# OPT-IN: Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity

Protocol

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# 1 Introduction

## *1.1 Study Abstract*

Obesity is a major public health concern. INtensive Lifestyle Intervention (INLI) addressing diet, physical activity, and behavior change is the gold standard weight loss treatment for adults with cardiometabolic risk factors. Typical treatment involving 16-36 face-to-face sessions with a specialist produces clinically significant (5-8%) weight loss in 50-67% of obese adults with or without medical comorbidities (Diabetes Prevention Program Research Group [DPP], 2002; Look AHEAD Research Group [Look AHEAD], 2007). However, a recent comparative effectiveness trial now has demonstrated that an INLI that incorporates technology and remote coaching can produce weight loss comparable to that achieved by face-to-face intensive treatment (Appel et al., 2011). That breakthrough opens the possibility that it may be feasible to optimize treatment still further to develop more effective, resource-efficient obesity interventions than previously was believed possible.

Traditional research methods have typically treated INLIs as bundled "treatment packages," making it difficult to assess definitively which aspects of an intervention can be reduced, eliminated, or replaced to improve efficiency. Using traditional research methods (i.e., multi-armed randomized clinical trials (RCTs) testing each new feature one at a time) would require running many studies over decades, an exorbitantly expensive process that would likely be outpaced by the development of newer technologies. This modern paradox prompts us to consider a new research methodology that may offer a quicker, more efficient way to test the effectiveness of multiple intervention components simultaneously.

## *1.2 Study Objective*

The overall objective of the proposed research is to use an innovative methodological framework, the Multiphase Optimization Strategy (MOST) (Collins et al., 2007), to design, for the first time, an optimized, scalable version of a technology-supported INLI for obesity. MOST involves highly efficient randomized experimentation to assess the effects of individual treatment components, and thereby identify which components and component levels make important contributions to the overall program effect on weight loss. This information then guides assembly of an optimized treatment package that achieves target outcomes with least resource consumption and participant burden. Because the intervention strategies being tested minimize in-person coaching and leverage technology that participants already own, the new optimized intervention, to be called Opt-IN, will be more scalable than traditional INLIs. Opt-IN will thus enjoy greatly increased reach, and enable significant progress in the fight against obesity.

## *1.3 Primary Aim 1*

To identify which components/component levels from five components under consideration for inclusion in Opt-IN contribute meaningfully to improvement in (a) average weight loss, and (b) percent achieving >7% weight loss among obese adults over a 6-month period. The five components to be tested will be: (1) coaching intensity (12 vs. 24 phone sessions), (2) text messaging (No vs. Yes), (3) progress report to participant's primary care provider (No vs. Yes), (4) recommendation to use meal replacements (No vs. Yes), (5) training participants' self-selected buddies to be supportive (No vs. Yes). We will use a highly efficient experimental strategy powered to detect effects of individual components as well as all two-way interactions.

### *1.4 Primary Aim 2*

To apply the results obtained in Primary Aim 1 to build (1) an intervention made up of only active components and (2) if necessary, a second intervention that is optimized for scalability. Intervention (1) will be made up of the best set of components and component levels, based on the results of the experiment conducted in Primary Aim 1. Our conversations with private insurers suggest that in order to be scalable, Opt- IN needs to be implementable for $500 or less. If Intervention (1) exceeds an estimated cost of $500, we will identify the combination of components and component levels corresponding to the largest treatment effect that can be obtained for implementation costs of $500 or less. This will be the new Opt-IN intervention.

### *1.5 Secondary Exploratory Aim*

To improve understanding of how the five intervention components work and of differential response to intervention components by conducting analyses based on the data from the experiment in Primary Aim 1. The analyses will examine the following mediators of weight loss: (a) hypothesized: adherence to treatment, and (b) exploratory: social-cognitive variables (self-efficacy, self-regulation, supportive accountability, and facilitation). To investigate whether certain intervention components are more or less effective in certain subgroups, we will examine moderation by conducting analyses separately for subgroups defined by gender, ethnicity, and BMI categories. We will also conduct latent class analysis to identify latent subgroups and predictors of subgroup membership. The results will inform subsequent research aimed at developing interventions tailored and optimized for these subgroups.

# 2 Background

## *2.1 Significance*

The World Health Organization reports that more than one billion adults globally exceed healthy body weight. In the U.S. in 2007, 30% of the adult population was obese, double the rate in 1980 (Flegal et al, 2010). Currently, more than 69% of U.S. adults are either overweight or obese (Flegal et al., 2012). Obesity is an expensive condition because of its association with chronic disease. U.S. obesity-attributable medical expenditures are estimated at $75 billion annually, with $17 billion financed by Medicare and $21 billion financed by Medicaid (Finkelstein et al., 2004). Given the U.S. obese population of 60 million, this yields annual obesity-attributable medical expenditures of $1,250 per obese individual. Effective weight loss interventions have the potential to reduce the risk of chronic diseases, and save millions of health care dollars. Yet the most effective intensive lifestyle interventions (INLIs) are not accessible to most people because they have not been viewed as feasible for widespread implementation.

The most extensively studied INLIs for weight loss are the multi-session, in-person Diabetes Prevention Program (DPP) (2002), and related Action for Health in Diabetes (Look AHEAD) (2007). Although both have proved strongly efficacious in multi-site randomized controlled clinical trials (RCTs), neither these programs nor any other INLI has been widely adopted because they are considered too burdensome and expensive to be sustainable (Eddy et al., 2005). The weight loss initiation phase of most INLIs requires at least 16 in-person, face-to-face sessions with a specialist and costs about $1400/year per patient (DPP, 2002). Cost can be reduced below $500 per participant by training YMCA staff to deliver the program (Ackermann et al., 2008; Ackermann & Marrero, 2007), but that requires patients to have access, willingness, and ability to go a Y to attend multiple sessions. The other popular INLI implementation strategy has been to reduce cost by lowering treatment intensity (i.e., decreasing the number of sessions). However, that approach has yielded mixed results (Mau et al., 2010; Whittemore, 2011; Whittemore et al., 2009). Reducing intensity sacrifices opportunities for feedback and accountability, and usually leads weight loss to diminish as frequent face-to-face meetings are pruned back (Davis-Smith et al., 2007). The still unmet challenge of INLI implementation is how to reduce treatment burden, intensity, and cost without eliminating intervention components that are essential to successful weight loss.

The importance of the proposed research lies in the objective to reconfigure weight loss treatment so as to achieve the intended outcome more efficiently and in a manner that allows greater reach. New technologies now make it feasible to deliver treatment and support behavior change from a distance, reducing the need for burdensome in-person contact. A recent comparative effectiveness trial by Appel and colleagues (2011) demonstrated that a technology-supported INLI that delivers lessons via the web and coaching via telephone can be as effective for fostering weight loss as a traditional in-person delivery method. In that study, those randomized to receive 33 telephone coaching sessions lost approximately as much weight as those receiving in-person support (-4.6kg vs. -5.1kg). Because costs for trained personnel are the most expensive part of any INLI, more efficient treatment requiring fewer sessions would be highly advantageous. An optimized treatment could have a reduced number of sessions (e.g., 12 calls able to be delivered by paraprofessionals), but acquire increased impact by adding other low-cost active components. Several candidate components exist, but none has a known, quantified impact independent of other bundled treatment elements. For example, text messaging for obesity treatment has been bundled with telephone coaching (Patrick et al., 2009; Shrewsbury et al., 2009). Informing the primary care provider (PCP) about the patient's weight loss progress has been confounded with having the physician provide behavioral weight loss treatment or having allied health professionals deliver treatment in high-cost medical space, neither of which is cost-efficient (Wadden et al., 2011; Institute of Medicine [IOM], 2010). Other components, e.g., meal

replacements, have been tested in such expensive formats (e.g., free food provision) as to preclude real world implementation (Look AHEAD, 2007; Wadden et al., 2011). Another example involves the use of peers to provide social support who are given so much training (e.g., 36 hours) that they can more aptly be described as semiprofessionals (Katula et al., 2011).

The proposed research is significant in representing the first principled and systematic effort to design a weight loss treatment that is as effective and efficient as possible, such that all of its components are active, feasible for real world implementation, and make the lowest possible resource demands. The resulting treatment will be readily scalable and will support significant progress in the fight against obesity.

### *2.1.1* Methodological Innovation (MOST)

Intervention development commonly relies on establishing an intervention a priori and then testing its efficacy or effectiveness in a standard two-group RCT. The RCT is an excellent way of confirming the efficacy or effectiveness of an intervention as a whole treatment package. However, to make systematic gains in efficacy and effectiveness, it is necessary to have information about which aspects of the intervention are having the desired effect and which are not. The standard RCT used alone does not yield reliable information about the effects of individual intervention components. In a standard two-group RCT all intervention components are set to "On" in the treatment group and "Off" in the control group; therefore, the effect of any individual component on weight loss cannot be disentangled from the others. The standard two-group RCT, even followed by post-hoc analyses intended to disentangle component effects, is not a principled or systematic way to achieve gains in the effectiveness of weight loss treatment.

Although the statistical significance of a bundled intervention's effect, as established in an RCT, is important, we argue that other criteria are equally important. Such criteria include clinically meaningful effect sizes, efficient resource utilization achieved by eliminating ineffective components, and demanding the maximal effect size that can be achieved given an upper limit on implementation budget. These criteria are quite different from statistical significance, and a standard evaluation via a RCT offers little help in achieving them. Faced with similar problems in a different context, engineers developed optimization methods. These research methodologies, designed to evaluate components efficiently, have enabled engineers to develop new technologies very rapidly. We propose here to apply these methods, for the very first time, to the development of an obesity intervention.

