Preventive Medicine 114 (2018) 223–231

Contents lists available at ScienceDirect

Preventive Medicine

journal homepage: www.elsevier.com/locate/ypmed

Planned care for obesity and cardiovascular risk reduction using a stepped-down approach: A randomized-controlled trial

Jie Liu[a], Job G. Godino[b,c], Gregory J. Norman[b,c], Linda Hill[a,b], Karen Calfas[b], James F. Sallis[b], Elva Arredondo[d], Cheryl L. Rock[b], Michael Criqui[b], Shu-Hong Zhu[b], Kenneth Griffiths[b], Jennifer Covin[b], Lindsay Dillon[c], Kevin Patrick[b,c,*]

[a] School of Medicine, University of California, San Diego, La Jolla, CA, United States of America
[b] Department of Family Medicine and Public Health, University of California, San Diego, La Jolla, CA, United States of America
[c] Center for Wireless and Population Health Systems, University of California, San Diego, La Jolla, CA, United States of America
[d] Graduate School of Public Health, San Diego State University, San Diego, CA, United States of America

ARTICLE INFO

Keywords:
Obesity
Randomized controlled trial
Weight loss
Cardiovascular disease risk factors

ABSTRACT

Primary care-based approaches to address concurrent obesity and cardiovascular disease risk factors (CVDRFs) that begin with a high intensity intervention that is subsequently decreased (i.e., stepped-down) if weight loss is achieved have not been rigorously examined. Our study is a 20-month, single-blind randomized controlled trial at five primary care clinics in San Diego, CA, in 2013, where 262 obese adults (aged 25–70 years; 32.1% male; 59.2% white) with at least one CVDRF were enrolled into planned care for obesity and risk reduction (PCORR) using a stepped-down approach or enhanced usual care (EUC). All patients received physician recommendations for weight loss and CVDRFs. EUC patients (n = 132) received an individual session with a health educator every 4 months. PCORR patients (n = 130) received individual and group sessions (in-person, mail, telephone, and email) in three steps, characterized by less contact if success was achieved. At 20 months, 40.7%, 23.8%, and 15.4% of PCORR patients were in steps 1, 2, and 3, respectively (25.2% were lost to follow-up). PCORR resulted in a between-group difference in reduction in body weight of 6.1% [95% CI, 5.3 to 6.9] compared to EUC 2.8% [95% CI, 2.0 to 3.6] p = 0.007, with a greater reduction in BMI (35.2 [95% CI, 34.4 to 35.9] to 33.7 [95% CI, 32.9 to 34.5] kg/m^2) than EUC (36.0 [95% CI, 35.3 to 36.8] to 35.1 [95% CI, 34.3 to 35.9] kg/m^2), as indicated by a significant treatment by time interaction (p = 0.009). PCORR resulted in greater weight loss over 20 months than EUC.

Trial Registration: ClinicalTrials.gov, NCT01134029

1. Introduction

By 2030, 50% of the US population is projected to be obese (body mass index (BMI) ≥ 30 kg/m^2) (Wang et al., 2011). Obesity is associated with substantial increases in the risk of morbidity (e.g., hypertension, dyslipidemia, type 2 diabetes, and cardiovascular disease) and mortality (Kramer et al., 2013; Lavie et al., 2009). Previous research has demonstrated that modest reductions in weight (5% to 10% of body weight) through healthy changes in diet and physical activity can result in significant improvements in cardiovascular disease risk factors (CVDRFs) (Lavie et al., 2009; Wing, 2010). Given the increasing burden of obesity and the health benefits of weight-loss, there is a great need for clinically effective and resource-efficient weight-loss interventions.

Intensive multicomponent weight loss interventions are recommended for all obese adults (Moyer, 2012; National Institutes of Health, 2000). Stepped-care approaches that vary treatment intensity depending upon individual treatment response enable more efficient allocation of resources (Von Korff and Tiemens, 2000). The typical stepped-care approach uses a stepped-up process in which patients receive a low-intensity intervention to start, and if treatment goals are not met at designated time points, patients are given a more intensive intervention (Carels et al., 2012, 2009, 2007, 2005; Jakicic et al., 2012). Weight-loss studies that have utilized this approach report modest intervention effects and the need for a substantial number of participants to be stepped-up to a higher intensity intervention (Carels et al., 2012,

* Corresponding author at: Center for Wireless and Population Health Systems, University of California, San Diego, 9500 Gilman Drive, Dept. 0811, La Jolla, CA 92093-0811, United States of America
E-mail address: kpatrick@ucsd.edu (K. Patrick).

https://doi.org/10.1016/j.ypmed.2018.07.015
Received 11 March 2018; Received in revised form 21 July 2018; Accepted 24 July 2018
Available online 25 July 2018

2009, 2007, 2005; Jakicic et al., 2012).

Stepped-down interventions that begin with high intensity treatment that is subsequently decreased if goals are achieved have not been rigorously examined in randomized controlled trials with adequate sample sizes. The most effective intensive multicomponent behavioral interventions include 12 to 26 behavioral management sessions in the first year (Moyer, 2012; National Institutes of Health, 2000; Wadden et al., 2014). These typically include individual and group sessions that focus on weight-loss goal setting and self-monitoring, ways to improve diet and physical activity, and reducing barriers to adopting or maintaining healthy changes in behavior (Moyer, 2012; National Institutes of Health, 2000; Wadden et al., 2014). The amount of weight-loss early in treatment predicts success in achieving long-term weight-loss goals (Waring et al., 2014; Wing et al., 2004), suggesting that stepped-down approaches may be well suited for the treatment of obesity. However, to our knowledge, there has been only one pilot weight-loss study that has compared a stepped-down intervention to usual care among overweight or obese adults (Carels et al., 2013). The findings did not support efficacy of the stepped-down method but were limited by a small sample size and short follow-up (Carels et al., 2013). Another study conducted by our group did find some evidence supporting the efficacy of a stepped-down approach to generate weight-loss in adolescent boys (Norman et al., 2016).

In the present study, we utilized a stepped-down approach to deliver planned care for obesity and risk reduction (PCORR) that integrated behavior change theory with a delivery strategy based on the principles of the Chronic Care Model (CCM, also called the "Planned Care Model") (Bodenheimer et al., 2002; Coleman et al., 2009; Group Health Research Institute, n.d.). We are aware of no studies that explicitly incorporated these two approaches—a stepped-down behavioral intervention anchored in the CCM—to treat obese patients with increasingly common comorbidities. We hypothesized that PCORR would result in greater weight loss and improvement in CVDRFs than enhanced usual care (EUC) over the study period.

