1. **Protocol Title:** Incentivizing behavior change skills to promote weight loss

2. **Purpose of the Study:**

Aim 1: Determine feasibility of using automated algorithms that analyze dietary self-monitoring and interim weight loss data to provide real-time positive reinforcement using variable-ratio financial incentives.

Aim 2: Evaluate intervention acceptability, as indicated by recruitment, intervention adherence, and outcome measurement rates as well as feedback from qualitative interviews.

Aim 3: Estimate cost of delivering the intervention and cost to patients for participating in the program.

3. **Background & Significance:**

Two-thirds of the United States (US) population is classified as obese or overweight. This epidemic has profound negative physical, psychological, and financial consequences. Despite the existence of effective behavioral weight loss interventions, many people do not achieve adequate weight loss during the intervention period, and most people regain lost weight in the year following intervention. Therefore, novel methods are needed to improve initial weight loss and promote long-term weight loss maintenance. One promising strategy is reinforcement via financial incentives. Reinforcement may be negative (removal of a stimulus to increase desired behavior) or positive (addition of a reward to increase desired behavior) and may be delivered on a fixed-ratio (predictable) or variable-ratio (unpredictable) schedule. Despite theoretical and empirical support in other behavioral domains, in the context of weight loss, few studies have examined positive reinforcement delivered on a variable-ratio schedule. Those few studies involved lotteries or gifts and primarily incented behaviors indirectly associated with weight loss (e.g., walking). Thus, more research is needed to evaluate the effect of positive reinforcement delivered on a variable-ratio schedule.

A key issue is whether incentives should be provided for weight loss itself or for building behavioral skills that support weight loss. Incenting weight loss alone does not ensure that important cognitive/behavioral skills (e.g., dietary self-monitoring) will be learned because other, less enduring strategies (e.g., extreme caloric restriction) might be utilized in the short-term. By the same token, incenting skill-building alone does not ensure that sufficient weight loss will be achieved. Therefore, incenting skill-building ***and*** weight loss may be more effective than incenting either alone. To our knowledge, no study has examined this issue.

4. Design & Procedures: This 2X2 between-subjects factorial study involves incentives for dietary self-monitoring (yes vs. no) and/or interim weight loss (yes vs. no) (Table 1).

Table 1. Study design

Incentives for interim weight loss	Incentives for dietary self-monitoring	
	Yes	No
Yes	A	C
No	B	D

Three cohorts of 40 overweight/obese patients (10 randomized to each condition in each cohort) will be enrolled (total n=120). In each cohort, four dietary groups will be created, one corresponding to each of the four study conditions. These patients will participate in a 24-week weight loss program involving a low-carbohydrate diet protocol that is delivered

in person every 2 weeks. Participants will be instructed to record their daily dietary and liquid intake on a mobile telephone dietary application (app) and weigh themselves daily at home on a study-provided cellular scale. We will develop an innovative information technology (IT) solution that will collate dietary self-monitoring data, input by patients via an app, and interim weight loss data, obtained from the cellular scale. Using these data, an algorithm will classify participants weekly as achieving adequate dietary self-monitoring and/or interim weight loss to earn unpredictable, intermittent cash rewards. Notice of reward will be provided via text message, and credit will be uploaded to a Duke ClinCard in real-time.

5. Selection of Subjects: Inclusion criteria are listed in Table 2.

Table 2. Inclusion and exclusion criteria

Inclusion criteria determined by telephone	Exclusion criteria determined by telephone
• aged 18-70 years • self-reported BMI ≥ 29 kg/m^2 (to allow for error; final criterion will be BMI ≥ 30 kg/m^2) • desire to lose weight • agree to attend visits per protocol • access to telephone and reliable transportation • no errors on a validated 6-item cognitive screener[1] • able to complete study measures • English speaking • smart phone with data and texting plan	• dementia, psychiatric illness, or substance abuse that might interfere with the intervention • weight loss ≥ 4.5 kg in the month prior to screening • enrollment in a research study focusing on weight loss or health behavior change • residing in a nursing home or receiving home health care • impaired hearing • medication other than metformin, incretin mimetics and incretin enhancers for type 2 diabetes due to increased risk for hypoglycemia • unable to attend sessions at the four scheduled times • unstable heart disease in the 3 months prior to screening: o having Acute coronary syndrome (ACS) including STEMI (ST-elevation myocardial infarction), NSTEMI (non-ST elevation myocardial infarction) and unstable angina (UA) o recent coronary revascularization [recent coronary bypass grafting (CABG) or percutaneous coronary intervention (PCI) o unstable arrhythmia (supraventricular tachycardia, ventricular tachycardia, ventricular fibrillation) o recent acute congestive heart failure exacerbation [requiring increased doses of oral or

	intravenous (IV) diuretics or hospitalization] • furosemide ≥40 mg or equivalent • chronic kidney disease at stage 3 or higher • Weight > 380 lb
Inclusion criteria determined in person • stable health by medical history • BMI ≥ 30 kg/m^2	Exclusion criteria determined in person • blood pressure ≥ 160/100 mmHg • pregnancy (determined by urine pregnancy test) pregnancy, breastfeeding, or lack of birth control if premenopausal Weight > 380 lb

Subject Recruitment & Compensation: Initially, we will recruit from the Durham community via flyers, paid advertisements, Research Match and social media. If we do not achieve sufficient enrollment for the first cohort, then we will obtain referrals from Duke Primary Care physicians and targeted recruitment via electronic health record screening and recruitment letters/calls. We will wait approximately 10 days after mailing the recruitment letter and then call patients to assess interest and eligibility. As part of the intervention, some participants will receive financial incentives (section 8). All participants may choose to receive $25 for week-24 outcome visits or keep their scale in lieu of the $25. Anyone who participates in a qualitative interview will receive an additional $25.

