A Chronic Care Model Program Incorporating Group Office Visits for Obesity Treatment in Primary Care

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Abstract

Background. Obesity is a chronic disease of epidemic proportions. Primary care providers are on the front line of diagnosing and treating obesity and need better tools to deliver top-notch obesity care.

Methods. A pilot randomized trial was conducted to test a chronic care model (CCM) program for obesity compared to usual care. Primary care patients, 18 years and older, with a body mass index (BMI) between 27 and 45 were enrolled. Sixteen weekly 90-minute group office visits were structured with the first 30 minutes encompassing individualized clinical assessments and the final 60 minutes containing the group-based standardized intensive lifestyle training. The primary outcome was weight change at 16 weeks. Secondary outcomes were weight change at 24 weeks, change in diet and physical activity behaviors, self-efficacy for weight control behaviors, and physiologic markers of cardiovascular risk at 16 and 24 weeks.

Results. The participants (19 in the active arm and 10 in the control arm) were 49.8 ± 11.5 years old (mean ± SD), 97% women, 55% white, and 41% black. Weight change in the control arm at week 16 was 0.25± 2.21 kg (mean ± SD) and that for the active arm was -5.74 ± 4.50 kg (n=16). The difference between the two arms was significant (p = 0.0002). Both the intent-to-treat analysis using the last observation carried forward approach and the analysis including completers only provided similar siginificant results.

Conclusions. This study demonstrated that a CCM program incorporating group office visits was feasible and effective for obesity treatment in primary care settings.

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Introduction

According to a recent World Health Organization (WHO) report, overweight and obesity are the fifth leading cause for global deaths: at least 2.8 million adults die each year as a result of being overweight or obese.[1] In addition, 44% of the diabetes burden, 23% of the ischemic heart disease burden, and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity. In the US, the obesity epidemic is particularly severe and elevating. According to the Center for Disease Control and Prevention (CDC), no state met the Healthy People 2010 obesity target of 15%.[2] Nine states have obesity rates over 30%, and the self-reported overall prevalence of obesity among US adults had increased 1.1 percentage points from 2007 to 2009. Obesity and obesity-related health issues have been a heavy burden on health

care costs. Obesity accounts for 9.1% of annual health care spending in the US. The medical care costs of obesity in the US are staggering. In 2008 dollars, these costs totaled about $147 billion.[3]

Primary care providers play a critical role in curbing the escalating obesity epidemic. There are many important reasons for mobilizing the primary care workforce around this leading public health threat, including the above-average prevalence of obesity among primary care patients compared with the general population,[4,5] the positive impact of physician advice on behavior change,[6] and routine patient-provider contact affording many opportunities for obesity care. Nonetheless, a well-known gap exists between best practices for obesity and actual care. Using a nationally representative sample, Galuska et al.[7] reported that only 42% of obese patients had been advised by their physician to lose weight in the prior 12 months. In the same study, those that received physician advice for weight loss had 3-fold higher odds of attempting weight loss than those without physician advice. Improving the recognition and treatment of obesity in primary care settings is an important national objective.[8,9]

Primary care physicians have identified a number of barriers that impact obesity care, including time, resources, insurance reimbursement, and lack of knowledge about how to incorporate obesity interventions in primary care.[4,10] A system-based, multi-disciplinary approach to obesity care may overcome some of these barriers.[11] As a previous study pointed out, basic treatment of overweight and obese patients in primary care requires a comprehensive approach involving diet and nutrition, regular physical activity, and behavioral change, with an emphasis on long-term weight management rather than short-term extreme weight reduction.[12]

The chronic care model (CCM) is an interdisciplinary team approach to chronic disease management that engages patients, providers, office staff, health system administrators, and communities.[13] Given that obesity is a chronic disease with links to several common and serious chronic diseases,[14] this clinical approach holds much promise for obesity care.[15]

Components of the CCM may be promising in obesity intervention in primary care. For example, group office visits have been supported by several prominent national medical societies as an innovation with great potential to improve chronic disease management in primary care.[16] There has been much excitement for group visits and several practice-based group case reports of improved chronic disease outcomes, more patient satisfaction, and lower costs, yet there are only a handful of studies in which group office visits have been rigorously tested.[17]

Another important component of the CCM is intensive lifestyle training. Structured behavioral interventions consistently have demonstrated adequate weight loss and weight loss maintenance.[18,19] Herein, a pilot randomized trial of a CCM program for obesity incorporating clinician group office visits and intensive lifestyle training in two academic primary care practices is described. The intensive lifestyle behavioral intervention model of the Diabetes Prevention Program (DPP) was adopted. It had been used successfully for diabetes prevention.[19] The primary goal of this study was to evaluate the feasibility of the program and to assess effect sizes for future definitive trials of the intervention.

