A Toolbox Approach to Obesity Treatment in Urban Safety-Net Primary Care Clinics: a Pragmatic Clinical Trial

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BACKGROUND: There is a need for new strategies to improve the success of obesity treatment within the primary care setting.

OBJECTIVE: To determine if patients offered low out-of-pocket cost weight management tools achieved more weight loss compared to usual care.

DESIGN: Twelve-month pragmatic clinical weight loss trial with a registry-based comparator group performed in primary care clinics of an urban safety-net hospital.

PARTICIPANTS: From a large clinical registry, we randomly selected 428 patients to have the opportunity to receive the intervention.

INTERVENTIONS: Medical weight management tools—partial meal replacements, recreation center vouchers, pharmacotherapy, commercial weight loss program vouchers, and a group behavioral weight loss program—for $5 or $10 monthly. Patients chose their tools, could switch tools, and could add a second tool at 6 months.

MAIN MEASURES: The primary outcome was the proportion of intervention-eligible patients who achieved ≥ 5% weight loss. The main secondary outcome was the proportion of on-treatment patients who achieved ≥ 5% weight loss.

KEY RESULTS: Overall, 71.3% (305 of 428) had available weight measurement data/PCP visit data to observe the primary outcome. At 12 months, 23.3% (71 of 305) of intervention-eligible participants and 15.7% (415 of 2640) of registry-based comparators had achieved 5% weight loss ($p < 0.001$). Of the on-treatment participants, 34.5% (39 of 113) achieved 5% weight loss. Mean percentage weight loss was −3.15% ± 6.41% for on-treatment participants and −0.30% ± 6.10% for comparators ($p < 0.001$). The initially preferred tools were meal replacements, pharmacotherapy, and recreation center passes.

CONCLUSIONS: Access to a variety of low out-of-pocket cost weight management tools within primary care resulted in ≥ 5% body weight loss in approximately one quarter of low-income patients with obesity.

TRIAL REGISTRATION: https://clinicaltrials.gov/ct2/show/NCT01922934

KEY WORDS: weight management; obesity; primary care.

J Gen Intern Med 34(11):2405–13
DOI: 10.1007/s11606-019-05222-0

Prior Presentations *Oral presentation, ObesityWeek, October 29–November 2, 2017, Oxon Hill, MD.*

Electronic supplementary material *The online version of this article (https://doi.org/10.1007/s11606-019-05222-0) contains supplementary material, which is available to authorized users.*

Received April 23, 2018
Revised December 4, 2018
Accepted June 26, 2019
Published online August 26, 2019

INTRODUCTION

Despite known health benefits,[1–4] weight management treatment infrequently occurs within routine clinical settings. As US obesity rates have climbed, weight loss counseling in primary care has declined and the majority of primary care providers (PCPs) rarely counsel on diet and exercise.[5–7] Furthermore, reimbursement remains limited for intensive weight management services. Little is known about how patients might engage, and their potential weight loss achieved, when systems allow for improved access to intensive medical weight loss interventions in primary care.

Several medical organizations advocate for wider availability of weight management tools and obesity treatment.[8–11] Yet, little evidence exists to inform patients, providers, payers, and administrators about the potential clinical impact of providing affordable evidence-based medical weight management services within primary care.

Like other medical treatments, weight management may be more successful when treatments are tailored to individual needs. Mindful of flexibility, we conducted a pragmatic trial offering a "toolbox" of weight management options to a randomly selected group of racially and ethnically diverse patients. We aimed to test whether a greater proportion of patients offered low out-of-pocket cost tools would achieve

≥ 5% weight loss compared to those receiving usual primary care, as well as to determine tool uptake and utilization.

METHODS

Design

This is a 12-month pragmatic, open-label, single-institution intervention study with a registry-based comparator group. From a registry of patients with obesity, we offered a "toolbox" of weight management services for $5 or $10/month (Table 1). The setting was primary care clinics at Denver Health (DH), an urban safety-net healthcare organization serving ethnically diverse people. Participants chose their tool and could switch tools anytime. All intervention participants provided consent at their initial visit. Consent was waived for comparators as de-identified patient-level data were used. Patient stakeholder feedback influenced the trial's design (Online Supplementary Methods). DH and University of Colorado institutional review boards approved the trial.

Patients

In May 2014, an obesity registry was created from a computerized data warehouse. Inclusion criteria were age > 18, BMI 30–45 kg/m^2, ≥ 1 weight-related comorbidity (defined by ICD-9 codes for diabetes, prediabetes, osteoarthritis, back pain, hypertension, hyperlipidemia, metabolic syndrome, coronary artery disease, atherosclerosis, cerebrovascular disease, sleep disorder, or congestive heart failure), and receipt of primary care at DH at least twice within the previous 12 months and once within the previous 6 months. The registry consisted of patients from 9 primary care clinics. A random sample of registry patients was selected for the "toolbox" intervention, but for logistical reasons, only patients from 4 clinics were designated to the intervention arm (intervention clinics). However, since all patients not assigned to the

Table 1 Offered Weight Management Tools (the "Toolbox" Intervention)