2. Methods

2.1. Study design

We conducted a single-blind randomized controlled trial among obese adults with additional CVDRFs in five primary care clinics in San Diego, California. Participants were followed for 20 months. The University of California, San Diego (UCSD) Institutional Review Board (#071942, 12/11/2007 to 5/20/2016) approved all study procedures and the trial was registered with ClinicalTrials.gov (NCT01134029). The funding source had no involvement in the design, data collection, analysis or interpretation of the data.

2.2. Setting and patients

From January 2010 to January 2012, physicians identified potential study participants during routine patient visits. Additionally, community-based advertisements, media, newsletters, and electronic mailing lists were used to elicit external providers to refer potential study participants. Patients who were referred by their physicians or who responded to advertisements were screened for eligibility by study staff via telephone interview.

Patients were English or Spanish-speaking adults aged 25 to 70 years living in San Diego County, CA with a BMI of 30 to 45.0 kg/m^2 and at least one additional CVDRF. CVDRFs included 1) hypertension defined as taking prescription of blood pressure-lowering medication or blood pressure > 140/90 mmHg; 2) metabolic syndrome defined as the presence of at least 3 of the following 5 factors: i) elevated waist circumference (≥ 40 in. (102 cm) for men and ≥35 in. (88 cm) for women), ii) elevated triglycerides (≥ 150 mg/dL), iii) reduced high density lipoprotein (HDL) cholesterol (< 40 mg/dL for men and < 50 mg/dL for women), iv) elevated blood pressure (≥130/85 mmHg), and v) elevated fasting blood glucose (100 to 125 mg/dL); 3) controlled type 2 diabetes defined as an hemoglobin A_{1c} (HbA_{1c}) < 8.5%; or 4) current smoker defined as the use of tobacco in cigarettes, cigars, or pipes at least once in the last 30 days. Exclusion criteria included having any type of bariatric surgery, the use of medications that alter weight, or enrollment in another weight loss program. Patients were also excluded if they had a diagnosis of type 2 diabetes within the previous 6 months or an HbA_{1c} level ≥ 8.5%, were unable to engage in moderate-intensity physical activity (e.g., walking) due to any pulmonary, cardiovascular, or musculoskeletal problem, were pregnant or planning to become pregnant during the study period, or had a history of substance abuse or other psychiatric disorder that would impair compliance with the study protocol.

Eligible patients provided written informed consent to participate in a 2-week run-in period that included activities similar to those that occurred throughout the 20-month study. The goal of this was to provide patients with a better understanding of the expected level of engagement in weight-loss related activities. Patients who satisfactorily completed the run-in period were enrolled in the study and provided written informed consent at their baseline visit. The study was originally planned for 24 months; however, unforeseen staffing circumstances, delays, as well as resource constraints necessitated a cutback to 20 months.

2.3. Randomization and blinding

After completing their baseline visit, participants were allocated to the study groups using computer-based permuted-block randomization with varying block sizes. Allocation was concealed from the participants, physicians, study staff, and investigators until the interventions were assigned. It was not possible to blind participants or the physicians and study staff who delivered the interventions. However, investigators who analyzed the data remained blinded to allocation throughout the study.

2.4. Interventions

All participants received physician recommendations for weight loss. Participants allocated to PCORR received: 1) primary care physician visits; 2) health educator visits; 3) health educator phone calls; 4) group sessions; and 5) mailed or emailed materials (see Table 1 for an outline of the intervention). These were delivered based on the CCM, where clinical information systems, decision support, delivery system design, self-management support, healthcare policy and community resources are integrated to provide obesity management within the primary care setting (Bodenheimer et al., 2002; Wagner et al., 1996). Within the framework of the CCM, non-physician health educators were utilized in PCORR as case-managers to improve clinical outcomes. PCORR applied a behavioral determinants model (Sallis et al., 1992). The behavioral determinants model, based on Social Cognitive Theory, specifies that there are personal, social, and environmental antecedents, or mediators, to changes in diet and physical activity behaviors (Bandura, 1986; Baranowski et al., 1997). This combined framework offered guidance for selecting the most appropriate mediators for behavior change for individual participants while providing support to promote success with long-term disease management.

The intensity and frequency of PCORR content was adapted to the needs of participants based upon their success in achieving weight loss during 4-month periods (i.e., steps). All participants began with Step 1, the most intensive step. Those who achieved 5% weight loss after 4 months were stepped-down to a less intense intervention, Step 2. Participants who failed to graduate to Step 2 continued the intervention activities of Step 1. If participants achieved 5% weight loss by month 8, they then progressed to Step 2. Participants who graduated to Step 2 after 4 months had the goal of continued weight loss to achieve an

Table 1
Intervention components for Planned CORR participants compared to Enhanced Usual Care participants, San Diego, CA, 2013.

Intervention	PCORR		EUC	
	Description	Frequency	Description	Frequency
1. Primary care provider-patient visits	Providers review with the participant his/her weight status and progress after each step Providers review lab results of CVRFs with patients and treat accordingly	Every 4 mo	Participants receive recommendations regarding the need for weight loss Providers may initiate interventions for obesity or CVRF management as part of routine care	Baseline and end of year 1
2. Health educator face-to-face visits	HE review concepts in behavior change strategies regarding healthy eating and physical activity with participant HE help participants identify barriers to weight loss and address ways to overcome difficulties	Step 1: One 60 min session per month Step 2: One 60 min session every 2 months Step 3: None	HE recommends community resources HE recommends weekly weighing and routine monitoring of CVRFs	One 60 min session every 4 months over 20 months
3. Health educator phone calls	Participants received individualized counseling calls for continued weight loss and physical activity goal attainment	Step 1: 20–30 min weekly Step 2: 20–30 min every 2 weeks Step 3: 20–30 min every month	None	
4. Group sessions	HE lead chronic disease self-management course HE promote weight loss and maintenance by reinforcing concepts from other components of the intervention	Monthly 1.5 h sessions, open to participants in all steps	None	
5. Email/mail materials	Participants receive seasonal mailing materials about healthy eating and physical activity Reminders for participants to track behaviors with respect to diet and physical activity every week	Monthly for all steps		

PCORR: Planned Care for Obesity and Cardiovascular Risk Reduction intervention group.
HE: health educator.