Optimization is defined as the process of finding the best possible solution to a problem, *subject to given constraints.* Note that this definition refers not to the best solution in an absolute or ideal sense, but rather to the best solution that is realistically possible, given inevitable time and money constraints. Also note that optimization is defined as a process rather than a product, because further improvements can always be made when more resources become available or other constraints are lifted. Optimization methods developed in engineering have been widely adopted (Collins et al., 2007) and now are used routinely in, for example, manufacturing, chemical synthesis, electric power generation, transportation, aviation, health care, genetic engineering, and computing. These engineering-based optimization principles have rarely been applied to the development of behavioral interventions, however.

Dr. Collins (Co-PI) and her collaborators have been working to bring the power of engineering principles to bear on methods to develop and optimize behavioral interventions. Their work has produced the innovative and comprehensive MOST framework to optimize and evaluate multi-component behavioral interventions (Collins et al., 2007; Collins et al., 2009; Collins et al., 2011). MOST's aspirational goal is to maximize an intervention's public health impact, defined as the product of efficacy x population reach. The operational goal for any particular project is a clearly defined improvement in public health impact that is achievable with available resources.

Opt-IN, the treatment to-be-developed, will achieve the amount of weight loss customary for an INLI but will do so with maximal efficiency (i.e., no wasted resources due to inactive treatment components and cost under $500).

### *2.2 Potential for Prevention*

The intervention delivered in this study has been adapted from the Diabetes Prevention Program (DPP, 2002), which has been found to reduce risk of the development of diabetes. Our sample differs from most of the DPP studies in that they are not required to have diabetes risk factors to be eligible. However, given the co-occurrence of diabetes and obesity, this program may lead to a reduction of risk factors associated with the development of diabetes.

# 3 Study Design

## *3.1 Primary Research Question*

Which components/component levels from five components under consideration for inclusion in Opt-IN contribute meaningfully to improvement in (a) average weight loss, and (b) percent achieving ≥7% weight loss among obese adults over a 6-month period? The five components to be tested will be: (1) coaching intensity (12 vs. 24 phone sessions), (2) text messaging (No vs. Yes), (3) progress report to participant's primary care provider (No vs. Yes), (4) recommendation to use meal replacements (No vs. Yes), (5) training participants' self-selected buddies to be supportive (No vs. Yes).

## *3.2 Design Summary*

The goal of the proposed study is to determine the optimal composition of a technology supported intervention for obesity that minimizes expense and burden to participants, while achieving 6 month weight loss outcomes comparable or superior to those achieved by the current full cost, full burden form of INLIs (DPP, 2002; Look AHEAD, 2007). All intervention components to be examined were selected based on the Opt-IN model's prediction that they enhance behavioral adherence to weight regulation via the designated pathways. Additionally, all components meet two criteria: (i) that their relative advantage in terms of influence on weight loss is currently unknown, and (ii) that their relative advantage in terms of cost and/or burden is clear. Components and their mechanisms are outlined in Table 1; the rationale for each component follows.

### *3.2.1* Intervention Component Selection

The CORE will be delivered to all participants to build essential competencies needed for weight loss. The CORE conveys knowledge about energy balance and the energy contribution of different foods and activities. It also includes training in how to set intake/ expenditure goals and how to conform behavioral choices to goals. The CORE will be conveyed via internet lessons, telephone coaching, and provision of a tool that reinforces participants for making healthy choices in their own environment. The tool, an application installed on participant's Smartphone, prompts real time tracking of diet and physical activity, with data uploaded to a coach who fosters accountability.

**1. Telephone Coaching Intensity**. A greater number of treatment sessions is well-established to result in greater weight loss (National Heart, Lung and Blood Institute [NHLBI], 1998; Wadden et al., 2005), but more sessions are also more costly and more burdensome to participants and providers. The original DPP and Look AHEAD INLIs included 16 and 36 core sessions, respectively (Boltri et al., 2009; Lipscomb et al., 2009); current standard of care for behavioral weight loss is 24 sessions (Thomas et al., 1992). Others have shortened obesity treatment to fewer than 16 sessions, with variable results (Davis-Smith et al., 2007; Martin et al., 2008; Whittemore, 2011; Whittemore et al., 2009), and with the general finding that achieving weight loss comparable to longer treatment requires adding supplemental intervention (Whittemore, 2011; Whittemore et al., 2009). We expect the supplemental treatment components tested in Opt-IN to bolster the impact of the lower intensity 12 session treatment. Since paying for the time of trained interventionists is usually the greatest cost of an INLI, a 12 session INLI with supplemental components that make its yield equivalent to a treatment twice its length would represent a very substantial advance in scalability.

**2. Report to Primary Care Provider (PCP).** Except when medication or food provision has been part of treatment, weight loss treatment offered by providers in the primary care setting has yielded disappointing results (Tsai & Wadden, 2009; Martin et al., 2008; Christian et al., 2008; Wadden et al., 2011). Nevertheless, patients want and expect their PCP to support their weight management (Potter et al., 2001). Reporting the patient's weight loss progress to their PCP for discussion during regular check-ups was part of Appel et al's (2011) successful bundled treatment. Although the impact of PCP reporting on its own currently cannot be disentangled, providing a report that engages the PCP to endorse the patient's weight loss is certainly less costly and more scalable than requiring the PCP to directly provide weight loss treatment. We posit that informing patients that their progress is being reported to the PCP supports weight loss efforts by supportive accountability: creating the perception that the health care team is "looped in" and paying attention, encouraging the patient to feel supported and held accountable.

**3. Text Messages**. Text messaging shows promise as a cost-effective channel to prompt health behavior change (Free et al., 2011; Patrick et al., 2009; Haapala et al., 2009). We are using texts in ENGAGED, as we previously used e-mails in MBC, to sustain motivation and connection in between coaching contacts.

**4. Meal Replacements.** The use of meal replacements to foster weight loss has a strong evidence base (Heymsfield et al., 2003; Noakes et al., 2004; Wadden et al., 2011; Spring et al., 2004). However, most trials, including our own, have provided the food products free of charge (Goodpaster et al., 2010; Wadden et al., 2011; Look AHEAD, 2007). We judge that providing many months of free food is an unsustainable strategy for most treatment contexts, and will therefore test a more scalable real world version. Those Opt-IN participants randomized to the active arm of the meal replacement treatment component will be advised to use meal replacement products as part of their approach to controlling dietary intake. Slimfast products, as tested in Look AHEAD (2007) and widely available in grocery stores, or similar meal replacement products will be recommended as offering a low-cost way to achieve calorie control. Participants randomized to active meal replacement will also be provided with one week's supply of meal replacements (e.g., 2 shakes and 2 bars per day), as an initial introduction.

**5. Buddy Training.** Social support is a well-documented correlate of successful health behavior change, prompting numerous efforts to harness peers as treatment agents. Engaging peers together in treatment groups has augmented weight loss (Wadden et al., 2011), and training peers to be supportive has yielded varying degrees of improved health behavior change (Gruder et al., 1993; Hogan et al., 2002; May & West, 2000; Katula et al., 2011). While we find it unrealistic to expect all individuals to have a buddy able to attend in-person groups, pilot data from ENGAGED indicate that 100% of participants can identify a support person from either their local or virtual environment. All buddies will first receive a document with information on how to provide support for his/her friend or family member after consenting to participate. The chosen support person for those randomized to receive buddy training will be coached further on how to provide support for his/her friend. Training will occur via one individual telephone coaching session, followed by four online webinar lessons; two of the webinars will be "core" sessions focusing on an introduction to healthy weight loss and how to be a supportive buddy, while the remaining two webinars will comprise additional relevant support topics (e.g., dealing with difficult situations or plateaus). Each webinar will last approximately 30-45 minutes. These trainings will be delivered quarterly, and content will be adapted from existing curricula (Nettles & Belton, 2010; West et al., 1998). Each webinar will comprise didactics followed by a group supervision for buddies. Supervision will involve shared problem solving about challenges in supporting participants. Buddies who are randomized to a condition requiring training and webinar participation will receive a $5 online gift card after attending each required webinar, and will have the opportunity to receive an additional $20 gift card if they attend 3 or 4 of the 4 required webinars.

The effects of the five individual intervention components will be examined by means of a factorial experiment (see Table 3) involving the following factors: 1) Number of telephone coaching Sessions (12 vs. 24); 2) PCP receives reports (no vs. yes); 3) Text messaging (not provided vs. provided); 4) Meal replacements (recommended vs. not recommended); 5) Buddy Training (not provided vs. provided). Although each of these intervention components has been part of a bundled weight loss intervention previously found to be successful, none of those studies was designed to estimate the impact of any individual component. Weight will be measured at baseline, 3, and 6 months. Measurements will be taken without shoes, wearing light clothing on a calibrated beam balance scale. Height will also be measured using a stadiometer, and Body Mass Index (BMI) will be calculated as weight in pounds/(height in inches)$^2$) x 704.5. Waist circumference, a predictor of abdominal visceral fat also will be assessed. Measurement will be done twice during expiration, taking the average for analyses, by positioning an anthropometric tape midway between the palpated iliac crest and the palpated lowest rib margin in the mid-axillary lines.

