

Study Protocol and Statistical Analysis Plan  
for Research Project:  
"Is MyPlate.gov approach to helping overweight patients lose  
weight more patient-centered?"

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Patterned after protocol published online in association with Appel et al. (2011)<sup>15</sup>

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#### **LIST OF ABBREVIATIONS / GLOSSARY**

BMI Body Mass Index  
 BP Blood Pressure  
 CAB Community Advisory Board  
 CC Calorie Counting  
 CPHHD Center for Population Health and Health Disparities  
 CHW Community Health Worker  
 CVD Cardiovascular Disease  
 DASH Dietary Approaches to Stop Hypertension  
 DPP Diabetes Prevention Program  
 ESRD End Stage Renal Disease  
 F&V Fruits and vegetables  
 FFQ Food Frequency Questionnaire  
 FU Follow-up  
 HDL-C high density lipoprotein cholesterol  
 HIPAA Health Insurance Portability and Accountability Act  
 IRB Institutional Review Board

Patterned after protocol published online in association with Appel et al. (2011)<sup>15</sup>

ITT Intention-to-treat  
kg Kilogram  
LDL-C low density lipoprotein cholesterol  
MI Multiple Imputation  
MyP MyPlate.gov  
NHLBI National Health of Lung and Blood Institute  
NIH National Institutes of Health  
PCP Primary Care Provider  
PHQ-9 Patient Health Questionnaire to measure depressive symptoms  
QA Quality Assurance  
QC Quality Control  
QoL Quality of Life  
RCT Randomized Controlled Trial  
RE-AIM Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance  
SAE Serious Adverse Events  
SE Standard error  
SF-12 Abbreviated version of the Medical Outcomes, Short Form-36  
TCC The Childrens Clinic of Long Beach, CA  
UCLA University of California, Los Angeles  
WEL-SF Weight Efficacy Lifestyle questionnaire – Short Form

## **1. ABSTRACT**

### **BACKGROUND**

Prolonged adult obesity is a consistent predictor of major chronic disease risk, including diabetes, heart disease, stroke, and hormone-related cancers. The traditional government-recommended approach to weight loss for obese patients has been calorie-counting / portion control (CC). In 2011 the government began recommending the MyPlate approach (MyP). The CC condition asks overweight patients to reduce their daily calorie intake to less than a recommended calorie target. The MyP approach also limits daily calories but emphasizes eating MORE high-satiation/ high-satiety foods by making  $\frac{1}{2}$  of daily food choices minimally processed fruits and vegetables, and  $\frac{1}{4}$  of daily food choices whole grains. The relative effectiveness of the MyP approach compared to the CC approach has not been clinically tested to date in urban, low-income populations.

### **OBJECTIVES**

We propose a randomized controlled trial comparing the patient-centeredness and efficacy of the CC and MyP approaches. MyP uses progressive goal-setting to facilitate a doubling of usual fruit and vegetable intake. To facilitate adherence, both approaches also include changes in the home environment to make healthier choices easier choices. Both conditions encourage patients to do 150 minutes of moderate to vigorous physical activity a week.

### **Specific Aims**

Aim #1. Use qualitative information from patients and clinicians to revise proposed intervention materials and procedures.

Aim #2. Use results of a pilot test of the intervention conditions to revise intervention materials and procedures.

Aim #3. Conduct a 12-months randomized controlled trial involving two home visits, two group education classes, and 7 telephone support/ lifestyle change coaching calls in both conditions.

Aim #4. Obtain qualitative data from providers and coaches; combine with patient survey data to assess intervention feasibility, acceptability and perceived usefulness.

Aim #5. Disseminate results and recommendations to stakeholder groups.

### **METHODS**

Study participants are 261 overweight or obese patients with a BMI range of 27.0-40.3, low-income, mostly Latino and African American adult patients attending community health centers in Long Beach, California. The MyP and CC interventions will be implemented by trained community lifestyle change coaches (promotoras) with brief support from clinicians.

**Primary hypotheses:** Compared to the CC approach, the MyP approach will yield better 12 months outcomes in terms of lower levels of everyday hunger, higher meal satisfaction, higher patient quality of life, higher patient self-efficacy at adhering to federal nutrition and physical activity recommendations, higher patient weight loss self-efficacy, and higher patient satisfaction with the weight loss program. **Secondary hypotheses:** Both intervention conditions will yield significant and similar declines in body weight and waist circumference; the MyP condition will yield greater reduction in systolic blood pressure than the CC condition.

### **PATIENT OUTCOMES (PROJECTED)**

Patient-centered outcomes include: level of everyday hunger, health-related quality of life, self-efficacy to eat more fruits and vegetables as recommended on choosemyplate.gov, and patient satisfaction with the weight loss program, all of which are expected to favor the MyP condition at 12 months follow-up relative to the CC condition. Medical outcomes include changes in body

weight, waist circumference, and blood pressure. Body composition was expected to improve in both conditions but systolic blood pressure reduction was expected only in the MyP condition.

## **2. SPECIFIC AIMS**

We propose a randomized controlled trial (RCT) comparing the patient-centeredness and efficacy of two government-supported lifestyle change approaches to reducing patient obesity risk. Study participants are 261 obese, low income, mostly Latino and African American adult patients or staff associated with community health centers in Long Beach, California. The interventions will be implemented by trained community lifestyle change coaches (promotoras) with brief support from clinicians.

The first weight loss approach is the calorie-counting (CC), portion-cutting approach recommended at [www.nutrition.gov](http://www.nutrition.gov). The second is the fill-up-sooner-on-fewer-calories approach found at [www.choosemyplate.gov](http://www.choosemyplate.gov) (MyP). The CC condition asks overweight patients to reduce their daily calorie intake to less than a recommended calorie target. The MyP approach also limits daily calories but emphasizes eating MORE high-satiation/ high-satiety foods by making  $\frac{1}{2}$  of daily food choices fruits and vegetables, and  $\frac{1}{4}$  of daily food choices whole grains. MyP uses ipsative, progressive goal-setting to facilitate a doubling of usual fruit and vegetable intake. To facilitate adherence, the MyP approach also includes home environment changes to make healthier choices easier choices. All conditions encourage doing at least 150 minutes of moderate to vigorous physical activity a week.

Primary patient-centered outcomes include levels of everyday hunger, meal satisfaction, health-related quality of life, self-efficacy to eat more fruits and vegetables as recommended on [choosemyplate.gov](http://choosemyplate.gov), and patient satisfaction with the weight loss program, all of which are expected to favor the MyP condition at 12 months follow-up relative to the CC condition. The primary medical outcomes are a reduction in body weight and waist circumference

### Specific Aims

Aim #1. Use qualitative information from patients and clinical staff to revise intervention materials and procedures.

Aim #2. Use results of a pilot test of the intervention conditions to revise intervention materials and procedures.

Aim #3. Conduct a 12-months RCT involving two home visits, two group education classes, and seven telephone support/ lifestyle change coaching calls.

Aim #4. Obtain qualitative data from providers and coaches; combine with participant data to assess intervention feasibility, acceptability and perceived usefulness.

Aim #5. Disseminate results and recommendations to community groups and public health professionals.

Primary patient-centered hypotheses: Compared to the CC approach, the MyP approach will yield better 12-months outcomes in terms of reduced everyday hunger, increased meal satisfaction, increased participant quality of life, increased participant self-efficacy to eat more fruits and vegetables, and participant satisfaction with the weight control program. Primary medical hypotheses: Both government-recommended conditions will yield significant and similar 12-months declines in body weight. The MyP condition will reduce systolic blood pressure more than the CC condition.

### 3. BACKGROUND

#### **Part A: Background and Significance**

#### **Impact of the Condition on the Health of Individuals and Populations (PCORI Criterion 1)** ***Public Health and Clinical Burden of Obesity, Especially Among Low-Income Urban Latinos and African Americans.***

U.S. overweight and obesity prevalence have increased greatly over the past 30 years.<sup>1</sup> Approximately one third of adults are overweight (BMI between 25 and 29.9 kg/m<sup>2</sup>) and another one third are obese (BMI > 30 kg/m<sup>2</sup>).<sup>1</sup> Low-income urban Latinos appear to be at especially high risk.<sup>2</sup> The lifetime medical cost burden of overweight and obesity is substantial and could be reduced through early treatment and prevention.<sup>3</sup> Through a variety of mechanisms, obesity increases the risk of CVD. These include effects mediated through traditional CVD risk factors and effects that are independent of established risk factors. Specifically, in addition to increasing BP, excess body weight increases low density lipoprotein cholesterol (LDL-C), triglyceride levels, and blood glucose levels and reduces high lipoprotein cholesterol (HDL-C) levels. As reviewed by Rashid<sup>4</sup> and as recently documented by Yan,<sup>5</sup> overweight and obesity have additional impact on CVD outcomes independent of their strong associations with established risk factors. The most recent American Heart Association statement recommends weight loss and regular physical activity for the prevention and treatment of obesity-related cardiovascular disease.<sup>6</sup> Numerous professional organizations recommend weight loss as an integral component of CVD risk factor management, often as first-line therapy prior to the initiation of medications.<sup>7-9</sup>

Similarly, overweight and obesity increase the risk of type 2 diabetes, especially in ethnic minority groups.<sup>10</sup> Lifestyle change efforts promoting weight loss in obese patients through increased physical activity and healthier food choices can reduce risk of type 2 diabetes.<sup>11</sup> About 23.6 million people in the United States have diabetes.<sup>12</sup> Of those, 17.9 million are diagnosed and 5.7 million are undiagnosed. Ninety to 95 percent of people with diabetes have type 2 diabetes. Diabetes is the main cause of kidney failure, limb amputation, and new-onset blindness in American adults. People with diabetes are more likely than people without diabetes to develop and die from diseases of the heart and blood vessels, that is, cardiovascular disease. Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes, and the risk for stroke is two to four times higher among people with diabetes.<sup>12</sup> Latinos and African Americans are particularly at risk of having type 2 diabetes.<sup>10</sup>

The decision by the American Medical Association<sup>13</sup> to designate obesity as a disease has increased interest in practical, effective clinical approaches to reducing patients' obesity risk long before obesity-related biomarkers indicate proximal risk of diabetes or heart disease.

#### **Innovation and Potential for Improvement through Research (PCORI Criterion 2)**

Two rigorously designed trials of behavioral change weight loss interventions administered to patients recruited from community health clinics were reported in the New England Journal of Medicine.<sup>14,15</sup> Their contrasting findings with respect to the long-term weight control benefits of lifestyle change alone were noteworthy and merited further exploring, in part because the different approaches may be associated with different patient quality of life outcomes. Both trials included an experimental arm that featured a lifestyle change intervention with no adjunctive medical assistance, adjuncts such as meal replacement products or use of pharmaceutical products approved for use as weight loss drugs. One of these lifestyle interventions featured a conventional energy restriction approach to weight loss but also featured the DASH diet,<sup>16-18</sup> a model dietary pattern that all healthy American adults are encouraged to consume, regardless of weight status.<sup>19</sup> The other lifestyle intervention was patterned after the behavioral intervention used in the Diabetes Prevention Program (DPP).<sup>11</sup>

The DPP lifestyle change approach seeks to create a calorie deficit in overweight patients by increasing energy expenditure in daily physical activity and simultaneously limiting daily intake of calories. This approach had yielded 7% weight loss over 2.8 years on average and a 58% reduction in risk of diabetes compared to usual care.<sup>11</sup> In the present instance, however, the DASH-like diet yielded a 5.4 kg weight loss at 1 year whereas the DPP-like intervention yielded a 3.4 kg weight loss at 1 year. This difference mirrored the results of a 1-year trial where a fruit and vegetable-supplemented fat-restricted diet yielded better 1-year weight loss than a standard fat-restrictive weight loss regimen.<sup>20</sup> The satiation/satiety/weight control benefits of encouraging obese clinic patients to eat more fruits and vegetables was also corroborated by a clinical trial in which Weight Watchers bested a variety of clinic-provided programs.<sup>21</sup> The Weight Watchers program a decade ago replaced its previous portion-controlled, calorie-counting approach with an approach encouraging increased consumption of high-satiation/ high-satiety foods, especially fruits and vegetables.<sup>22,23</sup>

Although both lifestyle change approaches recommended energy restriction, the DASH-diet investigators<sup>15</sup> focused more of their lifestyle change efforts on increasing patients' adherence to the DASH dietary pattern. A defining feature of the DASH dietary pattern is that it encourages daily intake of twice the quantity of fruits and vegetables as is typically consumed in the usual American diet. This feature has recently been given more prominence as one of the seven dietary recommendations associated with [www.MyPlate.gov](http://www.MyPlate.gov), the federal initiative designed to replace the food pyramid with a food plate as the nation's leading nutrition education icon. ([www.MyPlate.gov](http://www.MyPlate.gov)) The specific recommendation is for Americans to fill half their plate with minimally processed fruits and vegetables (fruit juice is highly processed and therefore not included). The naive observer might question the wisdom of Americans doubling their consumption of any food groups, given their documentably high prevalence of obesity. Counterintuitively, interventions that induce overweight individuals to eat substantially more minimally processed fruits and vegetables than usual are consistently (but not always) associated with reduced body weight at 6-months,<sup>16</sup> 12-months<sup>20</sup>, 2-years follow-up<sup>24</sup> and 4-years follow-up.<sup>25</sup> One exception was a fruit and vegetable intervention involving breast cancer survivors.<sup>26</sup> A noteworthy difference between the previous fruit and vegetable interventions and this last one, however, is that this last one featured 12 fluid ounces of fruit/vegetable juice a day as a replacement for three servings of whole fruit or whole vegetable. The metabolic consequences of consuming carrots in the form of juice are quite different from the metabolic consequences of consuming minimally processed, whole carrots.<sup>27</sup> In general, calories consumed in liquid form have less satiety value than calories consumed in solid form.<sup>28</sup> More specifically, the conversion of whole fruit to fruit juice usually entails removal of dietary fiber.<sup>29</sup> If consumed, dietary fiber from fruit can serve as substrate for butyrate-generating or acetate-generating commensal microbes in the large bowel, which in turn can stimulate satiety-signaling via increased expression of the satiety hormones glucagon-like peptide-1 (GLP-1) or peptide tyrosine tyrosine (PYY).<sup>30</sup> Chronically depriving commensal gut microbes of dietary fiber substrate by consuming fruit in the form of juice instead of as whole fruit can contribute to gut dysbiosis, inflammation, insulin resistance, reduced satiety-signaling and eventually, obesity.<sup>31</sup>

While both the DPP and DASH dietary approaches have been shown to reduce excess body weight in the short run, the ability of patients to maintain these approaches for the long-term remains to be determined. Several steps were taken to ensure that the intervention effects for the MyP condition would be long-lasting.

#### **Additional steps incorporated in the current proposal to ensure sustainable intervention impact.**

We will take several steps to ensure that the intervention effects for the MyP condition would be sustainable by the community clinics. One step is to replace the masters or doctoral-level health



educators/counselors typically used in behavioral weight loss interventions<sup>32</sup> with trained community health workers (promotoras). The social modeling of Social Cognitive Theory<sup>33,34</sup> and experience<sup>35</sup> suggest that the predominantly low income Latino immigrant patient population comprising the study population can relate to non-college-educated Latino community health workers better than they can to bilingual but non-Latino masters or doctoral-level counselors.<sup>35</sup> African American type 2 diabetes patients as well as Latino patients have benefited from use of community health workers as behavior change agents.<sup>36,37</sup> On the other hand, community health workers need substantially more training and supervision to carry out the intervention according to protocol. Substantial time is devoted in Year 1 of the present proposal to the training of the community health workers. The Intervention Director's primary responsibility during the active intervention phase is to supervise the community workers in the MyP condition weekly, monitor their lifestyle coaching, and provide guidance as needed to ensure adherence to the MyPlate.gov messages. TCC nutritionists will supervise the community health workers weekly in the CC condition to ensure good adherence to the CC intervention protocol. The use of coaches with closer community ties to the participants holds promise for more sustained lifestyle behavior change benefit.<sup>36,38-40</sup>

A second step was to increase the number of coaching sessions so that the maximum number of contacts was 11 contacts (2 in-home, 2 group education sessions, 7 telephone coaching sessions), to more closely approximate the number of contacts used in previous clinic-originated weight loss efforts,<sup>14,15,40-44</sup> to allow for more opportunities for participant-coach problem-solving and participant trialing of specific lifestyle change strategies, and to capitalize on the motivational benefits of continued monitoring by health care professionals.<sup>45</sup> For this study, the health sessions were delivered in the order give below, in Table 2.

Table 2. Chronological Order and Type of Intervention Session

1) In-home health education session #1
2) Telephone coaching session #1
3) Group education session #1
4) Telephone coaching session #2
5) Telephone coaching session #3
6) Telephone coaching session #4
7) In-home health education session #2
8) Telephone coaching session #5
9) Group education session #2
10) Telephone coaching session #6
11) Telephone coaching session #7

Although patients were encouraged to complete health education sessions in this order, they were allowed to complete the lessons in the order that best fit their schedules. In addition, patients were encouraged to complete health education sessions within a 3 months period after enrollment; however, they were allowed to complete as many lessons as possible before their 6 months follow-up assessment.

A third step was to devote more intervention resources to ensuring that the participant's home environment is optimally supportive of healthier lifestyle choices. Two thirds of calories are typically consumed in the home.<sup>46</sup> There is increasing evidence that, if not addressed, the visual cues in the typical home environment can undermine individual efforts to adopt healthier lifestyle behaviors and can contribute to relapse despite the strongest behavioral modification

Patterned after protocol published online in association with Appel et al. (2011)<sup>15</sup>

efforts.<sup>46</sup> Both physical (e.g., type of food available) and social (e.g., support from family) factors in this setting have been associated with weight, dietary habits, and activity patterns.<sup>47,48</sup> Demonstrated links between the physical home environment and behavior include relationships between available high-fat foods and fat intake,<sup>49</sup> access to home exercise equipment and activity levels,<sup>50,51</sup> and number of TV sets and amount of television viewing.<sup>52</sup> In the most ambitious home environment-focused weight loss intervention published to date,<sup>46</sup> researchers used checklists to get participants to rid the home of high-calorie, high-fat foods and to stock the kitchen with healthier fare. They also provided participants with a treadmill or stationary bicycle for home use, and a pedometer for brisk walking outside. They restricted TV use to one communal room of the home, and attached a timer to the TV to limit the daily time spent watching TV. Finally, the investigators gave the participants a digital body weight scale and encouraged them to self-weigh daily. In conjunction with weekly counseling sessions for the first 6 months, all participants in the home environment-focused intervention lost significant weight at 6 months; the women participants maintained the weight loss at 18 months. What is particularly exciting is that the partners of the study participants all lost and maintained significantly more weight loss, male or female, than partners in the more traditional behavioral weight loss arm, even though they were not the primary targets of the intervention.<sup>46</sup> Most of these environmental changes are home environment intervention features in our on-going research.<sup>53</sup> Several innovations to the foregoing home environment intervention approach need to be noted that will be incorporated in the current intervention design. One difference is that the current proposal features two coaching sessions that actually take place in the home, so that the health coach together with the patient can scan food products in the pantry and the refrigerator and designate each food product as a red light food (limit to no more than once a month), green light food (an everyday food), or yellow light food (nutritiously intermediate food – limit to once a week).<sup>54</sup> Our community advisory board approved the home visits and our community health workers have been warmly welcomed into participants' homes. The second difference is that our intervention does not seek to ban less healthful choices from the home but instead to position the healthier choices so that they are the most conspicuous and the easiest choice. The literature on behavioral economics suggests that changing the “decision architecture” around the home will be enough to alter food choices; bans are not necessary.<sup>55,56</sup> We avoided bans because bans can be seen as taking away legitimate choices and lead to pushback by other household members. We also avoided bans because some low-income families have doubled up with other families to share a single apartment and therefore do not have the latitude to ban legitimate food choices.

