the Research Electronic Data Capture (REDCap) system [68], a secure web-based data management system supported by the University of Florida Clinical and Translational Science Institute. Self-report data are entered directly by participants into REDCap's online survey module. All other data are entered by study personnel according to the protocol and in compliance with the U.S. Health Insurance Portability and Accountability (HIPAA) Privacy Rule. Data will be exported to a SAS dataset for statistical analyses [69].

2.9.2. Missing data—Data analyses for this effectiveness trial will be performed using an intent-to-treat approach that includes all randomized participants. It will be assumed that individuals who discontinue participation in the study prior to Month 22 regained weight, on average, at a rate of 0.3 kg per month after leaving the study, up to their baseline weight. This conservative approach to imputing missing weight values has been employed by numerous prior studies [34,35,70] and is consistent with published reviews of weight regain following lifestyle treatment for obesity [18,71,72]. To account for the uncertainty regarding the exact amount of weight regained, the corresponding (co-)variance of these regain values will be identified under assumptions consistent with missing at random for the covariance structure [73,74]. Sensitivity to the assumptions about the missing data [75] will be examined in our final analysis.

2.9.3. Sample size justification—The primary outcome will be change in body weight from Month 4 to Month 22, comparing the GRP and IND phone-based conditions to the education CTRL condition. It is assumed that the county size, county, and session time

effects will be negligible due to the balance in the randomization assignments. The analysis will, however, take into account a random effect that allows for correlation among individuals in the same GRP sessions. Based upon prior studies [35,76], a 20% attrition rate is expected by Month 22. The recruitment target included a total of 540 individuals entering Phase I (180 per condition). Power calculations were computed using the expected attrition rate and a Bonferroni adjustment to account for comparisons of the three treatment conditions. The study is expected to have > 80% power (two-sided tests, type I error rate of 0.05) to detect a 2.5 kg difference in regain from Month 4 to Month 22 between GRP vs. CTRL and IND vs. CTRL.

2.9.4. Primary analyses—Participants' weight change will be calculated as the difference between weight in kilograms at Month 22 and weight at Month 4. The primary hypothesis is that both the GRP and IND telephone conditions will produce greater weight reductions at Month 22 than the education CTRL condition. To test this hypothesis, a mixed model for longitudinal data will be utilized. Fixed effects will include treatment condition, time since study initiation, and session time. Random effects will include county. The GRP arm will also include a random effect for group. Treatment condition was randomly assigned, with session times serving as blocking factors. Two primary contrasts of interest will be tested for significance: GRP vs. CTRL and IND vs. CTRL. Bonferroni corrections will be used to control for type I error. Covariates (e.g., age, race, initial weight loss) can be included in the model and analyzed using the same procedure in SAS. It is not anticipated that the effects of county or session time will be of consequence.

2.9.5. Secondary analyses—For the secondary aim, the outcome of interest is the proportion of participants within a treatment condition who lost ≥ 5% of body weight by Month 4 and then maintained a ≥ 5% loss in body weight at Month 22. It is hypothesized that both the GRP and IND conditions will result in greater proportions of participants maintaining ≥ 5% losses at Month 22 than the CTRL condition. Two contrasts will be tested for significance: GRP vs. CTRL and IND vs. CTRL. Each contrast will use an exact test for binomial proportions to test the null hypothesis that the relevant proportions are equal versus the alternative that they are not equal. Bonferroni corrections will be used to control for type I error.

2.9.6. Additional analyses

2.9.6.1. Exploratory analyses.: Changes from Month 4 to Month 22 will be examined for systolic and diastolic blood pressure, resting heart rate, blood lipids profile (LDL and HDL cholesterol and triglycerides), glycemic control (HbA1c), dietary intake, self-reported physical activity, physical performance (400 Meter Walk Test [58]), and health-related quality of life. Process measures will include intervention-related activities (e.g., attendance, self-monitoring) and participants' evaluation of program components and interventionist effectiveness. These endpoints are continuous variables, and analyses will be the same as that described for the primary endpoint. No adjustments will be made for multiple comparisons due to the exploratory nature of these analyses.

2.9.6.2. Moderator analyses.: Age, race/ethnicity, socioeconomic status, and social support differences across participants and counties [77] will be evaluated as potential moderators of the effect of the intervention conditions on weight change at Month 22.