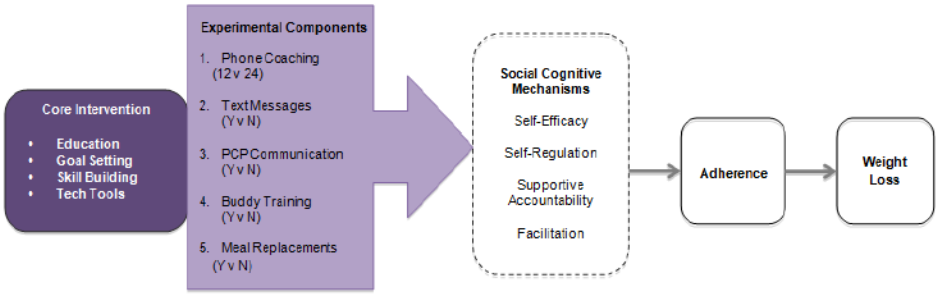
### *3.2.2* Data Management and Quality Control

Participants and coaches will complete all study assessments on a computer using secure foroms delivered via RedCap data management system housed at Northwestern University Biomedical Informatics Center (NUBIC). Paper versions of all instruments will be available to be administered as a backup system in the event of technical difficulties with the electronic administration system. The data will be visually checked by the data manager who will record the presence of each assessment battery file for each participant. In the event of the presence of paper data, all hand-computations will be double-checked and all data double entered. Web administered screening data and Smartphone data uploaded to the study server will be backed up each evening, and downloaded for local backup and storage with other study data. After checking for accuracy and completeness of each file, all electronic data will be stored on the project manager's and data manager's computers, and backed up to a secure remote hard drive. All database files will be password protected, and only study staff will have access to staff computers or the secure remote hard drive. Paper data will be kept in the access-controlled laboratory in a locked cabinet.

### *3.2.3 Theoretical Framework/Description*

Hundreds of smartphone weight loss applications are disseminated, but very few have been evaluated and none, to our knowledge, reflects an underlying theoretical model. Tools developed by Co-PI Spring's group are guided by Carver and Scheier's (Carver & Scheier, 1981) control systems theory. The theory posits that self-regulation occurs via feedback loops, wherein people: (1) set a goal, (2) self-monitor their current status to identify discrepancy from a goal, and then (3) modify their behavior to close a perceived discrepancy. In our framework, weight self-regulation failures occur because people have difficulty cumulatively appraising their energy balance status, determining whether behavioral options (e.g., available foods) match goal (e.g., calorie allowance), and maintaining continued adherence. To foster weight loss, Spring and colleagues develop innovative diet and activity intervention systems (cf., 3c.1 preliminary studies) that integrate skills training, self-regulatory prosthetic tools, and real-time coach support (Coons et al., 2011). Our interdisciplinary development team (with experts from Motorola, Orbitz, virtual reality programmers) enables tool design to reflect best practices in persuasive technology development (Fogg, 2003), extensive usability testing, and unique cutting edge functionalities (e.g., wireless accelerometry transmission to smartphone graphics display).

Figure 1: Opt-IN Conceptual Model




Experience implementing these novel behavior change systems has led us to conceptualize mediators of successful weight loss treatment in a new way that includes both intra-individual and environmental influences (cf., Figure 1). As shown, we design all intervention elements to heighten adherence (self-monitoring and treatment participation), the strongest predictor of weight loss success (Baker & Kirschenbaum, 1993, 1998; Boutelle & Kirschenbaum, 1998; Burke et al., 2011). We posit four social cognitive causal pathways to adherence (Bandura, 2008; Glanz, 2008). The two intra-individual mediators are: *self-regulation* (skill at controlling oneself through self-monitoring, goal-setting, and use of feedback) and s*elf-efficacy* (confidence in one's personal ability to behave in ways that bring about desired outcomes). The two environmental mediators are facilitation and supportive accountability. *Facilitation* entails reliable access to tools (e.g., Opt-IN Smartphone app) and environmental resources (e.g., meal replacements) that make healthy behavior changes easier to perform. *Supportive accountability* is the manner in which a coaching relationship conveys positive expectations, support, and a sense of holding the participant responsible to attain behavioral goals (Coons et al., 2011; Mohr et al., 2011; Spring et al., in press). We derived this new concept because participants repeatedly emphasized that our technologies led them to feel benevolently monitored and supported (but, per Self-Determination Theory [Deci & Ryan, 2002]) not controlled. Opt-IN's mobile technology is innovative in functioning not only as a decision support tool, but also as a connective channel that links participant, coach and mobile tools in a continuous behavior change system.

### *3.3 Study Population and Eligibility Criteria*

#### *3.3.1 Source Population*

Enrollees will be adults between ages 18 and 60 with BMI 25-40. At least half will be >45 years of age. They must be weight stable (no loss or gain >25 lbs for the past 6 months), not enrolled in any formal weight loss program or taking anti-obesity medications, but interested in losing weight. Candidates must own a Smartphone and be willing to install our Opt-IN app so that their data can be transmitted wirelessly to a study coach. They must be able to use the app to record dietary intake, physical activity, and weight onto the Smartphone. Prior to participating in any study procedure, they must voluntarily provide informed consent.

#### *3.3.2 Inclusion Criteria*

Eligibility Criteria. Enrollees will be adults between ages 18 and 60 with BMI 25-40. At least half will be female; half will be ≥45 years of age. They must be weight stable (no loss or gain ≥25 lbs for the past 6 months), not enrolled in any formal weight loss program or taking anti-obesity medications, but interested in losing weight. Candidates must own a Smartphone (Android or iOS) and be willing to install our Opt-IN app so that their data can be transmitted wirelessly to a study coach. They must be able to use the app to record dietary intake, physical activity, and weight onto the Smartphone. Prior to participating in any study procedure, they must voluntarily

provide informed consent. "Buddy" participants must be at least 18 years old, have access to a computer and internet, be willing to undergo "Buddy Training" and participate in 4 webinars, and be willing to provide support and encouragement to the participant.

Exclusion Criteria. For safety, participants with unstable medical conditions (uncontrolled hypertension, diabetes, unstable angina pectoris, myocardial infarction, transient ischemic attack, cancer undergoing active treatment, or cerebrovascular accident within the past six months) will be excluded. Also excluded will be those with a history of diabetes requiring insulin supplementation, Crohn's Disease, or a diagnosis of obstructive sleep apnea requiring intervention (i.e. CPAP). Excluded for reasons of safety will be those who have been diagnosed with plantar fasciitis by a physician or podiatrist, require use of an assistive device for mobility (e.g., wheelchair, walker, cane), those with a BMI > 40, those hospitalized for a psychiatric disorder within the past 5 years, and those at risk for adverse cardiovascular (CVD) events with moderate intensity activity (e.g., has CVD symptoms while walking, scheduled for stress testing within 2 months). Those who cannot read the study questionnaires will be excluded, as will those taking weight loss medication or committed to following an incompatible dietary regimen. Female participants may not be pregnant, trying to get pregnant, or lactating. Candidates who meet criteria for bulimia or report active suicidal ideation will not be enrolled because they might practice overly severe dietary restrictions. Those with current binge eating disorder will be excluded, or current substance abuse or dependence besides nicotine dependence. Those on medications or supplements, prescribed or over the counter, known to cause changes in weight (e.g., prednisone) will be excluded. In order to prevent potential contamination of conditions and results, participants who live together will not be allowed to enroll in the study. We will cross-check and flag duplicate addresses and phone numbers as potential participants complete the online webscreener. During the Orientation session, we will discuss this exclusion criteria with potential participants. Only one person from each household may enroll in the study, concurrently or otherwise.

### *3.4 Informed Consent Procedures*

Written informed consent will be obtained before entry into the study from any participants who may be randomized if eligible. "Buddy" participants will undergo a verbal consent process over the telephone. Full disclosure will be made of the nature and potential risks of participating in the OPT-IN trial.

The consent and verbal consent forms have been developed according to the requirements of the Northwestern Institutional Review Board (IRB). A copy of the signed consent form for the study will be provided to each participant. "Buddy" participants will receive an electronic copy of the verbal consent via email.

### *3.5 Randomization Method*

Randomization, stratified by gender, will be computer-generated using the method of randomly permuted blocks. Participants will be informed of their treatment assignment by telephone. Candidates who, when queried, indicate unwillingness to participate in any condition will not be randomized.

# 4 Study Procedures

## *4.1 Screening/Recruitment*

Recruitment will target the channels that have proved successful in our prior Chicago-area studies. These include posting: a) promotions in publications with low advertising cost (*The Red Eye, Craig's List, The Chicago Reader, Google Ad Words*); b) Chicago Transit Authority bus and subway advertisements; c) flyers at downtown area worksites, clinics, and schools; d) clinical trial recruitment announcement on Northwestern University's website; e) social media (Facebook, Twitter, Reddit, Instagram, Metromix, Pinterest); f) relevant websites related to weight loss, health, nutrition, and physical activity that we will solicit to "post" current approved flyers and ads on their sites; g) health registries (Illinois Women's Health Registry at Northwestern University, NU NUCATS, Clinicalconnection.com); h) relevant local health fairs with information booths/tables where brochures and flyers will be available with staff to answer questions, and i) use of the Enterprise Data Warehouse (EDW), a joint initiative of NMFF, NU, and NMH, to recruit patients directly from Northwestern Memorial Hospital's General Internal Medicine Clinic. Postings will list study eligibility criteria and requirements and will provide the study web link, and will not deviate from IRB-approved ad language. The posting will also include a google voice phone number where participants can reach staff if they have any general questions regarding study participation. Registries will send the study coordinator lists of individuals who have agreed to be contacted and we will contact via sending flyers and ads via mail or email, or by calling. At the project's website, interested candidates may consent to research participation and complete on-line screening questionnaires, developed using RedCap, that assess study entry criteria and request good contact times. Scored questionnaire responses will be e-mailed to the laboratory, following which eligible candidates will be contacted by e-mail to arrange for further screening and a telephone interview.

### *4.1.1* Recruitment Process

On-line screeners assess for eligibility criteria (demographics, weight), physical activity preparedness, motivational readiness to change, and scheduling availability. (b).Telephone screening. Potentially eligible candidates will be contacted by telephone. Study staff will explain the research, ask the patient's interest in participating in the study, and proceed with a verbal informed consent process. Staff will screen for exclusion criteria, including checking all medications to see if any are listed on the study Exclusionary Medication list. In order to flag participants who live together, a study exclusion criteria, web screeners will be cross-checked for duplicate addresses and phone numbers. Candidates who remain interested and eligible will be scheduled for an in-person Orientation session. Those who provide informed consent will be invited to attend the baseline assessment where we will screen further for entry and exclusion criteria as well as gather baseline data. Anthropometric data will be gathered. We will administer the PRIME-MD to screen out candidates who meet criteria for bulimia, current substance abuse or dependence (besides nicotine dependence), or report active suicidal ideation. Eligible participants will also be required to obtain physicians approval and find a buddy in order to participate in the study. Once participants have been scheduled to attend Randomization, they will complete a pre-Randomization telephone call with their potential Lifestyle Coach in the Opt-IN study. This call will be used to develop rapport, as well as minimize withdrawal once participants have been randomized.