A third feature is the inclusion of taste-testing as a way to enlarge participants' repertoire of palatable fruits and vegetables. Persistent efforts by nutrition professionals to induce study participants to eat more fruits and vegetables consistently increases participants' liking for and consumption of a greater range of fruits and vegetables.<sup>25,57-60</sup> Absent the availability of consistent access to nutrition professionals, however, a more practical approach is needed to engender increased liking for a greater variety of fruits and vegetables. The taste-testing will mimic the “product-demonstration” food sampling techniques that food manufacturers use to gain population acceptance of new food products. The taste-testing to be incorporated in the current intervention will consist of fruit and vegetable-rich dishes cooked by a Master's Level nutrition specialist from culturally-tailored recipes contributed by study participants or obtained from governmental organizations (Example: Champions for Change, the California Department of Public Health). The taste-testing sessions will be offered to participants in the MyPlate arm during the group education sessions. The study Intervention Director will conduct nutritional analyses of the recipes for each taste-testing and select the 2 recipes to be presented during the group education sessions that are richest in minimally processed fruits and vegetables, while minimizing sodium. For this study, the two selected recipes were: 1) Vegetable Ceviche

Patterned after protocol published online in association with Appel et al. (2011)<sup>15</sup>

and 2) Whole-grain vegetable rich tortas. The selected recipes feature fruits and vegetables that patients most likely have not tasted before in these dishes. The principle behind taste-testing fruit and vegetable dishes that participants have not tasted before is that it can take up to 8-12 exposures (i.e. “tastings”) for humans to like eating a novel plant-based food.<sup>61,62</sup> Participants will be encouraged to do their own taste-testing experiments with new plant foods, minimally processed, modeling their experiments after the examples prepared for the taste-testing events. Once acquired, liking for a new plant food is unlikely to be lost, absent a change in physiology occasioned by pregnancy or disease.<sup>63,64</sup> Increased liking for plant-based foods, in turn, should facilitate adherence to the MyPlate recommendation that one half of the typical meal plate be occupied by fruits and vegetables.<sup>65</sup>

A fifth innovative feature is to conjoin the MyPlate nutrition messages with the recommendations from the *Physical Activity Guidelines for Americans*, so that increased daily physical activity can engender greater appetite for water-bearing and fiber-bearing foods. The most common nutritional deficit induced by physical activity is water.<sup>66</sup> The most common component of minimally processed, fresh fruits and vegetables, by weight, is water.<sup>67</sup> Not surprisingly, when presented with ad lib consumption of foods varying in water, healthy subjects who just completed two hours of aerobic exercise will prefer water-rich foods to calorie-dense foods.<sup>68-70</sup> The most important food component contributor to satiation is water.<sup>71,72</sup> But water by itself provides little satiation benefit; it must be integrated in foods, typically accompanying fiber, in order to promote satiation/ satiety.<sup>73</sup> Ironically, given the greater caloric needs of athletes relative to sedentary individuals, exercisers who have just completed a bout of exercise prefer beverages with less sugar in solution than non-exercisers.<sup>68,74</sup> Exercise may affect satiation and satiety processes through other pathways as well.<sup>75,76</sup> In short, for participants to develop increased preference for foods rich in water and for beverages with lower levels of sweetness, it would help for participants to engage in “sweat”-related activity every day, even if it is just brisk walking.<sup>77</sup> By itself increased physical activity seems not to result in sustainable weight loss<sup>78</sup> but increased physical activity is consistently a predictor of long-term weight loss when coupled with a dietary approach to weight loss, perhaps partly because of its effect on preference for water-bearing and fiber-bearing foods<sup>79-81</sup> and partly because of its effect on the transit time of the food remnants through the intestinal tract,<sup>82,83</sup> which could affect satiety-signaling in the large bowel.<sup>76</sup>

The common thread linking these last two steps is the increasing evidence that taste preferences are modifiable and can be shaped by conscious participant effort to overcome neophobic reactions to new plant tastes and by participants engaging in sweat-inducing daily physical activity, to motivate increased intake of high-satiation/ high-satiety foods and decreased intake of sugar sweetened beverages.

### ***Efficacy Trials of Weight Loss***

**In-Person Interventions.** Numerous trials<sup>16,84-87</sup> have demonstrated the efficacy of behavioral modification interventions in reducing weight and improving health outcomes in overweight or obese adults. The U.S. Preventive Services Task Force concluded from its review of the literature on clinic-based behavioral change approaches to obesity treatment<sup>88</sup> that the most effective interventions were comprehensive and of high intensity (12 to 26 sessions in a year). Effective intervention components included group health education sessions, individual coaching sessions, setting weight-loss goals, improving food choices, physical activity sessions, addressing barriers to change, active use of self-monitoring, and strategizing how to maintain lifestyle changes.

**Telephone Coaching.** Personal telephone contacts with a trained lifestyle change interventionist have been shown to improve adherence to recommended physical activity<sup>89,90</sup>

Patterned after protocol published online in association with Appel et al. (2011)<sup>15</sup>

and to promote self-monitoring of food intake and physical activity engagement.<sup>89</sup> More specifically, results from a study that tested the effects of structured and unstructured telephone prompts to increase adherence to a walking program showed a dose-response effect.<sup>89</sup> Participants assigned to receive one telephone call per week had greater adherence to physical activity guidelines than those who received one telephone call every 3 weeks. This “intermediate” group, in turn, had better adherence than those who received no telephone coaching. This is an important finding because adherence to exercise guidelines is a well-accepted determinant of weight loss outcomes, particularly once weight loss has been achieved.<sup>91</sup> Another study of telephone lifestyle change coaching found that self-monitoring among participants was higher in those who received phone calls and letters compared to those receiving no intervention.<sup>92</sup> This finding is important because self-monitoring is a consistent correlate of success in behavioral weight loss interventions.

### **Summary of Efficacy Trials and Implications for Effectiveness Studies**

Lifestyle change interventions provided in-person have been well-documented as an evidenced-based treatment for weight management, particularly when contacts are frequent and treatment is of sufficiently long duration.<sup>88</sup> Studies suggest that telephone coaching can complement in-person lifestyle change coaching and can promote behaviors documentably associated with successful weight loss (increased physical activity and self-monitoring). The proposed trial will compare two evidence-based approaches to treating patient overweight/obesity using modalities of treatment empirically shown to be effective in efficacy studies. Although historically experimental trials focused on a single modality to provide the intervention, collective consideration of the literature suggests that it is likely that a mix of different channels is optimal for generating sustained weight loss over the long-term.

### **Impact on Health Care Performance (PCORI Criterion 3)**

#### ***Effectiveness Studies: Weight Loss in the Health Care Setting***

*Results from clinical trials:* As previously noted, a rich literature of clinical trials has documented the efficacy of behavioral modification interventions in reducing excess body weight and improving health outcomes in overweight or obese adults. In a review that focused on screening and treatment of adults in clinical practice, a major limitation was that all but two trials were conducted in research settings, not in clinical practice settings.<sup>93</sup>

#### ***Barriers to implementing weight loss interventions in health care settings:***

It has long been a challenge to rely on the primary health care provider to implement weight loss interventions in clinical practice; the provider has to be willing and able to deliver the intervention. Observational data<sup>94</sup> have consistently shown providers to underdiagnose obesity and provide obesity-related counseling to only a minority of eligible patients.<sup>95</sup> Qualitative data and survey research data collected from primary care providers have identified barriers to providing weight loss counseling. The most common barriers include insufficient confidence, knowledge and skills.<sup>96</sup> The lack of publicly available, evidence-based weight loss programs may be an important reason why health care providers do not proactively recommend lifestyle modification to overweight and obese patients.<sup>97</sup> It also bears mention that providers may be aware that some studies have shown that counseling (with or without drug treatment) to be more effective if provided by someone other than the physician or primary health care provider, such as a dietitian or clinical psychologist.<sup>98,99</sup>

Because of these barriers, this study assumed that it would be more effective for primary care providers to refer patients to TCC-employed community health workers for intensive behavioral coaching using multiple modalities (home health education, group education, telephone

coaching).<sup>93,99</sup> Similar approaches have been used in primary care-based coaching to increase physical activity<sup>100,101</sup>, to promote a healthy diet<sup>102,103</sup> and to address multiple behavioral risk factor interventions.<sup>104</sup> For obesity management, the US Preventive Services Task Force stated “Some interventions, in particular intense counseling, may be difficult to incorporate into medical practice. One option may be referral to programs that offer intense counseling with behavioral therapy.” This trial will be consistent with the referral option but not referral to an outside agency but rather referral to another clinic staff member, a well-trained community worker who knows well the community in which the patients live but who also knows well what other clinic resources can be called on, if needed. In any event, patients who qualify for the study are expected to be encouraged by their primary care provider at the time of enrollment to adhere to the federal lifestyle guidelines recommended in this trial.

## **Part B: Relevance to Patients (PCORI Criterion 4)**

**Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?** We seek answers to two PCORI questions:

1. *“Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”*

2. *“What are my options and what are the potential benefits and harms of those options?”*

We surmise that much of the recidivism in weight loss trials reviewed above can be attributed to the requirement for dietary restraint and the consequent feeling of deprivation that accompanies the calorie counting approach to weight loss. Because the MyP approach promotes consumption of high-satiation/ high-satiety foods, it improves patient-centeredness by reducing the feeling of chronic, everyday hunger and reduces the need for dietary restraint because patients will stop eating because they feel full, not because they feel they have to. The results of this trial will provide patients with answers to the question of which approach to weight loss will result in greater improvement in patient outcomes that matter most to them. Because most of the patients will be low income, issues that matter particularly to low-income patients, such as food insecurity, will be assessed and be investigated as potential effect modifiers. Because many of the participants will have low literacy levels, both interventions include in-home visits where prescriptive behaviors can be more easily described than in the clinic setting. Because 75% of the study participants will be Spanish-speaking, issues that matter particularly to non-English speaking patients will be studied as additional, potential effect modifiers.

**Is the proposed research focused on questions and outcomes of specific interest to patients and their caregivers?** This application was designed to focus on questions of specific interest to patients. Nearly all (97%) of obese patients and 84% of overweight patients wanted to lose their excess weight.<sup>105</sup> Less than half of them ever discussed their weight with their physicians. When asked what types of weight management assistance they would want from their physicians, they said (1) dietary advice, (2) help with setting realistic weight goals, and (3) exercise recommendations.<sup>105</sup> Both of the experimental conditions provide dietary advice, help with setting realistic weight goals, and the recommendation to exercise at least 30 minutes daily most days of the week. Further, this application focuses on these outcomes of specific interest to patients: freedom from hunger, health-related quality of life, weight control self-efficacy, and patient satisfaction with the intervention.

## **4. STUDY DESIGN**

**Research Question.** Which of two different government-recommended behavioral strategies for losing excess weight (MyP vs CC) should clinics feature in their lifestyle change efforts targeted

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to obese patients wanting to lose excess weight through lifestyle change? More specifically, do patient-centered outcomes at 12-months follow-up favor the traditional energy restriction, calorie-counting approach featured in <http://win.niddk.nih.gov>? Or do patient-centered outcomes favor the newer [www.MyPlate.gov](http://www.MyPlate.gov) approach, which emphasizes filling up faster on fewer calories by greatly increasing the intake of water-rich, fiber-rich foods such as fruits and vegetables and other high-satiation/ high-satiety foods (like nuts) in addition to encouraging patients to restrict saturated fat and sugar?

**Choice of comparators.** Overweight patients are highly interested in receiving advice from their primary care physicians about effective lifestyle change approaches to losing excess weight.<sup>105</sup>

**Calorie Counting Approach.** The traditional government recommendation to clinicians about what this advice should be is well-reflected by the information at: <http://win.niddk.nih.gov/publications/talking.htm#staff> or at: <http://www.healthfinder.gov/prevention/ViewTopic.aspx?topicId=25>. This information focuses on getting the patient to deliberately adhere to an energy-deficit diet, where energy expenditure exceeds energy intake. The behavioral pathways to achieving a daily energy deficit include increased physical activity, careful monitoring of energy intake and deliberate reduction of portions of foods commonly consumed to ensure adherence to lower-than-usual daily calorie intake. While there is some mention of substituting low-calorie foods such as fruits and vegetables for high-calorie foods, the focus is more on reducing the amount of current food choices rather than on changing the nature of the foods consumed.

**My Plate Approach.** By contrast, the [www.MyPlate.gov](http://www.MyPlate.gov) initiative explicitly calls on Americans to change the proportion of their plate that is devoted to different food groups, to eat more minimally processed fruits and vegetables relative to other food groups, to favor whole grains when grains are consumed, to replace high-fat dairy with low-fat or nonfat dairy, to replace sugary drinks with water, and to choose lower-sodium alternatives. The behavioral pathways to achieving a daily energy deficit using the MyPlate approach include doubling typical intake of fruits and vegetables, limiting intake of caloric beverages, engaging in moderate physical activity every day, not skipping breakfast, and limiting sodium intake. The message that Americans can achieve a healthier weight by eating MORE of some foods is a relatively new message and one that would benefit from comparative assessment with the government's more traditional calorie-counting, portion-control approach. Differential adherence to these two different approaches was not a problem in a clinical trial of overweight adult women<sup>20</sup> and is not expected to be a problem here. Protocols for both approaches have been well-detailed in recent clinical trials and have been associated with good study retention at 2 year follow-up.<sup>14,15</sup>

**Choice of study design.** We propose a randomized controlled study involving 300 (later reduced to 261)<sup>1</sup> low-income obese adults recruited from community clinics located in the Long Beach, California metropolitan area. To ensure broad generalizability of results, we will be including not only patients with a primary diagnosis of obesity but also patients who are obese and also have a primary diagnosis of uncomplicated type 2 diabetes and uncomplicated hypertension. Because of their disproportionate prevalence in the TCC population (76%) and because of their disproportionately high risk of obesity, we confidently predict that most of the enrollees will be Latinos, half of whom will prefer to speak Spanish. A minority (7% according to baseline data; 13% according to TCC statistics%) will be African American. We anticipate

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<sup>1</sup> Accrual took longer than expected. Planned subgroup analyses by sex and ethnicity requiring the original sample size were obviated by the recruitment of fewer men than anticipated (4.6% versus 30% expected) and fewer African Americans than expected (7.7% versus 15% expected). Statistical power for remaining planned subgroup analyses involving women and Latinos exceeded 80% at the lower sample size of N=261.

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enrolling mostly women. Randomization will occur at the individual level despite the risk of patients assigned to different conditions talking to each other in the waiting room and discovering that their health coaching messages are different. Except for brief encounters with trained clinical staff about their participation in the lifestyle change coaching program, most of the health information transmitted in this program will occur in the home, by phone or in group education classes, not in the examination room. Analyses will take into account the fact that patients are nested within clinics and within providers but previous experience with randomization at the clinic level convinced us that the study design was stronger, easier to administer and easier to analyze when randomization occurred at the level of the individual patient instead of at the level of the primary care clinic.

The Community Advisory Board. The Community Advisory Board (CAB) is comprised of members representing all major stakeholders: UCLA investigators, TCC investigators, TCC patient representatives, community public health leaders, thought leaders in lifestyle change interventions. The CAB can be viewed as equivalent to the Board of Directors. Members' input will help shape the design of the proposed research, interpretation of results and the nature of the final recommendations, but will generally leave the day-to-day decision-making to the TCC and UCLA investigators. Members with equivalent ability to represent specific stakeholders with respect to community approaches to weight control will be selected to replace those who can no longer serve on the CAB, with the objective of continuing to represent fairly the full range of stakeholders. Study investigators are part of the CAB because their presence validates the stated authority of the CAB to make decisions about study implementation, interpretation of results and final recommendations.

Culturally tailored materials. All print materials and study measures will be translated into Spanish, back-translated to ensure accuracy and subjected to cognitive interviews, to ensure that they communicate the same constructs as the corresponding English print materials and study measures. Study print materials and measures will be reviewed in focus group discussions to ensure community acceptance of the final versions.

Qualitative assessment of intervention features and specific measures proposed for use in this study. The intervention features and specific measures described below are included in the study conditional on their being accepted by participants in focus groups and key stakeholder interviews (report of qualitative results due July 31, 2014) and conditional on the results of the pilot randomized controlled clinical trial (report of pilot study results due January 30, 2014). The Community Advisory Board will also vet the proposed intervention design and study measures. Relying on their past experience conducting and publishing qualitative research<sup>106,107</sup> the investigators will use well-accepted protocols for preparing the discussion guide, facilitating the focus group discussion, identifying common themes from the resulting transcripts and using these results to modify draft intervention protocols and proposed measures. These procedures were adapted from ones well-described in the 3<sup>rd</sup> edition of Krueger & Casey (2000).<sup>108</sup>

Laying the groundwork: overview of key stakeholder interviews. The initial six key stakeholder interviews will be drawn primarily from community members and interested TCC staff who are knowledgeable about the challenges typically faced by TCC patients in their obesity control efforts and knowledgeable about the obesity control resources and limitations that characterize the typical TCC clinic. Input from some of these key stakeholders would continue to be sought throughout the data collection phase and intervention design phase as members of an informal "brain trust" and would include the signatories of some of the support letters submitted with the application. Key stakeholders will be paid a nominal incentive worth \$20 for spending 30-50 minutes responding to structured questions about designing the optimal obesity control program for TCC patients.