2.9.6.3. Mediator analyses.: Completion of written self-monitoring records (percent of days with records) and change in problem-solving skills (change in SPSI-R total score) will be evaluated as key mediators of the relationship between the intervention conditions and weight change at Month 22. In a previous study conducted by our research team [35], completion of written self-monitoring records during initial treatment (number of days recorded from baseline to Month 6) was the single best behavioral predictor of weight change at Month 18 ($r = .51$), and change in problem-solving skills also showed a significant positive association with long-term weight change ($r = .19$). These findings provide support for an examination of weight-related vigilance (i.e., self-monitoring) and problem-solving abilities as potential mediators of long-term changes in body weight. Mediation analyses will be conducted using both traditional [78] and more recent nonparametric, formal causal approaches [79,80].

2.9.6.4. Cost-effectiveness analyses.: The analytic framework will follow the guidelines of the Second Panel on Cost-Effectiveness in Health and Medicine [81]. Costs of each condition will be tracked from the service provider perspective [35]. Cost effectiveness will be measured primarily as “dollars per kg loss per treatment condition” [82]. Cost effectiveness will also be measured according to the recommended clinical cut-points of maintaining ≥ 5% loss of initial weight [15]. Similar effectiveness for the GRP and IND conditions are expected, with lower effectiveness in the CTRL condition. Cost effectiveness will also be assessed based on Quality-Adjusted Life Year (QALY) gains related to weight change and will be calculated using data from the SF-36 questionnaires completed at baseline, Month 4, Month 16, and Month 22 to derive a preference score using the Short Form-6 Dimension (SF6D) method; 10 items from the SF-36 are used to calculate a QALY score [83,84].

Incremental cost effectiveness ratios (ICERs) will identify the differential costs and outcomes of switching from individual to group-based telephone counseling. A priori, it is expected that the GRP condition will be less expensive than the IND condition but with similar effectiveness. All costs will be adjusted to reflect constant 2017 dollars. Sensitivity analyses will be conducted to determine whether costs and cost-effectiveness estimates are sensitive to study-specific wage rates and other program costs. Extrapolation using sample median wage rates or national wage data will be calculated and the analysis will be rerun to determine any change in results. Additional sensitivity analyses will rely on either probabilistic models or tornado charts to gauge whether ICER results depend on various model assumptions.

2.10. Attrition

Phase I of the Rural LEAP Trial has been completed. The observed attrition rate at Month 4 was 15.7%. Based on previous studies [35,76], the expected attrition at Month 22 is 20%.

2.11. Weight Loss During Phase I

Weight loss over the first four weeks of Phase I treatment was compared for participants randomized to Phase II and those who did not qualify for randomization based on attendance at < 50% of Phase I sessions. During the first four weeks of Phase I treatment, participants randomized to Phase II had a mean weight loss of 2.1 kg (SD = 1.2), whereas those not randomized to Phase II had a mean weight loss of 0.8 kg (SD = 1.5).

Table 3 provides the mean weight and BMI changes at the completion of Phase I (Month 4) for participants who were randomized to Phase II. Table 3 also includes the percent of randomized participants who achieved different categories of weight loss.

3. Discussion

Rural LEAP is a randomized trial, conducted via CES offices in rural communities and designed to evaluate the effectiveness and cost-effectiveness of extended-care programs for weight management delivered via group or individual telephone counseling compared to an education control condition. Accomplishments to date include: (a) the recruitment of a diverse sample of 528 adults with obesity from 14 rural communities in Florida into the initial weight-loss phase of the trial; (b) the achievement of mean initial weight reduction of 8.3 kg; and (c) the advancement of 445 participants (84.3%) to the randomized extended-care phase of the trial. Those not randomized were more likely to have Class III obesity and a slow rate of initial weight loss. Overall, the results to date are on par with expectations, and the magnitude of initial weight loss is comparable to the reductions observed in large multi-site efficacy trials such as the DPP [23] and Look AHEAD [30].

Comprehensive lifestyle interventions can produce weight reductions of sufficient magnitude to improve health, but the existing research is limited with respect to two critical factors: (a) the long-term maintenance of treatment effects and (b) translation and dissemination to underserved populations. Most weight-loss trials have been efficacy studies, conducted with middle-class, urban and suburban participants and delivered by teams of experts working in academic medical centers. Very few trials have been conducted in medically underserved community settings with treatment delivered by local staff, and relatively little attention has been given to the maintenance of treatment effects. Two prior trials [35,76] have demonstrated the feasibility and effectiveness of delivering lifestyle programs through the existing infrastructure of the CES, which has offices covering more than 87% of the 1,889 rural counties in the U.S. [25,85].