6. Consent Process – see Section 14 of the e-IRB submission form and complete the questions in that section.

7. Subject's Capacity to Give Legally Effective Consent: Ability to give consent will be assessed in the recruitment call and in-person visit. We will not enroll participants unable to provide consent.

8. Study Interventions: In this study, overweight/obese outpatients will participate in a 24-week weight loss program involving either a low-carbohydrate diet (LCD) or low-fat/low-calorie diet (LFD) protocol, which will be delivered in person every 2 weeks. Participants in each condition A-D will meet in a separate group. In cohort 1, we used the LCD because reviews have indicated that short-term weight loss (6 months) is greater with LCD than with LFD. Furthermore, to our knowledge, every financial incentive study has used the more common LFD approach, making use of the LCD innovative. As we conducted cohort 1, we realized that there was a mismatch between the dietary self-monitoring that we are encouraging and the LCD. That is, although people on the LCD would normally be encouraged to monitor their carbohydrate intake, the app that we are using, MyFitnessPal, readily displays calories rather than carbohydrates. Furthermore, in the LCD, participants focus less on portion control as portions are not restricted for some foods. Yet, accurate accounting of dietary intake via an app requires knowledge of portion sizes for all foods, even those that are carbohydrate-free. Finally, one criterion for earning a financial incentive each week is to eat a minimal amount of calories (1000 for females, 1200 for males), encouraging participants to self-monitor their food intake. We use a lower calorie limit to ensure that people are eating enough because participants may overly restrict their calorie intake because they believe it will increase weight loss. We teach them that they should eat a

minimum number of calories per day because eating less may be unsafe without closer monitoring and is not a long-term, sustainable habit. For all of these reasons, we decided to evaluate use of the LFD during cohort 2 to see if it provides a better match for the self-monitoring behavior that we are teaching via MyFitnessPal. This type of change is consistent with the nature of the R34 mechanism that funds this study.

In cohort 2, we observed lower retention for the primary outcome assessment (81% compared to 88% on cohort 1; minimum goal is 80%) and less mean weight loss. These differences could be due to two major differences between cohorts 1 and 2: (a) Use of the low-fat diet. Dr. Yancy's previous studies show a slight advantage for the LCD during the first 4-6 months; and (b) Our population had different demographics, likely due to differences in where we advertised the study. Cohort 2 was more racially diverse and lower socioeconomic status. We feel it is important to recruit a more diverse sample to enhance external validity. **Therefore, for cohort 3, we will use the same recruitment methods but return to the LCD to see if we can enhance weight loss.** We will also make a more concerted effort to discuss the importance of returning for outcome assessments at various points in the study. We will also add an extra in-person session at week 1 so that we can spend greater time showing participants how to use MyFitnessPal at week 0 and have the opportunity to teach participants about portion sizes during week 1. We typically have not focused on portion sizes when teaching the LCD because portions are not restricted, and people seem to spontaneously reduce their calorie intake due to greater satiety.

8a. **LCD PROTCOL (cohort 1 & Cohort 3)**

Weight-Loss Intervention. A registered dietitian (RD) will lead all meetings. Upon arrival at all meetings, participants will have their weight measured. After the first meeting, participants will have their blood pressure measured at every meeting. Diabetic patients will be asked to report any abnormal blood glucose levels by filling out a short survey. At the first meeting, participants will create an individualized weight loss goal. They will also receive a cellular scale, a lay press diet book (*The New Atkins for a New You*), and education about the initial phase of the diet. This instruction will include a review of foods to emphasize and foods to avoid or minimize. Initially, carbohydrate intake will be restricted to 20 grams per day. Caloric intake will not be specified, as *ad libitum* instruction in an LCD typically leads to spontaneous calorie reduction.[2,3] The diet will begin with unlimited amounts of animal foods (meat, chicken, turkey, other fowl, fish, shellfish) and eggs, limited amounts of hard cheese, and limited servings of salad and low-carbohydrate vegetables. Artificial sweeteners can be used, whereas caffeine and alcohol are to be limited. Due to the diuresis that can occur at diet initiation, participants will be warned of the symptoms of dehydration and instructed to drink adequate fluids to prevent dehydration. A cup of broth daily will be recommended at diet initiation to prevent dehydration. Participants will be monitored for hypotension at the group visits. Participants will be given contact information for the study physician, who will be on 24-hour call.

At every meeting, the participants will receive handouts that cover information specific to that session's topic (see table titled 'Log2Lose Class Descriptions'). The first 15 minutes of each meeting will be devoted to practicing behavioral goal-setting using the group-based goal-setting protocol from our previous weight loss maintenance trial. Participants will set 2-week behavioral goals using SMART (specific, measurable, attainable, relevant, time-bound) criteria. At each meeting, the group will review goals set at the previous meeting, their level of success achieving those goals, and refine their goals. To

facilitate goal attainment, participants will be instructed to log their daily food intake through the MyFitnessPal® dietary app, which contains an extensive food database. To prevent fatigue, the software app is designed to facilitate ease of entering foods that are most commonly consumed. MyFitnessPal® readily provides detail on calories, although information on calorie type (including carbohydrates) is provided within the app as well. MyFitnessPal connects with Fitbit®, another mobile app, which sends data to a Duke-run system called Prompt.