Methods

This study was approved by the institutional review board at the University of Kansas Medical Center (KUMC).

Study design. This study was a randomized clinical trial with two arms. Eligible primary care patients were randomized to receive either: 1) standard of care consisting of patient educational materials about obesity (the control arm) or 2) a 16-week chronic care model program integrating clinician group visits with intensive lifestyle training and other components of the chronic care model program (the active arm). The randomization ratio of active to control was 2:1.

The intervention components of the active arm were derived from the general principles of the CCM,[17] including 16 weekly 90-minute group office visits. The first 30 minutes of the visit were for individualized assessments and the other 60 minutes were for intensive lifestyle training including dietary modification, physical activity, goal setting for weight control, self-monitoring, and behavioral change strategies. Weekly self-administered surveys and semi-structured individual interviews also were included to evaluate subject satisfaction with the intervention.

An interview guide was developed that consisted of a series of questions designed to elicit information about facilitators and barriers of the weight management program. To reduce potential bias, the interviewer (CG) was not involved in the trial and participants were assured that their responses would be de-identified. The interviews were not tape recorded. During the interviews, brief notes were taken and immediately following each interview, the interviewer elaborated on her notes.

At baseline, 16 weeks, and 24 weeks, all participants in the active and control arms completed a self-administered, 60-item survey and physiologic assessments querying: 1) sociodemographics, 2) comorbid obesity-related medical illnesses, 3) self-efficacy for weight control as measured by the 20-item Weight Efficacy Lifestyle Questionnaire, 4) health-related quality of life using the Short Form-12,[20] 5) depressive status using the Patient Health Questionnaire-2,[21] 6) blood pressure, fasting cholesterol profile, and fasting glucose, 7) usual dietary patterns using 24-hour dietary recalls and recorded on the Nutrition Data System Software (Univ. of MN, 2007) for daily energy, fat, fruit and vegetable, and fiber intake,[22,23] and 8) regular physical activity patterns using the International Physical Activity Questionnaire.[24] These dietary and physical activity self-report assessments have been validated and widely used for similar purposes. Health status,[25,26] and depression[27,28] are potentially important moderators of weight loss completion and maintenance. The primary outcome measure was weight (kg); all other measures were secondary outcome measures.

Participants. Eligible participants were 18 years or older with a body mass index (BMI) between 27 and 45 and weight stable in the last 3 months (i.e., within +/- 10 pounds), not taking obesity pharmacotherapy, not planning bariatric surgery in the next 12 months, not pregnant or lactating in the last 12 months, and free from terminal illness with a life expectancy greater than 12 months.

Procedure. Subjects were identified from the General Internal Medicine (GIM) and Family Medicine (FM) clinics at University of Kansas Medical Center (KUMC). The group office visits were conducted in the General Clinic Research Center (GCRC) at KUMC due to space and staff limitations in the primary care clinics. Participants were recruited during the course of clinical care during October 2007 and the protocol was conducted from November 2007 through March 2008.

In total, 78 patients were screened and 29 eligible participants agreed to participate in the study. At a 2:1 ratio, 19 participants were randomly assigned to the active arm

and 10 to the control arm and had baseline measurements. At week 16, eight participants in the control arm and 16 participants in the active arm returned for assessment. Six participants in the control arm and 17 participants returned for the assessment at week 24. Among the participants of the active arm, 14 participants returned for the assessment at week 16 and attended more than 50% of the 16 weekly sessions. These subjects were program "completers". Figure 1 describes participant enrollment and retention in greater detail.