Weight loss tool	Description of intervention	Anticipated percentage weight loss from baseline*	Out-of-pocket cost to patient per month
Partial meal replacements	30 portion-controlled entrees and 60 low-calorie shakes were provided per month. Individuals were instructed to supplement meal replacements with 2 servings of fruit and at least 3 servings of vegetables daily.	5–8%	$10
Recreation center membership†	A monthly membership allowed for up to 30 visits per month. Facility services include cardiovascular training, weight training, swimming, and formal exercise instruction (e.g., aerobics, yoga). During the time of the study, 27 recreation centers were available throughout the Denver metropolitan area and pass membership allowed for visits at any location.	Variable	$5
Phentermine	FDA-approved weight loss medication. The initial dose was 15 mg daily, with a blood pressure follow-up visit in 4 weeks. The dose was escalated to 30 mg per day after 4 weeks and depended on patient preference, a loss of at last 2% of initial weight, and no significant increase in blood pressure or pulse. Standard contraindications and precautions were followed in prescribing the drug.	3–5%	$5
Phentermine/ topiramate ER	FDA-approved weight loss medication. Dose titration and discontinuation were followed per prescribing guidelines. A dose of phentermine 3.75 mg/topiramate 23 mg extended-release once daily for 14 days and then an increase to 7.5 mg/46 mg once daily. If at 12 weeks of treatment the patient had not lost at least 3% of baseline body weight, the medication was either discontinued or the dose was escalated to 11.25 mg/69 mg daily for 14 days and then 15 mg/92 mg once daily. After 12 weeks, if at least 5% of baseline body weight had not been lost, the medication was discontinued.	8–10%	$10
Weight Watchers® vouchers	Largest commercial behavioral weight loss program in the USA. Monthly pass to 4 meetings per month.	5–6%	$5
Group behavioral weight loss program‡	*As initial tool*: a 3-phase group behavioral weight loss program modeled on the Diabetes Prevention Program (DPP). Phase 1 was aimed at producing weight loss (1–2 lb/week). Phase 2 helped patients transition between weight loss and weight loss maintenance. Phase 3 was focused on weight loss maintenance. Participants met weekly for 12 weeks, then biweekly for 12 weeks, and then once monthly up to 1 year.	8–10%	$10 for first 3 months, then $5 per month
	As add-on tool at 6 months: a once monthly program providing group support and didactic sessions. Monthly topics were selected from the DPP. Emphasis was on long-term weight maintenance strategies and accountability.	Variable	$5

**During the initial study visit, patients were provided with information about the best estimate of weight loss that might be expected should they adhere to each listed intervention. This information was also provided each time the participant chose to switch tools during the study*

†Available as either an initial tool or as an add-on second tool for engaged individuals with at least 6 months of participation

‡Available as either an initial tool or as an add-on second tool (as described in the table) for engaged individuals with at least 6 months of participation

intervention arm became part of the comparator group, intervention clinics had both intervention and comparator patients. Patients age 80 or greater and those who were deceased were then excluded. Phone recruitment by a research assistant (RA) occurred between October 2014 and June 2015. A $20 gift card was offered for attending an initial visit (visit 0).

At visit 0, a computer program described the weight management tools available from which subjects could choose one tool. Reports describing the chosen intervention and the patient's goals and challenges were given to the participant and their PCP. Two weeks later, at a non-incentivized visit (visit 1), participants finalized their tool choice for the first month and paid a copay.

For the comparator patients and patients randomly selected to receive the intervention but not consented, weights from all primary care and specialty visits were extracted from the data warehouse over a 12-month period coinciding with the trial period (see Online Supplementary Methods for further study design including information about the Patient Advisory Council).

Intervention

Between January 2015 and August 2016, on-treatment participants met monthly for 12 months with RAs trained in weight management counseling. These follow-up visits focused on tool utilization and weight loss efforts. Patients could continue their current tool or switch to another one (Table 1). After 6 months, participants could pay an additional $5/month for a second tool (either recreation center vouchers or a behavioral weight loss/maintenance support group). Participants were called and encouraged to reschedule missed visits and could return for care anytime during their 12-month enrollment. PCPs were notified of missed appointments.

Outcome Measures

The primary outcome was the proportion of intervention-eligible patients who achieved ≥ 5% weight loss at 12 months. For the intervention and comparator groups, the final weight was the measurement closest to an individual's 12-month end date ± 6 months. Secondary outcomes included the proportion of on-treatment patients who achieved ≥ 5% weight loss at 12 months, visit attendance, and tool utilization.

Chart Review

Randomly selected comparator charts ($n = 120$) were reviewed to determine how often obesity was identified as a problem and treated with an evidence-based tool during usual care (Online Appendix S1). Charts of all patients with ≥ 15% weight gain or loss were reviewed to check weight measurement validity.

Participant Characteristics

Baseline characteristics obtained from the registry included age, sex, race, ethnicity, height, weight, BMI, weight-related comorbidities, insurance status, and primary care clinic. At study visit 0, race, ethnicity, primary language, and medical conditions were confirmed in person, and household income and education were self-reported.

