Extended-Care Programs for Weight Management in Rural Communities

The Treatment of Obesity in Underserved Rural Settings (TOURS) Randomized Trial

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Background: Rural counties in the United States have higher rates of obesity, sedentary lifestyle, and associated chronic diseases than nonrural areas, yet the management of obesity in rural communities has received little attention from researchers.

Methods: Obese women from rural communities who completed an initial 6-month weight-loss program at Cooperative Extension Service offices in 6 medically underserved rural counties (n=234) were randomized to extended care or to an education control group. The extended-care programs entailed problem-solving counseling delivered in 26 biweekly sessions via telephone or face to face. Control group participants received 26 biweekly newsletters containing weight-control advice.

Results: Mean weight at study entry was 96.4 kg. Mean weight loss during the initial 6-month intervention was 10.0 kg. One year after randomization, participants in the telephone and face-to-face extended-care programs regained less weight (mean [SE], 1.2 [0.7] and 1.2 [0.6] kg, respectively) than those in the education control group (3.7 [0.7] kg; *P*=.03 and .02, respectively). The beneficial effects of extended-care counseling were mediated by greater adherence to behavioral weight-management strategies, and cost analyses indicated that telephone counseling was less expensive than face-to-face intervention.

Conclusions: Extended care delivered either by telephone or in face-to-face sessions improved the 1-year maintenance of lost weight compared with education alone. Telephone counseling constitutes an effective and cost-efficient option for long-term weight management. Delivering lifestyle interventions via the existing infrastructure of the Cooperative Extension Service represents a viable means of adapting research for rural communities with limited access to preventive health services.

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RURAL COUNTIES IN THE United States have higher rates of obesity,[1-3] sedentary lifestyle,[3,4] and associated chronic diseases[1,5-7] than nonrural areas, yet treatment of obesity in the rural population has received little research attention. Efficacy trials, typically conducted with urban participants and by experts working in academic medical centers, show that lifestyle interventions involving diet, exercise, and behavior modification produce clinically significant weight reductions.[8-11] Nonetheless, participants commonly regain one-third to one-half of their lost weight during the year following treatment.[8,12,13] If lost weight is not maintained, the associated health benefits also may not be sustained.[8,14] Extended-care programs that include clinic-based follow-up sessions may improve the maintenance of lost weight.[8,11,12,15] However, in rural communities, distance to health care centers represents a significant barrier to ongoing care.[1,5,7] Therefore, it is important to examine alternative venues for the treatment of obesity as well as alternative methods of delivering extended care, such as the use of telephone counseling rather than face-to-face sessions.[7]

This randomized trial compared the effectiveness of extended-care programs designed to promote successful long-term weight management. Cooperative Extension Service (CES)[16] offices in rural communities served as the venues for the trial. Participants completed a standard 6-month lifestyle modification program and then were assigned randomly to telephone counseling, face-to-face counseling, or an education control group. We hypoth-

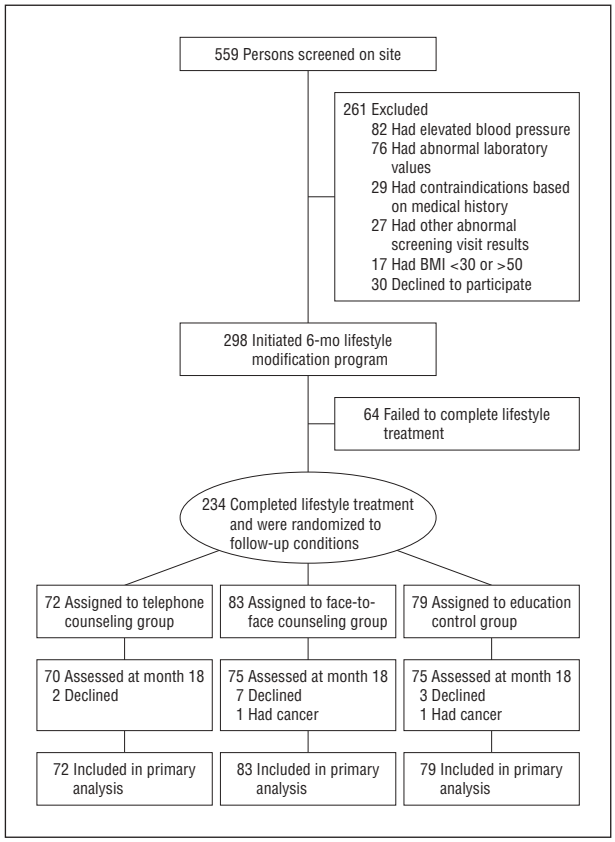

Figure 1. Flowchart of enrollment, randomization, and follow-up. BMI indicates body mass index (calculated as weight in kilograms divided by height in meters squared).