For the intervention arm, each individualized assessments session prior to group meetings was provided by a primary care physician (author ACE), a clinic RN, or a psychologist (authors CAB or ABD). During the course of the 16-week intervention, four individualized assessments were provided by the physician, four by the nurse, and eight by one of the psychologists. For each session, all participants were assessed by the same provider. Participants were advised to set realistic, guideline-based goals for weight control including 1-2 pound weight loss per week, 150 minutes of moderate/vigorous physical activity per week, less than 25% daily calories from fat, five servings or more of fruits and vegetables per day, and an overall goal of 10% body weight loss and weight loss maintenance. At each meeting, participants reviewed goals and problem-solved to reduce barriers of weight control adherence.

Statistical analysis. Univariate analysis compared patient characteristics at baseline between the two arms. For continuous variables, such as weight, the two sample t-test was used for comparison if the normality assumptions were satisfied; otherwise, the Wilcoxon rank sum test was used. The Chi-square test was used for categorical variables such as gender and race. For the changes of outcome variables from baseline to 16 and 24 weeks, two-sided, a two-sample t-test or Wilcoxon rank sum test was used.

Three different sets of analysis were used on the changes of outcome measures. First, an analysis based on observed data only. All individuals with missing information were excluded for the corresponding analysis. Second, an intent-to-treat analysis included all individuals randomized, for which the simple last-observation-carried-forward (LOCF) strategy was used to replace missing values. The LOCF strategy is equivalent to assuming no changes since last time of measurement. Finally, given the well-known problem of recidivism in weight control studies, an analysis of "completers" included individuals in the control arm who had no missing observations and those in the active arm who had no missing measures and completed at least 50% of group office visits. As an exploratory pilot study, no control for multiple tests was considered. All analyses were conducted using STATA 10 (STATACorp LP, College Station, TX).

Analysis of the interviews was thematic in approach.[29] The participants' responses were reviewed and reduced to key themes. Discussion of the themes and topics were held between the first author (EAC) and the interviewer (CG).

Results

The 29 participants were 49.8 ± 11.5 years old (mean ± SD), 97% female, 55% white, and 41% black. Baseline body mass index (BMI) was 37.5 ± 5.4 (mean ± SD), baseline body fat percentage was 48.7% ± 4.9%, and baseline total daily energy intake as measured by one baseline 24-hour diet recall was 1738.1 ± 821.9. Additional baseline descriptions are in Table 1. Except for body fat, variables were not significantly different between the two arms.