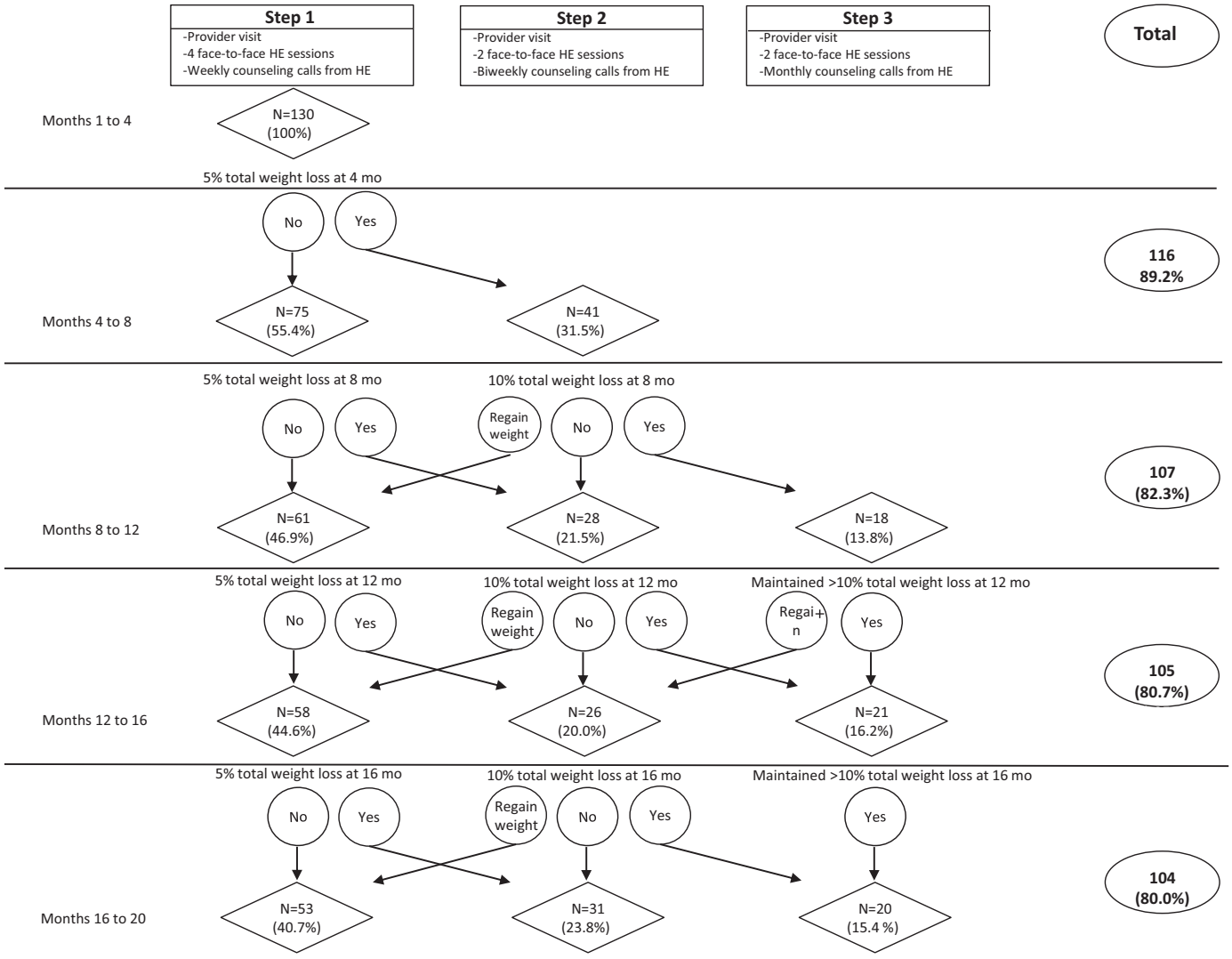

Fig. 1. Step progression of Planned CORR participants, months 1–20.

additional 5% weight loss by month 8. Participants who achieved this goal of 10% reduction in body weight from baseline graduated to the least intensive intervention, Step 3. Participants who did not achieve 10% weight loss but maintained their 5% weight loss from the first 4 months remained in Step 2. Finally, participants who progressed to Step 2 after 4 months but did not maintain their 5% weight loss from the first 4 months returned to Step 1. The logic described above was also applied to months 12 and 16 and the intervention was terminated after 20 months. Fig. 1 details the flow of participants through each step of the intervention.

Participants allocated to receive EUC served as controls, and received an individual session with a health educator every 4 months for a total of 6 visits. The content of the health education sessions was more general than that given as a component of PCORR and included information about community resources for weight loss. Health educators recommended weekly weighing and routine monitoring of CVDRFs in accordance with the usual practices of the participant's primary care physician.

2.5. Measurements

Demographic information on sex, age, race, language, education, marital status and income were self-reported through a survey collected during the run-in period. Trained study staff took standardized anthropometric and blood pressure measurements at baseline and every 4 months thereafter, for a total of 6 measurements. Weight was measured to the nearest 0.1 kg using a calibrated digital scale, and height was measured to the nearest 0.1 cm using a stadiometer with participants standing erect with their heels against the wall. Both weight and height were measured with participants clothed but without shoes, two separate measures were averaged, and BMI was calculated as weight in kg divided by height in m^2. Waist circumference was measured from the narrowest area between the base of the ribs and the top of the iliac crest, and hip circumference was measured from the maximum protuberance of the buttocks. Both waist and hip circumference were measured to the nearest 0.1 cm, two separate measures were averaged, and the ratio of waist-to-hip was calculated in cm. Blood pressure measurements were taken by trained research staff using a Critikon Dinamap 8100 digital blood pressure monitor. After 5 min of rest, 3 consecutive readings were taken at 1-min intervals from the right arm while the participant was seated with their forearm supported on a table. The first reading was dropped, and the average of the second and third readings was calculated.

Approximately 40 mL of blood was drawn at baseline, 12 months, and 20 months by trained phlebotomists or nurses after participants fasted for at least 8 h. Samples were sent to Quest Diagnostics Inc. (Quest Diagnostics Inc., West Hills, California) and HbA_{1c}, glucose, insulin, C-reactive protein, and a lipid profile including triglycerides,