esized that the interventions delivered either by telephone or by face-to-face sessions would produce better maintenance of lost weight than the control condition and that the beneficial effects of extended care would be mediated by improved adherence to behavioral weight-management strategies.

METHODS

PARTICIPANTS

The study included 234 women, aged 50 to 75 years, with a body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) greater than 30 and a body weight less than 159.1 kg. Eligible participants did not have uncontrolled hypertension or diabetes mellitus and had no active (within 12 months) manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease. The use of medications known to affect body weight and a weight loss of 4.5 kg or more in the preceding 6 months also were exclusion criteria. Psychosocial contraindications included substance abuse and clinically significant depression.

Study announcements were mailed to households in 6 rural[17] counties in northern Florida designated in whole or in part as health professional shortage areas.[18] Women who responded to the announcements (N=559) were invited to an orientation/screening session wherein the study was described and informed consent was obtained. Height, weight, and blood pressure were measured by a registered nurse, who took a medical history, drew a fasting sample of blood, and obtained a 12-lead electrocardiogram. The blood sample was analyzed for metabolic and lipid profiles. Findings from the screening visit were reviewed by the study physician (M.C.L.), who determined medical eligibility; 261 women (46.7%) were excluded from participation (**Figure 1**).

The remaining 298 women (53.3%) participated in a standard 6-month lifestyle modification program for weight loss. The program was delivered to groups of 10 to 14 participants at local CES offices. Group leaders were CES family and consumer sciences agents or individuals with bachelor's or master's degrees in nutrition, exercise science, or psychology (hired by the University of Florida). Family and consumer sciences agents, formerly known as home economists, have a minimum of a bachelor's degree with education and training in food science, dietetics, and nutrition. The group leaders were provided with extensive training in lifestyle weight-loss treatment that included session-by-session 1-hour supervisory contacts and 8 bimonthly 6-hour workshops.

The contents of the lifestyle program were modeled after the Diabetes Prevention Program[19] and included a low-calorie eating plan (1200 kcal/d), increased physical activity (30 min/d of walking), and training in behavior modification strategies such as goal setting and daily self-monitoring of food intake.[11,20] Modifications to the Diabetes Prevention Program approach included group rather than individual counseling[21] and home-based rather than center-based exercise.[22] We also included additions that our pilot testing suggested were issues of special concern to women from rural areas, such as cooking demonstrations to illustrate low-calorie preparation of Southern-style dishes, strategies for coping with a lack of family support for weight loss, and techniques for healthful eating while away from home.

A total of 234 women (78.5%) completed the initial lifestyle intervention; these participants constituted the sample for the randomized trial. The study, approved by the Institutional Review Board of the University of Florida, was conducted from June 1, 2003, to May 31, 2007.

EXTENDED-CARE CONDITIONS

Before the start of the extended-care phase, participants in all conditions received written handouts describing how to use problem-solving strategies to deal with obstacles to the maintenance of lost weight.[23] All participants were encouraged to continue using behavioral weight-control strategies and were asked to complete written self-monitoring logs of food intake on at least 2 weekdays and 1 weekend day per week. Participants in the telephone and education control groups were provided with postage-paid envelopes to return the records to the counselors. Participants in the face-to-face condition were asked to bring the records to their office-based sessions.