The final list of topics discussed with key stakeholders is given below and was established by the research partnership comprised of Dr. Chandler, the TCC patient representatives, other CAB members and the UCLA investigators.

#### Knowledge and attitudes about healthy eating habits

Federal nutrition guidelines<sup>109</sup> currently recommend that Americans make one half of everything that they eat per day fruits and vegetables (excluding juices), and that they make another quarter of everything that they eat per day grain foods high in fiber and low in salt and unhealthy fats.

- Would these healthy eating habits be easy or hard to follow? (Why/How?)
- What makes these healthy eating habits hard (or easy) to follow when you eat meals at home?
- What makes these healthy eating habits hard (or easy) to follow when you eat meals outside the home?
- What makes these healthy eating habits hard (or easy) to follow on special occasions (weddings, quinceañeras, church or social gatherings)?
- What makes these healthy eating habits hard (or easy) to follow when shopping in stores or markets?
- Do you have suggestions or ideas how to make it easier for people like you to follow these healthy eating habits?

#### Knowledge and attitudes about physical activity

Federal physical activity guidelines<sup>110</sup> recommend moderate physical activity of at least 30 minutes per day, five days per week of at least 10 minutes per bout of exercise. This may be any kind of activity (walking, dancing, going up and down stairs, playing a sport, etc.), and may be either 30 minutes at a time, or in three separate periods of ten minutes each. National experts<sup>111</sup> also recommend that people spend no more than 2 hours a day watching TV or doing computer or video games and instead engage in more physically active pursuits, such as walking, gardening or bicycling.

- Is this a physically active lifestyle that would be easy or hard to follow? (Why/How?)
- What makes this physically active lifestyle hard (or easy) to follow when you are at home?
- What makes this physically active lifestyle hard (or easy) to follow when you are outside of the home?
- Many people find that they can better follow a physically active lifestyle when they do so with friends or family members. What makes this physically active lifestyle hard (or easy) for you to do with friends or family members?
- Do you have suggestions or ideas how to make it easier for people like you to follow this kind of physically active lifestyle?
- Are there programs and services that the Long Beach community could provide that would make it easier to increase your level of physical activity in the Long Beach area?
- Are there programs and services that the Long Beach community could provide that would make it easier to improve your eating habits in the Long Beach area?
- If you have participated in any healthy-eating programs or physical activity promotion programs here in the Long Beach area, could you tell me some of the good (bad) things about these programs?
- Would it be helpful if you had a form (like a daily chart or diary) to help you keep track of progress in your eating habits and physical activity?

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- How helpful would the following components of a possible health promotion program be in encouraging better eating and increased daily physical activity?
  - Having a pedometer that could be used to count the daily number of steps that you take in the course of the day?
  - A low-impact exercise video emphasizing slow-motion dance moves?
  - A health educator who visits you at home to discuss how your home can be made more supportive of healthy eating habits and increasing physical activity?
  - A community health worker who visits you at home to discuss how your home can be made more supportive of healthy eating habits and increasing physical activity?
  - Taste-testing of different fruit and vegetable-rich dishes that appeal to African Americans?
  - Taste-testing of different fruit and vegetable-rich dishes that appeal to Mexican Americans?
  - Taste-testing of different fruit and vegetable-rich dishes that appeal to Cambodians or Samoans or other Asian communities in Long Beach?
  - Community cooking classes featuring vegetable-rich dishes?

The discussion guide will be translated into Spanish, to be used in the focus group of TCC patients who voiced a preference to speak in Spanish. Questions in the Spanish version may be modified to capture issues specific to Spanish-speaking Latinas, such as immigration or linguistic issues. Cognitive interviewing strategies, involving two additional key stakeholders, will be used to ensure that the final forms (English, Spanish) of the Focus Group Discussion Guide include questions that are understood by the participants as the investigators had intended for them to be understood (see Tourangeau et al. 2000,<sup>112</sup> for a review of cognitive interviewing strategies). Cognitive interviewing is the most common way for the creators of survey research to test the practical acceptability of their research questions. The most common technique in cognitive interviewing is a think-a-loud technique which subjects can use as they complete the survey items. Items will be rephrased or replaced if this and other cognitive interviewing techniques demonstrate that the questionable items lead to respondent confusion or to interpretations at variance with the meaning that the investigators intended for the survey item to have.

#### Focus group data collection protocol

The investigators will use focus group data collection procedures that they have used in the past to collect high-quality information from men and women living in homeless shelters.<sup>107</sup> These procedures are well-described in the 3<sup>rd</sup> edition of Krueger & Casey (2000).<sup>108</sup>

Eight (4 English-speakers and 4 Spanish-speakers) participants, including TCC patients and TCC staff, will participate in two focus group discussions. One of these groups will be conducted in Spanish and one in English, so that the views of monolingual Spanish speakers can be included.

In brief, prior to starting the actual focus group discussion, the facilitator will want to get to know each participant by asking a few questions. The facilitator will query the participant about her / his age, ethnicity, favorite fruit, favorite vegetable, number of children living with her / him, and current housing status. The facilitator will also ask the participant to answer up to five questions similar to the questions in the Focus Group Discussion Guide. From past experience the investigators know that the facilitator can use prior knowledge of focus group members' views to stimulate discussion. Experience with conducting focus groups suggests that some of the

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inhibitions that naturally constrain conversations between strangers can be overcome if the facilitator can engender mini-debates by encouraging participants with differing initial views to share each one's perspective with the group. The preparatory "get-to-know-you" interview helps the facilitator to identify these opposing views prior to the actual focus group discussion.

Eligibility to participate in the focus group discussions will depend on the willingness of the would-be participant to agree to common rules concerning focus group participation. The rules include keeping everything said in the discussion confidential, being respectful of opinions that one might disagree with, letting others have a chance to voice their own opinion, and respecting the authority of the facilitator to determine who gets to speak and when to end discussion of a specific issue. The data collection protocol will abide by UCLA IRB stipulations, including maintaining each participant's confidentiality (see Human Subjects section for more detail). Error checking and data cleaning will take place at UCLA but will often require input from TCC investigators for resolution.

## 5. STUDY POPULATION

**Study population.** This population is primarily working poor families who would have to choose between food and medication were it not for TCC's services. Approximately 98% of TCC's patients are under 200% of the Federal Poverty Level. About 44% of TCC's patients are uninsured, and that number has been increasing. The ethnic composition of TCC's patient population is 76% Latino, 13% African American, 4% Asian, 4% White, 1% American Indian, less than 1% Alaskan Native, Native Hawaiian or Pacific Islander, and 2% Other. About 58% of patients are female, 42% are male; 66% are children, while 34% are adults. With nearly 100,000 patient visits in the last year and 8 clinics, TCC has more than enough obese adult patients (N ~2,000) to yield the number that the investigators plan to enroll in the proposed intervention trial. To ensure maximum range of patient participation, recruitment involved two clinic sites. These sites are located in Long Beach, California. General information about each medical practice and its providers, as well as specific information about weight loss management strategies, will be collected at baseline and during follow-up. The UCLA investigators are familiar with strategies for recruiting participants from the clinic waiting room in TCC clinics by virtue of having used these strategies as part of a predecessor NIH-funded intervention study.

## 6. ELIGIBILITY TO PARTICIPATE IN THE STUDY.

To optimize the internal validity of this study and minimize potential risks for individuals for whom participation would not be appropriate, the following eligibility criteria were developed:

**Table 1 Eligibility Criteria**  
**Inclusion Criteria**

- BMI  $\geq 27$  & BMI  $< 40.4$  kg/m<sup>2</sup> [had been BMI  $\geq 30$  & BMI  $< 40$ ]<sup>2</sup> and weight  $\leq 400$  lbs. if observed
- Age  $\geq 18$  years
- Willingness to change diet, physical activity and weight
- Willing to accept randomization to each group
- Able to give informed consent

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<sup>2</sup> Knowing that accrual could be challenging, from the outset participants whose BMI fell short of the lower limit of 30 were told that there was a chance that they might be eligible later. When accrual was determined to be slower than planned, with IRB approval the range was extended to those with a BMI  $\geq 27$ .

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- Persons with the following conditions are eligible with PCP approval:
  - i) Diabetes Mellitus
  - ii) Prior CVD event > 6 months
  - iii) Known stable CVD or peripheral vascular disease
- Speaks English or Spanish

#### **Exclusion Criteria**

- MI, Stroke or Atherosclerotic Cardiovascular Disease procedure within 6 months
- Serious medical condition likely to hinder accurate measurement of weight, or for which weight loss is contraindicated, or which would cause weight loss (e.g. End Stage Renal Disease patient on dialysis, cancer diagnosis or treatment within 2 years)
- Prior or planned bariatric surgery
- Use of prescription weight loss medication (including off label drugs e.g. topiramate, bupropion, byetta) or over-the-counter orlistat within 6 months
- Chronic use (at least past 6 months) of medications likely to cause weight gain or prevent weight loss (e.g. corticosteroids, lithium, olanzapine, risperidone, clozapine)
- Unintentional weight loss within past 6 months ( $\geq 5\%$  of body weight)
- Intentional weight loss within past 6 months ( $\geq 5\%$  of body weight)
- Pregnant or nursing within past 6 months
- Plans to become pregnant within 18 months
- Plans to relocate from area within 18 months
- Another member of household is a study participant or trial staff member
- Principal Investigator discretion
- Problem alcohol use: Self reported average consumption of > 14 alcoholic drinks per week or 5+ drinks on any occasion in past week for males and >7 drinks per week or 4+ drinks on any occasion in the past week for females. Problem use and heavy use of alcohol have been associated consistently with poor outcomes in behavioral weight loss programs.<sup>113</sup>
- Cigarette smoking or e-cigarette “vaping” any time in the last 6 months
- Psychiatric hospitalization in last year
- Unstable angina
- Blood pressure >160/100 (note: individuals may be rescreened) at discretion of patient's primary care provider

## **7. RECRUITMENT**

**Patients Recruited and Screened.** Patient participants will be recruited from all eligible adult patients in the clinic waiting room at each study site using a Tablet PC for data collection starting with a brief (<2 minute) Screener to assess eligibility. Inclusion criteria include 1) age 18 and older 2) English or Spanish-speaking 4) overweight or obese ( $27 \leq \text{BMI} < 40.4$ ) 3) willing to cooperate with data collection (e.g., completing interviews). Exclusion criteria include insulin dependent diabetes mellitus with complications, severe physical impairment, conditions precluding adherence to the two dietary approaches (Calorie Counting or MyPlate), and end-stage health conditions. All recruitment materials are in Spanish and English and culturally appropriate for Latinos and African Americans.

**Population to be Recruited.** This trial will recruit participants from primary care practices of The Children’s Clinic (TCC), a federally qualified health center in the Long Beach metropolitan area. TCC’s patients come from the most densely populated, diverse, low-income, underserved zip codes in greater Long Beach and its surrounding communities. TCC’s critical services target

a diverse population, identified as having significant barriers to affordable and accessible health care.

**Recruitment Procedures.** UCLA Investigators will identify a recruitment environment that is not only likely to be an effective venue for successful recruitment, but also one in which it would be easy to be in compliance with IRB regulations. Well-trained and supervised UCLA fieldwork staff plan to directly approach potential participants face to face within the waiting rooms of two TCC clinic sites. The screening process is designed to be seen as being respectful of the dignity of all potentially eligible individuals. Accordingly, research assistants will approach all adult patients, regardless of body size, despite the fact that only patients with a BMI exceeding 27 are eligible. We will do this to avoid creating the perception that we are approaching patients because of their overweight status. In addition, to our direct contact method, IRB approved flyers will be posted within each check-in station of the waiting room. Any prospective participants could then approach our research staff directly in the waiting room or contact our fieldwork staff by calling the toll-free number on the flyer. The fieldwork staff will then schedule a time to meet at the clinic to complete the screening process.

Lastly, potentially eligible patients will also be referred to us by others not associated with the project. These referrals included: 1) health care providers recommending patients who could potentially benefit from the program to speak to us in the waiting room. 2) participants referring other potential participants to visit us in the waiting room or call our recruitment numbers, or 3) the result of UCLA fieldwork staff providing IRB-approved flyers to ineligible patients in the waiting room to pass along to friends and family members.

To address the needs of our patient population, bilingual and bicultural UCLA fieldwork staff will be trained in the recruitment protocol approved by the UCLA IRB while concurrently maintaining PCORI patient centeredness in mind. Research assistants will be certified by the project manager and Principal investigator to carry out the recruitment protocol as follows: Research assistants will be assigned quadrants of the waiting rooms to observe, systematically approach and screen all patients in the waiting rooms. A research assistant (RA) will directly approach adult patients and identify themselves and their UCLA affiliation. The research staff will then introduce the study to the patient. If the patient provides verbal consent to continue with the screening questions, then the RAs will proceed with the screening questions. The RA then explains that 18 statements would be read to them. The statements will be read in 4 groups of 2 to 5 statements each. After each group of statements the patient will be asked to respond yes or no to the group of questions as a whole as a strategy to ensure confidentiality even if another patient in the waiting room were to eavesdrop. If the patient states that any of the statements applies to him or her, then they will be told that they are ineligible to participate in the study, will be thanked and exited from the study. The exclusion screening statements are as described below in Table 3.

Table 3. Exclusionary Screening Statements

**GROUP ONE**

1. I am younger than 18.
2. I live outside the Long Beach area.
3. I am planning on moving away from the Long Beach area in the next 12 months.
4. Another member of my household is a participant in this weight loss study.
5. In the last week, I had more than [if men: 5; if women or 65+ years old: 4] glasses of beer or other alcohol that I drank on one occasion.

**GROUP TWO**

6. I have experienced intentional or unintentional weight loss in the last 6 months [ $>5\%$  of body weight].
7. I am taking or have taken a weight loss medication/prescription medication likely to cause weight gain or weight loss.
8. I am currently taking insulin.
9. I had a heart attack in the last 12 months.
10. I had treatment for cancer.

#### GROUP THREE

11. I have a condition that limits what I eat and how much I exercise.
12. I had or plan to have bariatric surgery (stomach stapling).
13. I hospitalized for a mental health problem in the past 12 months.
14. I am a new patient receiving health services for the first time at this clinic.
15. I am pregnant or planning to become pregnant in the next year [FOR WOMEN ONLY].
16. I am currently breast-feeding [FOR WOMEN ONLY].

#### GROUP FOUR

17. I am NOT interested in losing unwanted weight at this time.
18. I smoked cigarettes or used e-cigarettes in the last 6 months.

### ***Tracking of Recruitment Progress***

The tracking of recruitment, i.e. defining and counting the number contacted and the number interested at each stage and then characterizing enrollees and non-enrollees, is complex. To the extent possible, we will describe the recruitment funnel beginning with the number contacted (denominator). This is most easily accomplished for targeted mailings and, to a lesser extent, for in-person clinic contacts. It cannot be done for those who view a poster, review a notice on a clinic website, or talk to clinic staff. Using the TCC administrative database, we will compare basic characteristics of enrollees to the general population of individuals seeking medical care at the facilities. Using information collected at in-person visits and on the web, we can compare characteristics of enrollees to non-enrollees.

### ***Recruitment of women and minorities***

UCLA/TCC investigators have a strong interest and proven track record in recruiting diverse populations. We anticipate that at least 60% of participants will be women, at least 70% will be Latinos and at least 10% will be African American. Given the demographic characteristics of TCC's patients, these goals should be achievable without targeted recruitment efforts.

## **8. DATA COLLECTION AND MEASUREMENTS**

### **Data Collection Assessment Periods**

Eligibility, baseline and follow-up data will be collected by phone and at in-person visits in the home or in the clinic site waiting room. Intervention process data will be collected separately. In-person data collection visits will be conducted in the waiting rooms of the participating clinics. The following contacts describe the primary data collection points for participant level data.

Prescreen Contacts: During the initial waiting room contact, research staff will provide information about the trial and will collect additional data on eligibility. Those who remain interested and eligible will be consented to participate in the screening phase and will begin to complete screening visit measures. Most patients will complete screening and enrollment activities in this initial visit, some will finish the self-report data assessment but many will be

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called up for their appointment and therefore will have to leave off completion of the self-report data assessment at a later time. The study participant will be scheduled for an in-person screening visit and will be provided a number to call if interested in asking additional questions.

Screening Visit: Interested persons who are unable to complete screening and enrollment procedures during their first contact will be schedule at their TCC clinic site from which they were recruited, where their blood pressure, waist circumference, height and weight will be measured. If these measures indicate continued eligibility then the participant will be provided more detail about the trial. Written informed consent to participate in the full trial will be obtained. After consent has been signed, the patient will be randomized and questionnaire data be collected.

Randomization procedure. If all screening and baseline measures indicate that the patient remains eligible, a programmed application in REDCap generates a random assignment to experimental condition for the patient at the end of the screening assessment. The lifestyle change coaches can look up in REDCap's database the study participants assigned to their condition. The coach will then call the patient and arrange for the first coaching session, if appropriate. The research assistants will be kept ignorant of the patient's assignment to experimental condition, to reduce the chance for bias. Of necessity, the lifestyle change coaches will be aware of the patient's experimental assignment but will be instructed to follow the protocol carefully, so as not to introduce any personal bias.

The REDCap data entry system has also been programmed to generate a randomly determined assignment to condition, if the would-be participant met all inclusion criteria and reported no exclusion criteria. Hence, at the completion of the screening visit the study participant will be informed about the experimental condition that he/she had been assigned to and the name and contact number of his/her lifestyle coach. More information about the randomization process is provided below.

Follow-Up (FU) Visits: Participants will be asked to attend in-person follow-up visits at 6 and 12 months after randomization. Most of these data will be collected in-person at the clinic but the FFQ may be administered over the phone, depending on the time constraints of the study participant. The target windows used to schedule participants will coincide with a one month period around the 6 and 12 months follow-up visits. During follow-ups, e will also ask patients to evaluate the trial, including their perceptions of the acceptability and usefulness of the intervention and its components (MyPlate or Calorie Counting).

#### Measurement intervals.

Most measures will be assessed at baseline, at 6 months and 12 months follow-up. The Block Food Frequency Questionnaires will be administered only at baseline and 12-months follow-up, not at 6-months follow-up, to minimize the burden on study participants. Questionnaires were administered in the order described below in Table 4.