As a participant's weight loss approaches half of his/her 24-week weight loss goal, the participant will be instructed to add approximately 5 grams to the daily carbohydrate intake each week as long as weight loss continues. If the participant maintains weight or adds weight, then he/she will return to the daily carbohydrate intake of the previous week. Similarly, as the participant approaches goal weight, he/she will add approximately 5 grams to the daily carbohydrate intake each week until weight regain occurs. At that point, the participant will return to the daily carbohydrate intake from the previous week. This will become the maintenance level of carbohydrate intake for the individual. Added carbohydrates can be extra servings of salad vegetables, low-carbohydrate vegetables, avocado, or cheese, or the addition of servings of fruits, nuts, or soft cheese. Participants can also choose low-carbohydrate marketed products such as snack bars and shakes to satisfy cravings for sweet foods. Patients will be mailed a letter 4-8 weeks prior to the end of the study asking them to schedule a final visit with the study team following completion of the class

Log2Lose Class Descriptions			**(Handouts used)**
Class 1	**Week 0: Let's Get Started -**	Participants will receive basic introductions to the study design, opportunities to receive incentives throughout the study based on group assignment, how to use the cellular scale and dietary tracking smartphone app, and a quick introduction to the low carb diet.	• Atkins book • Session weigh-in log
Class 2:	**Week 1 – Introduction to the Low Carb Diet & Using SMART Goals**	We will review basic weight loss principles including concepts of energy balance and calorie content in macronutrients. Participants will learn to distinguish high carb foods from low carb foods, and learn their initial carbohydrate restriction level. We will also introduce SMART goal setting, teaching participants how to create specific behavioral goals at each group session.	• Introduction to Low Carb Diet • • SMART Goal Sheets
Class 3:	**Week 2- Reviewing the Low Carb Diet, Interpreting the Food Label,**	Participants will learn how to calculate net carbs, understand the carbohydrate content of different food groups and products, and learn how to use the food label to help achieve success. A variety of class exercises will lead participants to understand the meaning of various	• Low Carb Quiz • Net Carbs • Interpreting Label Claims for the Low Carb Diet •

		types of information on the nutrition facts label.	
Class 4:	**Week 4- Troubleshooting Common Low Carb Questions**	This class will address common areas of concern for the low carb diet, and will allow participants to ask questions and share ideas. Topics will include ketosis, brainstorming new meal ideas, how to deal with side effects and cravings. We will also discuss realistic rates of weight loss for the study duration.	• Common Pitfalls and the Low Carb Diet
Class 5:	**Week 6 – Grocery Shopping: Stocking a Low Carb Kitchen**	Participants will learn strategies for purchasing food in the grocery store that is compliant with the low carb diet. The instructor will discuss how to select options from each section of the grocery store, including produce, meat/dairy, and specialty grocery items that participants may find helpful. Food packages/labels will be brought in for demonstration.	• Low Carb Shopping List
Class 6:	**Week 8 – Restaurant Eating: Dining Out Strategies**	Participants will learn how to make healthy, low-carb selections when dining out in a variety of restaurants. Using restaurant menus (a mix of actual and hypothetical), participants will work to develop meal plans for various types of cuisines. Helpful strategies for meal modifications and special requests will be discussed. Participants will learn resources to help them locate the nutritional information for restaurant foods.	• Strategies for Low Carb Dining • Menu Exercise/Activity
Class 7:	**Week 10 – Modifying your Recipes: Low Carb Cooking**	This class will feature a discussion of low carb cooking techniques, as well as a video that highlights several low carb recipes. Participants will learn how to modify recipes to be lower in carbohydrates, using different ingredients and cooking/preparation techniques. Participants will be led through an interactive exercise where they will try their hand at modifying recipes. Participants will be introduced to various web sites and other resources for finding healthy, low-carb recipes.	• Eazy Cookin' Low Carb Cooking Video Recipes • Low Carb Resources
Note* *We will be showing participants a cooking video and providing recipes for them to take home and try. The name of the video is "Eazy Cookin: Low Carb, Volume 1" by Chef Robert van Houten. We will be playing this 35 minute video in the classroom using a laptop and projector, and the purpose is to demonstrate cooking techniques described in our classes, and to provide meal examples that are appropriate for the diet.*			

Class 8:	**Week 12 – Sharing Your Success, and Phasing in Additional Carbohydrates**	This class is designed to allow participants the opportunity to share their success: new recipes, food products, behavioral habits or strategies that have helped with their success on the low carb diet. At the halfway point in the study, this week is also a time to discuss when and how to increase carbohydrate intake, providing individual guidance for participants.	• Sharing Your Success • Introducing Carbs Back into Your Diet
Class 9:	**Week 14 - Mindful Eating**	Participants will learn the importance of mindful eating for successful weight loss. They will learn how to distinguish mindful versus mindless eating behaviors and develop strategies to deal with the latter. A class exercise will be conducted to demonstrate mindful eating	• Mindful Eating • Mindful Eating Exercises / Activities
Class 10:	**Week 16 – Physical Activity & Weight Loss**	Participants will learn the difference between physical activity and exercise, as well as the health benefits of physical activity and general recommendations. As a group, participants will brainstorm and plan for realistic ways to incorporate more activity into their daily life.	• Physical Activity Guidelines • Infographic of "Taking Breaks"
Class 11:	**Week 18 – Planning for High-Risk Situations**	This class will discuss various types of high-risk situations that can act as obstacles to successful weight loss using a low carb diet. These situations can be emotional or social, and may differ for each participant. We will review common high-risk situations, and discuss strategies, such as planning ahead, so that these situations do not lead to lapses and weight gain. Worksheets will be provided so participants can develop individual plans.	• Planning for High-Risk Situations
Class 12:	**Week 20 – How to Build Your Support Network**	This class will discuss different forms of support needed during weight loss, such as the social support found in group sessions, individual support persons (spouse/partner, exercise buddy, health care provider), as well as how technology can be used to support. Participants will also review different support strategies (encouragement, co-participation, etc.), and reflect and what best suits their needs.	• Enlisting Support

Class 13:	**Week 22 – Success for Long-term Weight Loss Maintenance**	This class will review important strategies for long-term weight management, including the more liberal phase of the low carb diet using a carbohydrate threshold. Participants will also learn the importance of regular increase physical activity to combat a reduced metabolic rate after weight loss. In addition to emphasizing self-monitoring behaviors long-term, previous class topics will be reviewed: planning ahead for high-risk situations and enlisting helpful social support.	• Habits of Highly Successful Losers • National Weight Control Registry
Class 14:	**Week 24 – Graduation and Low Carb Potluck with recipe exchange**	Participants will end the program with a celebration of their success. Participants will have the opportunity to take part in a low carb potluck complete with recipes to take home. Study personnel will also ask for feedback regarding the content and structure of the group sessions.	