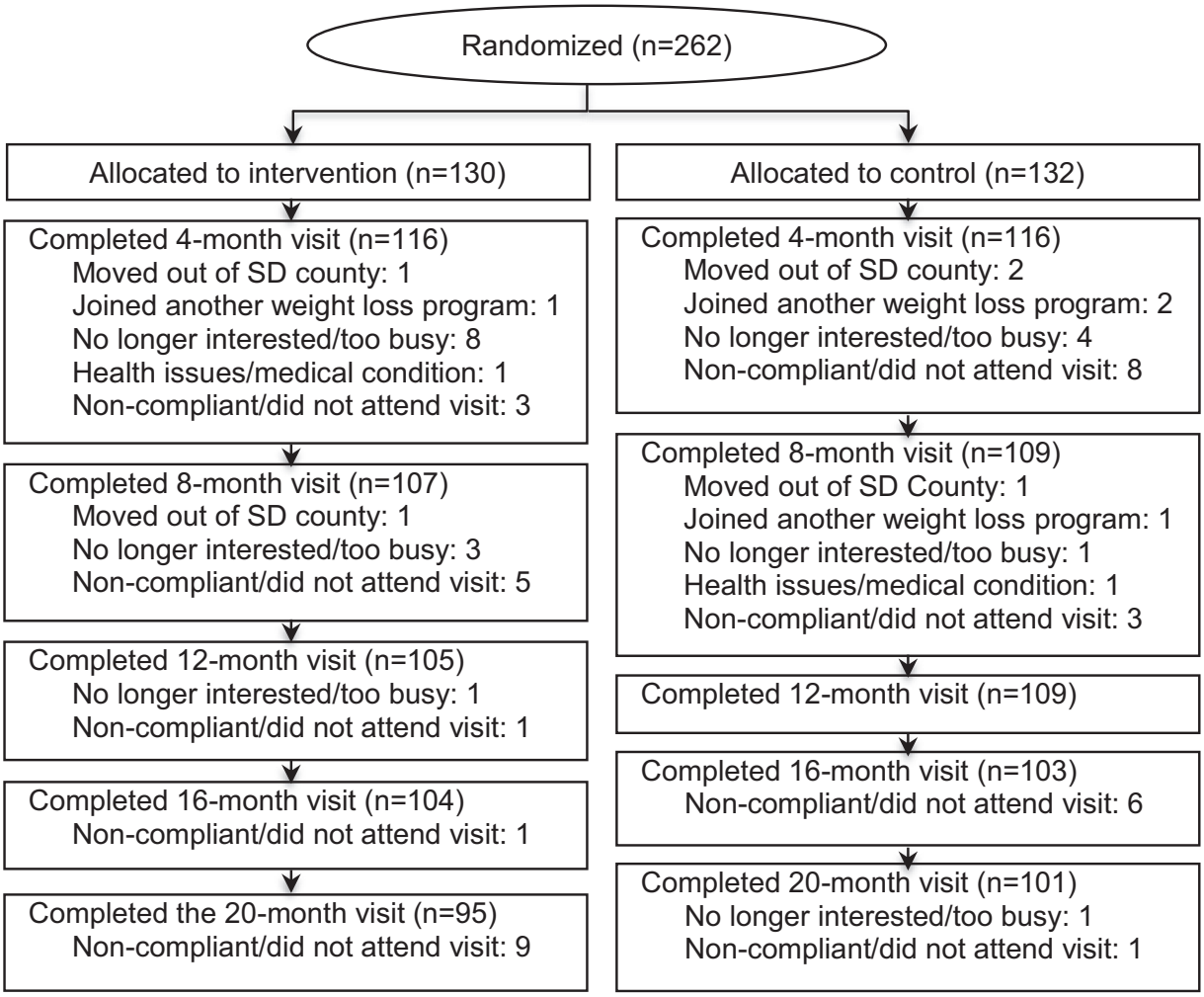

Fig. 2. Flow of participants through the Planned CORR study.

total cholesterol, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol were measured using established clinical assay protocols.

2.6. Statistical analysis

All statistical analyses were conducted using STATA version 13 (StataCorp, College Station, TX) and two-tailed *p*-values with the pre-defined cut-off for statistical significance set at 0.05.

An a priori power calculation was conducted to determine the sample size required to detect a difference in the primary outcome, BMI, at 20 months between the PCORR and EUC groups using a *t*-test with 0.80 statistical power. For moderately obese adults, a 1 to 2 unit BMI change is equivalent to 5% weight loss, which was the minimal goal of PCORR. Based on previous studies, we determined that a high estimate of variability in change in BMI was 2.2 standard deviations (SD) (Dansinger et al., 2005; Tate et al., 2003; Williams et al., 2015). A variability estimate of 2.2 resulted in an effect size estimate of 0.45. This effect size may be both clinically meaningful and statistically significant, and it required 80 participants per group. Anticipating a maximum attrition of 35% between baseline and 12 months and an additional 10% attrition from 12 to 20 months, we planned to allocate approximately 137 participants to each group.

Descriptive statistics (proportions, means, and SD) were used to describe key demographic characteristics and CVDRFs. Baseline differences between the PCORR and EUC groups were assessed using chi-square tests for categorical variables and *t*-tests for continuous variables. Differences between the PCORR and EUC groups were assessed with linear mixed-effects regression models for continuous outcomes and generalized estimating equations for binary outcomes. Models were specified with a between-subject factor of treatment group; a within-subject factor of time; and a treatment group × time interaction. Sex, age, and race/ethnicity were included as covariates. Statistical significance of the treatment group × time interaction effect in the model indicates the differential between-group change in the outcome from baseline to 20 months. Estimated marginal means, probabilities, and corresponding 95% confidence intervals of outcomes were computed at each time point. All analyses were performed using an intention-to-treat framework, and parameter estimates were based on all available data at each time point, allowing for the inclusion of participants with missing data. This approach increases power compared to the t-test used to determine the sample size and is an appropriate method for handling missing data when the extent of missing data is small and appears to be missing at random (Mallinckrodt et al., 2003; Schafer and Graham, 2002).

3. Results

A total of 262 participants completed the run-in phase and baseline visit and were subsequently randomized. Fig. 2 shows the flow of participants from recruitment through the final measurement visit at 20 months. Of these participants, 130 (49.6%) were allocated to PCORR and 132 (50.4%) were allocated to EUC. Treatment groups did not differ according to demographic characteristics or CVDRFs, with the

Table 2
Baseline demographic characteristics and CVRF status by group in the Planned CORR intervention, San Diego, CA, 2013.