Telephone Counseling

Of 234 participants who completed the lifestyle intervention, 72 (30.8%) were assigned to receive individual telephone counseling that included 26 biweekly sessions conducted with the same counselors who led the initial lifestyle program. The telephone contacts were scheduled in advance. The 15- to 20-minute sessions addressed barriers to maintaining eating and exercise behaviors required for sustaining lost weight. The counselors used the 5-stage problem-solving model described by Perri et al[23,24]: (1) orientation (ie, developing an appropriate coping perspective): "Problems are a normal part of managing your weight, but they can be dealt with effectively"; (2) definition (ie, 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 (ie, brainstorming potential solutions): "The greater the range of possible so-

lutions you consider, the greater your chances of developing an effective solution"; (4) decision making (ie, 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 (ie, trying out a plan and evaluating its effectiveness): "What solution plan are you going to try, and how will you know if it works?"

Face-to-Face Counseling

Eighty-three participants (35.5%) received face-to-face counseling, including 26 biweekly group sessions, that was conducted at CES offices by the same counselors who led the initial lifestyle program. The 60-minute sessions addressed barriers to the maintenance of eating and exercise behaviors required for sustaining lost weight. The group leaders used the problem-solving model described in the "Telephone Counseling" subsection.

Education Control

In the education control group, 79 participants (33.8%) received 26 biweekly newsletters that contained tips for maintaining weight-loss progress along with recipes for low-calorie meals. Before the extended-care phase began, control participants received the same problem-solving handouts used in the telephone and face-to-face conditions.

OUTCOMES

Primary outcomes included changes in body weight and BMI during the 1-year experimental period. Secondary outcomes included changes in selected cardiovascular risk factors (blood pressure, blood lipid level, and glycemic control). Outcomes were measured at months 6 and 18 by a mobile assessment team that included a registered nurse and medical technician who were masked to participants' randomized assignment. Certified scales were used to measure weight. Blood pressure was measured after a 5-minute rest. Levels of triglycerides, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein cholesterol, and hemoglobin A_{1c} levels were analyzed by Quest Diagnostics Inc (Madison, New Jersey) from a blood sample obtained after an overnight fast.

Behavioral adherence was calculated by counting the number of self-monitoring records completed during the yearlong experimental period. Written self-monitoring, a central component of behavior modification interventions, is the behavioral strategy most closely associated with successful weight management.[25-28]

ATTRITION, ATTENDANCE, AND TELEPHONE CALL COMPLETION

Of 234 participants, 14 (6.0%) were lost to follow-up (Figure 1). This number included any randomized participant who completed the initial lifestyle program and 6-month assessment but failed to return for the 18-month evaluation. There were no significant differences in attrition among groups. In the face-to-face condition, the mean (SD) number of sessions attended was 13.8 (8.6). In the telephone condition, the mean (SD) number of completed sessions was 21.1 (5.7).

STATISTICAL ANALYSIS

The sample size was selected to provide a statistical power of 0.80 to detect a 2.5% difference in weight regain among groups (2-tailed testing with Bonferroni adjustments). We used a replicated Latin square design with county and session time serving as factors.

Data were analyzed using SAS statistical software.[29] Preliminary analyses revealed that more black women were randomized to the telephone group ($P = .04$). There were no other significant differences in baseline characteristics among conditions (**Table 1**) or in changes in weight and other outcomes following the initial weight-loss program (**Table 2**). Differences in weight and secondary outcomes between 6 and 18 months' follow-up were analyzed using pattern mixture models.[30] For each treatment group, we computed:

$$(P \times \Delta) + [(1 - P) \times (\text{Y\_18} - \text{Y\_6 for completers})],$$

where P is the proportion that did not complete extended care, (Y_18 – Y_6) is the estimated difference in means for the completers, and Δ is a sensitivity parameter that corresponds to the difference in means for the study noncompleters. Different values of Δ correspond to common missing data assumptions for participants who were lost to follow-up:

1. $\Delta = 3.6$ corresponds to regaining 0.3 kg/mo after leaving the study;
2. $\Delta = (\text{Y\_0} - \text{Y\_6})$ corresponds to returning to baseline weight, where Y_0 is the baseline weight and Y_6 is the weight after initial treatment (at 6 months' follow-up);
3. $\Delta = 0$ corresponds to weight staying constant after month 6.