### *4.1.2* Recruitment tracking

The Project Coordinator will track all participants recruited for the study. Participants will initially complete a web survey using RedCap, used by Northwestern University Biomedical

Informatics Center (NUBIC) of the Northwestern University Clinical and Translational Sciences (NUCATS) program. Data from RedCap will be downloaded, and descriptive statistics will be generated. Information to be collected will include participant name, screening date, date of birth, race, ethnicity, self-reported height, self-reported weight (BMI will be automatically calculated), screening status, and reason for exclusion.

### *4.1.3* Recruitment of Minorities/ Low SES Participants

The Chicago metropolitan area is racially, ethnically, and socio-economically diverse. Of the entire sample, we plan to recruit 55% non-Hispanic Whites, 22% African Americans, 9% Hispanics, 4% other minority (45% minority). Our experience indicates that targeted recruitment of minorities has not been necessary to attain substantial, representative minority enrollment because the Chicago area population is so diverse. However, in the event that these minority groups are not adequately represented in our sample, we plan to target media outlets that are specific to these various ethnic groups.

## *4.2 Pre-Treatment Session*

Although the intervention components will all be delivered remotely, we will have one in-person, pretreatment training meeting with participants in order to complete screening and ensure measurement accuracy. A) Technology. Participants will have the Opt-IN app installed on their Smartphone. The program connects to a cloud server that organizes participant's time-stamped eating and activity data and transmits it to a study coach. B) Randomization. Participants will be notified of which condition they are randomized to. D) Training. After installing the app and learning which condition they have been randomized to, staff will provide instruction on how to locate and enter foods from the CalorieKing nutrient database of >50,000 foods that is resident on the server (with back-up copy on the Smartphone). Participants will learn how to interpret traffic light-colored icons that depict calorie and fat intake relative to goals. They will be taught to enter physical activity. They will also be trained, using food models, and tested on how to accurately estimate and record portion sizes, condiments, and food preparation methods. Participants in all conditions will be asked to enter their dietary intake, physical activity, and weight into the Smartphone daily throughout the day for the duration of the study. Time stamped data from the Smartphone will upload automatically to the study server throughout the day, where it will be visible to the coach. Over a 6-month period, the coach will provide either 12 or 24 sessions of telephone coaching, motivational support, and problem solving about diet, activity, and self-regulation based upon web based lessons and the participant's self-monitoring data.

### *4.2.1* Screening Tools

Standardized screening questionnaires will ask about demographics, anthropometrics, motivational readiness to change, physical activity readiness, and scheduling availability. The Physical Activity Readiness Questionnaire (PAR-Q) (Thomas et al., 1992), designed for adults aged 15-69, asks about 7 physical risk factors (e.g., chest pain, dizziness, joint problems). Participants who report any one factor are asked to obtain their physician's approval to enroll in Opt-IN. To screen out pre-contemplators whose low motivation to change would likely impede their success in the trial, we will use Logue's Readiness to Adopt Weight Control Behaviors scale to assess motivational readiness to change. The scale assesses readiness to change physical activity (Sutton et al., 2003). The PRIME-MD and PHQ (Spitzer et al., 1999) will be administered to screen out candidates whose suicidality or bulimia could place them at risk in a weight loss trial, or whose uncontrolled substance abuse or binge eating disorder could interfere with program adherence. Candidates for this trial will be screened for substance abuse/dependence to identify those who have substantial substance abuse issues that could interfere with program adherence,

as well as identifies severe risk behaviors related to substance abuse that would be best addressed before those that we are targeting. Similarly, study candidates who screen positive for either Bulimia Nervosa or Binge Eating Disorder (PRIME-MD) or Major Depressive Disorder (PHQ-9) would benefit from more intensive care than the targeted behavior change that is addressed in this trial. Enrolling those who have any of these conditions would put them at more risk that what is admissible to protect research subjects. Prior to the screening, participants will be notified that all information will be kept confidential, with the exception of the limits of confidentiality by mandated reporters who are required to report suspected abuse, neglect or clear intention to do harm to themselves or anybody else. In the incidence that participants do indicate substance abuse/dependence, Bulimia Nervosa, or Binge Eating Disorder, they will be given referrals to local professionals and human service agencies. If participants indicate, or the screener assesses that they are in need of emergency services, they will be escorted to the emergency room at Northwestern University, where they will be assessed and given the opportunity to deny further care. A list of local referrals and alcohol and substance abuse services are located in the Appendix.

### *4.2.2* Primary Outcome: Weight

Weight will be measured at baseline, 3, and 6 months. Measurements will be taken without shoes, wearing light clothing on a calibrated beam balance scale. Height will also be measured using a stadiometer, and Body Mass Index (BMI) will be calculated as weight in pounds/(height in inches)$^2$) x 704.5. Waist circumference, a predictor of abdominal visceral fat also will be assessed. Measurement will be done twice during expiration, taking the average for analyses, by positioning an anthropometric tape midway between the palpated iliac crest and the palpated lowest rib margin in the mid-axillary lines. If participants are unable to attend in-person assessments, a self-reported weight will be obtained from the participant (see Appendix).

Participants will also complete an Exit Interview at the 6-month assessment assessing general feedback about the study, as well as any potential confounding variables. Specifically, the Exit Interview will examine intervention component preference, social support (both with the coach and other participants/buddies), and participation in other weight loss programs.

Table 5: Assessment Schedule

| | Measure | Screening | Baseline | 3 months | 6 months |
|---|---|---|---|---|---|
| Primary Outcome | Anthropometric Measures (Weight, Waist Circumference) | x | x | x | x |
| Hypothesized Mediators | Adherence (call session participation; diet, activity, & weight self-monitoring) | | x | x | x |
| Exploratory Mediators | Self-Efficacy | | x | x | x |
| | Self-Regulation | | x | x | x |
| | Supportive Accountability | | x | x | x |
| | Facilitation | | x | x | x |
| Exploratory Moderators | Demographics | x | | | |
| Exploratory Confounding Variables | Intervention component preference, social support (with coach and other participants/buddies), and participation in other programs | | | | x |

| | | | | | |
|---|---|---|---|---|---|
| Screeners | Logue's Readiness to Adopt Weight Control Behaviors scale | x | | | |
| | PRIME-MD | x | | | |
| | PAR-Q | x | | | |

### *4.2.3* Mediators

A. Hypothesized Mediator: Adherence. 1. Treatment Adherence will be operationalized as the number of treatment sessions completed, divided by the number of treatment sessions offered (12 or 24). Make-up sessions completed within a week of the target date will count as attended. 2. Self-Monitoring Adherence will be operationalized as the number of days of recording: a) *weight*; b) *dietary intake* (totaling at least 1000 kcal); c. *physical Activity* operationalized as the number of days of recording physical activity.

B. Exploratory Mediators. 1. Self-Efficacy. Self-efficacy will be assessed to examine treatment effects on confidence about performing two categories of behaviors associated with weight loss: diet (Stich et al., 2009) and physical activity (Marcus et al., 1992). The Scenario-Based Dieting Self-Efficacy Scale (DIET-SE) is 11 items long, and there are three subscales: High-Caloric Food (HCF; 4 items), Social and Internal Factors (SIF, 4 items), and Negative Emotional Events (NEE; 3 items). The internal consistency of the DIET-SE is good (α = .77 for HCF; α = .79, 4 items; and α = .79 for NEE; total score α = .87). Test–retest correlations for a 2- to 3-week interval were *r* = .83 for the DIET-SE scale, *r* = .75 for the HCF, *r* = .77 for the SIF, and *r* = .80 for the NEE subscale, indicating high test–retest reliability. The Self-Efficacy of Exercise Behavior Change measure includes 18 items. The scales are 13 and 18 items long, respectively. Participants use a 5-point Likert scale (1 = not at all confident; 5 = completely confident) to rate how confident they are that they will be able to eat healthy/exercise when "other things get in the way" such as being depressed, anxious, busy, or being tired. 2. Self-Regulation. Self-Regulation will be assessed by the Restraint and Disinhibition subscales of the *Three Factor Eating Questionnaire (TFEQ)* (Stunkard & Messick, 1985). Autonomous versus Controlled Motivation for Self-Regulation will be assessed using both subscales of the 15-item *Treatment Self-Regulation Questionnaire* (TSRQ). The TSRQ shows evidence of acceptable reliability and validity; (Cronbach's α; Controlled Motivation = .79; Autonomous Motivation = .58) (Williams et al., 1996). 3. Supportive Accountability. This exploratory mediator will be measured by assessing two constructs that define supportive accountability: therapeutic alliance and perceived autonomy support. Therapeutic alliance will be measured by the *Combined Alliance Short Form- Patient Version (CASF-P*) (Hatcher & Barends, 1996), a 20-item measure with Cronbach's α =.93. Perceived autonomy support will be measured by an adapted version of the *Perceived Autonomy Support Scale for Exercise Settings (PASSES*; α = .92) (Hagger et al., 2007). 4. Facilitation. Facilitation will be measured by having participants use a 5-point Likert scale (1 = not at all; 5 = very much) to rate how much the tools provided by the study have changed their environment to make it easier to: "eat healthier," "be more physically active," and "lose weight." We will also assess facilitation via the 26-item *Weight Management Support Inventory* (*WMSI*) (Rieder & Ruderman, 2007) which assesses the degree to which the social environment discourages excess eating and encourage exercise ($\alpha$ = .90, test-retest reliability = .75, $p < .001$.)