Beyond demonstrating the feasibility of delivering weight-loss interventions via the CES, the TOURS Trial [35] showed that the long-term effects of obesity treatment can be enhanced via extended-care programs consisting of either face-to-face treatment sessions or individual telephone counseling. However, both of these options entail relatively high costs, which inhibit their adoption in rural communities. Group-based telephone counseling may represent a lower cost option for the delivery of extended-care programs for weight management in rural communities. Two trials conducted with residents of rural communities [36,37] demonstrated the effectiveness of weight-management interventions delivered via group-based, telephone conference calls. In a pilot study, Befort and colleagues [36] found

that group-based phone counseling produced weight losses equivalent to individual phone counseling, but at lower costs. In a subsequent trial, Befort et al. [37] showed that extended care delivered via group phone counseling improved the maintenance of weight loss compared with a newsletter control group. Thus, the use of conference call technology to deliver extended care combines the convenience of phone counseling with the benefits of group support, which may be especially important for rural residents who tend to be isolated, have heightened concerns about privacy, and report lower levels of quality of life [86].

Limitations of the current study should be noted, particularly with respect to the selection of an appropriate control group or comparison treatment and to the vexing challenge of widespread dissemination and implementation. Alternative control group and comparison treatment arms were considered, including the use of a no-treatment “waiting list” control group and an Internet-based comparison treatment. Rather than adopting either of these options, an education control group was included that provides participants with written modules focused on information and guidance regarding weight-loss maintenance. This option was deemed preferable to the use of a “waiting list” control group that would leave participants without ongoing assistance following initial treatment and potentially result in differential attrition and diminish the methodological soundness of the trial. Alternatively, the inclusion of a comparison treatment arm that would receive an Internet-based intervention was considered but not adopted for two reasons. First, engagement in web-based interventions has been shown to decline dramatically during extended care resulting in poor long-term outcomes [31,34], and second, 45% of rural area residents do not have Internet access with sufficient bandwidth to run interactive weight-management software [87].

Finally, it should be noted that testing innovative extended-care interventions for translation into community settings represents a necessary but *not sufficient* step toward providing residents of rural counties with access to effective treatment for obesity. Ultimately, the availability of lifestyle interventions for obesity via the CES infrastructure will represent a policy decision made by key leaders at county, state, and national levels. An important objective of the Rural LEAP Trial is to provide policy makers, as well as researchers and interventionists, with evidence regarding potentially effective and cost-efficient interventions that could be readily disseminated and implemented via the CES in rural communities across the country.

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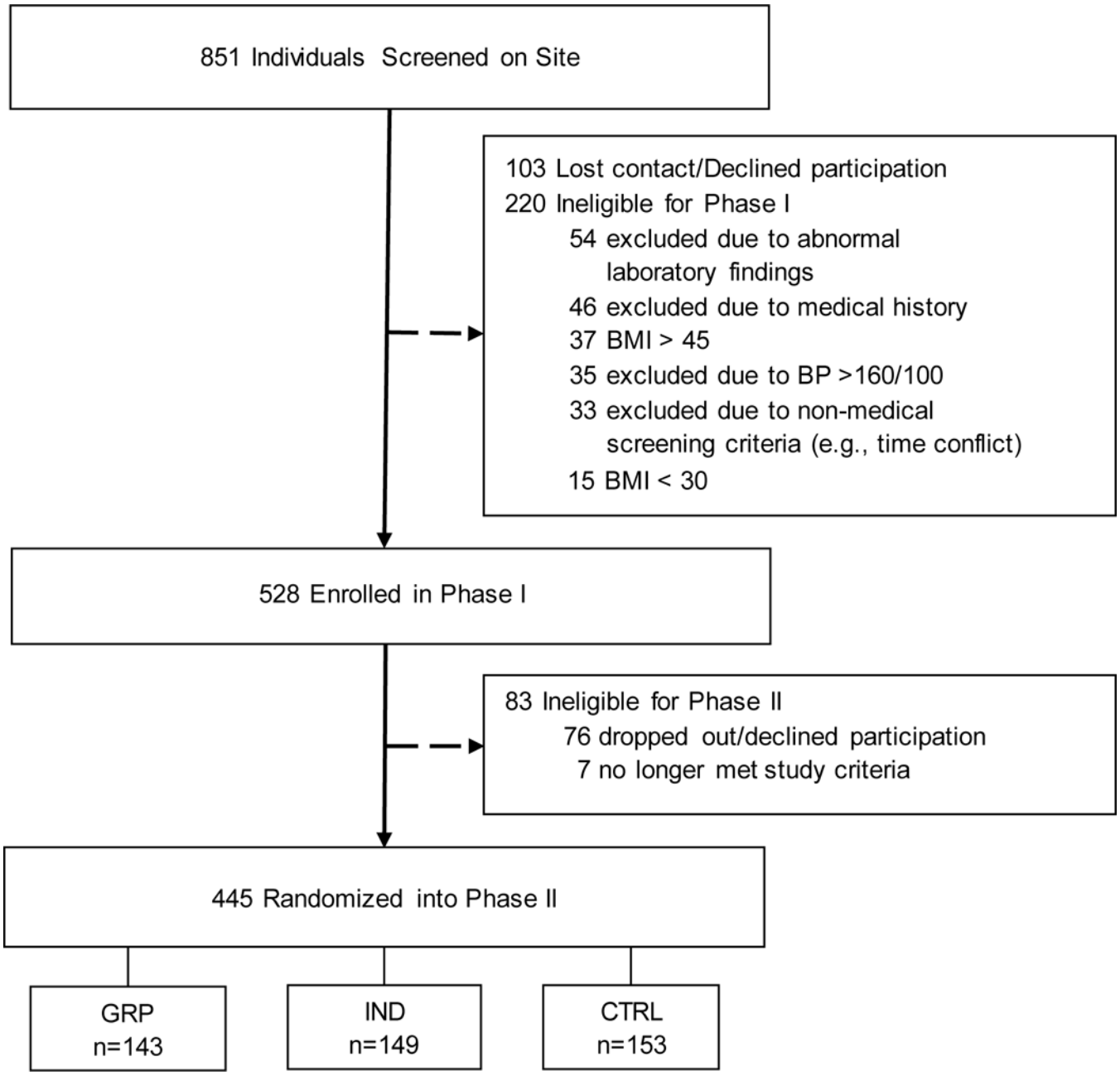