	Total	PCORR	Enhanced usual care	*p*-Value
All participants, no. (%)	262 (100%)	130 (100%)	132 (100%)	
Sex, no. (%)				0.379
Male	84 (32.1%)	45 (34.6%)	39 (29.6%)	
Female	178 (67.9%)	85 (65.4%)	93 (70.5%)	
Age, mean (SD), yr				0.955
	51.5 (10.36)	52.6 (9.48)	50.4 (11.09)	
Race, no. (%)				0.827
White	155 (59.2%)	73 (56.1%)	82 (62.1%)	
American Indian/Alaskan Native	2 (0.8%)	1 (0.8%)	1 (0.8%)	
African American/Black	35 (13.4%)	20 (15.4%)	15 (11.4%)	
Pacific Islander/Native Hawaiian	8 (3.1%)	4 (3.1%)	4 (3.0%)	
Asian	22 (8.4%)	9 (6.9%)	13 (9.9%)	
Multiracial/multiethnicity	12 (4.6%)	7 (5.4%)	5 (3.8%)	
Unknown	28 (10.7%)	16 (12.3%)	12 (9.1%)	
Language preference, no. (%)				0.965
English	232 (88.6%)	115 (99.5%)	117 (88.6%)	
Spanish	30 (11.5%)	15 (11.5%)	15 (11.4%)	
Education, no. (%)				0.566
Less than high school graduate	30 (11.5%)	16 (12.4%)	14 (10.6%)	
High school graduate or GED	23 (8.81%)	13 (10.1%)	10 (7.6%)	
Some college or trade school	94 (36.0%)	40 (31.0%)	54 (40.9%)	
College graduate	71 (27.2%)	38 (29.5%)	33 (25.0%)	
Post-graduate	43 (16.5%)	22 (17.0%)	21 (15.9%)	
Other		1 (0.7%)		
Marital status, no. (%)				0.161
Single	49 (18.7%)	24 (18.5%)	25 (18.9%)	
Married/living with partner	141 (53.8%)	71 (54.6%)	70 (53.0%)	
Divorced/separated	59 (22.5%)	25 (19.2%)	34 (25.8%)	
Widowed	13 (5.0%)	10 (7.7%)	3 (2.3%)	
Monthly income, no. (%)				0.371
Less than $2000	90 (34.4%)	41 (31.5%)	49 (37.1%)	
$2000–3999	45 (17.2%)	22 (16.9%)	23 (17.4%)	
$4000–5999	27 (10.3%)	14 (10.8%)	13 (9.9%)	
More than $6000	61 (23.3%)	28 (21.5%)	33 (25.0%)	
Unknown	39 (14.9%)	25 (19.2%)	14 (10.6%)	
Baseline Weight and BMI				
Mean (SD) weight in kg	100.0 (16.3)	99.2 (15.7)	100.7 (16.8)	0.448
Mean (standard deviation) BMI in kg/m^2	35.9 (4.2)	35.7 (4.0)	36.0 (4.5)	0.678
CVRF at time of referral				
Hypertension on treatment, no. (%)				0.562
No	83 (31.7%)	39 (30.0%)	44 (33.3%)	
Yes	179 (68.3%)	91 (70.0%)	88 (66.7%)	
Smoker, no. (%)				0.089
No	243 (92.8%)	117 (90.0%)	126 (95.5%)	
Yes	19 (7.3%)	13 (10.0%)	6 (4.6%)	
Diabetes, no. (%)				0.085
No	188 (71.8%)	87 (66.9%)	101 (76.5%)	
Yes	74 (29.2%)	43 (33.08%)	31 (23.5%)	
Metabolic syndrome, no. (%)				0.918
No	154 (58.8%)	76 (58.5%)	78 (59.1%)	
Yes	108 (41.2%)	54 (41.5%)	54 (40.9%)	
Elevated fasting glucose (100 to 125 mg/dL), no. (%)				0.924
No	211 (80.5%)	105 (80.8%)	106 (80.3%)	
Yes	51 (19.5%)	25 (19.2%)	26 (19.7%)	
Waist circumference (≥35 in if female, ≥40 in if male), no. (%)				0.201
No	155 (59.2%)	82 (63.1%)	73 (55.3%)	
Yes	107 (40.8%)	48 (36.9%)	59 (44.7%)	
Triglyceride (> 150 mg/dL), no. (%)				0.036
No	167 (63.7%)	91 (70.0%)	76 (57.6%)	
Yes	95 (36.3%)	39 (30.0%)	56 (42.4%)	
HDL (< 50 mL/dL if female, < 40 mL/dL if male), no. (%)				0.090
No	202 (77.1%)	106 (81.5%)	96 (72.7%)	
Yes	60 (22.9%)	24 (18.5%)	36 (27.3%)	
Elevated blood pressure (≥ 130/85 mmHg), no. (%)				0.297
No	192 (73.3%)	99 (76.2%)	93 (70.5%)	
Yes	70 (26.7%)	31 (23.9%)	39 (29.6%)	

SD: standard deviation; BMI: body mass index; CVRF: cardiovascular risk factor; HDL: high-density lipoprotein.

exception of triglyceride level (Table 2). Specifically, the PCORR group had a greater proportion of participants with elevated triglycerides (≥150 mg/dL) compared to the EUC group, however the difference is small.

After randomization, 29 (16 from the PCORR group, 13 from the EUC group, 11.1% total) participants were removed or withdrawn due to moving out of San Diego County, joining another weight loss program, having a health issue that prevented participation, or being no longer interested/too busy, and 37 (19 from PCORR group, 18 from EUC group, 14.1% of total) were non-compliant/did not attend

Table 3
Changes in anthroprometric outcomes in the Planned CORR group versus the Enhanced Usual Care group, San Diego, CA, 2013.

	PCORR	Enhanced usual care	*p*-value (group × time)
BMI, kg/m^2 (95% CI)			0.009
4 mo	34.9 (34.1, 35.6)	35.8 (35.1, 36.6)	
8 mo	34.6 (33.8, 35.3)	35.6 (34.9, 36.4)	
12 mo	34.3 (33.5, 35.0)	35.5 (34.7, 36.2)	
16 mo	34.0 (33.2, 34.7)	35.3 (34.5, 36.0)	
20 mo	33.7 (32.9, 34.4)	35.1 (34.3, 35.9)	
Weight, kg (95% CI)			0.008
4 mo	96.2 (93.8, 98.6)	100.1 (97.7, 102.5)	
8 mo	95.3 (92.9, 97.7)	99.5 (97.1, 101.9)	
12 mo	94.4 (92.0, 96.8)	99.0 (96.6, 101.4)	
16 mo	93.5 (91.1, 96.0)	98.5 (96.0, 100.9)	
20 mo	92.7 (90.2, 95.1)	97.9 (95.5, 100.4)	
Percent change in weight from baseline, % (95% CI)			0.007
4 mo	−2.7 (−3.4, −2.0)	−0.6 (−1.3, 0.1)	
8 mo	−3.5 (−4.2, −2.9)	−1.2 (−1.8, −0.5)	
12 mo	−4.4 (−5.1, −3.7)	−1.7 (−2.4, −1.0)	
16 mo	−5.2 (−6.0, −4.5)	−2.2 (−3.0, −1.5)	
20 mo	−6.1 (−6.9, −5.3)	−2.8 (−3.6, −2.0)	
Waist-to-hip ratio, % (95% CI)			0.05
Baseline	0.93 (0.91, 0.94)	0.92 (0.91, 0.93)	
4 mo	0.93 (0.92, 0.94)	0.92 (0.91, 0.93)	
8 mo	0.93 (0.92, 0.94)	0.92 (0.91, 0.93)	
12 mo	0.93 (0.92, 0.94)	0.93 (0.92, 0.94)	
16 mo	0.93 (0.92, 0.94)	0.93 (0.92, 0.94)	
20 mo	0.93 (0.92, 0.94)	0.93 (0.92, 0.95)	
Percentage of participants who lost at least 5% of their initial weight, % (95% CI)			0.018
4 mo	23.3% (18.5%, 28.0%)	7.3% (4.5%, 10.2%)	
8 mo	30.2% (24.6%, 35.7%)	11.8% (7.9%, 15.7%)	
12 mo	38.1% (31.3%, 44.8%)	18.6% (13.2%, 23.9%)	
16 mo	46.6% (38.4%, 54.8%)	27.8% (20.3%, 35.3%)	
20 mo	55.3% (45.8%, 64.8%)	39.4% (29.2%, 49.5%)	
Percentage of participants who lost at least 10% of their initial weight, % (95% CI)			0.038
4 mo	9.1% (5.8%, 12.5%)	1.6% (0.1%, 3.0%)	
8 mo	12.4% (8.5%, 16.4%)	2.8% (0.7%, 5.0%)	
12 mo	16.7% (11.7%, 21.6%)	5.2% (2.1%, 8.3%)	
16 mo	21.9% (15.2%, 28.6%)	9.2% (4.6%, 13.8%)	
20 mo	28.3% (19.2%, 37.5%)	15.8% (8.3%, 23.3%)	