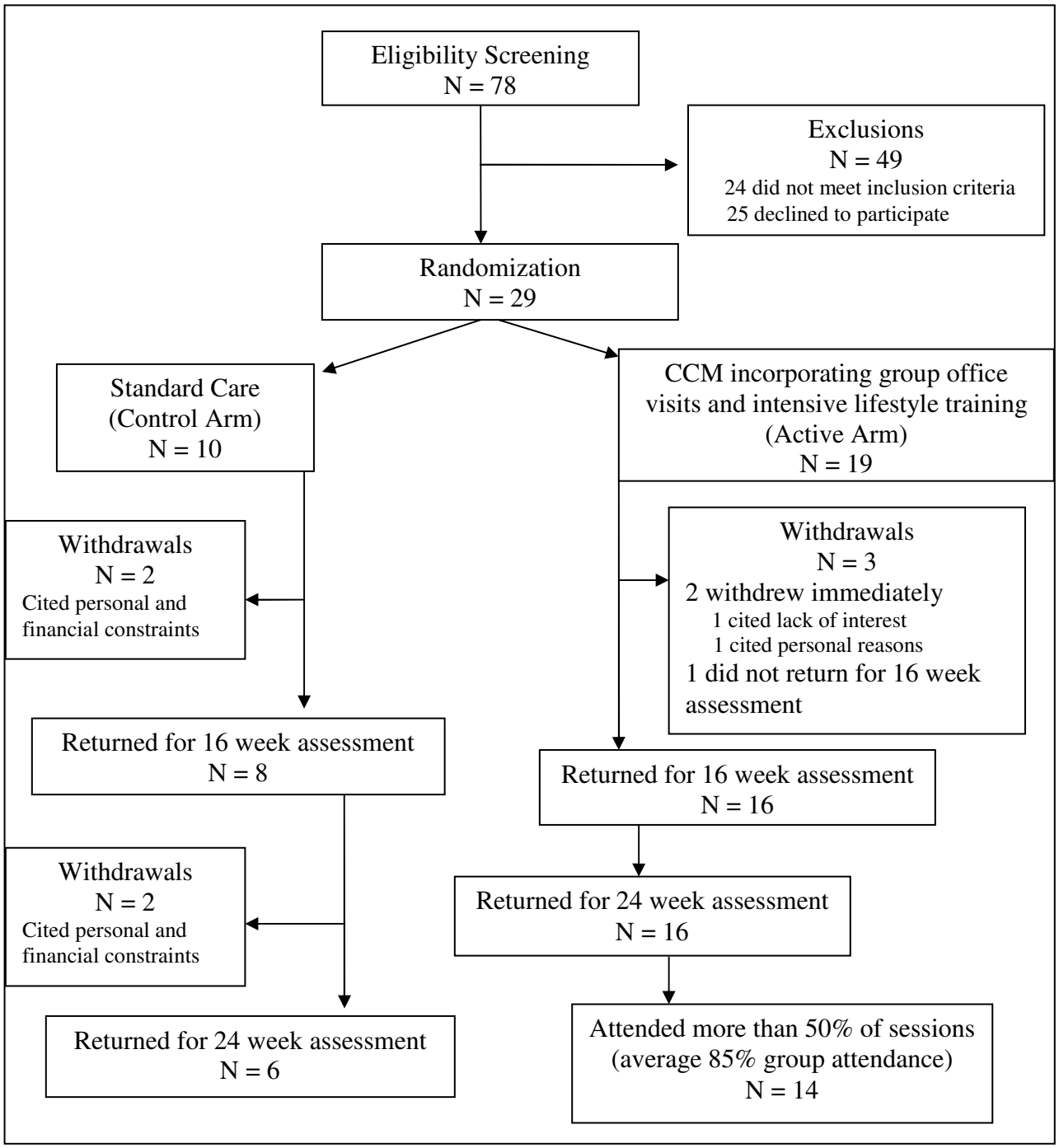

Figure 1. Participant enrollment and study completion

Based on patients with observed measures only (see Table 2), weight change in the control arm at week 16 (n = 8) was 0.25± 2.21 kg (mean ± SD) and that for the active arm was -5.74 ± 4.50 kg (n = 16). The difference between the two arms was significant (p = 0.0002) using a two-sided two-sample t-test. Figure 2 demonstrates the distributions of the observed weight change at week 16 for the two arms, showing that participants in the active arm had significant weight loss while those in

Table 1. Participant baseline characteristics by study arm.*

Participant Characteristic	Active Arm (%); N=19	Control Arm (%); N=10
Age		
Mean years ± SD	51 ± 10	48 ± 15
Gender		
Female	19 (100%)	9 (90%)
Race/ethnicity		
Black	7 (37%)	2 (20%)
White	11 (58%)	4 (40%)
Latino	1 (5%)	2 (20%)
Other	1 (5%)	
Annual Income		
<$10K	1 (5%)	1 (10%)
$10K-$20K	3 (16%)	0 (0%)
$21K-$50K	12 (63%)	6 (60%)
>$50K	3 (16%)	3 (30%)
Insurance Type		
Medicare	4 (21%)	2 (20%)
Medicaid	3 (16%)	0 (0%)
Employer Based	11 (58%)	4 (40%)
Other	2 (11%)	2 (20%)
Comorbidities		
Hypertension	9 (47%)	5 (50%)
Diabetes	5 (26%)	3 (30%)
Hyperlipidemia	10 (53%)	6 (60%)
Heart Disease	2 (11%)	2 (20%)
Arthritis	10 (53%)	4 (40%)
Sleep apnea	8 (42%)	1 (10%)
Depression	9 (47%)	3 (30%)
Anxiety	6 (32%)	4 (40%)
Regular alcohol use	2 (11%)	1 (10%)
Tobacco use	1 (5%)	2 (20%)
Body Mass Index		
Mean ± SD	38 ± 5	37 ± 6
Body Fat (DEXA assessed) **		
Mean % ± SD	50 ± 4	46 ± 6
Fasting biomarkers		
Mean ± SD		
Glucose mg/dl	103 ± 15	112 ± 39
Triglycerides mg/dl	128 ± 47	110 ± 54
HDL mg/dl	50 ± 9	48 ± 16
LDL mg/dl	115 ± 34	98 ± 37
Health Status^		
SF-12 PCS, Mean ± SD	38 ± 12	44 ± 13
SF-12 MCS, Mean ± SD	46 ± 13	51 ± 15
Depression Screening#		
PHQ 2		
Positive	3 (16%)	1 (10%)

* Cells may not sum to 100% secondary to rounding and/or missing values. Missing values are not listed here, but are available on request.