Statistical Analysis

For the primary analysis, the intervention-eligible group was defined as those who were randomly selected for the opportunity to receive the toolbox intervention and had available weight measurement data from either the registry (for non-consented patients) or from study clinic visits (for consented patients utilizing a tool), and comparators were those with a baseline weight ± 3 months from trial commencement and at least one follow-up weight 12 ± 6 months after the initial weight (Fig. 1). For our secondary analysis of the on-treatment group, we excluded intervention-eligible patients if they had had a myocardial infarction or stroke within the previous 6 months; were pregnant; had contraindications to weight loss (e.g., active cancer treatment, severe collagen vascular disease, end-stage liver disease, or end-stage renal disease requiring dialysis); or were deemed poor candidates by their PCP (see Figure S1). In a per-protocol analysis, the population was restricted to those on-treatment participants who attended ≥ 4 visits within 12 months. We compared baseline characteristics between intervention and comparator participants using chi-square test for categorical variables and *t* test with unequal variance for continuous variables.

We used a chi-square test to compare the proportion of intervention participants (eligible, on-treatment, and per-protocol) achieving ≥ 5% weight loss at 12 months to that in the comparator group. We used a *t* test with unequal variance to compare the mean weight change by group (kg) and as a percentage of initial weight. Based on a sample size of 305 versus 2640, the study had 90% power (alpha = 0.05) to detect a difference of 5–8% of patients achieving ≥ 5% weight loss in the intervention group as compared to the comparator group, assuming that the percentage of patients achieving ≥ 5% weight loss among comparators was 5–15%.

We conducted several sensitivity analyses for the primary analysis intervention-eligible population: (1) restricting the comparator group to those at control clinics only; (2) using a window of ± 3 months as an alternative to the ±6 months window; (3) a propensity-matched analysis adjusting for measured confounders; (4) a sensitivity analysis adjusting for cluster effects to address potential effects across clinics; and (5) assuming participants with a baseline weight but no final study weight did not achieve ≥ 5% weight loss.

In the secondary analysis on-treatment population, we estimated weight trajectory using all weights during the study and fit a longitudinal linear mixed model on weight change from baseline (kg) using random slopes and unstructured covariance. We allowed for an interaction between treatment group and time and for change in weight trajectory at 6 months.

In post hoc analysis, we compared the proportion who gained ≥ 3% of initial weight between on-treatment