The first scenario is based on the documented pattern of weight regain following lifestyle treatment.[13,26,27] The second scenario assumes a return to baseline values for participants lost to follow-up.[24,31] The third scenario is based on the less conservative but commonly used last observation carried forward approach,[31] which assumes that participants lost to follow-up have fully maintained the progress observed at their last assessment visit. Because there is no consensus on the approach to missing data in weight-loss studies,[31] we examined the data using 3 missing-not-at-random scenarios. However, all 3 approaches revealed the same pattern of significant findings. Because the rate of weight regain following lifestyle treatment has been well documented, we present the weight change outcomes according to the first scenario. Changes in cardiovascular risk factors during the year following lifestyle treatment are less well known; therefore, we present those outcomes according to the second scenario.

Finally, we fit linear regression models with treatment and adherence as covariates to test the hypothesis that adherence served as a mediator[32] of the relationship between extended care and weight change from months 6 to 18.

EXAMINATION OF COSTS

We conducted an exploratory analysis to assess costs of the extended-care conditions from the perspectives of both the participants and the program. Participants completed a cost questionnaire at enrollment, with updates at months 6 and 18. Information regarding time spent in extended-care activities, including counseling, program-related reading and record keeping, exercise, and other activities (eg, trying new recipes) were included in the 18-month assessment.

Data regarding workforce participation and wages as valuations for time spent in program-related activities were collected at all time points. The overall median of self-reported wages ($10.50 per hour) was used to value participant time. Travel costs for program participation were calculated for face-to-face participants using the self-reported round-trip mileage multiplied by a standard rate of $0.44 per mile, plus an estimate of time spent in transit. Travel costs (distance and time) were multiplied by the number of face-to-face sessions at-

Table 1. Baseline Characteristics of Randomized Participants[a]

Characteristic	Telephone Counseling[b] (n=72)	Face-to-Face Counseling (n=83)	Education Control Group (n=79)	Total Randomized Population (N=234)
Age, y	59.8 (6.2)	59.2 (6.2)	58.6 (6.0)	59.4 (6.1)
Race/ethnicity, No. (%)				
Black, non-Hispanic[b]	21 (29.2)	13 (15.7)	9 (11.4)	43 (18.3)
Hispanic	1 (1.4)	1 (1.2)	3 (3.8)	5 (2.1)
White	48 (66.7)	69 (83.1)	64 (81.0)	181 (77.3)
Asian, Native American, or Pacific Islander	2 (2.8)	0	3 (3.8)	5 (2.1)
Education, y, No. (%)				
≤12	26 (36.1)	30 (36.1)	32 (40.5)	88 (37.6)
13-15	28 (38.9)	41 (49.4)	27 (34.2)	96 (41.0)
≥16	18 (25.0)	12 (14.4)	20 (25.3)	50 (21.4)
Annual household income, No. (%)				
<$35 000	35 (48.6)	44 (53.0)	25 (31.6)	104 (44.4)
$35 000-$49 999	12 (16.7)	18 (21.7)	21 (26.6)	51 (21.8)
$50 000-$74 999	14 (13.9)	14 (16.9)	18 (22.8)	46 (19.7)
≥$75 000	10 (13.9)	6 (7.2)	14 (17.7)	30 (12.8)
Not reported	1 (1.4)	1 (1.2)	1 (1.3)	3 (1.3)
Body weight, kg	96.4 (16.8)	97.8 (14.3)	95.0 (13.4)	96.4 (15.6)
BMI	36.9 (5.7)	37.1 (4.5)	36.2 (4.3)	36.8 (4.9)
Systolic BP, mm Hg	125.4 (9.6)	125.4 (9.6)	126.6 (8.4)	125.8 (9.2)
Diastolic BP, mm Hg	74.4 (8.3)	74.5 (8.0)	76.2 (6.4)	75.0 (7.6)
Triglyceride level, mg/dL	134.3 (64.2)	150.8 (59.0)	149.2 (60.4)	145.2 (61.3)
Cholesterol level, mg/dL				
Total	206.1 (34.1)	208.3 (29.1)	206.1 (29.9)	206.9 (30.9)
HDL	58.3 (14.6)	54.8 (11.6)	55.7 (13.1)	56.2 (13.2)
LDL	120.9 (31.6)	123.4 (27.7)	120.5 (29.5)	121.7 (29.4)
Hemoglobin A_{1c} level, %	6.0 (0.6)	6.0 (0.8)	5.8 (0.6)	6.0 (0.7)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; glucose to millimoles per liter, multiply by 0.0555; and triglycerides to millimoles per liter, multiply by 0.0113.