**Table 4: Data Collection Items and Schedule by Contact**

	Screening	Baseline	F-up-6	F-up-12
Eligibility/Interest	X			
Informed Consent	X	X		
Weight (self-reported)	X			
Height (self-reported)	X			
Weight (measured)		X	X	X
Height (measured)		X	X	X
Waist (measured)		X	X	X
BP (measured)		X	X	X

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Randomization		X		
<b>Questionnaire topics (administered in this order)</b>				
Demographics/Medical	X	X		X
WHO Health and performance questionnaire		X	X	X
Health-Related QoL-SF-12		X	X	X
Mental Health Inventory (MHI-5)		X	X	X
Physical Activity Quest. (IPAQ)		X	X	X
Physical Activity self-efficacy		X	X	X
Outcomes: hunger – fullness - satisfaction		X	X	X
MyPlate adherence		X	X	X
MyPlate self-efficacy		X	X	X
Weight loss history		X	X	X
Weight control self-efficacy (WEL-SF)		X	X	X
Patient sense of autonomy		X	X	X
Patient satisfaction with care			X	X
Social support and eating habits survey		X	X	X
Social support and exercise survey		X	X	X
TV/Monitor use time		X	X	X
USDA Short-Form Food Security survey		X	X	X
Medical History survey			X	X
Patient satisfaction with weight loss program			X	X
Block Food Freq. Quest.		X		X

\*note. F-up-6 = follow-up assessment 6 months after randomization; F-up-12 =follow-up assessment 12 months after randomization.

### ***Principal Measures***

The following sections describe the specific measurements to be collected from participants at each contact point in the trial. After considering the total burden of data collection procedures and measurements, we may drop or modify some items. We may also add questionnaires. For example, to improve study procedures and interventions, we will query participants about their experiences in the study.

*Choice of outcomes.* The primary patient-centered outcome is **level of everyday hunger**; the primary patient medical outcome is **body weight** (kg). Secondary patient-centered outcomes include: patient weight control self-efficacy, patient autonomy, patient quality of life, and patient satisfaction with obesity treatment efforts by TCC. Secondary patient medical outcomes include: waist circumference, blood pressure and weight. Most of these measures were used in the two clinical weight loss intervention trials whose protocols are the basis for the comparative effectiveness study protocol being described here.<sup>14,15</sup> Our primary patient-centered outcome measure, however, was not included, and so is described in detail below. Two additional indicators of satiation/satiety were added to the study to optimize capture of the satiation/satiety construct, namely meal satisfaction and feeling of fullness after eating. These additional measures are further described below.

Prior to examining patient-centered or medical outcomes, however, we plan to conduct a check on the dietary impact of the intervention conditions, by examining weekly fruit and vegetable intake. **F&V Intervention checks: 1) Daily fruit and vegetable intake.** Because of its importance to intervention success, daily fruit and vegetable intake will be assessed in both the

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overall assessment questionnaire and concurrently using the Block Food Frequency Questionnaire (FFQ). The Block FFQ has been used in previous community-based intervention research to document changes in fruit and vegetable intake.<sup>114</sup> The Block FFQ has been translated into Spanish and has been demonstrated effective in capturing valid food intake data from Mexican American respondents.<sup>115</sup> FFQs typically capture 85-90% of the variation in food intake as measured by multiple 24-hour dietary recalls<sup>116</sup> but are less burdensome to study participants and less expensive for investigators to administer. Because the MyP approach features the DASH diet,<sup>16</sup> adherent study participants assigned to the MyP condition are expected to report twice the daily intake of fruits and vegetables as study participants assigned to the DPP-like dietary prescription. This measure will be important for sensitivity analyses, to gauge whether the magnitude of the quality of life benefits and weight control benefits of the MyP condition covary with the degree of participant adherence to the DASH diet, as reflected by the Block FFQ measures of fruit and vegetable intake. The corresponding fruit and vegetable intake questions on the overall questionnaire were developed specifically to evaluate adherence to the [www.choosemyplate.gov](http://www.choosemyplate.gov) recommendation<sup>117</sup> that Americans fill half their plate with fruits and vegetables.

**Primary patient-centered outcome: Level of everyday hunger (Before start of study added meal satisfaction and feeling full as additional indicators of satiety<sup>118</sup>).** An understudied but potent influence on adherence to therapeutic diets is level of everyday hunger.<sup>119-121</sup> The published intervention trial that comes closest to the study proposed here was a comparison between a standard low-fat energy restriction (only) approach compared to a low-fat energy restriction approach combined with the goal of increasing intake of water rich foods, particularly fruits and vegetables (F&V).<sup>20</sup> A key finding in this study was that the F&V intervention yielded greater 1-year weight loss but significantly LESS daily feelings of hunger than the more conventional low-fat energy restriction approach.<sup>20</sup> The particular item used in the Ello-Martin et al. trial was this: “How hungry did you feel today?” The type of scale used was a “Visual Analogue Scale (VAS).” The VAS consists of a 100 mm line anchored from “Not at all hungry” to “Extremely hungry.” Participants place a hash mark on the line that represents their level of appetite. Each VAS item is scored by measuring the distance from the left end of the line to the participant’s hash mark.<sup>122,123</sup> The effect of increasing intake of water-rich foods (i.e., minimally processed fruits and vegetables) on repeated hunger ratings over one year was significant, with a moderate effect size (Cohen’s Effect Size =  $(53.5 - 46.7) / 13.2 = .52$ ). Part of the reason for this salubrious effect on feelings of hunger was that the water-rich food intervention was associated with a 25% increase in the daily weight of the food consumed, even though the daily calories consumed were lower in the low-fat + water-rich foods condition than in the low-fat (only) condition. When people can fill up faster on fewer calories, risk of passive overconsumption of calories is diminished.<sup>20</sup> The emerging science of the gut microbiome suggests that consumption of polysaccharides in minimally processed fruits and vegetable also enhances satiety by providing substrate to large bowel microbes that then generate short chain fatty acids that then trigger expression of the satiety-signaling hormones glucagon-like peptide-1 and peptide tyrosine tyrosine (PYY).<sup>124</sup>

Although feeling hunger has face validity as the antithesis of satiation/satiety, two additional indicators of satiation/satiety were added to the study, namely meal satisfaction and feeling full after a meal. The same 100mm VAS response scale was used to measure these two additional indicators of satiation/satiety as was used for assessing feelings of hunger. The 100mm VAS fullness measure has been used in previous research on satiety/satiation.<sup>125,126</sup>

Cognitive testing with Spanish-speaking bilingual patients will be used to ensure that the Spanish translation of “How hungry do you feel today” measures the same construct as the original question. For low-literacy patients, the question will be administered by a research

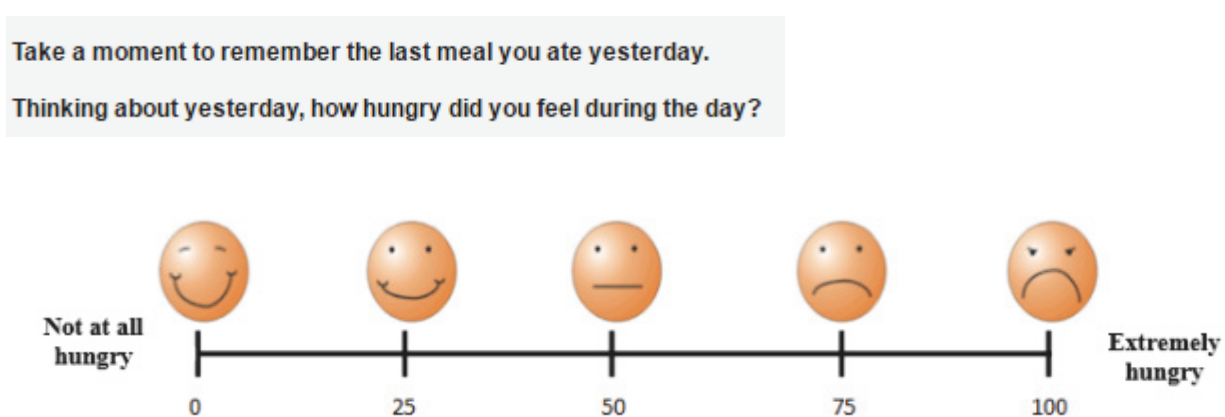
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assistant instead of being self-administered. As noted in the PCORI Methodology Report, there is no easy way to address the challenge of low literacy. Fortunately, hunger is a universally understood construct with strong face validity and high sensitivity, so we anticipate obtaining meaningful data in response to this question from all study participants, regardless of literacy level.

While we are hypothesizing that the MyPlate diet, with its doubling of fruits and vegetables, will yield greater satiation/satiety and less daily hunger than the DPP-like diet, a confounding contributor to hunger is meal-skipping, both voluntary and involuntary. The lifestyle change coaches will be trained to encourage breakfast-eating in both conditions and to discourage meal-skipping. For patients dependent on government food assistance, there may be periods of involuntary hunger. Questions about food insecurity will be asked of all participants and used as covariates to help control for the hunger-generating effects of periodic meal-skipping.

The 100mm visual analogue scale used to assess the everyday hunger measure is shown below:



**Primary Patient Medical Outcome: Weight (kg)** will be measured at each assessment in the clinic setting. Weight in light indoor clothes without shoes will be recorded by trained, certified staff using a high-quality digital scale (Tanita). Duplicate measurements will be made to ensure accuracy. Weight will be measured in pounds for ease of interpretation by the participants and subsequently converted to kilograms for data analysis. Scales will be calibrated weekly using standardized weights. The weight at screening/baseline will be used to determine eligibility ( $27.0 \leq \text{BMI} \leq 40.4$ ). The difference between body weight obtained at screening/baseline and 12 months follow-up will be the primary patient medical outcome.

**Secondary patient-centered outcomes** include: weight control self-efficacy, patient autonomy, health-related quality of life, and patient satisfaction.

**Weight control self-efficacy** will be assessed using the 8-item short version<sup>127</sup> of the 20-item Weight Efficacy Life-style Questionnaire (WEL), a measure judged reliable and valid in obese populations.<sup>128,129</sup> The WEL-SF provides a total weight self-efficacy score based on the sum of the item scores (total range = 0– 80). Higher scores indicate greater self-efficacy. The WEL has demonstrated good internal consistency reliability in a general overweight patient population (Cronbach's coefficient alpha = 0.95 for men, 0.93 for women).<sup>129,130</sup> The WEL-SF correlates  $r = .968$  (shared variance = .937) with the WEL, despite the 60% reduction in the number of items.<sup>127</sup> Because of the high shared variance, the short version was chosen over the long version in order to minimize respondent burden.

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We also plan to gauge patients' patient activation **sense of autonomy** in medical decision-making occurring during the visit, drawing on recent work <sup>131,132</sup> for measuring both patient perception of the actual autonomy that they experienced during the visit and the amount of autonomy they wanted to experience. We will explore the use of the stem question – "When considering ways to lose weight, please think about who should make the decision, your doctor or yourself? Please select which of these statements is most appropriate for you: Considering your visit today (or last visit): (1) who made the decisions about your care?" (doctor or patient); and (2) "Who **should** have made the decisions about your care?" (doctor or patient)."

We plan to administer the SF-12, an abbreviated **health-related quality of life** instrument, based on the SF-36. <sup>133</sup> Test-retest (2-week) correlations of 0.89 and 0.76 were observed for the 12-item Physical Component Summary and the 12-item Mental Component Summary, respectively, in the general US population (n = 232). <sup>133</sup> A Spanish translation of this instrument is available and has similar psychometric properties. <sup>134,135</sup> Our **patient satisfaction with their weight loss program** is adapted from literature evaluating consumer satisfaction with consumer products. <sup>136</sup> As part of a set of post-intervention evaluation questions concerning patient judgments about intervention components the question was asked: "Would you recommend this Program to your family members or friends?" Answer options included: "Yes, definitely," " Maybe," and "No." In evaluating business products, this single item has been unusually effective in discriminating high consumer satisfaction with products from less successful products. <sup>136</sup>

We will test the reliability of these scales for our minority clinic populations and evaluate the meaning of these items when translated into Spanish, during cognitive testing prior to study implementation.

**Secondary patient medical outcomes** include: BMI, waist circumference, and blood pressure.

**Height (cm)** to the nearest 0.1 cm will be measured once at entry using a calibrated, wall-mounted stadiometer in the clinic. The participant stands shoeless on a level surface, with his/her head in the horizontal (Frankfort) plane.

**Waist Circumference (cm)** will be measured by trained staff using an anthropometric measuring tape (Gulick anthropometric ), at a horizontal plane around the abdomen just above the uppermost lateral border of the right iliac crest (i.e. the top of the hip bone). <sup>137</sup> Obesity cutpoints of 88 cm (women) and 102 cm (men) <sup>137</sup> will be used in analyses. Because visceral fat expresses inflammatory cytokines that increase cardiovascular risk, <sup>138</sup> waist circumference is arguably more predictive of future heart disease than overall obesity. <sup>139</sup>

For the waist circumference measurement, the subject should be wearing a top and short, pants, or skirt, adjusted to obtain access to the waistline. If it is not possible to access the waistline, the measurement can be taken over thin clothing (thin shirt or blouse), and this should be noted on the data entry form. The participant should stand with abdomen relaxed, arms at sides, and feet close together with weight equally distributed between both legs.

Participant's preference of Research Assistant's gender taking waist circumference should be taken into consideration prior to taking measurement. In addition Research Assistant (RA) should ask patient if they feel more comfortable having the measurement taken under or over clothing. RAs will ask patients:

*"The next measurement is your waist circumference. This measurement is more accurate if we measure it under clothes and directly on top of the skin. Would it be OK if we measure your waist circumference under your clothes? Or do you prefer over your clothes?"*

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Analytically, the bias introduced by measurements over clothing instead of against the skin- which is ideally the way waist circumference should be measured- can be corrected for by subtracting the mean increase in waist circumference associated with measuring the waist circumference over clothing compared to waist circumference associated with measuring the waist circumference over skin.<sup>140</sup>

**BMI** will be calculated as the Quetelet index (kg/m<sup>2</sup>). Although BMI is collinear with body weight, it is included in order to provide comparability with other studies, where BMI was the primary outcome.

**Blood Pressure (BP)** will be determined via automatic blood pressure cuff using Life Source UA-767 Plus, A&D Medical digital blood pressure monitor. BP will be obtained by trained data collectors according to a standard protocol, adapted from that used in the OmniHeart trial. The cuff size will vary by degree of patient obesity status, with leg cuffs for the most obese. Two measurements (each separated by 1 minute seconds) will be obtained at each visit on the left arm of participants after they have rested quietly in the seated position for at least 5 minutes. A cuff of appropriate size will be identified at the initial visit and used thereafter at all subsequent visits.

**Questionnaires (self-report survey items that include weight control self-efficacy, patient quality of life (SF-12), patient satisfaction and patient sense of autonomy previously described)**

The trial will collect questionnaire data from participants. These data will be used for a variety of purposes - baseline data to describe participants, outcome data to assess the effects of the trial interventions, and mediating variables to assess potential causal pathways. Questionnaires will be added or removed depending on scientific and logistic considerations, including burden to participants and staff.

**Demographic:** The demographic questionnaire is a self-report assessment of basic patient characteristics. It assesses age, gender, race/ethnicity, health insurance status, employment, education level, tobacco use, postmenopausal status, and current health conditions (presence of diabetes, hypertension, and cardiovascular disease).

**Has a doctor ever diagnosed you with diabetes, heart disease or high blood pressure?**  
Get medication use from electronic health record, with participant's permission.

**MyPlate Adherence Questionnaire:** Developed for a previous nutrition intervention trial, the MyPlate Adherence Questionnaire consists of 5 items assessing awareness of the 7 nutrition messages associated with MyPlate and 5 items that assess adherence to five of the 7 MyPlate messages on a typical day (<http://www.choosemyplate.gov/print-materials-ordering/selected-messages.html>). The messages include: 1) Make half your plate fruits and vegetables, 2) Make at least half your grains whole grains, 3) Switch to low-fat or non-fat milk, 4) Choose the foods with lower sodium, and 5) Drink water instead of sugary drinks.

**MyPlate Self-efficacy:** Developed for a previous nutrition intervention trial, the MyPlate Self-efficacy scale consists of 5 items querying the participant about her/his confidence that she/he can adhere to the 5 nutrition messages associated with MyPlate (<http://www.choosemyplate.gov/print-materials-ordering/selected-messages.html>)

**Physical Activity:** The short format, self administered version of the International Physical Activity Questionnaire (IPAQ: <http://ipaq.ki.se>) will be used to assess participants' usual level of moderate to vigorous physical activity. The IPAQ is a standardized self-reported measure of physical activity that has demonstrated validity and reliability.<sup>141</sup> It will be used to estimate levels of moderate and vigorous physical activity from the previous week.

**Physical Activity Self-efficacy:** A 10-item scale was adapted from the 12-item Exercise Self-efficacy scale.<sup>142</sup> Most of the items asked the respondent to indicate how sure she/he was that she/he could stick to the recommended exercise goal despite specific challenges such as when the family demands too much time, there is too much other work to do, when you feel depressed, etc. The test-retest reliability for the 12-item scale was .68; the Cronbach's alpha measure of internal consistency averaged  $\alpha = .85$  across two subscales that made up this overall scale.

**Depressive Symptoms:** The MHI-5 will be used to measure depressive symptoms. The MHI-5 is a five-item mental health Likert measure derived from the SF-36 that was established in 1991.<sup>133</sup> Each MHI-5 item has six answer options ranging from 'All of the time' to 'Most of the time' to 'A good bit of the time' to 'Some of the time' to 'A little of the time' to 'Not at all', with a sum score ranging from 5 to 30. High scores indicate good mental health. This measure has been found to be a reliable measure of distress/ mental health.<sup>143</sup>

**Health-Related TV viewing time:** The NHANES item used to assess typical respondent time spent watching television each day will be used.<sup>144</sup> To assess TV-viewing time, participants were asked: *Over the past 30 days, on average about how many hours per day did you sit and watch TV or videos?* Possible responses included: <1 hour, 1 hour, 2 hours, 3 hours, 4 hours, and > 5 hours. This item was shown to predict obesity status in both children (girls 12y – 18y) and adults (men)<sup>144</sup> and correlated inversely with scores on the Healthy Eating Index.<sup>145</sup>

**Weight Loss History:** Weight loss history will be assessed using questions drawn from the NHANES survey. Questions will pertain to weight history, weight loss methods, and frequency and outcome of weight loss attempts.