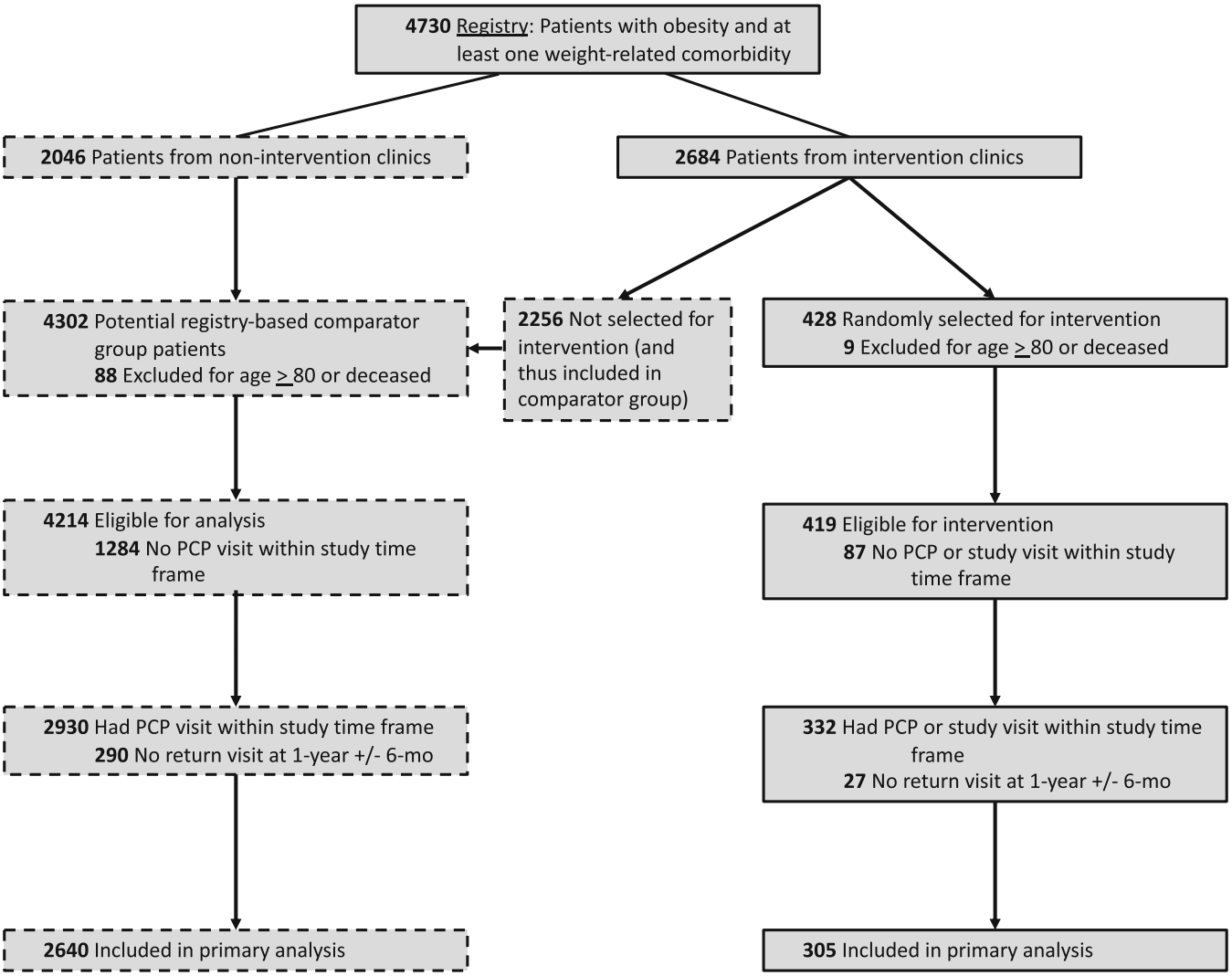

Figure 1 Flow diagram of progress through phases of a pragmatic trial comparing an intervention offering a choice of a variety of weight loss tools to usual care for weight management within primary care. A total of 4730 patients met criteria to be included in the registry (2046 received their care in non-intervention clinics and 2684 received care in intervention clinics). From the intervention clinics, 428 patients were randomly sampled to be offered the toolbox intervention and 309 of the eligible patients could be contacted to be offered the intervention [dashed lines indicate comparators that had no contact with the study and for whom data was obtained exclusively from electronic health records and stored within a registry; the comparator group consisted of all patients from non-intervention clinics and also of non-contacted patients from intervention clinics].

participants and comparators. We also performed a post hoc analysis to determine any dose-response relationship between visit attendance and weight loss by calculating the proportion of on-treatment participants who achieved ≥ 5% weight loss by number of visits attended. Because we allowed for multiple tool exposures, we could not compare individual tool effectiveness. However, we calculated the proportion of participants who lost ≥ 5% initial weight as a function of whether they had ever utilized a specific tool.

Intervention group data were stored using Research Electronic Data Capture (REDCap) software. Comparator group data were stored in DH's data warehouse. Analyses were performed using SAS version 9.4 (SAS Inc., Cary, NC) and the statistical software system R, version 3.1.2. Online Supplementary Methods contains more detailed information about the trial.

RESULTS

Baseline Characteristics

The registry consisted of 4730 patients (68.7% women, 63.0% Hispanic/Latino) with a mean age of 52.0 ± 13.8 years and a mean BMI of 35.0 ± 3.9 kg/m^2 (Fig. 1; Online Supplement Tables S1 and S2). Of the 428 randomly sampled patients offered the intervention, 305 (71.3%) met criteria to be included in the primary analysis. For secondary analyses, 113 (26.4%) met inclusion criteria in the on-treatment population (Figure S1).

Intervention-eligible participants were predominantly female, white, middle-aged, and had government insurance (Table 2). Nearly half (43.3%) had a BMI ≥ 35 kg/m^2; 82.3% had either diabetes, hypertension, or

Table 2 Baseline Characteristics of Intervention Group Versus Eligible Comparators

Characteristic*	Intervention ($n = 305$)	Eligible comparators ($n = 2640$)	p value
Sex—no. of patients (%)			
Female	200 (65.6%)	1877 (71.1%)	0.045
Male	105 (34.4%)	763 (28.9%)	
Race—no. of patients (%)†			
White/Caucasian	259 (84.9%)	2107 (79.8%)	0.10
Black/African American	43 (14.1%)	485 (18.4%)	
Asian	0 (0.0%)	8 (0.3%)	
Native Indian/Alaskan	0	0	
Other	0 (0.0%)	23 (0.9%)	
Unknown	3 (1.0%)	17 (0.6%)	
Ethnicity—no. of patients (%)†			
Hispanic or Latino	189 (62.0%)	1690 (64.0%)	0.48
Primary language—no. of patients (%)†			
English	219 (71.8%)	1836 (69.5%)	0.42
Spanish	86 (28.2%)	804 (30.5%)	
Insurance—no. of patients (%)‡			
Medicaid	112 (36.7%)	1091 (41.3%)	0.20
Medicare	95 (31.1%)	751 (28.4%)	
CICP/DFAP§	75 (24.6%)	670 (25.4%)	
Commercial	14 (4.6%)	77 (2.9%)	
Self-pay/other	9 (3.0%)	51 (1.9%)	
Age, mean (SD), year	53.0 (12.7)	51.1 (12.9)	0.015
Weight, mean (SD), kg	95.63 (16.69)	94.22 (15.97)	0.16
Height, mean (SD), cm	164.4 (10.74)	163.5 (9.90)	0.19
BMI, mean (SD), kg/m^2	35.22 (3.90)	35.17 (3.89)	0.83
BMI category			
Class I obesity (BMI 30–34.9 kg/m^2)	173 (56.7%)	1446 (54.8%)	0.74
Class II obesity (BMI 35–39.9 kg/m^2)	88 (28.9%)	818 (31.0%)	
Class III obesity (BMI 40–45 kg/m^2)	44 (14.4%)	376 (14.2%)	
Medical conditions—no. of patients (%)†			
Diabetes, hypertension, or dyslipidemia	251 (82.3%)	2158 (81.7%)	0.81
Diabetes	157 (51.5%)	1405 (53.2%)	0.56
Hypertension	213 (69.8%)	1880 (71.2%)	0.62
Dyslipidemia	179 (58.7%)	1461 (55.3%)	0.27