[a] Data are given as mean (SD) unless otherwise indicated. All values are at the start of the initial weight-loss program.

[b] There was a larger proportion of black women assigned to the telephone condition than to the other groups (P=.04).

Table 2. Changes in Outcomes During the Initial 6-Month Weight-Loss Program[a]

Outcome[a]	Telephone Counseling (n=72)	Face-to-Face Counseling (n=83)	Education Control Group (n=79)	Total Randomized Population[b] (N=234)
Body weight, kg	−9.4 (0.6)	−10.1 (0.6)	−10.5 (0.6)	−10.0 (0.4)
BMI	−3.6 (0.2)	−3.8 (0.2)	−4.0 (0.2)	−3.8 (0.1)
Waist size, cm	−8.1 (0.7)	−8.6 (0.6)	−8.2 (0.7)	−8.3 (0.4)
Systolic BP, mm Hg	−7.3 (1.4)	−7.6 (1.3)	−9.0 (1.3)	−8.0 (0.8)
Diastolic BP, mm Hg	−4.0 (1.0)	−3.3 (0.9)	−3.4 (0.9)	−3.5 (0.5)
Triglyceride level, mg/dL	−14.0 (6.9)	−29.6 (6.7)	−17.6 (6.7)	−20.5 (3.0)
Cholesterol level, mg/dL				
Total	−10.7 (3.6)	−18.8 (3.4)	−12.9 (3.5)	−14.2 (2.0)
HDL	−3.7 (0.9)	−3.2 (0.9)	−3.3 (0.9)	−3.4 (0.5)
LDL	−3.9 (3.3)	−9.7 (3.2)	−5.8 (3.2)	−6.5 (1.9)
Hemoglobin A_{1c} level, %	−0.2 (0.1)	−0.3 (0.1)	−0.3 (0.1)	−0.3 (0.03)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; glucose to millimoles per liter, multiply by 0.0555; and triglycerides to millimoles per liter, multiply by 0.0113.

[a] Data are given as mean (SE) unless otherwise indicated. Missing values for secondary outcomes were accounted for using SAS Proc Mixed[28] under a missing-at-random assumption.

[b] Significant changes in all outcomes were observed from month 0 to month 6 for the total study population (all P<.001), but there were no significant differences among the 3 groups on any outcomes before the start of the randomized extended-care phase at month 6.

tended. For the telephone condition, we assumed each participant completed the average number of telephone sessions. Other data needed to assess participant time were collected via the cost survey. For extreme outliers and cases with missing values, we substituted the median value for that study arm.

Costs of program operations, based on data collected by the research team, included the value of time for group leaders ($14.31 per hour) and assistants ($11.45 per hour) in all program-related activities, including preparation, session time, and training. Other program operating costs included telephone service

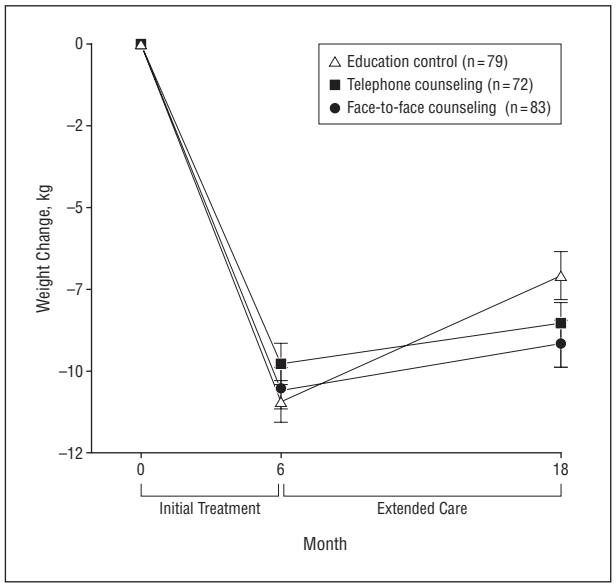

Figure 2. Weight changes (mean [SE]) during the initial weight-loss phase (months 0-6) and during the extended-care phase (months 6-18).

for telephone counseling sessions, space rental fees for face-to-face counseling sessions, time and materials for preparing the newsletters, and staff time related to program administration.