## *4.3 Study Procedures*

The goal of the proposed study is to determine the optimal composition of a technology supported intervention for obesity that minimizes expense and burden to participants, while achieving 6 month weight loss outcomes comparable or superior to those achieved by the current full cost, full burden form of INLIs (DPP, 2002; Look AHEAD, 2007). All intervention components to be examined were selected based on the Opt-IN model's prediction that they enhance behavioral adherence to weight regulation via the designated pathways. Additionally, all

components meet two criteria: (i) that their relative advantage in terms of influence on weight loss is currently unknown, and (ii) that their relative advantage in terms of cost and/or burden is clear. Components and their mechanisms are outlined in Table 1; the rationale for each component follows.

### *4.3.1 Intervention Component Selection*

The CORE will be delivered to all participants to build essential competencies needed for weight loss. The CORE conveys knowledge about energy balance and the energy contribution of different foods and activities. It also includes training in how to set intake/ expenditure goals and how to conform behavioral choices to goals. The CORE will be conveyed via internet lessons, telephone coaching, and provision of a tool that reinforces participants for making healthy choices in their own environment. The tool, an application installed on participant's Smartphone, prompts real time tracking of diet and physical activity, with data uploaded to a coach who fosters accountability.

1. Telephone Coaching Intensity. A greater number of treatment sessions is well-established to result in greater weight loss (NHLBI, 1998; Wadden et al., 2005), but more sessions are also more costly and more burdensome to participants and providers. The original DPP and Look AHEAD INLIs included 16 and 36 core sessions, respectively; current standard of care for behavioral weight loss is 24 sessions (Thomas et al., 1992). Others have shortened obesity treatment to fewer than 16 sessions, with variable results (Davis-Smith et al., 2007; Martin et al., 2008; Whittemore, 2011; Whittemore et al., 2009), and with the general finding that achieving weight loss comparable to longer treatment requires adding supplemental intervention (Whittemore, 2011; Whittemore et al., 2009). We expect the supplemental treatment components tested in Opt-IN to bolster the impact of the lower intensity 12 session treatment. Since paying for the time of trained interventionists is usually the greatest cost of an INLI, a 12 session INLI with supplemental components that make its yield equivalent to a treatment twice its length would represent a very substantial advance in scalability.

2. Report to Primary Care Provider (PCP). Except when medication or food provision has been part of treatment, weight loss treatment offered by providers in the primary care setting has yielded disappointing results (Tsai & Wadden, 2009; Martin et al., 2008; Christian et al., 2008; Wadden et al., 2011). Nevertheless, patients want and expect their PCP to support their weight management (Potter et al., 2001). Reporting the patient's weight loss progress to their PCP for discussion during regular check-ups was part of Appel et al's (2011) successful bundled treatment. Although the impact of PCP reporting on its own currently cannot be disentangled, providing a report that engages the PCP to endorse the patient's weight loss is certainly less costly and more scalable than requiring the PCP to directly provide weight loss treatment. We posit that informing patients that their progress is being reported to the PCP supports weight loss efforts by supportive accountability: creating the perception that the health care team is "looped in" and paying attention, encouraging the patient to feel supported and held accountable.

3. Text Messages. Text messaging shows promise as a cost-effective channel to prompt health behavior change (Free et al., 2011; Patrick et al., 2009; Haapala et al., 2009). We are using texts in ENGAGED, as we previously used e-mails in MBC, to sustain motivation and connection in between coaching contacts.

4. Meal Replacements. The use of meal replacements to foster weight loss has a strong evidence base (Heymsfield et al., 2003; Noakes et al., 2004; Wadden et al., 2011; Spring et al., 2004). However, most trials, including our own, have provided the food products free of charge

(Goodpaster et al., 2010; Wadden et al., 2011; Look AHEAD, 2007). We judge that providing many months of free food is an unsustainable strategy for most treatment contexts, and will therefore test a more scalable real world version. Those Opt-IN participants randomized to the active arm of the meal replacement treatment component will be advised to use meal replacement products as part of their approach to controlling dietary intake. Slimfast products, as tested in Look AHEAD and widely available in grocery stores, or similar meal replacements will be recommended as offering a low-cost way to achieve calorie control. Participants randomized to active meal replacement will also be provided with one week's supply of meal replacements (e.g., 2 shakes and 2 bars per day), as an initial introduction.

5. Buddy Training. Social support is a well-documented correlate of successful health behavior change, prompting numerous efforts to harness peers as treatment agents. Engaging peers together in treatment groups has augmented weight loss (Wadden et al., 2011), and training peers to be supportive has yielded varying degrees of improved health behavior change (Gruder et al., 1993; Hogan et al., 2002; May & West, 2000; Katula et al., 2011). While we find it unrealistic to expect all individuals to have a buddy able to attend in-person groups, pilot data from ENGAGED indicate that 100% of participants can identify a support person from either their local or virtual environment. All buddies will first receive a document with information on how to provide support for his/her friend or family member after consenting to participate. The chosen support person for those randomized to receive buddy training will be coached further on how to provide support for his/her friend. Training will occur via one individual telephone coaching session, followed by four online webinar lessons on empathy, facilitation, problem solving, and behavior change skill training. Each webinar will last approximately 30-45 minutes. These trainings will be delivered quarterly, and content will be adapted from existing curricula (Nettles & Belton, 2010; West et al., 1998). Each webinar will comprise didactics followed by a group supervision for buddies. Supervision will involve shared problem solving about challenges in supporting participants. Buddies who are randomized to a condition requiring training and webinar participation will receive a $5 online gift card after attending each required webinar, and will have the opportunity to receive a $20 gift card bonus if they attend 3 or 4 of the 4 required webinars.

### *4.3.2* Intervention Component Cost Estimation

Table 2 shows the estimated cost of implementing the CORE, plus the cost of the low and high

Table 2- Estimated Cost of Lowest vs. Highest Level of Intervention Components

| Intervention Component Levels | Cost/person Lowest Level | Cost/person Highest Level |
|---|---|---|
| 1. Phone Sessions: 12 or 24 | $86.52 | $173.04 |
| 2. PCP: no reports or reports | $0 | $34.88 |
| 3. Texts: no or yes | $0 | $0 |
| 4. Meal Replacements: no or yes | $0 | $29.96 |
| 5. Buddy Training: no or yes | $0 | $68.82 |
| +. Core intervention cost | $281.67 | $281.67 |
| | **Minimum cost** $ 368.19 | **Maximum cost** $588.37 |

levels of each supplemental intervention component. The CORE infrastructure that makes the intervention accessible to all participants involves a: (a) web portal on a server; (b) Smartphone application. The web portal will house a series of interactive lessons that can be assigned as 24 single lessons or as 12 pairs. The portal also receives weight, diet, and physical activity data transmitted by the patient. Uploaded data and information about lesson access and completion

are conveyed to coaches via a web interface. The Opt-IN Smartphone application, originally developed for ENGAGED, transmits dietary intake and physical activity data to the portal. To estimate the cost of implementing the intervention, we assume that all components of the system are fully developed. Two main implementation costs remain: 1) $70 annual fee to access the study's web infrastructure, including the CalorieKing food database, interactive lessons, and coach interface; 2) technical support, estimated at 20% effort for a technician with an annual salary of approximately $65k/year. We estimate the cost of maintenance per person to be ($65k * .20 effort) / 150 participants/year = $86.67/person. Thus, the total cost of the CORE is $70 + $125 + $86.67 = $281.67/person.

(1) Telephone Coaching session cost was estimated assuming that a health educator salaried at $30,000 year ($14.42/hour) offered 12 [14.42 * 0.5 * 12 = $86.52/person] or 24 [$14.42 * 0.5 * 24 = $173.04/person] sessions (up to 20 minutes of phone coaching, plus 5-minutes to prep for the call by reviewing notes, plus 5 minutes to record notes after the call). (2) PCP Reports. Half of the participants will have two reports of their weight loss progress sent to their PCP (at 3-months, and 6-months), as per Appel et al. (2011). Direct costs of sending these reports is for staff salary to generate and print reports and cover letters and obtain signatures ($30 x 1 = $30/person), and for postage stamps ($0.44 x 2 = $0.88/person). Indirect costs will cover the printing and stationary ($2 x 2 = $4/person). Total cost: $34.88/person. (3) Text Messaging. That half of the sample randomized to text messaging will receive automated texts seven times per week. Text messages will be sent from a computer terminal that permits us to send texts for free through the Opt-IN application. (4) Meal Replacement. Those recommended to use meal replacement products will be given a one-week supply of Slim Fast or similar meal replacement product (14 shakes and 14 bars). 14 shakes * $1.35/shake + 14 * $0.79/bar = $29.96/person. (5) Buddy Training. Project staff will perform the training. After an initial individual telephone training for those randomized into a Buddy Training condition, further training and supervision will occur via group phone calls/webinars. Every six weeks, study coordinators will offer the training at a variety of times/dates. Four different webinar topics will be offered to accommodate new buddies just joining the trial. Estimated staffing cost per person for this training is $28.82/person: 45 minutes for initial training + 1.25 hours for 3 shared 1-hour group teleconferences). Buddies randomized to receive additional training and webinars will receive $5 online gift cards after completion of each webinar, and an additional $20 online gift card for completing at least 3 of the 4 webinars. Total cost of buddy training is $68.82/person.