**See Table S1 in the Online Supplement for comparison of baseline characteristics for those randomly sampled for intervention (n = 428) versus registry-based comparators (n = 4302)*

†Race, ethnicity, primary language, and medical conditions were extracted from the registry for all patients, but answers were verified in-person with the intervention participants. Self-reported education and household income information about intervention participants is in Online Appendix S2

‡See Online Appendix S2 for detailed insurance information

§Colorado Indigent Care Program (CICP) and Denver Health Financial Assistance Program (DFAP): these programs are not considered health insurance, but are programs designed for adults in the Denver area who do not qualify for Medicaid, Medicare, or private insurance (see Online Appendix S2 for more detailed information about insurance plans and these other programs)

dyslipidemia; and 28.2% considered Spanish their primary language. Eligible registry-based comparators ($n = 2640$) and intervention participants ($n = 305$) were statistically different in gender, race/ethnicity, and age (Table 2).

Weight Loss

At month 12, the primary outcome of ≥5% weight loss was achieved in significantly more intervention-eligible participants (71 of 305, 23.3%) than comparators (415 of 2640, 15.7%) ($p < 0.001$) (Table 3). Sensitivity analyses yielded consistent results

Table 3 Percent with ≥5% Body Weight Loss, Mean Weight Loss, and Mean Percentage Weight Loss over 12 Months

Variable	Intervention group	Comparator group	p value*
Intervention-eligible population	$n = 305$	$n = 2640$	
Participants achieving ≥5% weight loss, no. (%)	71 (23.3)	415 (15.7)	< 0.001
Mean weight change, kg (SD)	−1.4 (6.4)	−0.4 (5.8)	0.007
Mean weight change, % (SD)	−1.4 (6.5)	−0.3 (6.1)	0.013
On-treatment population	$n = 113$	$n = 2640$	
Participants achieving ≥5% weight loss, no. (%)	39 (34.5)	415 (15.7)	< 0.001
Mean weight change, kg (SD)	−3.2 (6.7)	−0.4 (5.8)	< 0.001
Mean weight change, % (SD)	−3.2 (6.4)	−0.3 (6.1)	< 0.001
Per-protocol population (≥4 visits)	$n = 89$	$n = 2640$	
Participants achieving ≥5% weight loss, no. (%)	36 (40.4)	415 (15.7)	< 0.001
Mean weight change, kg (SD)	−3.8 (6.7)	−0.4 (5.8)	< 0.001
Mean weight change, % (SD)	−3.9 (6.4)	−0.3 (6.1)	< 0.001

**Chi-square test for categorical variables and t test with unequal variance for continuous variables*

with the primary analysis, with exception of the propensity-matched analysis ($p = 0.063$, Table S5). Median time between first and last weight measurements was 11.7 months (IQR 10.9–12.3) for intervention-eligible participants and 12.0 months (IQR 10.9–13.0) for comparators.

For the secondary analysis of on-treatment participants, 34.5% (39 of 113) achieved ≥ 5% weight loss (Table 3). Mean percentage weight loss was − 3.15% ± 6.41% for on-treatment participants and − 0.30% ± 6.10% for comparators ($p < 0.001$). In our longitudinal model fit on the secondary analysis population, on-treatment participants had a greater decline in weight during the first 6 months (Fig. 2a). Figure 2b, c depicts individual weight changes for all subjects in the on-treatment group ($n = 113$) and for a randomly selected group of 113 subjects from the comparator group ($n = 2640$). Weight gain of ≥ 3% occurred in significantly fewer on-treatment participants compared to comparators (16 of 113 [14.2%] versus 643 of 2640 [24.4%], respectively; $p = 0.013$) (Fig. 2b, c).