RESULTS

WEIGHT CHANGES

The mean (SE) weight loss accomplished by the 234 women who completed the initial lifestyle modification program was 10.0 (0.4) kg. There were no significant between-group differences in any outcome before the randomized phase of the trial (Table 2). At the conclusion of the initial lifestyle program, significant within-group improvements across all conditions were observed in blood pressure, blood lipid level, and glycemic control (Table 2).

At the conclusion of the 12-month extended-care period, participants who received either telephone or face-to-face counseling regained less weight (mean [SE], 1.2 [0.7] and 1.2 [0.6] kg) compared with those in the education control condition (3.7 [0.7] kg; $P = .03$ and .02, respectively) (**Figure 2**). Similarly, telephone and face-to-face counseling resulted in significantly smaller increases in BMI (mean [SE], 0.5 [0.3] and 0.4 [0.3]) compared with the education control group (1.4 [0.3]; $P = .03$ and .02, respectively). The effects for county and counselor on short- and long-term changes in weight were not significant.

SECONDARY OUTCOMES

There were no significant between-group changes for the secondary outcomes (**Table 3**). The improvements in cardiovascular risk factors observed at month 6 for the most part were maintained at month 18. However, improvements in LDL and total cholesterol levels observed at month 6 were not sustained at month 18 despite a mean decrease in body weight (from baseline) of more than 7%. Across the entire sample, weight gain was associated with a decrease in high-density lipoprotein cholesterol level ($\rho = -0.24$; $P < .001$) and with increases in triglyceride level ($\rho = 0.28$; $P < .001$) and hemoglobin A_{1c} level ($\rho = 0.25$; $P < .001$), but not with changes in LDL ($\rho = 0.01$; $P = .89$) or total cholesterol levels ($\rho = 0.03$; $P = .67$).

Table 3. Changes in Outcomes From Months 6 to 18 According to Extended-Care Condition[a]

Outcome[b]	Telephone Counseling (n=72)	Face-to-Face Counseling (n=83)	Education Control Group (n=79)
Body weight, kg	1.2 (0.7)[c]	1.2 (0.6)[c]	3.7 (0.7)[d]
BMI	0.5 (0.3)[c]	0.4 (0.3)[c]	1.4 (0.3)[d]
Systolic BP, mm Hg	2.1 (1.4)	3.1 (1.3)	3.3 (1.3)
Diastolic BP, mm Hg	2.5 (1.0)	3.0 (0.9)	1.1 (0.9)
Triglyceride level, mg/dL	1.4 (6.2)	9.7 (5.5)	6.1 (5.8)
Cholesterol level, mg/dL			
Total	3.8 (3.6)	11.6 (3.3)[d]	11.6 (3.4)[d]
HDL	1.1 (0.9)	2.8 (0.8)[d]	2.7 (0.9)[d]
LDL	2.3 (3.2)	6.9 (2.9)[e]	8.0 (3.0)[e]
Hemoglobin A_{1c} level, %	0.0 (0.1)	0.1 (0.1)	0.1 (0.1)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

SI conversion factors: To convert cholesterol to millimoles per liter, multiply by 0.0259; glucose to millimoles per liter, multiply by 0.0555; and triglycerides to millimoles per liter, multiply by 0.0113.

[a] Data are given as mean (SE).

[b] Estimates for body weight and BMI were calculated using a missing-not-at-random procedure in which participants lost to follow-up were assumed to have regained 0.3 kg per month since leaving the study. Estimates for other outcomes were completed using a missing-not-at-random procedure that corresponded to setting a sensitivity parameter equal to a value consistent with a baseline carried forward type of analysis.

[c] $P < .05$ (Bonferroni adjusted) for the between-group comparison vs the control group.

[d] $P < .01$ (Bonferroni adjusted) for the within-group change from month 6 to month 18.

[e] $P < .05$ (Bonferroni adjusted) for the within-group change from month 6 to month 18.