8b. LFD PROTOCOL (cohort 2)

Weight-Loss Intervention: A Registered Dietitian (RD) will lead all meetings. Upon arrival at all meetings, participants will have their weight measured. Patients with diabetes will be asked to report any abnormal blood glucose levels by filling out a short survey. At the first meeting, participants will create an individualized weight loss goal. They will also receive a cellular scale, a lay press diet book (*The American Heart Association No-Fad Diet*) and education about the diet. Participants will be given contact information of the study physician, who will be on 24-hour call.

This diet will restrict total fat intake to less than 30% of daily energy intake and saturated fat to less than 10% of daily energy intake. The diet will consist mainly of complex starches (e.g., whole grain bread, pasta, rice), vegetables, fruits, lean meats (e.g., poultry and fish), and low-fat dairy products. In keeping with research showing that whole grain sources of carbohydrates are healthier than refined carbohydrates in regard to CHD risk, we will emphasize whole grain foods. In addition, we will emphasize the intake of vegetable oils (e.g., olive and canola oils) that contain high proportions of mono- and polyunsaturated fats rather than solid oils that contain *trans* fats (e.g., shortening).

The goal for total caloric intake will be calculated by subtracting 500 calories per day from the maintenance energy requirement for each individual. In order to determine maintenance energy requirement, resting metabolic rate (RMR) will be calculated using the Mifflin-St Jeor formula. This formula was selected because it has been shown to be more accurate than other equations in estimating RMR for obese individuals. The RMR result will then be multiplied by an activity factor corresponding to an individual's activity level in order to determine maintenance energy needs (age is in years, weight is in kilograms, height is in centimeters.)

Incentives Research Summary

Women : Maintenance energy intake = [9.99 x actual weight + 6.25 x height – 4.92 x age – 161]

x Activity Factor [1.2=Sedentary; 1.4=Low Active to Moderate; 1.6=Active]

Men: Maintenance energy intake = [9.99 x actual weight + 6.25 x height – 4.92 x age +5] x Activity Factor [1.2=Sedentary; 1.4=Low Active to Moderate; 1.6=Active]

At every meeting, the participants will receive handouts that cover information specific to that session's topic (see table titled 'Log2Lose Low-Fat Class Descriptions'). The first 15 minutes of each meeting will be devoted to practicing behavioral goal-setting using the group-based goal-setting protocol described above. At each meeting, the group will review goals set at the previous meeting, their level of success achieving those goals, and refine their goals. To facilitate goal attainment, participants will be instructed to log their daily food intake through the MyFitnessPal® dietary app, which contains an extensive food database. MyFitnessPal® provides detail on calories and macronutrients. MyFitnessPal® connects with FitBit®, another mobile app, which sends data to a Duke-run system called prompt.

Group counseling will focus on the selection of desirable types and portions of foods, interpretation of food labels, common pitfalls, and behavioral modifications to reduce cravings. If a participant experiences a prolonged plateau after a previous downward weight trajectory, then energy intake may be reduced further by 300-500 kcal per day. If a participant achieves goal weight before the end of the 24-week period, energy intake will be adjusted to maintenance-level calories.

Log2Lose Low Fat Class Descriptions			**(Handouts used)**
Class 1:	**Week 0 – Let's Get Started: Introduction to the Low Fat Diet**	Participants will receive basic introductions to the study design, opportunities to receive incentives throughout the study based on group assignment, how to use the cellular scale and dietary tracking smartphone app, and a quick introduction to the low fat diet. Participants will also receive their personalized calorie and fat gram allowance. The serving size for each of the different food groups will be discussed. Participants will learn to distinguish high fat foods from low fat foods.	• Session weigh-in log • Calorie/ Fat Budgets • Low-Fat Diet Quiz
Class 2:	**Week 2 – Interpreting the Food / Nutrition Label**	Participants will learn how to interpret a nutrition facts label. This class will go will address more detailed areas of nutrition including different types of fat, cholesterol, fiber, sugar, protein, and vitamins and minerals. A variety of class exercises will lead participants to understand the meaning of various types	• Label Reading • Understanding Label Claims • Practice Food

		of information on the nutrition facts label.	Labels
Class 3:	**Week 4 – Energy Balance: Tracking Diet & Activity**	Participants will learn the concept of energy balance, and the importance of accurate tracking for calories consumed (dietary intake) and calories burned (physical activity). They will participate in an exercise showing the need for measuring portions with regards to accurate tracking. The dietary mobile app will be reviewed, including shortcuts and tips to make tracking easier and more convenient.	• Track Your Food • Track Your Activity
Class 4:	**Week 6 – Dining Out Strategies**	Participants will learn how to make healthy, low-fat selection when dining out in a variety of restaurants. Using actual restaurant menus, participants will work in team to develop meal plans for various types of cuisines. Participants will learn resources to help them locate the nutritional information for restaurant foods.	• Strategies for Dining Out • Strategies for Fast Food Eating • Menu Exercise
Class 5:	**Week 8 – Grocery Shopping: Stocking a Healthy Kitchen**	Participants will learn strategies for purchasing healthy food in the grocery store. The instructor will discuss how to select produce, meat, grains, dairy and condiments that are in line with their dietary goals. Common questions will also be answered regarding the benefits of eating seasonally and when to buy organic.	• Grocery Staples List • NC Seasonal Produce • Pesticides in Produce
Class 6:	**Week 10 – Low Fat Cooking 101**	Participants will view cooking videos that will review the basic kitchen tools one needs to have in the kitchen for low fat cooking along with a series of healthy recipes to prepare at home. Participants will have an opportunity to ask questions about healthy food preparation. Participants will be introduced to various web sites and other resources for finding healthy, low-fat recipes.	• Cooking Tips for Weight Management • Handout & Video: Integrative Nutrition Healthy Cooking
	Note* *We will be showing participants a cooking video and providing recipes for them to take home and try. The name of the video is "Healthy Cooking" by Integrative Nutrition. We will be playing this 50 minute DVD in the classroom using a laptop and projector, and the purpose is to demonstrate cooking techniques described in our classes, and to*		