Uptake of Toolbox Weight Loss Intervention

Overall, 119 of 309 (38.5%) contacted patients selected and paid for a tool (Figure S1). Of the 119 participants, 42 (35.3%) initially chose meal replacements, 34 (28.6%) weight loss medications

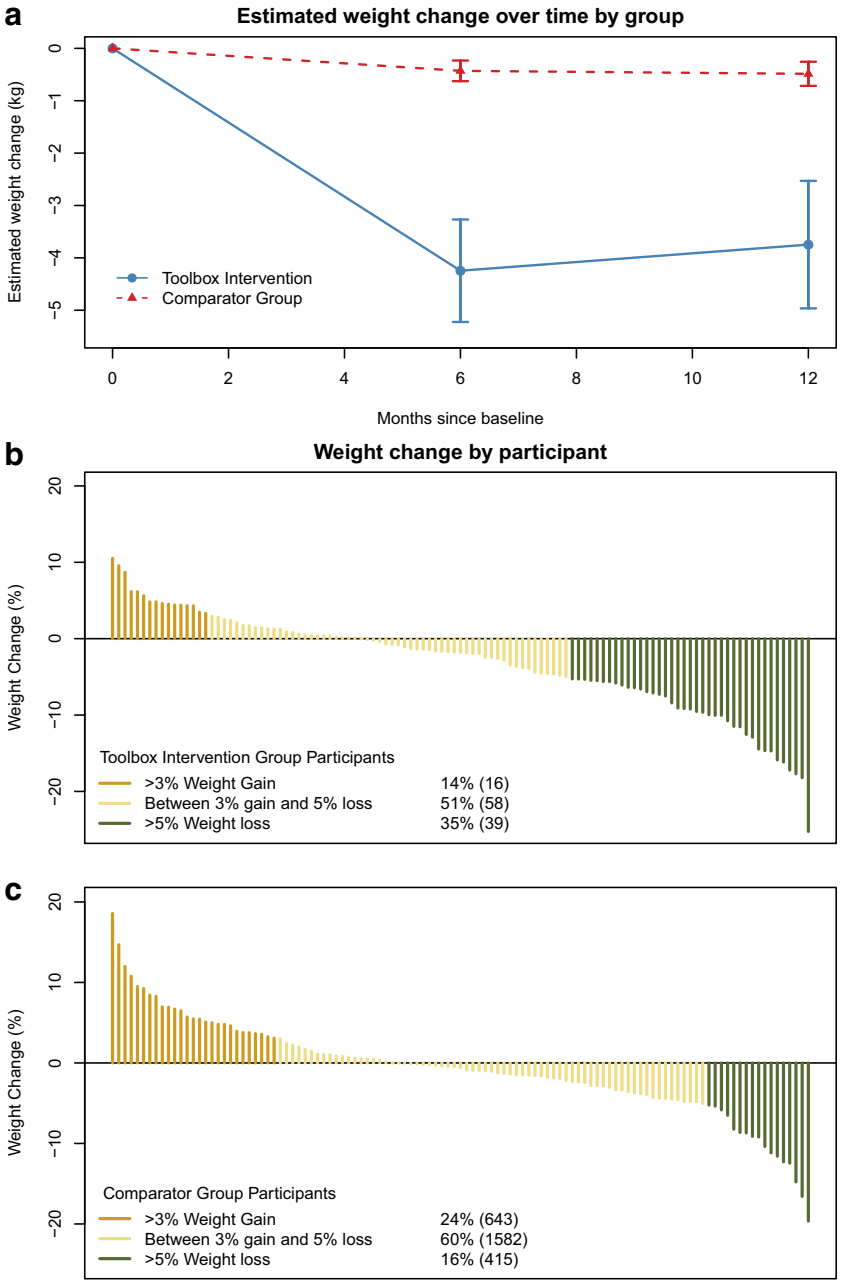

Figure 2 Weight change by treatment group over 12 months. a Weight change trajectory in the intervention and comparator groups over 12 months using a longitudinal model fit on the secondary analysis population. b Waterfall plot of weight change at 12 months for patients in the toolbox intervention group ($N = 113$). c Waterfall plot of weight change at 12 months for a random sample of 113 patients from the comparator group ($N = 2640$).

[33 phentermine/topiramate ER], 26 (21.8%) recreation center passes, 8 (6.7%) Weight Watchers® vouchers, 7 (5.9%) Diabetes Prevention Program (DPP)-based group behavioral weight loss program, and 2 (1.7%) ongoing contact. Overall, 67 of 119 (56.3%) participants switched tools at least once.

At 6 months, 35 of 119 (29.4%) participants added a second tool. Over time, there was an increase in the proportion of participants selecting phentermine/topiramate ER and a decline in those using meal replacements or recreation center passes (Fig. 3). More detailed information about tool selection can be found in Online Supplement Tables S6–S7.

Visit Attendance

Over 12 months, 119 consented participants attended 783 non-incentivized weight management visits (mean of 6.6 visits per participant). Of the 113 participants in the on-treatment analysis, 82 (72.6%) attended > 4 visits and 54 (47.8%) attended > 8 visits during their 12-month enrollment period. The likelihood of ≥ 5% weight loss increased with visit attendance with 3 of 31 (10%) losing ≥ 5% if they attended 1–4 visits and 21 of 28 (75%) if all 12 visits were attended (Figure S2).

Relationship of Tool Exposure to ≥ 5% Weight Loss

A higher proportion of participants who added a second tool or ever used anti-obesity pharmacotherapy during the study achieved ≥ 5% weight loss compared to those who never used. We did not observe a difference in weight loss when we compared patients who ever used meal replacements or recreation center passes to those who never used (Online Supplement Table S8).