ADHERENCE

Adherence to behavioral weight-management strategies, as measured by the mean (SE) number of days with self-monitoring records for food intake, was significantly higher in the telephone (131 [12]) and face-to-face (109 [10]) counseling arms compared with the control group (80 [10]; $P = .006$ and .03, respectively). A significant relationship between adherence and weight changes during months 6 to 18 was observed, with poorer adherence resulting in greater weight gain. A 10% decrease in adherence resulted in a weight gain of 0.9 kg ([1.3]; $P < .001$). Finally, controlling for the between-group differences in adherence reduced the effect of extended care to a nonsignificant level; the difference between the telephone and the control groups was reduced by more than 50%, and the difference between the face-to-face and the control conditions was decreased by approximately 25%. Thus, the beneficial effect of extended care on weight management was mediated by adherence to behavioral self-management strategies.[23]

Table 4. Participant and Program Costs From Months 6 to 18 According to Extended-Care Condition[a]

Costs	Telephone Counseling (n=72)	Face-to-Face Counseling (n=83)	Education Control Group (n=79)
Participant			
Reading/record keeping, h	16.0 (18.1)	15.7 (18.9)	10.4 (15.7)
Time in counseling, h	10.2 (12.4)	21.3 (16.0)	N/A
Time spent exercising, h	109.2 (87.9)	99.5 (88.8)	110.9 (115.5)
Other program-related time, h	48.8 (64.5)	35.5 (61.0)	41.4 (85.3)
Travel time, h	NA	13.4 (8.9)	NA
Total program time, h	199.1 (136.7)	185.4 (130.5)	177.7 (161.2)
Travel distance, miles	NA	472.1 (477.6)	NA
Total participant costs, $	1933 (1436)	2157 (1449)	1708 (1692)
Program[b]			
Interventionist time, h	63.0 (11.3)	126.0 (0)	NA
Program assistant time, h	24.0 (4.3)	78.0 (0)	104.0 (0)
Personnel costs, $	1863 (162)	3589 (0)	1191 (0)
Other costs, $[c]	396 (7)	1036 (7)	164 (30)
Program costs per participant, $	192 (21)	397 (73)	116 (19)
Total, $[d]	2125	2555	1824

Abbreviation: NA, not applicable.

[a] Data are given as mean (SD) unless otherwise indicated.

[b] For certain program costs, such as interventionist time to conduct a face-to-face group session, there is no variation by number of participants, hence the SD is 0.

[c] Other costs included telephone, postage, handouts, and space rental. The extension offices provided the space without charge for this study. However, given that the space available was limited and available on a competitive basis, we estimated the value based on rental charges for similar space by local churches in these communities.

[d] Mean of participant costs + mean of program costs.

COSTS

The pattern of costs across conditions showed that the face-to-face intervention incurred the highest costs, followed by the telephone condition and the educational control group (**Table 4**). The data for program costs and costs to the participant followed the same pattern. Face-to-face counseling entailed the largest costs to the participants owing to the travel expenses associated with session attendance. Program costs per participant were twice as high for the face-to-face intervention compared with the telephone counseling condition owing to greater staffing costs in the face-to-face condition.

COMMENT

This study demonstrated that 12-month extended-care programs delivered either via telephone or face-to-face counseling sessions significantly improved the maintenance of lost weight. Obese women from medically underserved rural counties, who initially lost a mean (SE) of 10.0 (0.4) kg via lifestyle modification, regained smaller amounts of weight when provided with telephone (1.2 [0.7] kg) or face-to-face (1.2 [0.6] kg) counseling sessions compared with participants assigned to an education control group (3.7 [0.7] kg). Similarly, during the 12 months following initial treatment, the control group experienced an increase in BMI that was approximately 3 times larger than increases observed in the telephone and face-to-face counseling conditions.

The Treatment of Obesity in Underserved Rural Settings (TOURS) Trial is the first randomized controlled trial to demonstrate the effectiveness of telephone counseling for the long-term management of obesity in rural communities. Because distance represents a major barrier to medical care in rural areas,[1,5,7] the availability of a treatment modality that does not require time and costs for travel and attendance at clinic visits represents a potentially important approach to providing ongoing care to rural residents. Moreover, in the present study, delivering extended care via telephone was less costly than providing face-to-face sessions. Travel expenses associated with the face-to-face program resulted in higher participant costs compared with the telephone condition (mean, $2157 vs $1933), and program costs per participant were twice as high for the face-to-face treatment compared with telephone counseling (mean, $397 vs $192) because of fixed program costs of conducting on-site sessions.