provide meal examples that are appropriate for the diet.			
Class 7:	**Week 12 – Modifying Your Recipes**	Participants will learn how to modify recipes to be lower in calories, fat, sodium and sugar as well as way to increase nutrients such as vitamins, minerals and fiber. Several class exercises will demonstrate how to take a high fat recipe and modify multiple ingredients to improve its nutritional profile. Participants will be led through an interactive exercise where they will try their hand at modifying recipes.	• Recipe Makeovers: 5 Simple Steps to Healthier Meals • Low-Fat Substitutions • Class Exercise: recipe makeovers
Class 8:	**Week 14 - Mindful Eating**	Participants will learn the importance of mindful eating for successful weight loss. They will learn how to distinguish mindful versus mindless eating behaviors and develop strategies to deal with the latter. A class exercise will be conducted to demonstrate mindful eating	• Mindful Eating • Mindful Eating Exercises / Activities
Class 9:	**Week 16 – Physical Activity & Weight Loss**	Participants will learn the difference between physical activity and exercise, as well as the health benefits of physical activity and general recommendations. As a group, participants will brainstorm and plan for realistic ways to incorporate more activity into their daily life.	• Physical Activity Guidelines • Infographic of “Taking Breaks”
Class 10:	**Week 18 – Planning for High-Risk Situations**	This class will discuss various types of high-risk situations that can act as obstacles to successful weight loss using a low fat diet. These situations can be emotional or social, and may differ for each participant. We will review common high-risk situations, and discuss strategies, such as planning ahead, so that these situations do not lead to lapses and weight gain. Worksheets will be provided so participants can develop individual plans.	• Preventing Relapse
Class 11:	**Week 20 – How to Build Your Support Network**	This class will discuss different forms of support needed during weight loss, such as the social support found in group sessions, individual support persons (spouse/partner, exercise buddy, health care provider), as well as how technology can be used to support. Participants will also review different support strategies (encouragement, co-	• Enlisting Support

		participation, etc.), and reflect and what best suits their needs.	
Class 12:	**Week 22 – Success for Long-term Weight Loss Maintenance**	This class will review important strategies for long-term weight management. Participants will also learn the importance of regular increase physical activity to combat a reduced metabolic rate after weight loss. In addition to emphasizing self-monitoring behaviors long-term, previous class topics will be reviewed: planning ahead for high-risk situations and enlisting helpful social support.	• Habits of Highly Successful Losers • National Weight Control Registry
Class 13:	**Week 24 – Graduation and Low Fat Potluck with recipe exchange**	Participants will end the program with a celebration of their success. Participants will have the opportunity to take part in a low fat potluck complete with recipes to take home. Study personnel will also ask for feedback regarding the content and structure of the group sessions.	

Incentive Structure. Table 3 shows the incentive schedule for each cell of the 2X2, which is informed by several learning theory principles. First, as previously discussed, we are using a variable-ratio incentive schedule, whereby the timing and amount of incentive will be unknown to participants. Second, the expected value (i.e., maximum that participants can earn) is the same in all conditions so that any advantage seen in the combined condition (A) cannot be attributed to patients having a larger expected value. Thus, the amount that condition (A) receives for self-monitoring is half of what condition (B) receives for dietary self-monitoring, and the amount that (A) receives for interim weight loss is half of what condition (C) receives for interim weight loss; however, the payment schedules are the same for conditions (A) and (B) for dietary self-monitoring and for conditions (A) and (C) for interim weight loss. Third, participants will be eligible to receive incentives every week during the first 4 weeks because learning of new behaviors is higher with initial continuous reinforcement. For Cohorts 1 & 2, Intermittent reinforcement will occur later in the schedule due to its beneficial impact on maintenance of behaviors. For Cohort 3, they will be eligible for incentives every week of the study, and intermittent payment will mean varying amounts of incentives each week. Further, the payment for dietary self-monitoring and weight loss is the same *throughout the study* so that the incentives do not have differential effects on motivation of dietary self-monitoring and interim weight loss. Fourth, patients in all conditions will be eligible for incentives during the same weeks so that any differential effects between conditions cannot be attributed to different reinforcement schedules (e.g., getting paid nearly every week or every week in combined condition A).

No study has defined the optimal amount of incentive for various reinforcement schedules. We selected an expected value of $300 per participant based on provider

pay for performance studies, in which providers receive incentives equivalent to 1-3% of their income for optimal clinic performance.[4,5] Our study population very likely will comprise patients of lower socioeconomic status. We expect that 1% of the median annual per capita income for a single person in Durham, NC (~$30,000),[6] and the absolute value of $300, will be perceived as significant by patients given their relatively low median income and the diminishing marginal utility of income (i.e., $300 provides more utility to a lower-income person than a higher-income person).[7] Based on feedback from participants in cohorts 1 & 2 – cohort 3 may receive up to $322. Instead of receiving $0 for achieving a goal on the reinforcement schedule, participants will receive $2. This will increase the maximum potential incentive to $322.

All participants will receive a Duke ClinCard card during the first group session that they attend. In all conditions, participants will be told that they will receive the payment for the outcome assessment visit via a credit to the Duke ClinCard. In conditions A-C, participants will be told that they may receive credits to the card at various times during the study for using the dietary app (A and B) or achieving weight loss (A and C). We chose this incentive type and delivery method instead of providing payment at the group sessions so as not to delay reward and to avoid the confound of requiring attendance to receive the award. Participants will not be informed of the reward schedule or the incentive amounts.