DISCUSSION

This study found that 38.5% of randomly selected low-income, ethnically diverse patients with obesity and weight-related comorbidities chose to engage in a clinic-based weight loss intervention offering monthly visits and a variety of medical weight management tools at a low out-of-pocket cost. Overall, 23% of intervention-eligible patients and 35% of on-treatment patients achieved ≥ 5% weight loss at 12 months, which represents a significantly greater proportion of patients

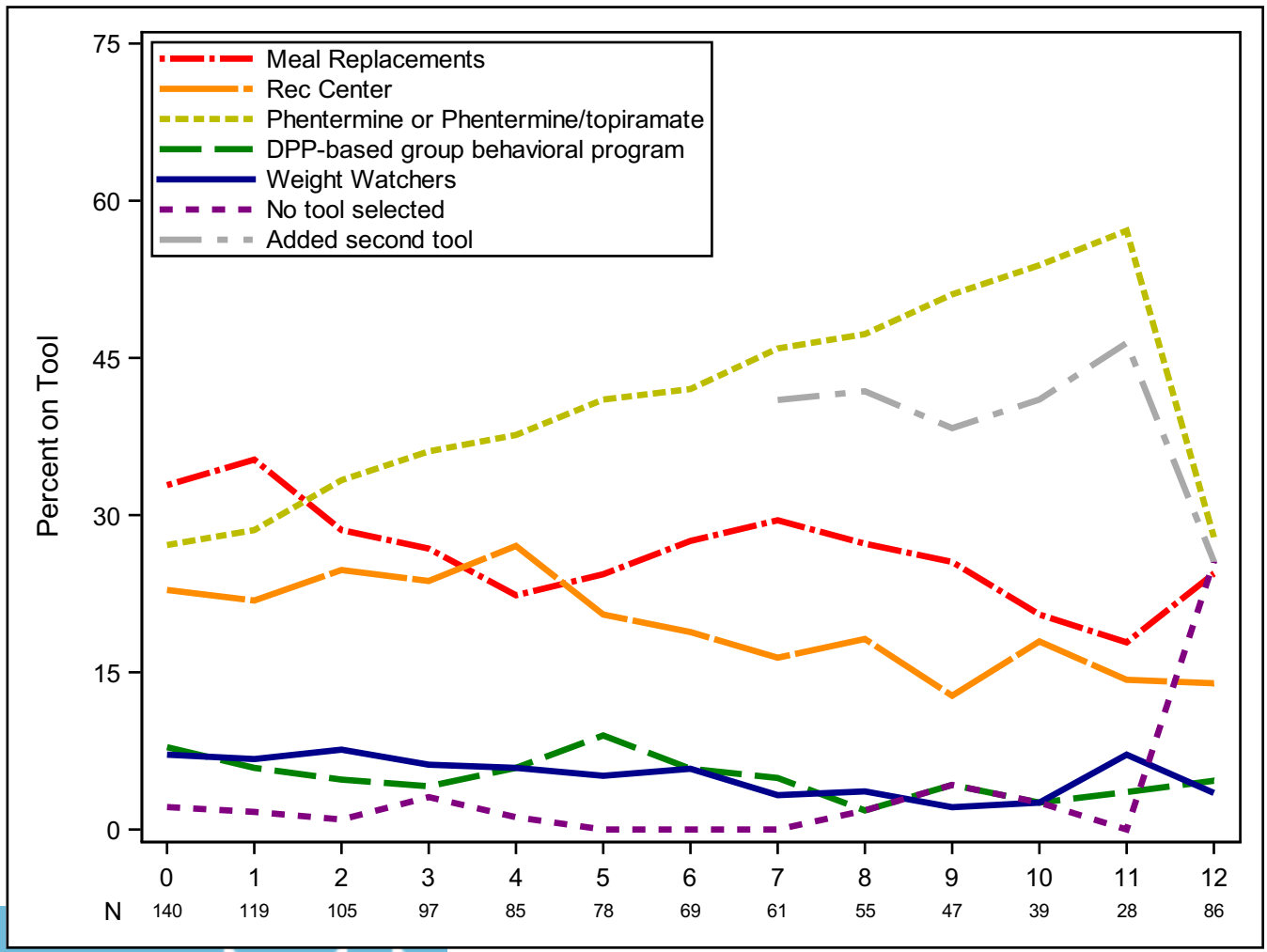

Figure 3 Trends in the proportion of intervention group participants choosing each weight management tool over 12 months.

achieving meaningful weight loss compared to a large observational group who received usual care. The "toolbox" approach resulted in average weight loss of 3.2% in on-treatment participants and 3.9% in those who attended ≥ 4 visits. These results are similar to or better than those from several primary care-based trials that primarily used behavioral weight loss interventions.[12–14] Specifically, in Wadden's 2-year pragmatic primary care-based 3-armed weight loss trial of usual care (i.e., quarterly PCP visits) versus brief lifestyle intervention (i.e., quarterly PCP visits with brief monthly sessions with lifestyle coaches) versus enhanced brief lifestyle intervention (i.e., brief lifestyle intervention plus meal replacements or weight-loss medication), weight decreased by at least 5% in 21.5%, 26.0%, and 34.9% of the participants in the three groups, respectively.[13]