^ Short Form 12, Physical and Mental Component Summary Scores are standardized and weighted using US population estimates that summarize general health status. Scores range from 0-100 with higher scores indicating better health status (Mean ± SD PCS for US is 50 ± 10, and MCS for US is 50 ± 10).

Patient Health Questionnaire 2, ≥ 3 is positive depression screen.

** P <.05 for a two-sided test of the difference between arms.

Table 2. Weight change, dietary, and physical activity outcomes at 16 weeks.*

Outcome variable	Active Arm		Control Arm	
	Baseline N=16	16 Weeks N=16	Baseline N=8	16 Weeks N=8
Weight **				
Mean kilograms ± SD	98 ± 16	92 ± 14	102 ± 20	102 ± 21
Total daily calorie intake ***				
Mean kcal ± SD	1845 ± 1116	1210 ± 414	1746 ± 776	2091 ± 758
Total daily fat intake ***				
Mean gm ± SD	80 ± 44	35 ± 19	71 ± 29	98 ± 52
Physical Activity				
Mean minutes per week ± SD				
Vigorous Activity	116 ± 410	117 ± 237	21 ± 38	6 ± 15
Moderate Activity	65 ± 152	158 ± 256	36 ± 37	37 ± 66
Walking	256 ± 546	281 ± 621	155 ± 84	220 ± 220
WEL-Global^	88 ± 32	100 ± 23	87 ± 46	97 ± 29
Body Fat (DEXA assessed)				
Mean % ± SD	50 ± 3	49 ± 4	46 ± 6	46 ± 6
Fasting biomarkers				
Mean ± SD				
Glucose mg/dl	100 ± 9	94 ± 10	102 ± 20	107 ± 28
Triglycerides mg/dl	122 ± 36	122 ± 63	98 ± 40	106 ± 59
HDL mg/dl	50 ± 10	48 ± 10	45 ± 20	45 ± 18
LDL mg/dl	116 ± 38	112 ±38	93 ± 48	109 ± 45
Daily fruits intake Mean servings per day ± SD	1.9 ± 3.4	2.0 ± 1.8	1.4 ± 1.8	.6 ± .6
Daily vegetable intake Mean servings per day ± SD	3.3 ± 2.5	3.5 ± 2.7	3.6 ± 2.4	4.4 ± 1.1
Blood Pressure				
Mean SBP mm Hg ± SD	125 ± 16	122 ± 12	134 ± 12	134 ± 17
Mean DBP mm Hg ± SD	75 ± 9	75 ± 6	74 ± 5	76 ± 10

*****Cells may not sum to 100% due to rounding and/or missing values. Missing values are not listed here, but are available on request.

^Weight Efficacy Lifestyle Questionnaire (20 Likert items), range 20-200 (higher score=higher self-efficacy).

** P<.001 for a two-sided test of the difference between arms in terms of change from baseline to week 16.

*** P<.05 for a two-sided test of the difference between arms in terms of change from baseline to week 16.

the control arm did not. Using last-observation-carried-forward to replace missing observations (for the control arm, it was equivalent to assuming no change from baseline), the weight change in the control arm at week 16 was 0.20 ± 1.95 kg (n = 10) and that for the active arm was -4.83 ± 4.64 kg (n = 19). This difference also was significant (p = 0.004). For the active arm, weight change for "completers" (n = 14) was -6.39 ± 4.39 kg. The weight change was significant (p = 0.0001) when compared with that of the eight control participants who returned for assessment at week 16. The observed weight change from baseline to week 24 in the active arm was -5.55 kg ± 5.38 kg (n = 17) and that in the control arm was -0.61 kg ± 2.57 kg (n = 6). The weight changes at week 24 were significantly different between the two arms (p = 0.006).