Instruction to self-monitor dietary intake and self-weigh will be the same across conditions. All participants will be urged to enter everything that they eat and drink in the app. In conditions A and B, the criterion for reinforcement of dietary self-monitoring is that patients must log at least two entries per day and a minimum number of calories per day for at least 5 days per week (one of which must be a weekend day). We are allowing up to 2 days of inadequate self-monitoring to allow for barriers such as an uncharged cell phone battery, being somewhere without the phone, etc. We are only requiring two entries per day because some individuals only eat two larger meals per day (although some people only eat once daily, our dietitian advises participants not to do this). Males must log at least 1200 calories, and females must log 1000 calories. We chose a daily caloric criterion because (1) carbohydrate intake may increase over time as patients achieve their weight loss goal, so caloric intake is more appropriate than carbohydrate intake. Moreover, caloric deficit is thought to be the mechanism underlying weight loss in the LCD as with other diets; (2) in our previous and ongoing studies involving a low-calorie diet, 1500 and 1200 are the lower limits of what we prescribe for males and females, respectively, so these criteria provide some flexibility given that food intake is frequently underestimated[8]; and (3) caloric intake is readily available on the app. Participants will be asked to contact the CRC if they are unable to use their phone for self-monitoring (e.g., they lose it); these participants will be ineligible to receive incentives. Such instances will be logged in our tracking database and inform our future R01.

Table 3. Incentive schedule for each study arm cohorts 1 & 2

Condition	Incentive for	Week															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
A	Interim WL	$10	$14	$11	$12	$0	$7	$0	$13	$10	$0	$0	$12	$0	$0	$14	$0
	Dietary SM	$10	$14	$11	$12	$0	$7	$0	$13	$10	$0	$0	$12	$0	$0	$14	$0
B	Dietary SM	$20	$28	$22	$24	$0	$14	$0	$26	$20	$0	$0	$24	$0	$0	$28	$0

C	Interim WL	$20	$28	$22	$24	$0	$14	$0	$26	$20	$0	$0	$24	$0	$0	$28	$0
D	Neither	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

Condition	Incentive for	Week 17	18	19	20	21	22	23	24
A	Interim WL loss	$13	$0	$0	$10	$15	$0	$9	$0
A	Dietary SM	$13	$0	$0	$10	$15	$0	$9	$0
B	Dietary SM	$26	$0	$0	$20	$30	$0	$18	$0
C	Interim WL	$26	$0	$0	$20	$30	$0	$18	$0
D	Neither	$0	$0	$0	$0	$0	$0	$0	$0

Note. WL=weight loss; SM=self-monitoring.

Table 4. Incentive schedule for each study arm cohorts 3

Condition	Incentive for	Week 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
A	Interim WL	$10	$14	$11	$12	$1	$7	$1	$13	$10	$1	$1	$12	$1	$1	$14
	Dietary SM	$10	$14	$11	$12	$1	$7	$1	$13	$10	$1	$1	$12	$1	$1	$14
B	Dietary SM	$20	$28	$22	$24	$2	$14	$2	$26	$20	$2	$2	$24	$2	$2	$28
C	Interim WL	$20	$28	$22	$24	$2	$14	$2	$26	$20	$2	$2	$24	$2	$2	$28
D	Neither	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

Condition	Incentive for	Week 17	18	19	20	21	22	23	24
A	Interim WL loss	$13	$1	$1	$10	$15	$1	$9	$1
A	Dietary SM	$13	$1	$1	$10	$15	$1	$9	$1
B	Dietary SM	$26	$2	$2	$20	$30	$2	$18	$2
C	Interim WL	$26	$2	$2	$20	$30	$2	$18	$2
D	Neither	$0	$0	$0	$0	$0	$0	$0	$0

All participants will also be encouraged to weigh themselves everyday given that patients who weigh daily achieve greater initial weight loss and weight loss maintenance than those who weigh less frequently.[9] In conditions A and C, the criterion for reinforcement of interim weight loss is that patients have lost weight. Because greatest weight loss would be expected at the end of the week, we will calculate weight loss based on the weight provided on Day 7 or the closest date for which data are available. We are not rewarding based on individualized weight goals so as to avoid rewarding participants with less ambitious goals and to avoid penalizing participants who do not achieve their more ambitious goals. Participants could “game” the system by having someone else weigh in for them or not putting all of their weight on the scale. Our software algorithm detects weight greater than 10% difference and removes them so the we have some assurance that a family member or friend is not stepping on the cellular

scale. As this is a planning study, we will provide patients with incentives even if their in-person weights differ from their home weights. We will characterize the extent to which in-person weights differ from home weights and use this information to inform our future trial.

For dietary self-monitoring and interim weight loss, Day 1 of each week will correspond to the day of the participant's in-person group visit. Because greatest weight loss would be expected at the end of the week, we will calculate weight loss based on the weight provided on Day 7 or the closest date for which data are available. For those weeks when an incentive is scheduled, patients who achieve the incentive criterion will receive a text message on Day 1 of the following week informing them that they have earned an incentive for the previous week's success and encouraging them to continue their efforts. The incentive will be credited to the Duke ClinCard as soon as possible after the text has been delivered (timing depends on availability of Duke staff who process payments). Patients who do not meet the criterion for reward will receive a text message informing them of the missed incentive and encouraging them to self-monitor and weigh daily to maximize loss aversion (i.e., the preference to avoid losses). We will program the software with algorithms to automatically analyze the dietary and weight data according to the aforementioned criteria. Pre-developed targeted text messages will be automatically delivered to participants with incentive information accordingly.

Participants who are eligible for a reward in a particular week will receive the following message: "Great job on (logging your food or losing weight) this week! $x will be added to your gift card. Keep up the good work!" Participants who are ineligible for a reward in a particular week will receive the following message: "You did not log your food or lose weight enough this week. If you had, you would have earned $(xx). Please log your food and lose weight for a chance to earn money." The message to ineligible participants emphasizes loss to enhance loss aversion. These messages are 160 characters or less so that they appear in a single message instead of breaking into 2 messages.