BMI, body mass index; PCORR: Planned Care for Obesity and Cardiovascular Risk Reduction intervention group.

subsequent visits. A total of 95 (73.1%) PCORR and 101 (76.5%) EUC participants completed the study at 20 months, and all 262 randomized participants were included in the analyses.

As outlined in Fig. 1, at the 4-month weigh-in, 31.5% of PCORR participants moved down to Step 2 after achieving a 5% weight loss. At the 8-month weigh-in, 21.5% of PCORR participants were in Step 2, while 13.8% moved down to Step 3. At the 12-month weigh-in, 20.0% of PCORR participants were in Step 2, and 16.2% moved down to Step 3. Between months 16–20, 40.7% of participants in the PCORR group remained in or returned to Step 1, the most intensive step; 23.8% were in Step 2, and 15.4% were in Step 3.

Table 3 shows the estimated marginal means, probabilities, and corresponding 95% confidence intervals for the anthropometric outcomes. The between-group difference in BMI at 20 months was −1.42 kg/m^2 [95% CI, −2.52 to −0.34], $p = 0.010$]. There was a significant group × time interaction effect for the primary outcome, BMI ($p = 0.009$). This indicates that the pattern of weight loss over the 20-month study was significantly different between the treatment groups, with overall weight loss favoring PCORR. Significant group × time interaction effects and between group differences in favor of PCORR at 20 months were also observed in absolute weight (−5.23 kg [95% CI, −8.72 to −1.74], $p = 0.003$), percentage weight change (−3.34% [95% CI, −4.50 to −2.18], $p < 0.001$), and the percentage of participants who lost at least 5% (15.90% [95% CI, 2.00 to 30.00], $p = 0.026$) and at least 10% (12.52% [95% CI, 00.79 to 24.25], $p = 0.036$) of their initial body weight. There was not a significant treatment effect on hip-to-waist ratio.

Table 4 shows the estimated marginal means and 95% confidence intervals for CVDRFs. Treatment effects were not observed on HbA_{1c}, glucose, C-reactive protein, cholesterol (total, HDL, or LDL), triglycerides, or systolic or diastolic blood pressure. However, there was a significant group × time interaction effect and between group difference in favor of PCORR at 20 months in insulin level (−2.82 μU/mL [95% CI, −5.50 to −0.15], $p = 0.009$).

4. Discussion

Among high-risk obese adults with at least one additional cardiovascular risk factor, PCORR resulted in clinically meaningful reductions in weight and BMI over 20 months that were significantly greater than those in EUC. To our knowledge, this is the first successful weight-loss study in adults to utilize a stepped-down approach to weight loss that integrated behavior change theory with a delivery strategy based on the Chronic Care Model (Bodenheimer et al., 2002; Carels et al., 2013; Coleman et al., 2009; Group Health Research Institute, n.d.; Norman et al., 2016).

With the exception of fasting insulin levels, secondary CVDRF outcomes including blood pressure, cholesterol, and HbA_{1c} did not differ between PCORR and the EUC group. Previous behavioral weight loss studies have shown that a modest weight loss is effective at reducing CVDRFs (Schwingshackl et al., 2014). In this study, however, significant group × time differences in CVDRFs was difficult to show perhaps because the EUC group also achieved some weight loss. Resource constraints limiting laboratory measurements to baseline, 12 months, and 20 months also caused gaps in data. It is worth noting that fasting blood glucose, HbA_{1c}, resting diastolic and systolic pressure

Table 4
Changes in cardiovascular risk factor outcomes in the Planned CORR group vs. the Enhanced Usual Care group, San Diego, CA, 2013.

	PCORR	Enhanced usual care	*p*-Value
Hemoglobin A1c, % (95% CI)			0.167
Baseline	6.2 (6.0, 6.4)	6.1 (5.9, 6.3)	
12 mo	6.2 (6.0, 6.4)	6.2 (6.0, 6.4)	
20 mo	6.2 (6.0, 6.5)	6.3 (6.1, 6.5)	
Fasting blood glucose, mg/dL			0.093
Baseline	112.4 (106.0, 118.7)	105.5 (99.2, 111.9)	
12 mo	112.5 (106.7, 118.3)	109.8 (104.1, 115.5)	
20 mo	112.6 (105.6, 119.7)	114.0 (107.1, 120.9)	
Fasting insulin, μU/mL (95% CI)			0.011
Baseline	11.2 (9.5, 12.9)	10.3 (8.6, 12.0)	
12 mo	10.5 (9.1, 12.0)	11.5 (10.0, 13.0)	
20 mo	9.9 (8.0, 11.8)	12.7 (10.9, 14.6)	
C-reactive protein, mg/dL (95% CI)			0.487
Baseline	4.4 (6.2, 6.2)	3.9 (5.7, 5.7)	
12 mo	5.3 (6.6, 6.6)	4.1 (5.4, 5.4)	
20 mo	6.2 (8.2, 8.2)	4.3 (6.3, 6.3)	
Total cholesterol, mg/dL (95% CI)			0.342
Baseline	186.7 (179.9, 193.4)	183.6 (176.8, 190.3)	
12 mo	190.5 (184.5, 196.5)	184.8 (178.8, 190.7)	
20 mo	194.3 (186.8, 201.8)	186.0 (178.6, 193.3)	
Calculated LDL, mg/dL (95% CI)			0.898
Baseline	107.1 (101.6, 112.7)	101.8 (96.3, 107.4)	
12 mo	108.5 (103.5, 113.6)	103.0 (97.9, 108.0)	
20 mo	109.9 (103.8, 116.0)	104.1 (98.1, 110.1)	
Direct LDL, mg/dL (95% CI)			0.675
Baseline	113.4 (82.0, 144.8)	113.8 (75.7, 151.9)	
12 mo	116.4 (96.6, 136.1)	107.5 (83.6, 131.3)	
20 mo	119.3 (84.3, 154.3)	101.1 (58.1, 144.2)	
HDL, mg/dL (95% CI)			0.223
Baseline	49.2 (47.1, 51.3)	50.0 (47.9, 52.1)	
12 mo	50.7 (48.7, 52.7)	50.8 (48.8, 52.8)	
20 mo	52.3 (50.0, 54.5)	51.6 (49.4, 53.8)	
Triglyceride, mg/dL (95% CI)			0.787
Baseline	152.5 (134.0, 171.0)	157.8 (139.4, 176.2)	
12 mo	149.6 (134.2, 165.0)	157.3 (142.2, 172.5)	
20 mo	146.7 (125.7, 167.7)	156.8 (136.4, 177.2)	
Resting SBP, mmHg (95% CI)			0.575
Baseline	125.1 (122.8, 127.4)	126.0 (123.7, 128.3)	
4 mo	125.2 (123.1, 127.3)	126.2 (124.1, 128.3)	
8 mo	125.2 (123.19 1, 27.2)	126.4 (124.4, 128.5)	
12 mo	125.2 (123.2, 127.3)	126.7 (124.6, 128.7)	
16 mo	125.3 (123.0, 127.5)	126.9 (124.7, 129.1)	
20 mo	125.3 (122.798 1, 27.8)	127.2 (124.7, 129.7)	
Resting DBP, mmHg (95% CI)			0.534
Baseline	82.7 (81.2, 84.3)	82.5 (80.9, 84.0)	
4 mo	82.6 (81.2, 84.1)	82.5 (81.1, 83.9)	
8 mo	82.5 (81.2, 83.9)	82.6 (81.2, 83.9)	
12 mo	82.4 (81.0, 83.8)	82.6 (81.2, 84.0)	
16 mo	82.3 (80.8, 83.8)	82.7 (81.2, 84.2)	
20 mo	82.2 (80.5, 83.9)	82.7 (81.1, 84.4)	