**Social support for eating and exercise:** Both active interventions are designed to provide social support through interactions with staff (both interventions) and participants (MyPlate only-participant menu exchanges during MyPlate cooking demonstrations). The instruments for measuring social support include the "Social Support and Eating Habits Survey" and the "Social Support and Exercise Survey." These instruments are reliable, have high internal consistency,<sup>146</sup> and are associated with other measures of physical activity and dietary behaviors.<sup>146,147</sup>

## 9. QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance (QA) pertains to activities that promote collection of high quality data, while Quality Control (QC) pertains to activities that detect emerging issues. Our basic approach to QA is as follows:

- prepare a well-documented fieldwork manual of procedures,
- implement a trainer model to train and certify other staff
- train and certify all primary data collectors, with special emphasis on procedures related to trial outcomes,
- establish proficiency requirements before initial certification of data collectors,

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- routinely observe data collectors,
- routinely calibrate equipment, including weekly calibration of the weight scales used for assessing body weight and regular calibration of the blood pressure equipment
- use cognitive testing to ensure that Spanish translations of questionnaires are comparable in meaning to the English versions; use cognitive testing to ensure that new and other conceptual questions measure what they were intended to measure
- pilot test new questionnaires and data collection procedures
- maintain logs of certified data collection staff and calibrated equipment.

To identify problems with sufficient time to institute appropriate corrective actions and to quantify the quality of data collected during the trial, we will perform the following QC activities:

- monitor counts of completed assessments and key data collection items,
- monitor distributions of trial outcomes, overall, by data collector,
- issue queries about missing data, out of range values, or illogical data relations,
- review types and distribution of data entry errors.

## 10. RANDOMIZATION AND MASKING

### ***Randomization***

**Randomization.** As mentioned above in describing the use of REDCap in recruitment, if all measures indicate that the patient remains eligible, a programmed application in REDCap will generate a random assignment to experimental condition for the patient at the end of the screening assessment. The lifestyle change coaches can look up in REDCap's database the study participants assigned to their condition. The coach will then call the patient and arrange for the first coaching session, if appropriate. The research assistants will be kept ignorant of the patient's assignment to experimental condition, to reduce the chance for bias. Of necessity, the behavior change / lifestyle change coaches will be aware of the patient's experimental assignment but will be instructed to follow the protocol carefully, so as not to introduce any personal bias.

### ***Masking***

Trial participants will know their intervention assignments, as will the community health worker staff that are involved in delivering the interventions. However, UCLA fieldwork staff involved in follow-up data collection will be kept masked to participants' randomization assignments.. At the conclusion of the trial, participants will receive a summary of clinically relevant measurements. .

## 11. INTERVENTIONS

**Overview of the interventions.** The MyP and CC interventions to be tested here are evidence-based lifestyle counseling programs that have been adapted from those implemented in other weight loss trials.<sup>14,15</sup> Other trials that have informed the design of our interventions include the Diabetes Prevention Program and LookAhead.<sup>86,148</sup> Although not weight loss trials, the DASH trials (DASH, DASH-Sodium and OmniHeart) helped to provide the scientific rationale for the dietary advice to be offered to achieve and maintain desirable weight loss.<sup>17,149-151</sup> Both the MyP and CC interventions seek to generate a daily energy deficit as long as the participant has excess weight to lose. Both interventions limit intake of high energy foods and both encourage increasing expenditure of energy in daily physical activity. Both interventions use standard cognitive behavioral approaches to behavior modification, including self-monitoring of behavior, relapse prevention, and mobilizing social support for sustaining adherence to the recommended lifestyle approach. The MyPlate/DASH-style intervention differs from the CC approach principally by its insistence that the form of the food in which calories come can influence

metabolic functioning and appetite and can make a difference to quality of life, to optimal nutritional health, and to the sustainability of the weight loss approach for a lifetime. The CC approach, by contrast, asserts that a calorie is a calorie and that it does not matter whether the calories come from minimally processed fruits and vegetables or from highly processed juices derived from fruits and vegetables. The DASH-style approach therefore limits intake of juices and limits the consumption of highly processed carbohydrate-rich foods including ready to eat breakfast cereals, refined wheat breads, pizza, chips, pastries, candies, power bars and fruit smoothies. As previously noted, the DASH-style approach also strongly encourages increasing the intake of fresh fruit and vegetables to at least twice the daily intake of the average American adult, as well as increased intake of whole grain cereals, legumes, seeds and nuts.

### ***Theoretical Rationale/ Model Underlying the Interventions***

The theoretical framework for the CC and MyP interventions draws largely upon the strengths of behavior changes theories, specifically, social cognitive theory,<sup>34,152</sup> Behavioral self-management and motivational enhancement<sup>153,154</sup> approaches are used as a foundation to teach participants strategies including goal setting, self-monitoring, problem solving and identification of barriers and strategies for overcoming these barriers. Both interventions are designed to promote weight control self-efficacy and to help participants identify and develop sources of social support. Both self-efficacy and social support are key components in social cognitive theory and have been identified as important determinants of behavior change.<sup>34</sup> These efforts will work in conjunction with behavior change counseling in the primary care setting. U.S. Preventive Services Task Force (USPSTF) has recommended this multi channel approach to promoting lifestyle change.<sup>103,155</sup> One feature that distinguishes the CC and MyP theoretically is the emphasis that the MyP approach places on environmental cues to support the recommended behavior changes initially achieved through goal-setting, self-management and motivational enhancement. This emphasis on the importance of the physical environment is more in keeping with Social Ecological Theory<sup>156</sup> than Social Learning theory.<sup>32</sup> Social ecological models of health promotion identify several levels of environmental influence on diet and physical activity, ranging from familial to global factors. At the most proximal level, there is increasing evidence that the home micro-environment can be obesogenic. Both physical (e.g., type of food available) and social (e.g., support from family) factors in this setting have been associated with weight, dietary habits, and activity patterns.<sup>47,48</sup> Demonstrated links between the physical home environment and behavior include relationships between available high-fat foods and fat intake,<sup>49</sup> access to home exercise equipment and activity levels,<sup>50,51</sup> and number of televisions and amount of television viewing.<sup>52</sup>

The utility of the calorie-counting (CC) approach to energy restriction was predicated on the assumption that a calorie is a calorie, no matter what its source, and that weight loss could be achieved regardless of where the calories were coming from, as long as calorie expenditure exceeded calorie intake. It is a simple matter of physics. To generate a chronic calorie deficit the patient either had to increase energy expenditure, through physical activity usually, or restrict their calorie intake to a level below the level of calories expended through daily metabolism and physical activity. The behavioral theory behind the DPP calorie-counting approach views participants as active problem solvers who are capable of regulating their affect, behavior, and cognition.<sup>157</sup> Self-monitoring is used to identify times, places, emotions, people, and events associated with eating (or exercising) appropriately or inappropriately. Goal setting is facilitated by specifying behaviors to be adapted and when, where, how, and with whom they will be performed. Behavior change is reinforced by increased self-efficacy, by the inherent rewards in reaching a goal (i.e., weight loss or improved fitness), by social support (including encouragement from medical personnel) or by the use of external rewards. The provision of

long-term treatment recognizes that obesity, for most individuals, is a chronic condition that requires long-term care. The delivery of the calorie-counting intervention in primary care practice is guided by Wagner's Chronic Care Model.<sup>158,159</sup> Using a community health worker lifestyle coaching approach, obese participants will be provided an evidence-based intervention (i.e., the Diabetes Prevention Program) that primary care providers can refer their obese patients to for obesity treatment. Community health worker lifestyle change coaches will be trained to guide and support participants' efforts to improve their eating behavior and physical activity using the DPP approach.

The utility of the DASH-style approach to energy restriction in MyP is predicated on helping the participant reach satiation / satiety sooner with fewer calories by careful choice of foods to consume.<sup>151</sup> Feeling full with fewer calories is possible by replacing highly processed, usually energy dense and nutrient poor food choices with minimally processed foods of Mother Nature, particularly fresh fruits and vegetables. Canned fruits and vegetables are typically processed foods, high in added sodium and often high in added sugar as well, and are therefore to be consumed only in limited quantities. Participants in the MyP condition are particularly encouraged to limit most caloric beverages, including: juices, juice drinks, sugar sweetened beverages and alcoholic beverages – because of the high potential for passive overconsumption of calories from these sources.<sup>160</sup> There are several important but addressable challenges to the DASH-style approach that can benefit from systematic tracking and encouragement by a lifestyle change coach. These challenges include: 1) the neophobic response of the human palate to the taste of botanically distinct new plant foods,<sup>61</sup> 2) the phenomenon of sensory-specific satiety,<sup>161</sup> whereby appetite for a specific food declines with every additional bite of the food, 3) the negative impact that fasting has on receptivity to low-calorie, high-fiber foods,<sup>162</sup> 4) the prerequisite importance of physical activity for generating optimal appetite for water-rich foods, specifically fruits and vegetables.<sup>163</sup> With supportive coaching and collaborative coach/participant problem-solving, these challenges can be overcome.

#### ***Description of Intervention Health Education / Coaching Sessions.***

For the 3-months pilot study, for both interventions there will be weekly meetings of the CHW with the participant throughout, including 2 one-hour group education sessions, 2 thirty-minute in-home visits and 8 (later reduced to 7 following stakeholder input) twenty-minute telephone coaching sessions.

For the 12-months full study, for both interventions, patients will be encouraged to complete four meetings each month with their CHW so that the intervention can be completed in three months. However, if patients are unable to complete the health education lessons within this timeline, they will be allowed to complete as many lessons out of the 11 possible before their final follow-up assessment. The meetings will include 2 group education sessions during months, 2 in-home visits during months, and 7 telephone coaching sessions that taper off in frequency during the first three months of the 12-months study period. For this study, the health sessions were delivered in the following order in as described below in Table 5.

Table 5. Order and Distribution of In-Home Health Education Sessions, telephone coaching sessions, and group education sessions.

- |   |
|---|
| <ol style="list-style-type: none"> <li>1) In-home health education session #1</li> <li>2) Telephone coaching session #1</li> <li>3) Group education session #1</li> <li>4) Telephone coaching session #2</li> <li>5) Telephone coaching session #3</li> <li>6) Telephone coaching session #4</li> </ol> |
|---|

- |   |
|---|
| <ul style="list-style-type: none"><li>7) In-home health education session #2</li><li>8) Telephone coaching session #5</li><li>9) Group education session #2</li><li>10) Telephone coaching session #6</li><li>11) Telephone coaching session #7</li></ul> |
|---|

The TCC community health workers responsible for the lifestyle change coaching sessions will be recruited from the local community and local colleges. They will be trained and supervised by the TCC health education department, who has years of experience supervising community health workers, including community health workers making home visits. Both the community health workers and the patients will be likely to view the in-home visits as part of routine TCC care because of TCC's previous history of community health worker lifestyle change coaching.

The budget includes the telephone lines for the community health workers, to facilitate their telephone and in-home visits with study participants. The budget also includes the cost of mileage incurred while making in-home visits. Because many patients may be prevented from attending the group health education because of the cost of transportation to the group education event or the cost of childcare, each participant attending the health education will receive \$10 towards deferring the transportation cost and the participant's infant children will be provided free child care. The group education will be open to participation by family members, including spouses and children old enough to benefit from the education.

**The Calorie-Counting (CC) Lifestyle Coaching Intervention Approach, as adapted by Wadden et al. (2011) from the Diabetes Prevention Program (DPP-like)**

**CC Behavior Change Goals.** The goals of this intervention are to induce a loss of 5% or more of initial weight through energy restriction by counting calories, limiting daily intake to prescribed amounts and increasing participants' physical activity to > 150 minutes per week and to maintain these improvements over 12 months. These goals will be achieved by providing participants a program of lifestyle modification, delivered by a community health worker lifestyle coach, with encouragement from the patient's primary care provider (PCP).

**Description and delivery of the CC intervention.** Participants in this group will meet with their PCPs on the same schedule as those in the MyP group and receive the same attention for their comorbid conditions, as well as the weight management handouts. Participants in this condition will receive a program of lifestyle modification based on the curriculum used in the Diabetes Prevention Program (DPP). The lifestyle modification program will be delivered to participants during regularly scheduled phone calls conducted by community health worker lifestyle change coaches. We elected to use the DPP materials because they have been shown to be effective across a wide range of participants and provide tailored dietary menus for African Americans and other ethnic minorities. The DPP materials have been adapted for delivery in primary care practice by community health worker lifestyle change coaches and have obtained a loss of approximately 3.8% of initial weight during 6 months of treatment. <sup>14</sup>

**Duration, and format of intervention contacts.** Each of the 7 health CC education/coaching sessions by phone will last 15 to 20 minutes and will begin with participants being asked about their progress and their weight and informed of their weight change. At each visit, the participant and Lifestyle Coach (i.e., community health worker lifestyle change coach) will review the participant's completion of food and activity records since the previous visit. This will include examining an estimate of the number of daily calories consumed and minutes walked each week, as well as any other homework assignments assigned during the previous contact. The Lifestyle Coach will assist participants with problem solving and will then introduce the lesson from the DPP curriculum to be completed for the next visit. Participants will receive enough food

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monitoring records and activity records to last until their next visit. Participants will have until before their last follow-up assessment to complete all sessions. Visits that cannot be completed on-site (because of illness, travel, etc.) may be completed by phone. *Group health education* sessions will last 1 hour for the CC participants but will last 1 ½ hours for the MyP participants because the last ½ hour will consist of taste-testing fruit- and vegetable-rich recipes. Finally, the two in-home visits will last 50 minutes and will involve a discussion of strategies for keeping calorie intake low (DPP-like condition), for keeping fruit and vegetable intake high (MyP condition), and for maintaining a daily regimen of 30 minutes or more of moderate to vigorous physical activity (both conditions).

**Dietary goals –CC condition:** Participants in the CC condition will be prescribed a daily calorie goal based on body weight. Following recommendations from the Diabetes Prevention Program, persons who weigh  $\leq 114$  kg ( $\leq 250$  lb) will be prescribed 1200-1499 kcal/d and those  $> 114$  kg ( $> 250$  lb) 1500-1800 kcal/d. All participants will be encouraged to aim for the lower end of their range. DPP-like participants will be instructed to consume a diet of conventional table foods with  $< 30\%$  of calories from fat (including  $< 10\%$  from saturated fat), approximately 15%-20% of calories from protein, and the remainder from carbohydrate. This includes a goal of consuming 5 servings of fruits and vegetables, including juices, each day. Participants in this group will be provided a calorie guide (e.g., Calorie King) to use as they wish. In addition, participants will be informed of the caloric content of common food and food-products found at their home.

CC participants, for at least the first few weeks, will be asked to record all foods and beverages consumed for at least 3 days (2 weekdays and 1 weekend). This will begin at the first meeting with the Lifestyle Coach (at week 1). At the second meeting (Week 2), CC participants will be instructed to record their calorie intake with the assistance of the calorie guide provided (e.g., Calorie King). Food records will be reviewed at each meeting to determine participants' success in meeting calorie goals, and problem solving will be used to facilitate adherence. Over time, the effort required to monitor their daily energy intake is expected to diminish as participants automate their monitoring of the times, places, and activities associated with their eating. Although originally developed for use by middle class patients, interventions such as the ones described here can be adapted and made useful for low-literacy patients with guidance from community-savvy lifestyle change coaches.<sup>164</sup> The lifestyle change coach will also help participants develop an eating plan in which they consume breakfast, lunch, and dinner, with snacks as needed. Snacks will include fruits and vegetables to meet the goals described previously. Participants also will be provided meal plans (from the DPP) that suggest choices for breakfast, lunch, dinner, and snacks.

CC participants' calorie goals will be evaluated after the each health education session and adjusted appropriately based on an individual's desire to remain weight stable or lose more weight. This reduced schedule recognizes that even the most motivated participants tire of keeping daily records after the first 6 months.

**Dietary goals –MyP condition:** As was the case for CC participants, MyP participants will be encouraged to restrict calories but not through calorie counting but by making sure that half their typical plate is devoted to minimally processed fruits and vegetables, and that one quarter of their plate be grains, mostly whole grain, and that one quarter of their plate be protein-rich foods such as meat, fish, nuts and legumes. Because not every meal is on a plate, the MyP participants will be asked to consider every serving of grains and every serving of protein-rich food to be yoked to a prerequisite serving of fruit or a serving of vegetables. Having a serving of pizza is fine as long as it is accompanied by a serving of low-calorie salad or a serving of fruit (not juice). In addition to this recommendation, the participants will be asked to adhere to the other non-portion-control messages accompanying the MyPlate icon.<sup>165</sup> These messages include: "Switch to nonfat or low-fat milk," "Choose lower sodium foods," "Drink water instead of

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sugary drinks.” These messages represent complementary weight control strategies that are likely to facilitate desirable weight loss. Reducing discretionary fat is consistently recommended for weight loss<sup>20,25</sup> and validated by the success of orlistat, a lipase inhibitor.<sup>166,167</sup> While sodium is not itself caloric, its level in a food is reflective of how highly processed the food is. The consumption of high-salt, low-nutrient snack foods, in turn, has been associated with obesity risk.<sup>168,169</sup> There is considerable consensus that sugary drink intake contributes to obesity<sup>160,170,171</sup> and that replacing sugary intake with water would reduce risk.<sup>172</sup>

Part of the challenge in trying suddenly to eat eight or more servings of F&V/day instead of the more usual four servings is that sensory-specific satiety will likely render larger quantities of fruit and vegetables increasingly unpalatable midway through a meal unless participants increase the variety and range of fruit and vegetable choices.<sup>161</sup> Increasing the variety and range of fruit and vegetable choices will, in turn, run up against the typical human neophobic response to new plant foods. Part of the lifestyle coach’s challenge is to get the participant in the MyP condition to be willing to try a new food 8-14 times, because overcoming (permanently) the neophobic response to a specific plant food typically takes 8-14 exposures.<sup>62</sup> The lifestyle coach will also suggest that a way to engender increased appetite for water-rich foods like fruits and vegetables is to exercise before the meal. In school children,<sup>173</sup> in athletes,<sup>74,174</sup> and in overweight undergraduates<sup>163</sup> exercise before a meal increases appetite for water-rich foods. Conversely, fasting or skipping breakfast before a meal are associated with decreased appetite for F&V,<sup>162,175</sup> so regularity of meal intake will be encouraged.

Another strategy for exposing participants to new plant foods in order to expand their repertoire of acceptable fruits and vegetables is to have the MyP participants take part in taste-testing dishes containing new plant foods. Vegetable-rich recipes will be solicited from study participants and submitted for review by the study Intervention Director. The recipes will be evaluated positively according to the quantity of the following dimensions: fruits and vegetables, minimally processed; whole grains; low-fat or non-fat dairy; lean proteins. The recipes will be evaluated negatively according to the quantity of the following: saturated fat; sodium; sugar. A score composed of the above dimensions will be used to rank order recipes. The ranking of recipe ingredients will favor selection of those recipes with the highest satiation/ highest satiety value for the fewest number of calories, thereby facilitating a program of weight loss featuring less hunger<sup>20</sup> and therefore greater likelihood of maintenance for the long-term.