Participants will also receive text messages before the group sessions as a reminder to attend. Study staff will also communicate with participants via text message if there is a cancellation or rescheduling of class. The text messages will indicate that participants should call the study team with questions rather than responding to the text message.

In order to send and receive text messages, we will use a software engine designed by Duke software engineers, called Prompt. Prompt uses Twilio, Heroku, and Amazon S3. Prompt will receive diet data that participants log into the MyFitnessPal app (that is connected with the Fitbit API) as well as weight data when they step on the BodyTrace scale. We will not collect names in this database; instead, we will only collect phone number and study ID of each participant, as well as data from MyFitnessPal (via the Fitbit API) (diet tracking information) and from BodyTrace (weights). The data will be automatically analyzed weekly according to algorithms we embed. Study staff will login to a password-protected database to view study ID and see a list of participants who met study criteria for the incentives each week, as well as the incentive amount. We will use Twilio to send text messages to participants each week. We will use Heroku to process data analysis for the engine. We will use Amazon S3 to store data; data will be encrypted when it is stored. These are companies outside of Duke that will have access to participants' personal information, including name, phone number, and data from MyFitnessPal and Fitbit. If these data are further disclosed by them or their business partners, it may no longer be covered under the privacy protections. Text messaging

does not provide a completely secure and confidential means of communication. Participants are made aware of the risks that are inherent in using consumer-based products such as MyFitnessPal® and Fitbit® (see Human Subjects document).

Survey data will be collected and stored in RedCap. All other data are stored on a Heroku server run by software engineers at Duke University Medical Center.

We developed a new scale to assess group factors that may impact weight loss in group members. This scale was developed from research-based, theoretical, and anecdotal constructs. The scale is composed of 28 items assessing 11 constructs: responsibility/accountability, attraction to the group-task, attraction to the group- social, instilling hope, observational learning, guidance, reliable alliance, normalizing, social support, attachment/cohesiveness, and counter-productivity. The scale will be administered on paper to participants prior to group sessions at weeks 2, 12, and 22. If participants miss any of these group sessions, we will give it to them at the next group session (weeks 4, 14 and 24).

Qualitative Interviews. Participants from each of the 4 conditions will participate in a qualitative interview within three weeks by telephone with Dr. Voils at the University of Wisconsin-Madison. Within each condition, we will attempt to recruit 5 participants who achieved 5% weight loss (minimum clinically significant) and 5 who did not (total n=40) so that we can obtain perspectives from those who were more versus less successful. Based on our experience, this sample size will be sufficient for evaluating feasibility and acceptability of the intervention and obtaining feedback on key issues. The interviews will be highly structured and conducted following a script, as in Dr. Voils' previous pilot intervention studies.[10] The script will include questions around usability of the dietary app and scale, barriers to self-monitoring and weighing, and financial incentive amount and delivery. All interviews will be recorded and then transcribed. The interview data will be content-analyzed,[11] organized around the categories that are covered by the interview script.

Outside Key Personnel. Dr. Voils from the University of Wisconsin-Madison leads the behavioral science aspects of this study. These responsibilities include the design, management, and coordination of the weight loss trial, qualitative interviews, and respective data analyses. Dr. Voils co-leads manuscript writing, dissemination of findings, and development of future grants.

9. Risk/Benefit Assessment: There are few potential risks associated with any of the measures or data to be collected. There are small risks of injury or heart problems due to increased participation in physical activity. The threat of this potential problem will be reduced by screening for contraindications to physical activity participation and by providing proper instruction regarding methods for engaging in physical activity safely, as well as contraindications for continuing physical activity. Because the main physical activity to be stressed is increased walking, we do not anticipate that the health risks will be over and above the risks normally associated with daily walking. Participants may feel uncomfortable talking about their experience in the intervention during the qualitative interviews. Participants do not have to answer any question that they do not wish to answer, as will be explained during the consent process.

10. Costs to the Subject: There will be no direct cost to subjects. If participants currently have restriction on the number of text messages or data, they may incur cell phone charges (text messaging or data charges) as a result of being in this study.

11. Data Analysis & Statistical Considerations: Aim 1: Determine feasibility of using automated algorithms that analyze dietary self-monitoring and interim weight loss data to provide real-time positive reinforcement using variable-ratio financial incentives.

We will develop the incentive algorithms and programming that analyze the dietary and self-monitoring data from the mobile diet app. The algorithms and programming will elicit an automated trigger to send a text message with content based upon the incentive thresholds. We will then embed them into the IT platform and perform quality assurance testing to determine that the algorithms appropriately recognize when self-monitoring occurs and trigger the correct text message response. At study completion, we will use descriptive statistics to describe the number of "data pulls" from the diet app on participants' mobile phones and the percentage of text messages that are successfully transmitted back to participants. Furthermore, our project coordinator will maintain logs of the technical assistance they provide to participants regarding the diet app and receipt of the incentive messages. This will allow us to determine how many times we were able to successfully pull in the dietary and self-monitoring data from participants' telephones and to understand and address technical challenges and barriers.

> **Aim 2:** Evaluate intervention acceptability, as indicated by recruitment, intervention adherence, and outcome measurement rates as well as feedback from qualitative interviews.

Key acceptability information includes rates of recruitment, intervention attendance, and retention for outcome assessment visits. The total number of patients screened by telephone and in person and reasons for nonparticipation will be recorded in our tracking database. The recruitment rate will be calculated for each cohort (the appropriate formula will be used for passive vs. active recruitment strategies). We will compare recruitment rates across cohorts, particularly if we have to implement additional recruitment strategies during the study. The outcome assessment retention rate will be calculated for each cohort as [#of participants who return for each outcome assessment/number who were eligible upon completion of the baseline assessment].