DBP, diastolic blood pressure; HDL, high density lipoprotein; LDL, low density lipoprotein; PCORR: Planned Care for Obesity and Cardiovascular Risk Reduction intervention group; SBP, systolic blood pressure.

all remained unchanged in the PCORR group, representing a pause in the progression of cardiovascular risk in those receiving the intervention, which is clinically important in delaying the onset of disease.

An increasing percentage of participants stayed out of Step 1 at each time point, and by 16 months, half of PCORR participants had moved on to Step 2 or Step 3 (Fig. 1). The biggest jumps were at the 4-month weigh-in from Step 1 to Step 2 (31.5%), and the 8-month weigh-in from Step 2 to Step 3 (13.8%). This is consistent with previous studies that have shown that the amount of weight lost early in an intervention predicts success in the entire treatment (Waring et al., 2014; Wilson, 1995; Wing et al., 2004). This pattern shows promise for the stepped-down approach, where the most intensive step is the first step. The approach maximizes early success in weight, which enhance self-efficacy and encourage persistent efforts. Additionally, the step-down technique may be a useful approach to systematically tailor weight loss interventions based on the needs of the patient, as it allows the patient to step back up to a more intense intervention if weight is regained.

We acknowledge that a limitation of this study was the number of participants lost-to-follow-up (25.2%). Considering the length of the study, and a variety of factors, including waning interest, busy schedules, and relocation, we find the above attrition rate satisfactory as our sample calculation allowed for 35% lost-to-follow-up. Further, selection bias during the eligibility phase due to participant self-selection and primary care provider referral may have led to a specific subset of motivated subjects for the study. Another limitation was the lack of objective measures of behaviors that lead to weight loss. Thus, we are limited in our understanding of how to specifically address these in a stepped-down intervention.

Resources did not support a cost effectiveness analysis as part of this study and, given the findings, should be included in further evaluations of this approach. Jakicic et al. has shown that a stepped-up approach was more cost effective than a standard behavior weight loss intervention (SBWI), though the amount of weight lost was greater in the SBWI group than the Step group (Jakicic et al., 2012). Finally, we are

aware of no stepped approach study (Carels et al., 2013, 2009, 2007, 2005; Moyer, 2012; Norman et al., 2016; Von Korff and Tiemens, 2000) that has compared stepped-up and stepped-down methods in the same population using the same behavioral weight loss components. Such a study might best inform clinical settings with an interest in these approaches.

Contributions

GN, LH, KC, JS, EA, CR, MC, SHZ, and KP were responsible for study concept and design. JL, JGG, JC, and LD were responsible for curation of data. JGG, JL, GN, and KP were responsible for analysis and interpretation of data. JL, JGG, LD, and KP drafted the manuscript. JL, JGG, GN, LH, KC, JS, EA, CR, MC, SHZ, KG, JC, LD, and KP were responsible for critical revision of the manuscript for important intellectual content. KP obtained the funding and supervised the study. JL, JGG and KP had full access to all of the data in the study and take responsibility for the integrity of the data, the data analysis, and the manuscript. KP affirms that everyone who contributed significantly to the work has been listed in this section.

Funding source

National Heart, Lung and Blood Institute, R01 HL089444-05.

Acknowledgments

We thank the primary care physicians and support staff at UC San Diego Family Medicine, Linda Vista Health Care Clinic, Mid-City Community Clinic, Dr. Ryan Dominguez, and Scripps Ranch Medical Clinic for assistance with recruitment and data collection. We also thank all those who participated in the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ypmed.2018.07.015.

References

Bandura, A., 1986. Social foundations of thought and action: a social cognitive theory/Albert Bandura. xiii. Prentice-Hall, Englewood Cliffs, N.J., pp. 617.

Baranowski, T., Lin, L.S., Wetter, D.W., Resnicow, K., Hearn, M.D., 1997. Theory as mediating variables: why aren't community interventions working as desired? Ann. Epidemiol. 7, S89–S95. https://doi.org/10.1016/S1047-2797(97)80011-7.

Bodenheimer, T., Wagner, E.H., Grumbach, K., 2002. Improving primary care for patients with chronic illness: the chronic care model, Part 2. JAMA 288, 1909–1914. https://doi.org/10.1001/jama.288.14.1775.

Carels, R.A., Darby, L., Cacciapaglia, H.M., Douglass, O.M., Harper, J., Kaplar, M.E., Konrad, K., Rydin, S., Tonkin, K., 2005. Applying a stepped-care approach to the treatment of obesity. J. Psychosom. Res. 59, 375–383. https://doi.org/10.1016/j.jpsychores.2005.06.060.

Carels, R.A., Darby, L., Cacciapaglia, H.M., Konrad, K., Coit, C., Harper, J., Kaplar, M.E., Young, K., Baylen, C.A., Versland, A., 2007. Using motivational interviewing as a supplement to obesity treatment: a stepped-care approach. Health Psychol. 26, 369–374.