Total daily calorie and fat intake decreased in the active arm by week 16 (-635 ± 702 kcal, mean ± SD, and -45 ± 25 gm, mean ± SD, respectively). Moderate physical activity increased in the active arm by week 16 (93 ± 104 minutes, mean ± SD), and walking minutes per week increased in the control arm by week 16 (65 ± 136

minutes, mean ± SD). Secondary outcomes at week 24 were not different from week 16, thus are not presented.

Attendance was 72% on average (excluding one active arm participant who dropped out before the first session). Overall, participants reported high satisfaction with the program as measured by the weekly satisfaction surveys. Results from the process evaluation via semi-structured individual interviews with participants were reviewed for common themes. The common themes are detailed in Table A1 in the Appendix. We believe this qualitative information offers important insight into the intervention process. This may be valuable in future work using a similar design to address participants' concerns and guide intervention development. Results from the interviews with providers and practice teams are available on request.

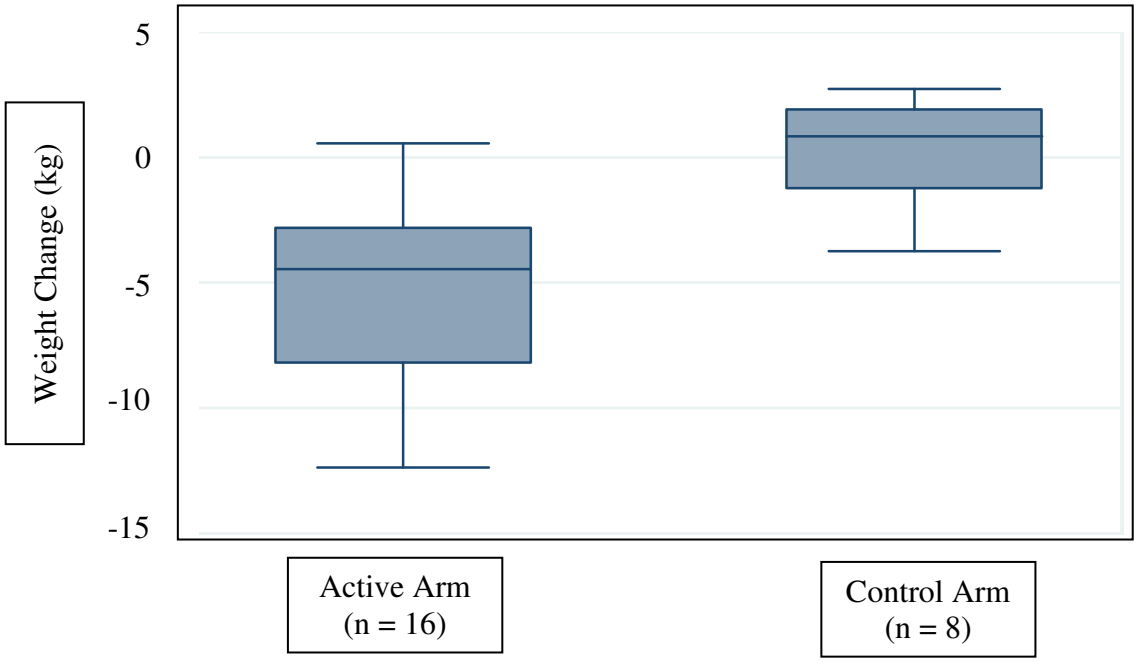

Figure 2. Weight Change at Week 16: Observed Changes Only

Discussion

This project was a pilot trial of a chronic care model for obesity incorporating group office visits and intensive lifestyle training in two academic primary care practices. Group office visits for obesity were feasible, acceptable, and effective for weight loss. Participants who completed at least 50% of sessions (74% of active arm) were successful at reaching their initial weight loss goal of 5-10% body weight loss. This goal was consistent with national guidelines for weight control in primary care settings.[8,9] This study was one of the first to translate the Diabetes Prevention Program into primary care practice, and to our knowledge was the first to use group office visits to treat obesity. Furthermore, it is one of the first studies to use the chronic care model for obesity care. These findings are promising and warrant exploration in definitive future trials.