Two coaching sessions take place in the home, so that an CHW can scan food products in the pantry and the refrigerator and designate each food product as a red light food (limit to no more than once a month), green light food (may eat every day), or yellow light food (nutritiously intermediate food – limit to no more than once a week).<sup>54</sup> The intervention does not seek to ban less healthful choices from the home but instead to position the healthier choices so that they are the most conspicuous and the easiest choice.<sup>56</sup> The literature on behavioral economics suggests that changing the “decision architecture” around the home will be enough to alter food choices; bans are not necessary.<sup>55,56</sup> We deliberately avoided bans because bans can be seen as taking away legitimate choices and lead to pushback by other household members. Hence the team dietitian will use adhesive-backed colored dots to indicate for every food product in the pantry, in the refrigerator, and on the counter whether a product was a red light, yellow light, or green light food. The household residents would be encouraged to rearrange their food products such that the red light foods would be placed out of sight, in the far back recesses of the refrigerator and the pantry and off the kitchen counter. Green light foods, by contrast, should be placed up front, so that they are the first choices that household members encounter when they open the refrigerator door or the pantry cabinet door. Research shows that the healthier choice can be the more popular choice when it is more conveniently located.<sup>176</sup>

**Physical Activity Goals for Both CC & MyPlate Participants.** Participants in the CC behavior change intervention will have the same activity prescription as those in the MyP condition (i.e., increasing their activity to > 150 minutes per week during the first 6 months). Participants will be instructed to engage in aerobic activity (e.g., walking) for a specific number of minutes each day, building to ≥ 30 minutes/day, 5 days a week. Participants will be instructed to exercise at a moderate intensity so that they could talk comfortably with a partner while walking. They will record daily their type and duration of activity, including only bouts in which they have been active for ≥ 10 minutes. Lifestyle change coaches will review physical activity records with participants and provide suggestions for improving adherence.

To facilitate adherence, participants in the MyP and CC conditions will receive a gym-in-the-bag. The gym-in-the-bag has been used in our previous health promotion interventions involving FQHC patients to good effect, leading to increased physical activity and objectively measured physical fitness. The gym-in-the-bag includes the following equipment: a pedometer, three resistance bands of varying thickness, instructions on how to use the pedometer and the resistance bands, a plastic tape measure with desirable waist circumferences indicated for men and women, portion control recipes for the CC condition, DASH recipes for the MyP condition, and self-monitoring forms that the study participant can use to log her/his daily minutes of physical activity, by type of physical activity (aerobic / resistance). The study participants will also be given a choice of “Instant Recess” DVDs featuring 10-minute dance/ calisthenics routines in a variety of ethnic flavors, including Salsa music, Gospel music, Cumbia, Filipino dance, etc. There is much support in the scientific literature for the cardiovascular benefit of engaging in several 10-minute bouts every day.<sup>177,178</sup>

Participants’ activity goals will be re-evaluated after each health session. Those who have met the 150 minute/week goal will be encouraged to increase to > 200 minutes/week. Problem solving will be used to improve adherence in those who have not met the initial goal. Participants will be given monthly step targets to help them reach 10,000 steps a day (by month 12). They will be instructed to keep daily records of their steps (and minutes of activity) for the first three months after enrolling. After this time, those who wish may decrease their recording (e.g. to 3 days a week, as discussed previously). Participants in this group also will receive the handouts that illustrate methods to increase strength/resistance training at home.

**Other behavior modification goals.** The CC intervention will include other traditional lifestyle modification topics (e.g., challenging negative thoughts, obtaining social support), most of which will be accompanied by a homework assignment to be completed before the next visit with the Behavior Change Coach. An important behavior will be having participants weigh themselves at least once a week and record their weight. Regular self monitoring of weight consistently facilitates long-term weight management.<sup>179</sup> Participants who do not have access to a scale for weekly weigh-ins will be provided an inexpensive bathroom scale. These participants also will receive the home strength training program, consisting of stretch bands and instructions for their use. The home strength training program covers activities intended to help participants increase muscular strength and endurance and promote weight loss. It is a standalone program that requires no further instruction.

**Table 6. Weight Goals and Behavioral Recommendations by Condition**

<b>Behavior change goals</b>	<b>CC condition</b>	<b>MyPlate condition</b>
<b><i>Weight loss goal</i></b>	Min. 5% weight loss	Min. 5% weight loss
<b><i>Daily calorie intake</i></b>	<b>Achieved weight loss &lt;5%</b>	no daily calorie limit but limit fat
	1200 kcal/d if ≤ 170	

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	lbs.	
	1500 kcal/d if >170 & < 220 lbs	
	1800 kcal/d if >220 & < 270 lbs.	
	2200 kcal/d if >270 lbs.	
	<b>Achieved weight loss <math>\geq</math> 5%</b>	
	1500-1900 kcal/d for women	
	1800-2200 kcal/d for men	
<b>Dietary pattern</b>	Aim for healthy weight	DASH dietary pattern
		7-12 servings/d of F&V
		2-3 servings/d of low-fat dairy
		lower sodium choices (target=1500mg)
		< 7% calories from saturated fat
		< 25% calories from fat
<b>Physical activity</b>	Build to $\geq$ 150 min./week of mod. to vigorous physical activity in bouts $\geq$ 10 min.each	Build to $\geq$ 150 min./week of mod. to vigorous physical activity in bouts $\geq$ 10 min.each

Table 7. Schedule of Lifestyle Change Coaching / Group Health Education Sessions

	Home visit	Group	Telephone	Total # sessions
Month 1	1	1	2	4
Month 2	1		3	4
Month 3		1	2	3
Month 4				
Month 5				
Month 6				
Study totals	2	2	7	11

**For the CC & MyPlate interventions:**

Goals. The goals of this intervention (during the first 3 months) are to induce a loss of 5% or more of initial weight and to maintain these improvements at 6 months, by meeting dietary and physical activity goals shown in Table 3.

**Description and delivery of the intervention.** Participants in this group will receive a lifestyle intervention consisting of: 1) 7 telephone lifestyle change coaching contacts; 2) 2 group education contacts; 3) 2 in-home lifestyle change coaching contacts (See Table 4). After enrolling, participants will be given a gym-in-the-bag during their first home visit. The gym-in-the-bag includes the following equipment: a pedometer, three resistance bands of varying thickness, instructions on how to use the pedometer and the resistance bands, a plastic tape measure with desirable waist circumferences indicated for men and women, portion control recipes for the CC condition, DASH recipes for the MyP condition, and self-monitoring forms that the study participant can use to log her/his daily minutes of physical activity, by type of physical activity (aerobic / resistance). The study participants will also be given a choice of “Instant Recess” DVDs featuring 10-minute dance/ calisthenics routines in a variety of ethnic flavors, including Salsa music, Gospel music, Kumbaya, Filipino dance, etc. There is much support in the scientific literature for the cardiovascular benefit of engaging in several 10-minute bouts every day.<sup>177,178</sup>

**Duration, and Format of Intervention Contacts for Both CC & MyPlate.** Each of the 7 health CC & MyP education/coaching sessions by phone will last 15 to 20 minutes and will begin with participants being asked about his/her most recent body weight measurement, which the coach will then use to calculate the participant's weight change since the last session. At each visit, the participant and Lifestyle Coach (i.e., community health worker lifestyle change coach) will review the participant's completion of food and activity records since the previous visit. For the CC participant, this will include examining the number of calories consumed and minutes walked each week, as well as any other homework assignments. The Behavior Change Coach will assist participants with problem solving and will then introduce the lesson from the DPP curriculum<sup>180</sup> to be completed for the next visit. For the MyP participant, the Lifestyle Change Coach will review the participant's food and activity records since the previous visit with the view of examining how well the participant adhered to the DASH diet.<sup>181</sup> Participants will receive enough food monitoring records and activity records to last until their next visit. Group education sessions will last 1 hour or as long as needed to complete the healthy grocery shopping tour. One will feature tips on making use of the physical activity equipment in the gym-in-the-bag (pedometer, resistance bands, “Instant Recess” DVDs, log sheets). A second will feature tips on how to shop for low-calorie foods. This last one will also feature the importance of community resources for sustaining prescribed levels of physical activity and reduced calorie intake. Finally, the two in-home visits will last 1 hour and will involve a discussion of strategies for keeping calorie intake low (DPP-like condition), for keeping fruit and vegetable intake high (MyP condition), and for maintaining a daily regimen of 30 minutes or more of moderate to vigorous physical activity (both conditions). Participants will have a window of opportunity until their last follow up assessment to make up previously missed sessions. Visits that cannot be completed on-site (because of illness, travel, etc.) may be completed by phone. See Table 5 for list of main topics to be discussed during each session.

Table 8. Main Topics for Lifestyle Change Coaching/Group Health Education Sessions

Health Education Session	Calorie Counting Topics	MyPlate Topics
<i>Home health education session #1</i>	<ul style="list-style-type: none"> <li>• Introduction to Calorie Counting and Portion Control</li> <li>• Portion control: What are portion sizes?</li> <li>• Dietary Guidelines for Americans</li> <li>• Importance of measuring your</li> </ul>	<ul style="list-style-type: none"> <li>• The MyPlate Approach and food groups.</li> <li>• What are the Dietary Guidelines for Americans</li> <li>• Importance of reducing and measuring your waist</li> </ul>

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	waist circumference. • Setting up realistic goals and Self-monitoring: What should I keep track of? • Introduction to the Gym-in-the-bag & Health Notebook • Staying in control of your environmental cues. • Home Audit Inventory • What high caloric foods should I eat and what foods should I avoid?	circumference. • Introduction to the Gym-in-a-Bag and Health booklet • Setting up realistic goals and self-monitoring: What to keep track of? • Redesigning your home and lifestyle to improve your health.
<i>Telephone coaching session #1</i>	• Calculation of Max number of calories to eat. • Physical Activity Guidelines • Number of Calories burned by Common Physical activities.	• The MyPlate Approach and food groups. Review of MyPlate Guidelines • Health benefits of eating more fruits and vegetables. • Mother Nature's gift to us: Fruits and vegetables form affects function.
<i>Group education session #1</i>	• Why be active? (Burning calories) • Physical Activity Guidelines. • What is moderate and vigorous physical activity? • How to use the Gym-in-the-bag. • What is BMI and how to measure it	• Why be active? (Regular exercise helps appetite for Mother Nature foods) • Physical Activity Guidelines. • What is moderate and vigorous physical activity? • How to use the Gym-in-the-bag. • What is BMI and how to measure it. • Healthy Cooking Demonstration*
<i>Telephone coaching session #2</i>	• Calculating the Max number of calories to eat. • Reading nutritional Labels • Importance of eating low-calorie foods and examples of low calorie foods.	• Reading nutritional Labels • Review of MyPlate Guidelines • Healthy lifestyles must include both diet and exercise. • Exercise will make you feel more energized.
<i>Telephone coaching session #3</i>	• Calculating the Max number of calories to eat. • Importance of self-monitoring and keeping track of your weight, calories, etc. • Self-monitoring does not cause psychological problems. • Avoid lapses from becoming relapses.	• Importance of self-monitoring and keeping track of your weight • Self-monitoring does not cause psychological problems. • Overcoming neophobia. • Eating more fruits and vegetables will help you regulate your weight.
<i>Telephone coaching session #4</i>	• Calculation of Max number of calories to eat. • Review of patient's current health goals. • Creating a behavioral contract. • Importance of healthy rewards for	• Review of patient's current health goals. • Creating a behavioral contract. • Importance of healthy rewards for following your contract (90% adherence is worthy of a reward).

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	following your contract (90% adherence is worthy of a reward).	<ul style="list-style-type: none"> <li>• TV watching: Limit to less than 2 hours a day.</li> <li>• Three Sisters diet.</li> </ul>
<i>Home health education session #2</i>	<ul style="list-style-type: none"> <li>• Calculation of Max number of calories to eat.</li> <li>• Tips for making the home more supportive of low calorie intake (Home Audit Inventory)</li> <li>• Buddy System (Social Support).</li> <li>• Who is your social support?</li> <li>• Signing the Behavioral Contract.</li> <li>• Addressing any patient concerns or questions.</li> </ul>	<ul style="list-style-type: none"> <li>• Tips for making the home more supportive of MyPlate guidelines (Home Audit Inventory)</li> <li>• Buddy System (Social Support).</li> <li>• Who is your social support?</li> <li>• Signing the Behavioral Contract.</li> <li>• Connecting patient to community resources needed to achieve health goals.</li> <li>• Addressing any patient concerns or questions</li> </ul>
<i>Telephone coaching session #5</i>	<ul style="list-style-type: none"> <li>• Calculation of Max number of calories to eat.</li> <li>• Review of patient's progress with behavioral contract.</li> <li>• Strategies to deal with lapses: (Urge Surfing, Road maps, Positive Addiction)</li> <li>• Stress reduction (Yoga, meditation, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Review of patient's progress with behavioral contract.</li> <li>• Don't let a lapse become a relapse.</li> <li>• Strategies to deal with lapses: (Urge Surfing, Road maps, Positive Addiction)</li> <li>• Stress reduction (Yoga, meditation, etc.)</li> <li>• Eating together as family</li> </ul>
<i>Group education session #2</i>	<ul style="list-style-type: none"> <li>• Reading Nutrition Labels (focused on calories).</li> <li>• Super Market Layout – Avoiding high caloric foods areas.</li> <li>• Smart Shopping tips: shopper beware of marketers' tricks</li> </ul>	<ul style="list-style-type: none"> <li>• Reading Nutrition Labels (focused on sodium content)</li> <li>• Super Market Layout – Avoiding processed foods areas.</li> <li>• Smart Shopping tips: shopper beware of marketers' tricks</li> <li>• Healthy Cooking Demonstration*</li> </ul>
<i>Telephone coaching session #6</i>	<ul style="list-style-type: none"> <li>• Calculation of Max number of calories to eat.</li> <li>• What is Quality of life for you?</li> <li>• Losing weight affects your health-related Quality of Life.</li> <li>• Achieving calorie balance through exercise and eating.</li> <li>• Progressive goal-setting to achieve your health goals.</li> </ul>	<ul style="list-style-type: none"> <li>• What is Quality of life for you?</li> <li>• Healthy eating and regular physical activity leads to a higher health related QOL</li> <li>• Lifestyle change is all about balance in physical activity and health eating.</li> <li>• Progressive goal-setting to achieve your health goals.</li> <li>• The importance of heritage fresh foods that are healthy and in season.</li> </ul>
<i>Telephone coaching session #7</i>	<ul style="list-style-type: none"> <li>• Review Calorie intake, portion control, and Physical activity guidelines.</li> <li>• Review of lessons learned.</li> <li>• Review of tips for making the home more supportive of low calorie intake.</li> </ul>	<ul style="list-style-type: none"> <li>• Review MyPlate and Physical activity guidelines with patients.</li> <li>• Review of lessons learned.</li> <li>• Review of Tips for making the home more supportive of MyPlate guidelines</li> <li>• Congratulate patient on</li> </ul>

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	<ul style="list-style-type: none"> <li>• Congratulate patient on achievements.</li> <li>• Answering any final patient questions.</li> <li>• New challenges will arise; you have the skills to cope.</li> </ul>	<ul style="list-style-type: none"> <li>• achievements.</li> <li>• Answering any final patient questions.</li> <li>• New challenges will arise; you have the skills to cope.</li> </ul>
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### ***Assessment of Participant Adherence to the Dietary Prescription.***

Adherence of CC participants to the DPP prescription will be assessed principally by tracking (i.e., recording) their calorie monitoring and their participation in the 12 planned health coaching sessions. This tracking information will be recorded by the community health workers using REDCap-generated questions on their laptop computers.

CC participants will be informed of the benefits of keeping food and activity records during the first few weeks of the study. Adherence to the dietary goals can be broadly assessed during the first few weeks by counting the number of days each week that participants complete a food record. Records can be scored dichotomously (i.e., 0 or 1) to indicate whether the participant completed a record for the day in question. At least two meals must be recorded to receive credit for the day. Adherence to physical activity can be assessed during the first few weeks by counting the number of minutes of aerobic exercise per week that participants report in their activity diaries. Minutes can be summed for all aerobic activities (with equal weightings) to obtain a weekly value. Strength training will be counted separately from aerobic activity for participants who report it.

Adherence to the MyPlate prescription will similarly be assessed via food and activity records during the 3-months main intervention program. In the case of dietary adherence, however, the information to be recorded will consist of reports of the proportion of fruit and vegetable servings relative to the grain and protein-rich food servings in the course of each day. Label reading will be necessary, to limit saturated fat, sodium and sugar but no calorie-counting will be needed. As with the CC participants, adherence to physical activity will be assessed for the first few weeks by recording the number of minutes of moderate to vigorous physical activity engaged in each day at end of each week. Minutes can be summed for all aerobic activities to obtain a weekly value. Minutes of strength training will be counted separately but will be encouraged as a consistent correlate of weight control.<sup>182</sup>

### ***Outline of the Content of the Behavior Change Sessions for CC participants:***

For the CC participants, the group health education content will include: 1) Tips on making use of the physical activity equipment in the gym-in-the-bag; 2) Tips on how to shop for low-calorie, portion-controlled food products (DPP) and discussion of the importance of community resources for sustaining prescribed levels of physical activity and reduced calorie intake.

For the CC participants, the in-home visits will focus on the importance of portion control and closely monitoring daily calorie intake. At the initial visit much time will be devoted to showing the participant how to complete the calorie intake, body weight and physical activity monitoring forms.

For the CC participants, the content of the 7 telephone lifestyle coaching sessions will include a focus on self-monitoring, portion control, stimulus control, social support, problem solving, and cognitive restructuring and to problem solve how these behavioral strategies can best be deployed when the participant reports challenges to her/his efforts to adhere to the DPP prescription.

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Self-Monitoring by CC participants. The frequency of self-monitoring depends on the CC participant's weight loss progress.

During weight loss (i.e. 5% weight loss not achieved), CC participants are advised to:

1. Daily write down: minutes of moderate intensity exercise in bouts of 10 or more minutes and all food and beverages consumed. Look up and record calories of each item consumed on hard copy of Tracking Form 3 days per week. Bodyweight need be recorded only once each week.
2. During first few weeks: Weekly reporting to lifestyle change coach of daily average calories consumed, average minutes of moderate to vigorous physical activity expended for the week, average body weight for the week, and delivery of food records for the week.