Authoritative guidelines encourage PCPs to screen all adults for obesity and offer treatment. Explanatory trials have proven that several options can achieve ≥ 5% weight loss in highly selected patients treated under ideal conditions.[15–18] However, widespread use of multi-dimensional obesity care by PCPs is nearly nonexistent and, therefore, the uptake and impact of offering a range of evidence-based weight management tools is uncertain. The "toolbox" study fills this evidence gap. Chart reviews of comparator patients confirmed that weight management rarely occurs in primary care at DH, but visit attendance in the study suggests that this medically underserved population is interested in receiving robust weight management care. Using an incentivized baseline visit to learn about treatment options may partially explain the large proportion of contacted patients who participated initially (140 of 309; 45.3%), but most returned and paid a treatment copay (119 of 309; 38.5%). Over 12 months, nearly 50% of patients included in the final analysis attended ≥ 8 visits. The number of visits per year needed to optimize clinically meaningful weight loss (i.e., ≥ 5%) is not known, but our study suggests many patients offered weight loss options can achieve this goal without monthly attendance. Furthermore, there appeared to be a dose-response between number of visits attended and ≥ 5% weight loss.

Greater than 80% of patients offered the intervention initially chose meal replacements, anti-obesity pharmacotherapy, or recreation center passes; the former two are rarely offered by PCPs.[19, 20] Although a standard approach to addressing obesity, few patients in this study chose the intensive group behavioral intervention. Similar to previous studies showing greater weight loss with anti-obesity pharmacotherapy or combination therapy,[21, 22] we found that pharmacotherapy use and addition of a second tool after 6 months were associated with ≥ 5% weight loss. Barriers to anti-obesity pharmacotherapies include cost, patient and provider concerns over safety, and lack of insurance coverage and provider knowledge. Thus, despite their popularity in this study, implementing medication-based weight loss interventions may be challenging without novel care delivery systems and reimbursement changes.

Significantly fewer patients in the "toolbox" intervention gained ≥ 3% of initial body weight. In the Nurse's Health Study and the Health Professionals Follow-Up Study, small weight gains during adulthood were associated with significantly increased risks of chronic diseases including type 2 diabetes, hypertension, and coronary artery disease.[23] Thus, while weight loss in patients with obesity is generally the primary goal, prevention of weight gain is also clinically important.

Study strengths include its pragmatic design (specifically treatment choice flexibility and use of copays), use of shared decision-making to make obesity treatment decisions, and enrollment of an ethnically diverse, low-income population that typically receives limited routine weight management. The use of a registry-based comparator group, as well as limited exclusion criteria, may allow for greater extrapolation of our results to real-world settings than would more traditional explanatory trials. This trial used formal patient engagement through focus groups and a Patient Advisory Council throughout the study to ensure patient needs and desires were considered.

The study had several limitations. First, due to the short duration, long-term weight loss maintenance beyond 12 months remains unknown. Second, observational weight data from the registry cannot address intentionality; therefore, unintentional weight loss in the comparator group may overestimate the weight loss success of usual care. Third, the comparator group was formed by individuals in both intervention and control clinics, which could have potentially introduced bias if intervention clinic providers offered more weight loss tools to non-intervention patients. However, such bias would be in the direction of the null hypothesis, so the results of this trial are conservative. Fourth, while more pragmatic than most weight loss trials, this study delivered the intervention utilizing study personnel as opposed to training clinic staff. In the real-world setting, a range of trained interventionists could deliver such an intervention.[24]

CONCLUSION

Offering the choice of a variety of low-cost medical weight management tools to a randomly sampled group of adults with obesity and ≥ 1 weight-related comorbidity who receive primary care in an urban safety-net healthcare system resulted in a significantly greater proportion of patients achieving ≥ 5% weight loss at 12 months compared to usual care. Patient engagement in the intervention was high and preferred tools were anti-obesity pharmacotherapy, meal replacements, and recreation center passes over group behavioral interventions.

Acknowledgments: *The authors thank Denver Health's patients who participated in this study and the PCPs and staff at intervention clinics. Angie Tong of the Rocky Mountain Poison & Drug Center assisted the design, construction, and support of the REDCap database. Kristin Breslin of Ambulatory Care Services provided support from the DH Data Warehouse.*

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Funders *Research reported in this work was primarily funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (IH-12-11-4571). Support also came from P30 DK048520 and T32 DK007446 (DS, SI). DS was also supported by NIH/NCATS Colorado CTSA Grant Number UL1 TR001082 and the VA Advanced Fellowship Program in Health Services Research and Development. The computer program used for participant education was developed by PHCC LP, Pueblo CO. Phentermine/topiramate ER was provided by Vivus Inc. Mountain View CA.*

Compliance with Ethical Standards:

DH and University of Colorado institutional review boards approved the trial.

Conflict of Interest: *AGT served as a MedIQ consultant. DHB serves on the Data Safety Monitoring Board of Enteromedics, Inc. All remaining authors declare that they do not have a conflict of interest."*

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