### *4.4 Intervention*

A. Behavioral Coaching and Curriculum. Treatment will be delivered as 24 online lessons supplemented by individual telephone coaching. All participants will be given the goal of 7% weight loss via calorie reduction from usual intake and increased physical activity. A login to a website will be provided, where participants will be able to access online interactive lessons. Lessons topics, shown in Appendix, will be based on the DPP and Look AHEAD (e.g., self-monitoring, portion size estimation, fat and calorie content of foods, meal and snack patterning, becoming active, stimulus control). Telephone coaching sessions will last approximately 10-15 minutes. At the beginning of each coaching call, coaches will confirm with the participant that they consented or did not consent for the telephone coaching session to be audio recorded, based on what they indicated on the study consent form. Coaches will discuss that week's lesson materials, recapping the main points. The phone session will also include feedback on self-monitoring and goal attainment (observed from uploaded diet and activity data), problem solving about barriers, and motivational interviewing.

B. Dietary Intervention. During the initial baseline assessment, per DPP, participants will receive both a calorie goal and a fat goal (based on 25% of total daily calories from fat). Those weighing 120 to 174 lb at baseline will be instructed to follow a 1200-kcal/d diet (33 grams fat);

participants weighing 175 to 219 lb will be advised to follow a 1500-kcal/d diet (42 grams fat); those 220 to 249 lb will be asked to follow an 1800-kcal/d diet (50 grams fat); and those over 250 lb will be instructed to follow a 2000-kcal/d diet (55 grams fat). Coaching provides feedback and advice on participants' self-monitoring and, when the participant has provided data, on diet and activity. Coaches discuss periods of apparent non-recording or nonsubmission of records. When the participant has supplied data, the coach reviews the foods that supplied the highest calorie and fat intake for the past week, notes any unusual features of meal or activity timing (e.g., skipped meals, night eating, long periods of inactivity), reviews fruit/vegetable, fiber and protein intakes, and develops a collaborative action plan. Frequently recommended dietary strategies include portion control, use of lower-calorie substitutes, increased intake (within calorie allowance) of fruits and vegetables, or (per randomization) use of meal replacement products. Coaches will monitor participants to ensure a safe rate of weight loss. If weight loss equals or exceeds 3 pounds/week for 4 consecutive weeks, the patient's calorie intake goal will be increased in 250 kcal increments until the goal of 1-2 lb/week weight loss has been achieved. For participants who request coach help because their weight appears non-responsive despite self-reported adherence to energy goals, a strategy for absence of weight loss is planned. Because under-reporting of energy intake is prevalent among overweight individuals, the coach will first address the diet documentation process (i.e., portion size estimation, omissions). If participants do not lose weight for two consecutive weeks, the calorie goal will be further reduced by 250 kcal increments toward an intake level that yields an average 1-2 lb weight loss per week. No patient's calorie goal will be set below 1200 kcal per day.

C. Physical Activity Intervention. Participants will be encouraged to engage in a variety of safe physical activities classified as moderate intensity by the Compendium of Physical Activities. Participants will be encouraged to self-monitor moderate intensity physical activity on the smartphone application. Physical activity goals will gradually increase number of minutes of moderate intensity activity needed to meet activity adherence criteria each week as follows: weeks 1-4 (100 minutes/week), 5-8 (150 minutes/week), 9-12 (200 minutes/week), 13-16 (250 minutes/week), and 17-24 (300 minutes/week).

D. Supplemental Intervention Components. Participants randomized to text messaging will receive text messages written by the Opt-IN team. The content of the texts will be responsive to participants' stated preferences as well as to their uploads. Texts will include positive feedback and encouragement as well as suggestions for change. Participants will have the opportunity to pick from different "schedules" of text messages (e.g., one text a day, every day; 2 texts per day, 3 days a week), but all participants randomized to text messaging will receive a minimum of 7 texts per week to distinguish them from non-texting participants. Participants will also have the opportunity to "step-up" these 7 text messages with an additional 2 "general information" texts per week. All texting participants may also receive general (mass) texts about holidays or weight management during special occasions.

For those randomized to have a report of their weight loss progress sent to their PCP, a report with cover letter will be mailed quarterly to both participant and provider, briefly explaining the study, graphing the patient's weight loss and providing several behavioral recommendations to support weight loss (Appel et al., 2011). Reports will be tailored to those participants that have lost no weight, lost a little weight, or have met the weight loss goal at that assessment point (i.e., 3.5% or more lost at 3-months, or 7% or more lost at 6-months).

All buddies (regardless of condition) will receive an e-mailed explanation of the study with a document about how to best support their friend or family member; they will first undergo a consent process by telephone. For those randomized to the buddy training condition, the buddy will receive an individual phone training session and participate in 4 webinars using gotomeeting.com. Buddies will choose a nickname and will be advised to use only this nickname and to only refer to their buddy as "My Buddy" to preserve confidentiality during group webinar/teleconferences.

Those participants randomized to receive 12 coaching telephone calls will review the A and B pair of lessons for each assignment, whereas those randomized to receive 24 calls will review A and B lessons as separate assignments.

Those randomized to meal replacements will receive their week's supply of meal replacements (14 shakes and 14 snack bars) at the time of their in-person Randomization session visit.

## *4.5 Participant Management and Follow-up*

All participants will be assigned a behavioral coach. This individual will provide all of the telephone coaching sessions, and will be the primary point of contact. A separate study coordinator will be in contact with all participants to schedule each of the follow-up visits and, once scheduled, will email participants a separate link to complete surveys. Surveys can be completed either at home or in-person during the follow-up assessments. During the final follow-up session at 6-months, participants will be administered an exit interview to collect information about their experience in the intervention, the components that they were assigned, and general feedback about the application. As mentioned in the IRB-approved Opt-IN consent form, all randomized participants are invited back at the conclusion of the study to an optional one-hour participant results session, in which study staff will overview study findings, and discuss study data and conclusions with participants.

### *4.5.1* Retention Strategies

At the outset of the intervention, participants will provide written and informed consent to be contacted by our research staff for the duration of their participation in the trial. Continued follow-up will be important for the collection of follow-up data. Our experience in previous clinical trials suggests that we are able to retain over 90% of the sample across all follow-up assessments. In our experience, establishing working relationships with participants, regardless of group assignment, is the single most important factor in enhancing retention. One technique commonly used is sending greeting cards such as birthday, holiday, or sympathy cards Our research staff is well versed in this approach. Additionally, the study staff will monitor participant follow up and participation, will follow the missed contact protocol (see appendix) following corresponding scripts and will send a missed contact letter (see appendix) if the individual fails to answer a coaching call or return messages to schedule follow-up sessions. After missed contact, attempts to contact will be made no more than 6 times by phone and 4 times by email over the course of the 6 month enrollment of the participant unless contact is re-established by the participant. Both participants and locator persons may request no further contact be made and the research study personnel will cease attempts to contact at that time and document this request in the study file.

Participants will receive a financial incentive for attending each of the follow-up visits. Participants will receive $20 for completing each in-person assessment for a total of up to $40, and their downtown Chicago parking will be reimbursed.

### *4.5.2* Strategies to Promote Adherence

Two forms of participant adherence are necessary in this intervention and include **assessment adherence**, and **behavior change adherence** (described below).

Assessment Adherence (needed for all groups) requires: a) reliable and accurate intermittent self-reporting of outcomes (dietary intake, mediators), and b) attendance at in-person assessment sessions.

Behavior Change Adherence requires adherence with following behavioral prescriptions. Several protocol features will enhance adherence for all groups. Participants are offered small

financial incentives contingent on assessment adherence at 3 months and 6 months. All participants will be well trained on dietary intake recording, food preparation methods, etc. to support collection of accurate baseline data prior to randomization, as well as to follow-up assessments. Automatic wireless uploading of data will enable rapid detection and outreach regarding skipped recording or obvious errors.

Additional procedures to support adherence to behavioral prescriptions include: a) visual goal thermometers to provide cues about intake and expenditure relative to targets; b) ability to access smartphone diet and activity information throughout the day to assist in making behavioral choices; c) use of stepped goals to facilitate incremental attainment of targets; d) use of self-monitoring, provision of personalized feedback, and tailored behavioral recommendations; and e) provision of sustained counselor support via scheduled telephone and e-mail contact throughout the protocol.

## *4.6 Safety Monitoring / Adverse Event Reporting*

All participants will be in contact with behavioral coaches on a regular basis. In the case of any adverse events that may arise during the study, OPT-IN staff will immediately consult with the PI and follow all necessary reporting procedures. Any participant that experiences an adverse medical event or refuses treatment following an elevated blood pressure (>180/120) during the study, which makes it no longer medically safe for the individual to participate in the OPT-IN intervention, will be withdrawn from the study. These cases will be promptly reported to the IRB and our standing DSMB committee.

### *4.6.1* Potential Risks

The risks of participating in OPT-IN are minimal. 1) Participants may experience muscle soreness or pain from walking on the treadmill and increasing physical activity. Participants will be encouraged to stretch and always exercise in a safe and reasonable manner. Participants will be instructed to contact their coach immediately if they have any pain from exercising. 2) Participants may experience an injury as a result of their physical activity. Participants are encouraged to stop exercising immediately if at any time they are injured. 3) Participants may experience feelings of hunger and deprivation from decreasing calorie and fat intake. 4). Some of the questions asked may be upsetting or may makes participants feel uncomfortable answering them.

Risks for the Buddy participants may include another “Buddy” in a webinar revealing personal information about another Buddy. The study staff will take all precautions to keep personal information confidential, but the study cannot fully control what the members of the webinar do with the information that is revealed to them.

### *4.6.2 Surveillance and Reporting Procedures*

The study coordinator will assess for any adverse events at each of the study visits. These events will be communicated to the Safety Officer within 7 days for determination of level of seriousness and relationship with the intervention. For each event, a form provided by the Northwestern University IRB will be completed. This form will then be reviewed and signed by Dr. Bonnie Spring (Principal Investigator), and submitted to the local IRB. A copy of this form will also be forwarded to the Safety Officer for review and confirmation as to whether the event appears to be related to the intervention.