During weight maintenance (i.e. > 5% weight loss achieved), participants are advised to:

1. Daily write down: minutes of moderate intensity exercise in bouts of 10 or more minutes and body weight.
2. Write down all foods, beverages and calories consumed 3 days/week.
3. During first few weeks: Weekly reporting of daily activity to lifestyle change coach. To include: average body weight for the week, number of days of food records were kept, total calories consumed per day, total minutes of moderate intensity physical activity expended each day.

Format, frequency, and duration of CC participant contact. CC participants receive telephone calls from lifestyle change coaches throughout the study to encourage recording of body weight, daily calories, food intake, and daily physical activity activity. Except for weeks when group health education is offered, calls / home visits will be encourage to be one session per week for months 1-3. Each call is expected to take 15-20 minutes.

Primary Care Provider role. At the screening visit as well as subsequent routine medical visits, these participants will be encouraged by their PCP to engage actively in whatever intervention they were assigned to.

**Outline of the Content of the Lifestyle Change Sessions for MyPlate Participants:**

For MyPlate participants, the group health education content will include: 1) Tips on making use of the physical activity equipment in the gym-in-the-bag; 2) Tips on how to shop for fresh produce, low-fat/non-fat dairy, lower sodium food products, whole grains and DASH-type mixed dishes. Also discussion of the importance of community resources for sustaining prescribed levels of physical activity and good adherence to DASH-style eating.

For the MyPlate participants, the in-home visits will focus on the importance of re-engineering the home environment to make healthy choices easier choices. In the most ambitious home environment-focused weight loss intervention published to date,<sup>46</sup> researchers used checklists to get participants to rid the home of high-calorie, high-fat foods and to stock the kitchen with healthier fare. They also provided participants with a treadmill or stationary bicycle for home use, and a pedometer for brisk walking outside. They restricted TV use to one communal room of the home, and attached a timer to the TV to limit the daily time spent watching TV. Finally, the investigators gave the participants a digital body weight scale and encouraged them to self-weigh daily.<sup>46</sup> We don't have the resources to provide a treadmill or stationary bicycle to the participants but we will provide a digital weighing scale for them to use if they don't have one. Moreover we will not ban high-calorie, high-fat foods for fear of inciting a rebellion by other household members not wishing to change their food choices. Instead, at the initial home visit the CHW and the patient will examine food products in the pantry, in the refrigerator, and on the kitchen counter and designate each food product as a red light food (limit to no more than once a month), green light food (may eat every day), or yellow light food (nutritiously intermediate food – limit to no more than once a week).<sup>54</sup> The intervention team will recommend that the

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study participant position the healthier choices so that they are the most conspicuous and the easiest choice. If the household member opens the pantry or refrigerator door and is visually confronted by a selection of green light foods, they are more likely to choose them over the red light foods that are hidden in the back. The literature on behavioral economics confirms that changing the “decision architecture” around the home will be enough to alter food choices; bans on problem foods are not necessary.<sup>55,56</sup>

For the MyPlate participants, the content of the 7 telephone lifestyle coaching sessions will include a focus on self-monitoring, stimulus control, social support, problem solving, and cognitive restructuring and to problem solve how these behavioral strategies can best be deployed when the participant reports challenges to her/his efforts to adhere to the MyPlate prescription. In addition, at each session the lifestyle change counselor will also ask how the participant can further improve the supportiveness of the home environment for facilitating participant adherence to the MyPlate prescription.

Self-Monitoring by MyPlate participants. The frequency of self-monitoring depends on the MyPlate participant's weight loss progress.

During weight loss (i.e. 5% weight loss not achieved), MyPlate participants are advised to:

1. For the first few weeks, write down each day their estimate of the proportion of their plate that was filled with fruits and vegetables, with whole grains, and with high-protein sources over the course of the day. Bodyweight need be recorded only once each week.
2. During months 1-3: Weekly reporting to lifestyle change coach of average minutes of moderate to vigorous physical activity expended for the week and average body weight for the week.

During weight maintenance (i.e. > 5% weight loss achieved), participants are advised to:

1. Daily write down: minutes of moderate intensity exercise in bouts of 10 or more minutes and body weight.
2. Write down all foods and beverages consumed 3 days/week.
3. During months 1-3: Weekly reporting of daily activity to lifestyle change coach. To include: average body weight for the week, number of days of food records were kept, and total minutes of moderate intensity physical activity expended each day.

Format, frequency, and duration of MyPlate participant contact. MyPlate participants receive telephone calls from lifestyle change coaches throughout the study to encourage recording of body weight, food intake, and daily physical activity and to problem solve challenges to adherence to the MyPlate prescription. Except for weeks when group health education is offered, calls / home visits will be weekly for months 1-3. . Each call will be 15-20 minutes long.

Primary Care Provider role for MyPlate participants. At routine medical visits, MyPlate participants will be encouraged by their PCP to actively engage in the intervention. Research staff will provide PCP with a report of their patient's progress and that provides key behavioral recommendations for the PCP to reinforce.

### ***Standardizing Delivery of the Intervention.***

The function of the Intervention Director is to monitor the delivery of the intervention on a weekly basis, provide corrective feedback if and when the community workers / lifestyle change coaches diverge from the intervention protocol, and learn from the coaches' weekly debriefings which solutions to lifestyle change challenges are effective. The lifestyle change coaches will meet weekly with the Intervention Director as part of a weekly "Learning Community" to problem

solve how to get patients to adhere better to both the dietary and the physical activity prescriptions in the CC and MyPlate conditions. The coaches will be well-trained in what should be covered in each of the 7 phone sessions as well as what should be covered in the two in-home visits.

All intervention print materials and study measures will be translated into Spanish, back-translated to ensure accuracy and subjected to cognitive interviews, to ensure that they communicate the same constructs as the corresponding English print materials and study measures. Drafts of intervention print materials and study measures will be reviewed in focus group discussions to ensure community acceptance of the final versions.

### **Interventionists/Delivery Systems**

The CC and MyPlate lifestyle interventions are designed to be delivered by community health workers (aka “lifestyle change coaches” or “promotoras”) recruited from the local community and local colleges and given extensive training and who have had previous experience with behavioral strategies for improving patient adherence to disease management protocols. The lifestyle change coaches will provide behavior change coaching to participants by being supportive, encouraging, empathetic, respectful, personable, informative and professionally competent in general nutrition, behavior-change and physical activity. They will undergo training and retraining to reinforce skills and techniques, including motivational interviewing, that facilitate behavior change. They will undergo periodic evaluation as part of routine quality control efforts. Specifically, a sample of their participant contacts (individual in-home sessions and telephone contacts) will be periodically reviewed. These expectations will be periodically reinforced throughout the trial.

All PCPs at the participating clinic sites will be invited to participate in the trial. They will receive 30 minutes brief training, follow the study protocol, and document contact with study participants. The study clinicians will also provide information and training related to the study, particularly the eligibility requirements and safety monitoring procedures. At the end of the study, there will be additional training of all clinical staff in light of lessons learned from the study. Budget has been set aside to permit training for clinicians and training for clinical staff to share the results of the study.

### **Use of Intervention Protocols**

Leader guides will be developed to provide a standardized framework for flow and format of each type of contact. For telephone calls, a REDCap computer-based system will drive the flow and content of the call.

### **Training Interventionists/Delivery System Personnel:**

Prior to delivery of the intervention, study investigators, the Intervention Director and the TCC MPH nutritionist will train the CC and MyPlate lifestyle change coaches and will certify that they are prepared to deliver the intervention. Retraining should occur periodically throughout the study to enhance the skills of the lifestyle change coaches.

### **Assessment of Interventionists’/Delivery System’s Fidelity to Protocol**

The Intervention director will implement quality control procedures that include: 1) direct observation of contacts to ensure adherence to study protocol and leader’s guides, 2) weekly case management to discuss clinical issues related to participants, and 3) regular quality control reports to assess completion of contacts as per protocol.

## **FACILITATING PARTICIPANTS' RETENTION IN THE STUDY FOR MEASUREMENT PURPOSES**

### *Facilitating Participants' Retention in the Study for Measurement Purposes*

From prior research we know that maintaining regular contact with study participants optimizes retention. The nature of the two interventions being compared here – namely 11 contacts over 3 months – provides a sufficient frequency of contact that retention is likely to be high. To ensure good participation at the baseline, 6-months and 12-months assessments, we are also providing \$20, \$30 and \$50 incentives, respectively. Incentives have been shown to be effective in increasing retention.<sup>46</sup>

### **Response to Missed Visits or Suboptimal Use of Intervention**

As noted above, a variety of aspects of adherence to the intervention will be assessed and monitored for participants in the CC and MyPlate interventions. These aspects include completion of scheduled contacts (phone contacts, group health education and in-home visits for both the CC and MyPlate participants), completion of weekly food intake, physical activity, and body weight reports, and for CC participants, daily calorie intake reports. Suboptimal compliance with these intervention requirements will lead to explicit problem-solving between the lifestyle change coach and the participant with respect to the barriers preventing compliance with the self-monitoring protocol. Participants will get encouragement for getting back on track and praise for aspects of the intervention where the participant is doing well. If personal phone calls from lifestyle change coaches are not enough, the participant will be referred for “case management” (i.e. consultation with the Intervention Director supervising the intervention).

### **Techniques to Facilitate Participant Retention in the Intervention and Continued Adherence to the Intervention Protocol**

We will employ a number of strategies to facilitate retention. First, a prime criterion for selecting intervention staff will be the individual's ability to engage participants. Experience from previous long-term trials makes it clear that participant retention is maximized when they bond closely with staff. Second, all communication with participants will be designed to maximize the participant's sense that the study understands the challenges involved in efforts to lose weight, and that the staff is committed to make dealing with these challenges as easy as possible. Third, the interventions themselves are designed to help participants succeed in their efforts to lose weight, thus providing substantial reinforcement for staying in the study. In addition, the regular monitoring reports study participants will receive are also designed to highlight the positive changes participants have made. Fourth, the logistic barriers to participation in the study will be minimized. For both interventions, sessions will be held in the evenings and weekends. Finally, PCPs will serve as intervention ‘cheerleaders’, encouraging participants to stay in the study and to maintain their weight loss efforts. Towards the end of the trial, a debriefing of PCPs will occur in order to assess their contributions to the MyPlate and CC intervention and identify strategies that might improve the effectiveness of the interventions.

## **12. SAFETY MONITORING**

The study will monitor participant safety. One aspect of safety monitoring is to evaluate potential study participants at screening to determine whether it is safe for them to participate in the interventions. This will be done in collaboration with the participant's PCP, who will have received information and training about the trial, particularly its eligibility criteria, interventions, and safety monitoring procedures. In this trial, primary care will be provided by the participant's PCP, not by study personnel. A second aspect is monitoring the safety of enrolled participants. If a participant develops a medical problem, the safety of continuing or resuming the intervention will be ascertained by the participant's PCP in collaboration with a study clinician. The

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investigators met weekly during the active intervention phase with the community health workers/ change agents to discuss, among other things, evidence of adverse events. Surveillance for serious adverse events and other relevant clinical events occurred as needed. Third, if we became aware of medical problems from abnormal physical measurements, such as blood pressure assessment, we referred the patient to her primary care physician and follow-up to make sure that she completed the referral. Results of routine physical measures obtained as part of study visits will be provided to the participant's PCP with patient's consent. In addition, the staff were prepared to address immediately items meeting the criteria for 'Alert Values' listed in the table below. A designated study clinician with appropriate expertise will be designated as the 'Health Safety Officer' and will review medical eligibility criteria and clinical measures as needed. The Safety Officer will also be responsible for reviewing and reporting SAEs for the site, as detailed elsewhere. This person or persons will have appropriate back-up during vacations or other absences to provide 24/7 medical safety coverage for the duration of the study.

### **Potential Risks**

The following sections describe potential risks associated with the study along with procedures to minimize risk.

### **Physical Activity**

We recognize the need to minimize the potential risks of physical activity in previously sedentary individuals with CVD risk factors. During the screening process, we will exclude persons with a CVD event within the past 6 months. In screenees with a prior CVD event (over 6 months ago), diabetes, peripheral vascular disease, or a positive Rose Angina Questionnaire, PCP approval is required specific to the patient's CVD risk. In order to protect the participants' safety, we will continuously reinforce our recommendation to engage in moderate-intensity physical activity. We will also recommend a safety evaluation by their PCP for those participants who wish to progress to vigorous physical activity. Still, it is important to acknowledge the participant's autonomy. We can recommend that participants follow safety advice but cannot force them to do so.

### **Nutrient Intake**

Calorie restriction can theoretically lead to inadequate nutrition or excessive, rapid weight loss. To minimize these risks, participants are encouraged to eat a variety of foods from all food groups and to maintain an adequate calorie level. 6 month follow-up to check that patients are not suffering excessive weight loss. Participants will be advised that marked and sustained caloric restriction can have serious health risks, e.g. gallstones and/or cholecystitis.

### **Hypoglycemia Related to Exercise and Lifestyle Interventions**

For patients who may be susceptible to hypoglycemia due to use of anti-diabetic medications, weight loss interventions have the potential to increase the risk of hypoglycemia, especially during the time when diet and/or physical activity interventions are implemented. To minimize the risk of hypoglycemia, we will require PCP approval prior to enrolling individuals with diabetes. PCPs are provided with relevant information, prepared by the study clinicians. In addition, participants are educated about symptoms of hypoglycemia. They are urged to contact their PCP if they have symptoms or blood glucose values suggestive of hypoglycemia. Changes in diabetic regimens and overall management of diabetes remain under the control of the participant's PCP.

### **Symptomatic Hypotension Related to Exercise and Lifestyle Interventions**

For patients who may be susceptible to hypotension because they are using medications that lower blood pressure, weight loss interventions have the potential to increase the risk of hypotension. Participants are educated about symptoms of hypotension and urged to contact their PCP if they have symptoms suggestive of hypotension. In addition, staff contact will notify PCP of participants who develop symptomatic hypotension while on anti-hypertensive medications. Changes in blood pressure regimens and overall management of hypertension remain under the control of the participant's PCP.

### Cardiovascular Events

All participants with cardiovascular disease (CVD) require approval from their PCP prior to enrolling. PCPs are provided with information about safety guidelines for physical activity for people with CVD. In addition, participants are educated about CVD symptoms and urged to contact their PCP if they have a change in their CVD symptoms. Overall CVD management remains under the control of the participant's PCP. Cardiovascular events are also assessed using a standardized questionnaire at regular, pre-specified intervals. When a staff member learns that a cardiovascular event (including a procedure) has occurred, the physical activity component of the intervention is suspended. The intervention may be resumed after approval from the participant's PCP.

### Alert Values

Table 8 lists the alert values and subsequent actions that will occur. In general, the participant, safety officer, and PCP will be notified.

Table 9. Alert Values and Actions

Measure	Alert Value	Notify participant
Blood pressure (avg.)	Level 1 SBP $\geq$ 180mm/Hg OR DBP $\geq$ 110mm/Hg	In clinic. Advise to follow-up with PCP within 1 week
	Level 2 SBP $\geq$ 140mm/Hg OR DBP $\geq$ 90mm/Hg	In clinic. Advise to follow-up with PCP within 1 month.
	Level 3 SBP $\leq$ 70mm/Hg OR DBP $\leq$ 50mm/Hg	In clinic. Advise to follow-up with PCP within 2 months.
PHQ-9 (Depression questionnaire)	Total score $\geq$ 16 & $<$ 21	In clinic. Advise to follow-up with PCP or mental health care provider within 1 month.
	Total score $\geq$ 21	In clinic. Advise to follow-up with PCP or mental health care provider within 1 week

### Surveillance and Reporting Procedures

#### Serious Adverse Events (SAE)

As defined by the Food and Drug Administration, serious adverse events include the following:

- ☐ death,
- ☐ a life-threatening experience,

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- ☐ ☐ inpatient hospitalization or prolongation of existing hospitalization,
- ☐ ☐ a persistent or significant disability/incapacity, or
- ☐ ☐ a congenital anomaly/birth defect.

Important medical events that do not result in death or require hospitalization may be considered serious adverse events if they jeopardize the participant's health or require medical or surgical intervention to prevent one of the outcomes in the definition. Surveillance for serious adverse events and other relevant clinical events that may be associated with study participation will occur at in-person visits scheduled at 6 months and 12 months after randomization. This is done using a standardized questionnaire. In addition to the fixed time points, participants may report events in other settings, e.g. phone and intervention contacts. These events will be referred to unmasked staff that will gather relevant information and complete the standardized questionnaire. A study clinician will review the completed forms, will classify the event according to several dimensions (expectedness, relatedness, and type), and will take appropriate action. Safety-related events will be reported in a timely fashion as required by the Safety officer, the IRB, and PCORI.

### **Expected Events**

Over the duration of the trial, which could last up to six months, a number of medical events may be expected to occur in obese adults, including routine surgeries and procedures, the development of cancer or other chronic conditions, increased symptoms from a chronic condition, musculoskeletal problems, motor vehicle accidents, and other types of accidents (e.g. falls, acts of violence).

### **Pregnancy and Other Exclusions**

If a participant becomes pregnant during study after enrollment she is then excluded. If a participant develops cancer, unstable angina, or another condition for which weight loss or exercise might be contraindicated, further participation will be determined by the participant's PCP in conjunction with a study clinician.

### **Data Safety and Monitoring Plan**

The data safety and monitoring plan for this study should be proportional to the degree of risks of the trial. We believe that this study has minimal risk based on our prior studies in this area. We therefore will not have a data safety and monitoring board for this study. However, based on our prior studies, we will conduct regular and thorough monitoring of the data by the PIs, project manager and director, and statistician, and lead research assistants. The PIs and study team will meet weekly to review recruitment, enrollment, retention, adverse events, and adherence to study protocols for data collection, and data storage. Cases will be reviewed for any issues related to privacy or confidentiality or potential cases of child abuse, victimization, or psychological distress. Patients will be provided with contact information for the project manager/director/PIs if questions arise. The IRB and PCORI will be informed if any patient experiences a serious adverse event or if the patient has concerns about the study. Staff will be fully trained to be able to address serious adverse events. The team will undergo human subjects protection training via the CITI modules of "Social & Behavioral Researchers & Staff" and HIPPA training.