The chronic care model for obesity was used in our past work in rural Kansas primary care settings.[30] However, patient

activation in that study was accomplished through individual telephone-based counseling rather than the group office visits used in the current study. In both the past work and the current study, provider and health system activation were more challenging than patient activation. This challenge may be related to more resource allocation, and a project focus on the patient-oriented chronic care model.

The multifaceted nature of these interventions renders it difficult to assess which aspect had the greatest impact on outcomes. Nonetheless, semi-structured process interviews with participants following the current study suggested that patient activation via the group office visits and intensive lifestyle training had the most powerful impact of any intervention piece in the current study. Given the experience of others using the chronic care model in improving outcomes in chronic disease,[31] this approach holds much promise for obesity care. Future work is needed to advance the chronic care model constructs that have not been well developed in obesity interventions to date.

In this study, group office visits were used in a novel way to manage obesity among primary care patients. Others have described successful experiences using group office visits for chronic disease management. Primary care patients with coronary artery disease were randomized to monthly group office visits including extensive nutritional education or usual care.[32] Group office visits resulted in improved physiologic outcomes, greater patient satisfaction, and better health-related quality of life. Also, group office visits improved dietary behaviors and physiologic outcomes among primary care patients with diabetes mellitus.[33]

The participants in the current study enjoyed the interface of medical management with the intensive lifestyle training. No significant changes were found in fruits and vegetables consumption, which may due to the short time frame of the study.

Limitations of this study were that the intervention was conducted in a research clinic separate from the point of care and that the medical management was directed by a research physician (ACE). This was done secondary to resource, time, and space limitations, and because it was an exploratory pilot intervention. Future work needs to test a similar model on a larger scale engaging the actual practice teams in primary care settings.

Other limitations to the current study were the small scale of the study (only 29 participants) and the disproportionate loss of the control arm participants to followup at 24 weeks (only 60% of controls returned for assessments). The loss of participants was consistent with our past work and that of others, which outlines the frustration of a usual care only arm in weight control studies. Nonetheless, clinically and statistically significant weight control outcomes were demonstrated. Also, the short time frame of the follow-up period (i.e., 24 weeks) rendered it difficult to assess the long term effect of the intervention. Weight loss maintenance as a critical component of weight control interventions in primary care settings should be examined in the future with larger studies. Other important aspects that were not covered in the pilot study, such as more effective strategies to improve compliance and cost-effective analysis, also need to be assessed in the future.

Obesity is a chronic disease of epidemic proportions in the United States. Primary care physicians have been called to optimize diagnosis and treatment of obesity. A chronic care model intervention for obesity incorporating group office visits and intensive lifestyle training may be one way of improving the quality of obesity care in primary care settings.

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Keywords: obesity, primary care, chronic disease

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Appendix

Table A1. Summary of semi-structured participant interviews by topic.

Topic Area	Summary Results from 30-Minute Interviews with 14 Participants
Visits with continuity primary care physician	About half of participants who had a clinical visit with their primary care physician during the study indicated improved obesity care
Brief structured individual visits with research physician during group office visit	Most participants indicated that these visits were helpful and encouraging. A few indicated that the visits were often rushed and disorganized.
Brief structured individual visits with study nurse during group office visit	About half indicated that the nursing visits were helpful and encouraging. The other half did not find them helpful because one of the nurses was not supportive at all, and there was not continuity of nursing care.
Brief structured individual visits with health psychologists to review health behavior goals related to weekly diet diaries	All participants found these visits very helpful in staying on track and learning new tips for weight control. Several did report that they often felt rushed and wanted more time.
Intensive lifestyle training group sessions	Most felt that the sessions were extremely helpful and they appreciated the support of others and the information learned. Several reported that sessions were rushed and they wished there was more time for in depth discussion.
Calorie and fat intake goals	Several felt that these were unattainable, but most felt that the goals were helpful in planning meals.
Food and activity logs	Several felt that the self-monitoring was cumbersome and not helpful at all. Most agreed that the idea was important, but the reality of self-monitoring was a lot of work.
Major barriers to reaching weight control goals during the study	Lack of will power, reluctance to monitor calories, lack of exercise, high stress, poor emotional state, comorbid medical conditions
General comments and feedback	Learned a lot, enjoyed the group camaraderie, would have preferred smaller group with a more comfortable room with a place to write and place materials