### *4.6.3 Safety Monitoring Plan*

Data Safety Monitoring Plan (DSMP). The NIH statement "NIH Policy for Data and Safety Monitoring" was modified by NIH Notice OD-00-018 dated June 5, 2000, entitled Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials, and states “For many

phase I and phase II trials, independent DSMBs may not be necessary or appropriate when the intervention is low risk. Continuous, close monitoring by the study investigator may be an adequate and appropriate format for monitoring." We believe that this modification applies to the present proposal, since the study interventions and assessment procedures pose a low level of risk, and because this trial is equivalent to a Phase II study (e.g. single site). However, we recognize that DSMBs can also be of considerable help and guidance to the Co-PIs both in preserving the safety of patients and data, and in the general conduct of the study. Therefore, we propose to have a DSMB that is partially independent, and is comprised of a broad range of specialists who can oversee the study and offer guidance to the PI. The Data Safety Monitoring Board (DSMB) will have two voting members and two non-voting members. It will be chaired by Michael Newcomb, Ph.D., Research Assistant Professor at Northwestern University. Dr. Newcomb will be a voting member. He has no other role on this study and is therefore independent. Dr. Siddique, a biostatistician in the Department of Preventive Medicine at Northwestern who is independent of the study will also be a voting member of the DSMB. Drs. Spring (Co-PI) and Collins (Co-PI) and Dr. Hedeker, project statistician, will be non-voting members of the DSMB. They will attend all meetings primarily to provide and receive information. The DSMB will convene in person or by telephone at least every six months. They will review all adverse events as well as data on study recruitment and retention. Study staff are instructed to inform the DSMB immediately if any participant is experiencing serious medical or psychiatric deterioration that is thought to be study-related. The appropriate member of the DSMB will evaluate or oversee the evaluation of the participant. If the patient is determined to have deteriorated, the patient will be referred for appropriate treatment and, if necessary, discontinued from the study protocol. Northwestern University's Office for the Protection of Research Subjects and IRB will be contacted immediately at all serious adverse events that are thought to be study-related. Reports will be written immediately for all events deemed significant by the Northwestern University IRB and reports will be provided to all DSMB members. DSMB members may also be called upon for advice in managing such problems. Reports from DSMB meetings will be given to the Northwestern University IRB and the NIH program officer. If there are any suspected signs of consistent adverse events, we will ask the Northwestern University IRB to assist in the appointment of an outside monitor to review data and protocols. The biostatistician and project coordinator will also perform all necessary checks and controls to ensure the reliability and validity of the data, including monitoring data collection and collection procedures, data storage, data management, and data analysis. Dr. Hedeker will provide the DSMB with a data report at each meeting.

### *4.6.4 Rules for Participant Termination*

Participants may withdraw from the study at any time. Permission will be sought to continue to collect outcome data for use in the analysis.

# 5 Statistical Considerations and Data Analytic Plan

The effects of the five individual intervention components will be examined by means of a factorial experiment (see Table 3) involving the following factors: 1) Number of telephone coaching Sessions (12 vs. 24); 2) PCP receives reports (no vs. yes); 3) Text messaging (not provided vs. provided); 4) Meal replacements (recommended vs. not recommended); 5) Buddy Training (not provided vs. provided). Although each of these intervention components has been part of a bundled weight loss intervention previously found to be successful, none of those studies was designed to estimate the impact of any individual component.

We initially chose a factorial experimental design with 16 experimental conditions, and have been conducting this experiment. We recently decided that a complete factorial experiment, obtained by adding 16 more experimental conditions to the design for a total of 32, would have statistical properties that better suit our scientific objectives. Table 3 shows all 32 experimental conditions, indicating which ones we have been running to date (not shaded) and which ones we propose to run (shaded).

Please note that we are not introducing any new experimental treatments; the conditions are merely different permutations of the same five individual components.

The statistical analysis plan for the data remains essentially the same as was originally submitted. The only difference is that in the previous design there was some aliasing of effects that does not occur in the new design.

Table 3
Experimental Conditions in Opt-In Design, with New Conditions Shaded

| Coaching Sessions | Report to PCP | Text Messages | Meal Replace | Buddy Training |
|---|---|---|---|---|
| 12 | NO | NO | NO | NO |
| 12 | NO | NO | NO | YES |
| 12 | NO | NO | YES | NO |
| 12 | NO | NO | YES | YES |
| 12 | NO | YES | NO | NO |
| 12 | NO | YES | NO | YES |
| 12 | NO | YES | YES | NO |
| 12 | NO | YES | YES | YES |
| 12 | YES | NO | NO | NO |
| 12 | YES | NO | NO | YES |
| 12 | YES | NO | YES | NO |
| 12 | YES | NO | YES | YES |
| 12 | YES | YES | NO | NO |
| 12 | YES | YES | NO | YES |
| 12 | YES | YES | YES | NO |
| 12 | YES | YES | YES | YES |
| 24 | NO | NO | NO | NO |
| 24 | NO | NO | NO | YES |
| 24 | NO | NO | YES | NO |
| 24 | NO | NO | YES | YES |
| 24 | NO | YES | NO | NO |

| | | | | |
|---|---|---|---|---|
| 24 | NO | YES | NO | YES |
| 24 | NO | YES | YES | NO |
| 24 | NO | YES | YES | YES |
| 24 | YES | NO | NO | NO |
| 24 | YES | NO | NO | YES |
| 24 | YES | NO | YES | NO |
| 24 | YES | NO | YES | YES |
| 24 | YES | YES | NO | NO |
| 24 | YES | YES | NO | YES |
| 24 | YES | YES | YES | NO |
| 24 | YES | YES | YES | YES |

All of the estimated main effects and interactions will be based on all 32 experimental conditions. For example, the main effect of Number of Coaching Sessions will be estimated by comparing the mean of Experimental Conditions with 12 coaching callsin Table 3 vs. the mean of Experimental Conditions with 24 coaching calls. Similarly, the main effect of PCP report will be estimated by comparing the mean of Experimental Conditions having PCP progress reports sent vs. the mean of Experimental Conditions not having PCP progress reports sent. Note that in each case, all experimental subjects are included in the estimate. That is why factorial experiments can have small sample size/condition and still have excellent power if the overall sample size is sufficiently large.

Primary Aim 1 is to test for differences in weight by intervention components across the timepoints (baseline, 3- & 6-months), under an intent-to-treat basis, using linear mixed models. For each of the five components, we will determine whether there is a difference in change across time using baseline as the reference cell (i.e., 3-months vs baseline and 6-months vs baseline). From one perspective this is a main effect of each component on the pre-post difference. However, statistically these effects will be modeled as component by time interactions, with the 6-month outcome as the primary endpoint. We will also include two way interactions between components (e.g., Component 1 by Component 2 by time interaction). We note that (a) testing 2-way interactions between intervention components is extremely novel, as traditional RCTs are not capable of looking at these effects, and (b) because we will be using effect (-1,1) coding rather

than dummy (0,1) coding, the power for tests of main effects and interactions are identical for effects of identical size. We expect that testing these effects will be valuable, as we may find, e.g., that two intervention components each have independent main effects, but that when combined they offer no incremental effect. Our plan for dealing with such cases is elaborated below.

Primary Aim 2 is to make decisions about intervention components and component levels based on the factorial experiment results. We propose to use a modified version of a decision making approach frequently used in engineering (Wu & Hamada, 2000), which emphasizes main effects, using interactions as additional valuable information. This emphasis is consistent with our objective of identifying a set of components and component levels in which each component is making a detectable contribution to the overall effect, and any inactive components have been eliminated. We remind the reader that the mixed model analysis will be performed using effect coding, which will keep any covariances among main effects and interactions to a minimum. This makes it reasonable to start the decision making process by examining main effects, and then to consider interactions carefully in subsequent steps in the process. (Recall that our theoretical model does not predict any substantially-sized higher-order interactions, which is the basis for selection of the highly economical fractional factorial design. This Resolution V design enables examination of all two-way interactions.) The decision making process can be summarized as follows: Step 1: Initial tentative selection of components and component levels, consisting of identification of the components that show a significant main effect on the primary outcome variable, weight. If buddy training, recommended meal replacements, texting, or PCP report have a significant main effect, they will tentatively be selected for inclusion in the intervention. If there is a significant positive main effect of Number of Phone Coaching sessions, this is evidence that the more expensive level (24 sessions) performs better than the less expensive level (12 sessions), so it should be selected; otherwise, the less expensive level should be selected. Step 2: Consideration of interactions and final decision. Next we will examine interactions to look for any indication that we should consider reversing a decision made in Step 1. For example, suppose both Texting and PCP Report have significant main effects, so they were tentatively selected in Step 1. If there is a significant negative interaction between them, this means that the combined effect of Texting and PCP Report is less than the sum of the main effects. Suppose Texting has the larger main effect of the two. In that case we will start from the premise that Texting is selected, and then pose this question: When Texting is selected, *does PCP Report have a large enough incremental effect to justify its selection*? This question can be addressed by examining the simple effect of PCP Report when Texting is at the Yes level. Similar decision making logic will be used to examine all significant interactions that involve any components selected in Step 1 to arrive at the final decisions about selection of components and component levels. Step 3: Identifying the combination of components and levels that produces the largest effect that can be obtained for $500 or less. If the costs associated with the combination of component and component levels selected in the process described above exceeds the upper limit of $500, it will be necessary to consider less expensive versions of the intervention. Using as a starting point the set of components and component levels selected in Step 2, we will examine various scenarios in which we remove Yes/No components and change the levels of Either/Or components, and compute the expected outcome based on the regression parameters obtained in the statistical analysis to select the one with the largest expected effect that can be delivered for under $500.