Fig. 1.
Participant flow during screening, enrollment, and randomization.

Table 1

Baseline characteristics for participants enrolled inPhase I (n = 528), those not randomized (n = 83), and those randomized to Phase II (n = 445).

	Phase I participants M (SD) or n (%)	Participants not randomized to Phase II M (SD) or n (%)	Participants randomized to Phase II M (SD) or n (%)
Age (years)	54.5 (10.7)	49.9 (11.8)	55.4 (10.3)
Body mass index (BMI, kg/m^2)	36.6 (3.8)	37.3 (4.3)	36.4 (3.7)
Obesity Class			
Class I (BMI = 30.0 to 34.9)	200 (37.9%)	28 (33.7%)	172 (38.6%)
Class II (BMI = 35.0 to 39.9)	223 (42.2%)	30 (36.1%)	193 (43.4%)
Class III (BMI = 40.0 to 45.0)	105 (19.9%)	25 (30.1%)	80 (18.0%)
Gender (female)	434 (82%)	66 (79.5%)	368 (83%)
Education, highest level completed			
< High school	12 (2%)	1 (1.2%)	11 (2%)
High school or GED	280 (53%)	53 (63.9%)	227 (51%)
Associate's degree	66 (13%)	12 (14.5%)	54 (12%)
Bachelor's degree	117 (22%)	14 (16.9%)	103 (23%)
Advanced degree	53 (10%)	3 (3.6%)	50 (11%)
Race/ethnicity			
White, Non-Hispanic/Latino	391 (74%)	63 (75.9%)	328 (74%)
Black, Non-Hispanic/Latino	100 (19%)	18 (21.7%)	82 (18%)
Other, Non-Hispanic/Latino	16 (3%)	0 (0.0%)	16 (4%)
White, Hispanic/Latino	16 (3%)	2 (2.4%)	14 (3%)
Black, Hispanic/Latino	1 (0%)	0 (0.0%)	1 (0%)
Other, Hispanic/Latino	4 (1%)	0 (0.0%)	4 (1%)
Annual household income			
< $20,000	67 (13%)	18 (21.7%)	49 (11%)
$20,000-$34,999	93 (18%)	11 (13.3%)	82 (18%)
$35,000-$49,999	93 (18%)	14 (16.9%)	79 (18%)
$50,000-$74,000	123 (23%)	16 (19.3%)	107 (24%)
> $75,000	120 (23%)	20 (24.1%)	100 (22%)
Unknown/refused	32 (6%)	4 (4.8%)	28 (6%)

Table 2

Weight-loss treatment modules.