Both the telephone and face-to-face counseling programs employed a structured problem-solving model[23] to guide clinical decision making, and both encouraged the continued use of behavioral self-regulation strategies,[33] particularly the self-monitoring of food intake.[27,34] Our findings showed higher levels of adherence to this recommendation in the telephone and face-to-face conditions compared with the control group. Consistent with self-regulation theory,[35,36] which emphasizes the integral role of vigilance (ie, self-monitoring) in behavior change, we hypothesized that the relationship between extended-care counseling and long-term weight-loss success would be mediated by the completion of food records during months 6 to 18. Our findings, which supported this hypothesis, highlight the critical role that vigilant monitoring of food intake may play in the maintenance of lost weight.[28,36]

Several potential limitations of our study should be noted. Middle-aged and older obese women who completed an initial program of lifestyle modification composed the study sample. The generalizability of our findings to the treatment of men, younger women, and those who drop out of initial treatment is unknown. We chose to focus on women aged 50 to 75 years for several reasons. The World Health Organization[37] has noted that the time of menopause and the 2 decades following it are associated with weight gain, and the WHO has emphasized the need for interventions that specifically target weight loss and increased physical activity among obese women aged 50 years and older. Moreover, for women, but not men, obesity poses a greater burden with regard to decreased quality of life[38] and increased rates of depression,[39] and women older than 50 years in rural areas experience higher rates of obesity,[1] depression,[40] and heart disease[1] than their urban counterparts.

The design of this trial did not permit an examination of the independent effects of changes in diet composition, physical activity, and weight change on the secondary outcomes. The maintenance of lost weight was associated with sustained improvement in some but not all secondary outcomes. From baseline to month 18, the study population demonstrated an overall mean (SE)

weight loss of 7.9 (0.7) kg, which was accompanied by significant decreases in systolic blood pressure (−5.2 [0.8] mm Hg), triglyceride level (−14.8 [3.4] mg/dL [to convert to millimoles per liter, multiply by 0.0113]), and hemoglobin A_{1c} level (−2.1% [0.4%]). However, the improvements in LDL and total cholesterol levels observed at month 6 were not sustained at month 18, yet the increases in LDL and total cholesterol levels from months 6 to 18 were not associated with a regaining of lost weight. These findings imply that a return toward baseline dietary composition patterns, rather than weight regain, may account for the lack of sustained improvement in LDL and total cholesterol levels.[41]

An additional study limitation involves the intensity of treatment provided to participants in this trial. Our initial program of lifestyle modification and our extended-care interventions provided a high frequency of contacts—a total of 50 sessions over 18 months. This level of treatment intensity is comparable to that provided in efficacy trials such as the Diabetes Prevention Program[9] and the Look AHEAD Study.[10] Indeed, the magnitude of weight reductions achieved with economically disadvantaged participants in the rural communities of the current study compares quite favorably to the weight losses achieved in large multisite trials, conducted in academic medical centers with middle-class participants.[9,10,12] Nonetheless, the intensity of our intervention may represent a barrier to widespread dissemination. Future studies should examine the effectiveness of lower doses of initial treatment and extended care.

The translation of findings derived from efficacy trials to community-based practices represents a key objective of the National Institutes of Health Roadmap initiative.[42] Most obesity treatment studies have been conducted in the resource-rich environments of academic medical centers, and few studies have translated efficacious interventions such as the Diabetes Prevention Program for dissemination into medically underserved community settings.[43,44] Delivering lifestyle interventions via the existing infrastructure of the CES[16] represents a potentially effective and efficient means of research translation into rural communities with limited access to preventive health services.[1,7] With offices in almost all 3100 counties of the United States, the CES[16] could make a significant contribution toward reducing geographic disparities in access to preventive health services, an objective of high national priority as detailed in Healthy People 2010.[45]

In summary, the results of the TOURS Trial support the National Institutes of Health guidelines[8] that recommend "continuous care" for the management of obesity. Our findings highlight the benefits of extended-care interventions[11,39] and indicate that telephone counseling represents an effective and cost-efficient approach to the management of obesity in underserved rural settings.

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