One aspect of intervention adherence is attendance at the in-person sessions, which will be calculated as [# of participants who attended each in-person session/number who were eligible upon completion of the baseline assessment]. Another aspect of intervention adherence is the extent to which participants engage in dietary self-monitoring using the app and self-weighing using their wireless scales. Each week, the platform will create a variable indicating whether each participant met criteria for the reward. This variable will be plotted longitudinally by study condition so that we can examine trends. For example, we will examine whether participants who were incented for dietary self-monitoring achieved adequate self-monitoring compared to participants who were not incented for doing so, and whether this effect was present throughout the study or, for example, just in the first few weeks. We will also examine for each week the proportion of days on which adequate dietary self-monitoring was obtained.

Other acceptability information includes consistency between home-based weights obtained by the platform and weights obtained at the in-person sessions. We will characterize discrepancies between study-based weights and home-based weights performed on the same day. If study-based weights are >2.5 lbs greater than home-based weights, then we will follow up with participants in a nonjudgmental manner to understand the nature of the discrepancy.

> **Aim 3:** Estimate cost of delivering the intervention and cost to patients for participating in the program.

We will assess the complete set of costs related to each of the four conditions and then estimate the incremental costs for the three incentive arms relative to the costs associated with condition D (Table 3) that lacks incentives for dietary self-monitoring or interim weight loss. To complete cost assessment across the four conditions, we will partition costs into labor and capital costs. Labor costs include time spent by the registered dietician (RD) leading biweekly group meetings in each condition and time spent by the project coordinator providing incentives for dietary self-monitoring or interim weight loss. The time spent by these individuals on these activities will be tracked in time logs that they complete during the first week of every month of the study. This time log will track the time needed by the RD and the coordinator to complete major research and non-research tasks so that research time costs can be excluded. RD and coordinator cost per hour will be based upon his/her annual compensation (salary+benefits) for full-time employment. We will not estimate cost of delivering the group-based intervention because this is constant across the four study conditions. Capital costs include the financial incentives (via Duke ClinCard) provided to each patient in the 3 arms (maximum of $300 per patient), overhead costs, office space, telephone service, text messaging, and administrative costs (i.e., monthly fees) associated with providing the Duke ClinCards. Costs associated with developing and refining the Prompt engine will not be included in the cost estimate because we will assume that costs to modify the software will be trivial upon scaling in the future trial.

Once the complete set of costs for each of the four conditions is computed for all patients, we will estimate arm-specific average costs and compare the incremental costs of the three incentive conditions (A-C from Table 3) compared to condition D that lacks incentives for dietary self-monitoring or interim weight loss. These incremental costs will be largely driven by differences in incentive costs, monthly fees for the Duke Clincards, and project coordinator time spent providing incentives to patients because the RD time spent conducting the group meetings are expected to be the same across all four arms (unless group attendance in condition D drops markedly over time). These incremental cost estimates will inform incremental cost-effectiveness analyses to be conducted in the future large-scale trial. Finally, we will assess patient costs for intervention participation, which will include the time they spend traveling to and from the group meetings, time spent with the group during the intervention, and time spent entering data into the app. The cost of patient time spent engaged in the group meetings will be based on patient survey data about their annual salary and work hours to compute an hourly wage. In cases in which participants are unwilling to provide their income, we will impute based on regional salary estimates.

12. Data & Safety Monitoring: This is a minimal risk study so the potential for serious adverse events related to the study is low--the intervention consists of diet and physical activity recommendations derived from widely-disseminated guidelines that are directed to the general population.

In protocol adequacy of protection from risks:
Additionally, a Data Monitoring Committee (DMC) consisting of the study statistician and two additional members (at least one will be a physician with experience in diabetes care and at least one will have research experience) who are independent of the study team, will review the clinical data routinely with safety as its primary objective. A study physician will be on call at all times. Hypoglycemic events, for patients who may have diabetes, and other clinical adverse effects will be recorded at each visit using standardized, self-administered forms. All adverse events will be reported to the IRB according to local IRB requirements. The DMC will also review adverse events, screening, enrollment, and data collection reports at each study meeting to maximize the efficiency of recruitment and the validity of the data. Meeting frequency will be determined by the members of the DMC but will occur at least yearly.

In data and safety monitoring:
All research material obtained from participants will be gathered prospectively and will include anthropometric, vital sign measurements and participants' responses to questionnaires. Serious (i.e., life-threatening, hospitalization, persistent disability) and unanticipated adverse events will be assessed at every visit using standardized questions. Anticipated adverse events and side effects for weight-reducing diets and/or medication intensification will also be collected at every visit. These may include hypoglycemia, hypotension, gallbladder disease, headache, weakness, muscle cramps, constipation, diarrhea, and dehydration. Many of these effects related to dietary change are transient or easily treated, and can be prevented with adequate hydration, which will be emphasized in the dietary counseling. A study physician will be on call at all times to manage any adverse events felt to be related to the study. Patients with adverse events that are not related to the study will be referred to appropriate health care sources. All adverse events will be reported to the IRB according to local IRB requirements and reviewed regularly by the study DMC.

In other adverse effects:
Serious adverse effects (i.e., life-threatening, hospitalization, persistent disability) will be assessed at a case-by-case basis. Anticipated adverse events and side effects for weight-reducing diets and/or medication intensification may include hypoglycemia, hypotension, gallbladder disease, headache, weakness, muscle cramps, constipation, diarrhea, and dehydration. Many of these effects related to dietary change are transient or easily treated, and can be prevented with adequate hydration, which will be emphasized in the dietary counseling. A study physician will be on call at all times to manage any adverse events felt to be related to the study. Patients with adverse events that are not related to the study will be referred to appropriate health care sources. All adverse events will be reported to the IRB according to local IRB requirements and reviewed by a Data Monitoring Committee (DMC) consisting of the study statistician and two additional members (at least one will be a physician with experience in diabetes care and at least one will have research experience) who are independent of the study team.

13. Privacy, Data Storage & Confidentiality – see Section 12 of the e-IRB submission form and complete the questions in that section.

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