Session	Topic	Objective
1	Getting Started for Success: Setting Goals	Review energy balance and weight management. Set personal calorie intake goals.
2	Taking Control of Eating Patterns	Learn difference between hunger vs. cravings. Review strategies to implement healthy eating patterns.
3	Stepping Up: Becoming Active	Review benefits of physical activity. Set personal step goals.
4	Becoming a Fat Gram Detective/Southern Cooking Made Healthier	Understand roles of fat, traditional Southern foods, and calories in long-term weight management. Review lower-fat food options.
5	Building a Healthy Diet	Review MyPlate recommended servings for each food group. Set total daily food serving goals.
6	Keep on Moving!	Discuss benefits of exercise/aerobic fitness and safety.
7	Scheduling Sleep	Identify current sleep habits and learn how sleep affects health and weight. Discuss sleep hygiene strategies.
8	Taking Charge: Eating and Activity Cues	Discuss triggers/cues for eating and physical activity. Discuss method to modify problematic eating and activity cues.
9	An Introduction to Problem Solving	Discuss steps in Problem Solving model and how to apply them to current and future problems.
10	Talking Back to Negative Thoughts	Discuss common weight-related negative thoughts and patterns. Demonstrate how to “talk back” to negative thoughts.
11	Slipping but not Falling: Preventing Relapse	Identify risk factors for experiencing a slip. Create a plan to prevent slips from becoming a relapse.
12	Coping with High-Risk Situations and Eating Out the Healthy Way	Identify high-risk situations, challenges faced, and coping strategies. Demonstrate how to budget calories for eating out.
13	Social Support and Making Social Cues Work for You	Discuss strategies for building social support and ways to effectively manage social cues.
14	Managing Stress	Discuss causes and effects related to stress. Introduce healthy strategies for stress reduction.
15	Having a Positive Body Image and Dealing with Plateaus	Discuss facts about body image and plateaus. Review tools for overcoming plateaus.
16	Looking Forward: Planning Ahead	Review current progress and discuss future goals.
17	Phase II Program Goals: Food Tracking Review	Review positive changes made, goal setting, and importance of accurate food tracking.
18	Tools for More Effective Problem Solving	Review problem solving model and apply to a current problem.
19	Meal Mastery: Build a Better Meal	Review benefits of planning ahead for meals. Identify small changes that can reduce calories in a meal.
20	Time for Health	Discuss importance of budgeting time for exercise. Set goals and problem solve how to make time for activity.
21	Plateau Busting	Review information about plateaus. Discuss ways to address a plateau.
22	Travel Triumphantly!	Identify barriers to healthy eating and activity while traveling.
23	Nutrition and Exercise During Illness	Identify strategies for overcoming illness by modifying physical activity and incorporating nutritious foods.
24	Super Sneakers, Stretching, and Safety	Identify appropriate footwear, clothing, and stretching techniques for physical activity.
25	Nutrition Myth Busters	Identify myths related to nutrition and healthy eating.
26	Planning Challenge: Perfectly Prepared	Review 7-day meal planning worksheet and strategies to prepare meals at home during busy times.

Session	Topic	Objective
27	Planning Challenge: Food Swaps	Identify lower calorie substitutes for high calorie food, beverages, and ingredients.
28	Fitness Challenge: Hike the Himalayas	Identify barriers preventing planned exercise and problem solving strategies to overcome them.
29	Preventing Chronic Disease	Identify lifestyle changes that could prevent chronic diseases and problem solve strategies to implement them.
30	Mind Challenge: Empowering Emotions	Discuss how to positively manage emotions and review ways to relieve stress.
31	Life Lessons: Renewing Your Vows	Identify ways to overcome stress and maintain positive changes. Identify ways to modify goals and stick to them during stressful times.
32	Life Lessons: Reaching New Heights	Discuss strategies to keep healthy eating and physical activity exciting.
33	Mastering Maintenance and Continuing Goals	Review strategies from National Weight Control Registry. Discuss SMART goals.
34	Reflection and Planning for the Next Step	Reflect on healthy lifestyle changes made throughout the program. Review the importance of self-monitoring and problem solving.

Table 3

Weight-loss progress at the conclusion of Phase 1 (Month 4) for participants randomized into Phase II (n = 445).

	Weight (kg)	
	M	SD
Baseline	99.9	14.6
Month 4	91.6	14.0
Change at Month 4	−8.3	4.9
	Body mass index (kg/m^2)	
	M	SD
Baseline	36.4	3.7
Month 4	33.4	3.9
Change at Month 4	−3.0	1.7
	Category of weight change at Month 4	
	n	%
Weight loss < 5%	100	22.5
Weight loss ≥ 5 to < 10%	191	42.9
Weight loss ≥ 10%	154	34.6