Carels, R.A., Wott, C.B., Young, K.M., Gumble, A., Darby, L.A., Oehlhof, M.W., Harper, J., Koball, A., 2009. Successful weight loss with self-help: a stepped-care approach. J. Behav. Med. 32, 503–509.

Carels, R.A., Young, K.M., Hinman, N., Gumble, A., Koball, A., Oehlhof, M.W., Darby, L., 2012. Stepped-care in obesity treatment: matching treatment intensity to participant performance. Eat. Behav. 13, 112–118. https://doi.org/10.1016/j.eatbeh.2012.01.002.

Carels, R.A., Hoffmann, D.A., Hinman, N., Burmeister, J.M., Koball, A., Ashrafioun, L., Oehlhof, M.W., Bannon, E., Leroy, M., Darby, L., 2013. Step-down approach to behavioural weight loss treatment: a pilot of a randomised clinical trial. Psychol. Health 28, 1121–1134.

Coleman, K., Austin, B.T., Brach, C., Wagner, E.H., 2009. Evidence on the chronic care model in the new millennium. Health Aff. 28, 75–85. https://doi.org/10.1377/hlthaff.28.1.75. (Millwood).

Dansinger, M.L., Gleason, J.A., Griffith, J.L., Selker, H.P., Schaefer, E.J., 2005. Comparison of the Atkins, Ornish, weight watchers, and zone diets for weight loss and heart disease risk reduction: a randomized trial. JAMA 293, 43–53. https://doi.org/10.1001/jama.293.1.43.

Group Health Research Institute, n.d. Model Elements:: Improving Chronic Illness Care [WWW Document]. URL http://www.improvingchroniccare.org/index.php?p=Model_Elements&s=18 (accessed 12.11.14).

Jakicic, J.M., Tate, D.F., Lang, W., Davis, K.K., Polzien, K., Rickman, A.D., Erickson, K., Neiberg, R.H., Finkelstein, E.A., 2012. Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial. JAMA 307, 2617–2626. https://doi.org/10.1001/jama.2012.6866.

Kramer, C., Zinman, B., Retnakaran, R., 2013. Are metabolically healthy overweight and obesity benign conditions? Ann. Intern. Med. 159, 758–769. https://doi.org/10.7326/0003-4819-159-11-201312030-00008.

Lavie, C.J., Milani, R.V., Ventura, H.O., 2009. Obesity and cardiovascular disease: risk factor, paradox, and impact of weight loss. J. Am. Coll. Cardiol. 53, 1925–1932. https://doi.org/10.1016/j.jacc.2008.12.068.

Mallinckrodt, C.H., Sanger, T.M., Dubé, S., DeBrota, D.J., Molenberghs, G., Carroll, R.J., Potter, W.Z., Tollefson, G.D., 2003. Assessing and interpreting treatment effects in longitudinal clinical trials with missing data. Biol. Psychiatry 53, 754–760. https://doi.org/10.1016/S0006-3223(02)01867-X.

Moyer, V., 2012. Screening for and management of obesity in adults: U.S. preventive services task force recommendation statement. Ann. Intern. Med. 157, 373–378. https://doi.org/10.7326/0003-4819-157-5-201209040-00475.

National Institutes of Health, 2000. The practical guide: identification. In: Evaluation, and Treatment of Overweight and Obesity in Adults.

Norman, G., Huang, J., Davila, E.P., Kolodziejczyk, J.K., Carlson, J., Covin, J.R., Gootschalk, M., Patrick, K., 2016. Outcomes of a 1-year randomized controlled trial to evaluate a behavioral "stepped-down" weight loss intervention for adolescent patients with obesity. Pediatr. Obes. 11 (1), 18–25.

Sallis, J.F., Simons-Morton, B.G., Stone, E.J., Corbin, C.B., Epstein, L.H., Faucette, N., Iannotti, R.J., Killen, J.D., Klesges, R.C., Petray, C.K., 1992. Determinants of physical activity and interventions in youth. Med. Sci. Sports Exerc. 24, S248–S257.

Schafer, J.L., Graham, J.W., 2002. Missing data: our view of the state of the art. Psychol. Methods 7, 147–177. https://doi.org/10.1037/1082-989X.7.2.147.

Schwingshackl, L., Dias, S., Hoffmann, G., 2014. Impact of long-term lifestyle programmes on weight loss and cardiovascular risk factors in overweight/obese participants: a systematic review and network meta-analysis. Syst. Rev. 3, 130. https://doi.org/10.1186/2046-4053-3-130.

Tate, D.F., Jackvony, E.H., Wing, R.R., 2003. Effects of internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. JAMA 289, 1833–1836. https://doi.org/10.1001/jama.289.14.1833.

Von Korff, M., Tiemens, B., 2000. Individualized stepped care of chronic illness. West. J. Med. 172, 133–137.

Wadden, T.A., Butryn, M.L., Hong, P.S., Tsai, A.G., 2014. Behavioral treatment of obesity in patients encountered in primary care settings. JAMA 312, 1779–1791. https://doi.org/10.1001/jama.2014.14173.

Wagner, E.H., Austin, B.T., Von Korff, M., 1996. Organizing care for patients with chronic illness. Milbank Q. 74, 511–544.

Wang, Y.C., McPherson, K., Marsh, T., Gortmaker, S.L., Brown, M., 2011. Health and economic burden of the projected obesity trends in the USA and the UK. Lancet 378, 815–825. https://doi.org/10.1016/S0140-6736(11)60814-3.

Waring, M.E., Schneider, K.L., Appelhans, B.M., Busch, A.M., Whited, M.C., Rodrigues, S., Lemon, S.C., Pagoto, S.L., 2014. Early-treatment weight loss predicts 6-month weight loss in women with obesity and depression: implications for stepped care. J. Psychosom. Res. 76, 394–399.

Williams, R.L., Wood, L.G., Collins, C.E., Callister, R., 2015. Effectiveness of weight loss interventions - is there a difference between men and women: a systematic review. Obes. Rev. 16, 171–186. https://doi.org/10.1111/obr.12241.

Wilson, G., 1995. Obesity Treatment. Springer US, Boston, MA. https://doi.org/10.1007/978-1-4615-1901-0.

Wing, R.R., 2010. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. Arch. Intern. Med. 170, 1566–1575. https://doi.org/10.1001/archinternmed.2010.334.

Wing, R.R., Hamman, R.F., Bray, G.A., Delahanty, L., Edelstein, S.L., Hill, J.O., Horton, E.S., Hoskin, M.A., Kriska, A., Lachin, J., Mayer-Davis, E.J., Pi-Sunyer, X., Regensteiner, J.G., Venditti, B., Wylie-Rosett, J., 2004. Achieving weight and activity goals among diabetes prevention program lifestyle participants. Obes. Res. https://doi.org/10.1038/oby.2004.179.