## **13. STATISTICAL POWER AND SAMPLE SIZE ESTIMATION**

**Hypotheses for the Two-Group Randomized Control Trial Design:** The aim is to conduct an RCT of the impact of CC versus MyP on patient-centered outcomes in up to eight community clinic sites in Long Beach. Participants will include: 150 patients randomly assigned to receive

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CC from trained health coaches, another 150 patients assigned to receive MyP from another group of trained health coaches over the course of 12 sessions in six months.

**Intervention check:** Does exposure to MyP versus CC lead to increased patient reports of fruit and vegetable intake in MyP? A preliminary check will be made to confirm that one of the defining features of the MyP approach, namely a doubling of F&V intake, was reflected in study participants' daily intake of F&V assessed at follow-up. If no difference were observed in F&V assessed at follow-up then the validity of the experimental contrast would be jeopardized. There could still be experimental effects, but the causal mechanisms would be unknown. Because numerous studies have succeeded in getting patients to double their intake of F&V for up to four years, a negative outcome of this intervention check is unlikely.<sup>25</sup>

**Question:** Does exposure to MyP versus CC lead to decreased patient 12-months reports of daily hunger ratings/ daily meal satisfaction ratings/ daily fullness ratings in MyP during a time when patients were trying to lose excess weight (primary)? Will exposure to MyP versus CC lead to increased patient weight control self-efficacy, patient quality of life and patient satisfaction with her/his weight control program (primary)?

**Question:** Will exposure to MyP versus CC lead to increased weight loss/ reduced waist circumference equally for both conditions sustained for 12 months (secondary)?

**Avoidance of bias. Covariates and effect modifiers.** Standard demographic variables, including gender, age, ethnicity, marital status, and educational attainment will be included as covariates. Possible effect modifiers will also be included as covariates, including language preference (English / Spanish), last month food security, meal-skipping status, and daily physical activity level.

**Sample size. (3) Statistical power.** We power this proposal for the two-group (MyP vs CC) randomized design, setting alpha at 0.025 in order to have an experiment wise type I error rate of 0.05 after testing two hypotheses. Test of hypothesis #1 is therefore a test of the effect of MyP versus CC on the 12 months report of freedom from hunger measure used in the trial most similar to the trial proposed here.<sup>183</sup> The intervention effect size reported by Ello-Martin and associates is Cohen's  $d = .52$ . (Cohen's Effect Size =  $(53.5 - 46.7) / 13.2 = .52$ ). The total sample size needed to detect this effect, given a two-tailed critical  $P = .025$ , minimum statistical power of .80, and  $\rho = .85$  the total sample size needed is approximately  $N = 144$ . The test of the second hypothesis is a test of MyP versus CC on the body weight lost over 12 months. We have three sources to draw on for estimating effect size involving weight loss over 12 months. The first is Ello-Martin and associates, whose low-fat, high fruit and vegetables intervention<sup>20</sup> was similar to but not identical to the DASH diet + (sat. fat & sugar restriction) featured in the current proposal.<sup>16</sup> Ello-Martin's DASH-similar + fat restricted diet yielded a 12-months weight loss of 7.9 kg (SE=0.9,  $n=35$ ) whereas the fat restriction-only condition yielded a 12-months weight loss of 6.4 kg (SE = 0.9,  $n=36$ ). The total sample size needed to detect a similar 12-months weight loss difference at  $\alpha=0.025$ , power=0.80,  $\rho = .7$  is  $N= 206$  ( $n=103$  per group). In Appel's recent clinical trial<sup>15</sup> the in-person DASH-like dietary intervention yielded a 5.4 kg (SE=0.7,  $n=124$ ) weight loss relative to baseline at 12 months follow-up.<sup>15</sup> The body weight lost in response to Wadden's DPP-like dietary intervention<sup>14</sup> was 3.4 kg (SE=0.6,  $n = 112$ ) at 12 months follow-up.<sup>184</sup> By design the protocols followed by Appel et al. (2011) and by Wadden et al. (2011) were similar, so comparing means across these two studies is informative. The sample size needed to detect this difference at 12 months at  $\alpha = 0.025$ , power=0.80,  $\rho=.7$  is  $N = 270$  ( $n = 135$  per group). Based on the best available sources in the literature for information about reasonable estimates of the effect size to be expected and given an expected attrition of 20% at 6 month follow-up, the baseline initial sample of 300 ( $N=300$  for 2 groups) appears to provide ample statistical power for the two experimental comparison hypotheses

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considered primary in this proposal. For a substudy involving only the 76% of participants who are Latino, the sample size (N =228) also yields acceptable statistical power. All additional hypothesis-testing will involve secondary hypotheses.

#### **14. ANALYSIS PLAN**

**General.** After the data have been cleaned, we will examine the distribution and dispersion of data through descriptive numerical summaries and graphical tools such as scatter plots and box plots, probability plots, scatter matrix plots, co-plots, and trellis graphics to assess distributional assumptions and relationships among important variables. Before attempting a longitudinal analysis of the change in our outcomes using a linear mixed model, we will use profile plots, empirical summary plots and correlograms to guide us in the formulation of our model.<sup>185</sup> Some data will be subjected to scale transformation (e.g., logarithmic), as needed, to meet statistical assumptions. Box Cox or Yeo-Johnson transformations may also be used for this purpose.

Because missingness can potentially spoil or invalidate a study, we will spare no effort to minimize incomplete or missing data. All data will be carefully inspected to identify missing items, outliers, or other influential features. We will strive to form conclusions that are robust to different missing-data mechanisms,<sup>186</sup> and we will consult with colleagues in the Fielding School of Public Health Biostatistics Department regarding the use of incomplete-data analysis strategies that make effective use of available information.

Preliminary analyses will compare treatment groups on descriptive and clinical characteristics at baseline to ensure that randomization has succeeded. SAS (PC version 9.3) and Stata (Intercooled version 13) comprehensive database management and statistical packages will be used for descriptive calculations, group comparisons, and conditional regression modeling.

Experimental contrasts will be examined *a priori* using Stata's mixed effects modeling procedures, with standard errors corrected for the effects of clustered data.<sup>187</sup> It is known that even with randomized designs, covariate imbalance between treatment groups can exist and threaten the integrity of the design.<sup>188</sup> Because the potential bias may result in misleading conclusions, we will perform a thorough examination for covariate imbalance. Specifically, we will examine the distributions of all important variables at baseline and at the major endpoint (12 months follow-up), and also at intermediate points if the covariate is time-varying. Formal statistical methods for testing selection bias (systematic baseline imbalances) based on response data will be followed.<sup>188,189</sup>

#### ***Missing and incomplete data***

Prevention is far superior to a statistical cure, and every effort will be made to collect outcome data on all randomized participants. For example, we will ask medical staff at the clinical practices to obtain weight measurements on individuals who have stopped participating in the trial. Due to the high longitudinal correlation, missed "interior" visits won't decrease information very much for a linear trend. However, they are needed to assess departures from a linear trend. As detailed in Little and Rubin 2002<sup>190</sup> and discussed by Mealli,<sup>191</sup> the underlying missing data process determines the biasing effects of missing data and structures valid analytic strategies. If data are missing completely at random, then there is no induced bias and a complete case analysis, while inefficient, is valid. Another approach to dealing with missing 12-months follow-up weights is to conduct "liberal" and "conservative" analyses. One would assume that on average there is neither weight loss nor gain,  $[W_{12} - W_0 = 0]$ .

#### ***Censoring***

In certain analyses, data may be censored. Types of potential censoring include:

1. Medical event censoring – a medical event (e.g. stroke, heart attack, or pregnancy), use of certain medications, or death. In this case, a weight may or may not be available. If available, the weight may be strongly influenced by the condition (e.g. extreme weight gain from use of oral steroids) such that the weight data should not be used subsequent to the event.
2. Dropouts not associated with a particular event (e.g., a participant refuses to continue). For our primary analysis we will use the weight change data for the pre-dropout period. Sensitivity analyses will evaluate the consequences of imputing subsequent weights using a statistical model, last-observation-carried-forward (equivalent to imputing 0 weight change subsequent to the dropout), or imputing a non-zero monthly weight gain subsequent to dropout.

### ***Intent to Treat Analyses***

Primary analyses will be performed on an intention-to-treat (ITT) basis. However, interpretation of weight loss trials is complicated because of drop-out from the intervention group and drop-in from the control group. Particularly common are early drop-outs, i.e. individuals randomized to intervention who attend only a few intervention sessions, sometimes none. Such persons are included in ITT analyses. In this setting, we will compute “on treatment” comparisons and variations on this approach that adjust such an analysis for differential correlates of adherence in the treatment groups.

Care is needed in answering such questions, and Bellamy et al, Mealli et al.<sup>191,192</sup> provide a useful framework for such analyses. For a basic case, we consider how to handle participants who complete at most 2 intervention sessions. They will be included in the primary, as randomized, intent to treat analysis. A secondary question is, “how does the treatment groups compare for those who adhered to treatment?” A straightforward comparison of treatments based only on “compliers” is attractive, but is biased if the compliers differ among the treatment groups. A valid comparison depends on adjusting for these differences, being careful not to adjust away the treatment effect. Propensity score approaches using information available at randomization and up through the first session can adjust for this imbalance. More sophisticated approaches using time-varying propensities allow accommodating more complicated patterns of non-adherence.

## **15. DATA MANAGEMENT**

Data will be collected from three main sources: 1) data entered by participants on Dell tablet PCs; 2) data entered by lifestyle change coaches during coaching sessions; 3) REDCap data entry by trial fieldwork staff of selected data (e.g. randomization date, clinic ID, recruitment data, clinical measurements, and attendance). Data entry is accessible via the secured websites. Web based data entry systems will include range and cross checks. All hard copy data forms will undergo editing/checking by a second Research Assistant. Missing and questionable data will be followed-up and corrected. Data clerks will perform data entry as soon as possible after receipt of forms. All data entered will pass through an extensive computer editing system with imbedded checks for internal consistency and biologic plausibility. All data centrally entered will be 100% verified. Daily back-ups of all study data will be done in the secured server and stored off-line on tape and/or laserdiscs in a locked area.

### ***Data confidentiality***

The investigative team is keenly aware of the need to protect participant confidentiality, as well as corresponding legal requirements, including those mandated by HIPAA (Health Insurance Portability and Accountability Act). All data collected and stored electronically will be password

protected and saved in a secured fashion. All study related computers will be under firewall protection and will maintain automated virus update mechanisms. Timely notification regarding relevant patches will be provide. Hard copy of the data collection forms will be store in locked cabinets or areas. Only authorized personnel will have access to these locked areas. In addition, all study staff annually sign a confidentiality statement attesting to their understanding of, and willingness to abide by, the staff written policies on research ethics and confidentiality. Access to the data entry website is password protected and restricted to personnel trained to use the system.

### ***Data analysis***

The data management team conducts all analysis of study data under the direction of the principal investigators and the trial statistician. A trial statistician will be assigned to all approved papers. Working with the lead investigator, the statistician will develop an appropriate analysis plan. Formal written analysis requests are reviewed for clarity before work is begun. This procedure minimizes rework and thus makes most efficient use of staff resources.

### ***Analysis guide***

To facilitate data analysis requests, the data management team will create a detailed analysis guide for the study investigators. This guide provides detailed, organized documentation of all study variables along with a process that allows researchers to request analyses in a clear, concise fashion. A summary data set including the most frequently used variables is provided, with variables in alphabetical order. Copies of every data form used in the study are also provided, each labeled with the specific variable name in the response field.

***Trial-wide data release.*** The data management/analysis team will prepare and distribute a limited access dataset to the PCORI project office for public use with the analysis guide. The data release documentation provides detailed, organized documentation of study variables and clear instructions on how to install and access the data.

## **16. TRIAL ADMINISTRATION – Organization of investigators and project staff**

The UCLA/TCC study operation will be organized into teams of investigators and staff. The type and number of subcommittees, ad hoc working groups, and other units depends on the phase of the trial and study needs. The organizational structure will be reviewed periodically and amended accordingly. Hence, the organizational structure summarized below, which is appropriate for the early implement phase of the trial, will likely change over time. The primary decision-making body is the Oversight Committee, chaired by the PIs and comprised of all investigators and senior staff (e.g., Intervention Director). This committee, which convenes monthly, reviews the progress of all components and focuses on high level scientific and administrative issues. This committee will also guide publications. An administrative subcommittee, comprised of the UCLA PI (Dr. McCarthy) and Co-PI (Dr. Gelberg) from UCLA, the PI from TCC (Dr. Chandler), and a few senior staff, meets weekly and addresses day-to-day operational issues and sets short-term priorities. The following are other working units of the trial:

- Field Operations Subcommittee, which focuses on recruitment, retention, measurements, quality assurance, quality control, and data collection.
- Intervention Subcommittee, which focuses on the design and implementation of the interventions.
- Data Management and Analysis Subcommittee.

## **17. TIMELINE**

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The trial consists of three main phases: planning (focus groups, pilot study), implementation (recruitment, intervention and data collection), and data analysis/dissemination. Planning for the trial will begin April, 2014. Recruitment for the full trial will commence in April 2015 and should last approximately six months. Closeout will occur 12 months after randomization. Remaining time will be devoted to data analyses, presentation/publication, and dissemination activities.

Table 9. Original Timeline for “Is MyPlate.gov approach to helping overweight patients lose weight more patient-centered?”

Activity	Year 1						Year 2						Year 3					
	Apr-May	June-July	Aug-Sept	Oct-Nov	Dec-Jan	Feb-Mar	Apr-May	June-July	Aug-Sept	Oct-Nov	Dec-Jan	Feb-Mar	Apr-May	June-July	Aug-Sept	Oct-Nov	Dec-Jan	Feb-Mar
Hire staff, train staff	X				X													
Obtain IRB approvals	X		X			X												
CAB, stakeholder input	X		X			X			X			X			X			X
Refine data input system, Spanish translation, clinician trainings, resource guide	X																	
Conduct cognitive testing, focus groups, key stakeholder interv.		X																
Conduct brief intervention training of providers and clinical staff		X																
Recruit pilot study subjects			X															
Finalize pilot interv. materials			X															
Conduct pilot study				X	X													
Evaluate pilot study results						X												
D: Report on pilot study & qualitative study results						X												
Conduct 30 weeks of accrual							X	X	X	X								
Recruit, randomize patients, baseline assessments							X	X	X	X								
Conduct 6-month intervention & 6-month follow-up							X	X	X	X	X	X						
Conduct analyses of baseline, 6-months, and 12-months data										X	X	X	X	X	X	X	X	X
D: Report on baseline and, 6-month and 12-month results												X		X		X		
Conduct focus groups, key stakeholder interviews																	X	
Write reports of final results																X	X	X
Conduct community dissemination of lessons learned																	X	X
Revise intervention protocol, disseminate best practices																	X	X
D: Report recommendations based on final conclusions																		X

\*Note. When “D” prefaces an activity, it indicates a deliverable that will be used to report progress to PCORI.

## 18. DISSEMINATION PLANS

The interventions tested in this trial are designed for implementation in routine medical practice. If either the MyPlate or CC intervention is found to be effective, the ultimate public health impact will be determined by the ability to disseminate it. Therefore, the dissemination component of the study includes identifying patient and practice characteristics that will affect acceptance and success of the programs. The RE-AIM (Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance) framework provides useful guidance for identifying and documenting dissemination issues (see [www.re-aim.org](http://www.re-aim.org)).<sup>193</sup> In this framework, optimal dissemination requires an intervention that has been found effective in a representative group of individuals (representative of the community or clinical population served, i.e. individual-level impact). The ability to translate the intervention into a usual practice setting (institutional impact) derives from the feasibility and cost of the program, the degree and quality of adoption, implementation, and sustainability of the program within the setting.

With this in mind, the primary objectives of our dissemination activities will be to: 1) collect quantitative and qualitative data related to dissemination issues; 2) determine an appropriate approach to disseminating components of the intervention that are found effective; and 3) implement and document dissemination activities. Plans for each type of activity are summarized below.

### **Collect quantitative and qualitative data related to potential dissemination issues.**

To estimate the representativeness of study participants compared to the overall clinic site, we will use administrative data. We will be unable to collect individual-level information of those invited but not enrolled. Potentially available data include age, gender, ethnicity, BMI, insurance

status, and prevalence of co-morbid conditions. To describe clinic site characteristics, we will collect data on size (average caseload, average number of encounters per week); number and types of providers (i.e., physicians, nurses, medical assistants); use of electronic medical record; available weight loss programs and resources; and census tract descriptors of the area where the clinic site is located. Quantitative data on clinicians will include number invited; number who declined or were excluded by the investigator or the clinic site; reasons for declinations or exclusions; demographic information; and physician characteristics (e.g. years at site, specialty, type of provider). After the 6 months follow-up data have been collected, focus group and key stakeholder information will be obtained from representative staff recruited from participating clinic sites and clinicians. These qualitative data will address feasibility issues, unanticipated costs attributed to delivering the intervention, and perceptions of the feasibility, logistical and cost issues potentially associated with continuing the program once the study has ended. Formal process data (e.g., on attendance, adherence, fidelity in delivery of the protocol) will provide insights on quality of the intervention and dose delivered.

#### ***Determine Ways for Disseminating Lessons Learned.***

Quantitative and qualitative variables described above will be analyzed in conjunction with the effects of the active intervention arms on study outcomes to characterize the dissemination potential of the program, including considerations that may apply to effective implementation at the individual and clinic site levels. The final program content, requirements, and recommended approach for implementation will be packaged for dissemination.

#### ***Implement and document dissemination.***

If results warrant, activities will be undertaken to market the program. Our primary focus will be health care providers, although activities might also be directed towards patients. These activities will be tracked. The success of dissemination, i.e. as characterized in the RE-AIM framework, cannot be determined within the time frame of this grant.

#### **Health care providers.**

In addition to publishing study results in peer-reviewed journals, we will send provider-focused descriptions of the study and its results to medical trade publications (e.g., American Medical News, American Nurse, American College of Physicians Observer). Training workshops and symposia will be offered at appropriate professional meetings or through other mechanisms, to increase the potential for dissemination. We will also post intervention materials and guidelines directly on the websites of relevant professional and scientific organizations (e.g., American Medical Association, American Heart Association). The information posted on websites also will include a summary of the feasibility issues, clinic site requirements, and ballpark costs of offering the program.

We plan to disseminate results of this study widely to other organizations that might implement or promote the interventions. Information on effectiveness, feasibility, and ballpark cost of the interventions will be provided. The targeted audience includes Long Beach and Los Angeles County health services departments and public health departments, directors of managed care organizations, health maintenance organizations, state Medicare and Medicaid programs, and Disease Management companies.

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