Secondary Aim (Mediation & Moderation). 1. Mediation analysis conducted on the data from a RCT enables the examination of the mediated effects of the intervention as a package. In contrast, we will be able to fit models specifying *which* intervention component is mediated by each putative mediator, where the putative mediators are (a) adherence (treatment attendance; diet, activity, and weight self-monitoring adherence), (b) supportive accountability (therapeutic alliance, autonomy support), (c) self-efficacy (diet, activity), (d) self-regulation (restraint,

disinhibition, autonomous motivation), (e) facilitation. We will test the mediation effects for significance using the general approach described in MacKinnon.[43] 2. Moderation analysis. To improve the field's understanding of differential response to individual intervention components we will conduct analyses separately for subgroups (e.g. men and women; different age and ethnic groups; different categories of BMI) to investigate whether certain intervention components are more effective or less effective in certain subgroups. We will also use latent class analysis to explore the data for latent subgroups, and will fit models predicting latent subgroup membership. The results will inform subsequent research aimed at developing interventions tailored to and optimized for these subgroups.

### *5.1 Attrition and Nonresponse*

Despite our efforts, some attrition and missing data are likely. The linear mixed model does allow missing data and provides valid results under the assumption of missing at random (MAR). MAR means that the missingness can be related to model covariates as well as observed values of the dependent variable, and is sometimes termed "ignorable" missingness. As Molenberghs et. al. (2007) detail, MAR is a relatively weak and non-restrictive assumption about the missing data. Nonetheless, the possibility of non-ignorable missingness cannot be ruled out and so, as advocated by Molenberghs et. al. (2007), we will conduct sensitivity analyses using non-ignorable pattern-mixture and selection models to investigate the robustness of our conclusions across these different models for missing data. This approach will follow our detailed exposition in Chapter 14 of our text (Ackermann & Marrero, 2007).

### *5.2 Sample Size and Power*

We base power on our primary endpoint: weight change from baseline to the 6-month timepoint. Our interest is in identifying the intervention components that make a more than minimal contribution to average weight loss, or conversely to identify those components that have minimal or no effect on weight loss. Our operational definition of more than minimal is a component effect size of .25 (mean difference divided by standard deviation). Thus, we have powered the study to detect effects of .25 or greater. Using the standard deviation estimate of 4 kg from Amundson et al (2009), which had a follow-up time similar to ours, this translates to a 1 kg difference in weight loss; we view weight loss of less than 1 kg as a minimal effect. There are five components in our $2^{5-1}$ fractional factorial design. Based on the minimal detectable effect size of .25, the total sample size will be 560 subjects. Based on our previous MBC and PDA+ studies, we conservatively assume an attrition rate of 10% at the 6-month timepoint, so that there will be approximately 504 subjects at this timepoint. Thus, each of the component main effect estimates will be based on 504 subjects, that is, 252 subjects in each of the two levels of the component. Based on these assumptions, we can detect a main effect or interaction effect size of .25 for each component with 80% power under a two-tailed hypothesis test.

Based on our current enrollment as of January 2017, approximately 45% of consented participants were eligible to be randomized after screening. We estimate that we will need to consent approximately 1250 subjects in order to obtain 560 eligible participants for randomization. Of the 560 eligible participants randomized, all will be asked to find a "Buddy" to participate in the study. We are estimating that approximately 850 "Buddies" will need to be verbally consented. (1250 participants + 850 Buddies = 2100 total to be consented).

### *5.3 Interim Monitoring Plan*

The DSMB will have overall responsibility for monitoring the emerging results. The focus of the DSMB will be on safety issues, recruitment, retention, protocol adherence and data quality and timeliness. The DSMB will meet twice each year, and more frequently if needed. Any explicit stopping rules for harm will be determined by the DSMB. In addition, futility as defined by low conditional power to show a benefit given the outcome data to date will not be assessed. However, recruitment will be monitored by the DSMB and the recommendations of the group will be sought if accrual is falling below the goal needed to complete the project by the conclusion of funding.

For each meeting, a formal detailed statistical report will address all aspects of the trial, including baseline variables, outcome variables, compliance with the protocol, data quality, loss to follow-up (primary outcome missing), and protocol violations (such as randomization of ineligible patients). Outcomes will be reported in a cohort of patients randomized before a given date. All adverse events reported to date will be included, with an indicator showing new events since the previous meeting. Adverse events may be reported to some or all of the DSMB members on a more frequent basis if applicable, as requested by the DSMB.

The DSMB will also consider new information from external sources such as the results of other randomized trials and results of meta-analyses of similar interventions. If this new information is judged relevant to all patients, the DSMB may recommend changes to the protocol or to the consent form.

### *5.4 Handling Early Termination/Censoring*

Patients can choose to withdraw from the study at any time. However, all participants randomized to the intervention will be accounted for in all follow-up analyses following the intent-to-treat principle. If participants withdraw from the study, and do not agree to return for follow-up assessments, data from their most recent assessment will be carried forward and imputed in subsequent assessment points (Last Observation Carried Forward).

# 6 Data Collection

### *6.1 Data Collection Forms*

The majority of data collection will be electronic, but paper versions of all instruments will be available to be administered or used as a backup system in the event of technical difficulties with the electronic administration system. Electronic data collection forms will be developed in-house by the Data Manager and Study Coordinator and administered utilizing the RedCap data management system in conjunction with Northwestern University Biomedical Informatics Center (NUBIC) of the Northwestern University Clinical and Translational Sciences (NUCATS) program. These forms will capture all data elements described in this protocol at each study visit. Any paper documents collected will be stored in participants folders in a locked suite and cabinet within the Department of Preventive Medicine.

### *6.2 Data Entry, Management System, and Data Security*

The majority of participant data (including all patient reported outcomes) will be collected using an online system (RedCap) housed at and maintained by Northwestern University Biomedical Informatics Center (NUBIC) of the Northwestern University Clinical and Translational Sciences (NUCATS) program. Redcap allows for a secure portal to complete all study-related forms including all self-report questionnaires. These data are stored behind an encrypted firewall, and automatically backed up. All database files will be password protected, and only study staff will have access to the study databases. Any paper data will be de-identified, and kept in the laboratory in a locked suite and cabinet. The legend for the codes will be stored in the laboratory in a locked cabinet on-site in access-controlled laboratory. All electronic data and records of those individuals who after screening are deemed ineligible for the study will be completely deidentified and retained in encrypted form on Northwestern University's secure server, within password protected folders to which only study personnel will have access. The study co-investigator, Dr. Linda Collins at Pennsylvania State University, and her team are not involved in the human subjects research (intervention) portion of the study. Their involvement is limited to receipt of de-identified participant databases, which will be used for data analysis purposes. Penn State will not receive any linkages between participant study information and “readily identifiable” information (e.g., names). Additionally, our collaborators at UCLA will be receiving de-identified participant databases, which will be used to analyze data related to the research question: “What are the most robust predictors of weight loss within Opt-IN study participants?”. UCLA will not receive any linkages between participant study information and “readily identifiable” information (e.g., names, addresses).

#### *6.2.1 Quality Control*

All study assessments administered electronically will be designed to disallow invalid response values and to flag and alert study personnel to incomplete instruments prior to saving the instrument. The data will be visually checked by the data manager who will record the presence of each assessment battery file for each participant. In the event of the presence of paper data, all hand-computations will be double-checked and all double entered. Web administered screening data and Smartphone data uploaded to the study server will be backed up each evening, and downloaded for local backup and storage with other study data. After checking for accuracy and completeness of each file, all electronic data will be backed up on the project manager’s and data manager’s computers, and backed up to a secure remote hard drive.

All database files will be password protected, and only study staff will have access to staff computers or the secure remote hard drive. Paper data will be kept in the laboratory in a locked cabinet.

### 6.2.2 Assessment of Intervention Fidelity

Treatment fidelity will be critically important to preserve since participants will be randomized to 16 different conditions. The coach interface will be programmed to reflect the participant's treatment assignment and will prompt the coach to intervene appropriately, using fidelity checklist items that display prescribed and proscribed intervention elements. The treatment for each condition will also be manualized for training purposes, and all coaches will be trained to deliver all intervention conditions. Telephone sessions will be audiotaped and a 15% sample rated for treatment fidelity on a quarterly basis. If fidelity falls below 80%, coaches will be retrained. Fidelity checklists specify: a) good counseling practices (e.g., positive regard, active listening); b) intended session content (e.g., portion size estimation); c) unintended session content (i.e., contamination such as evidence of texting a participant not assigned to text messaging or recommending meal replacement to a participant not assigned to that condition). Dr. Spring will train the coaches on the intervention and Dr. Pfammatter will serve as primary fidelity evaluator. Training will initially involve role-play as coach and participant. Next coaches will observe the Co-I's and Coordinator performing sessions with volunteers. Finally each coach will perform a live dress rehearsal of telephone delivery of each treatment session and condition. They will continue to rehearse until fidelity ratings show that each coach can be certified as competent to deliver all sessions for all conditions. DVD recordings of the trainings will be made and retained in case there is a need to train new coaches or retrain existing ones. Coaches will meet with Dr. Spring weekly as a group for clinical supervision.

# 7. Study Timetable

### *7.1 Study Timeline*

The study time line and randomization goals appear in Table 6. As shown, quarters 1, 2, and 3 will be dedicated to completing development of the protocol and study tools. Development activities include completing programming of the Opt-IN app for usability across all Smartphone platforms, programming online lessons, developing and programming algorithms needed to generate session guides, assessments and reports, preparing treatment manuals and fidelity check protocols, and training coaching staff. Recruitment, screening, and randomization activities will commence in Year 1, quarter 4 and continue through Quarter 1 of Year 5. The remainder of Year 5 is for final follow-up, data analyses and report writing.

| | Quarter 1 Sept - Nov | Quarter 2 Dec-Feb | Quarter 3 Mar-May | Quarter 4 June-Aug | Total |
|---|---|---|---|---|---|
| Year 1 | Development | | | | |
| Year 2 | Testing / 15 | 47 | 45 | 45 | (152) |
| Year 3 | 45 | 45 | 45 | 45 | (182) |
| Year 4 | 45 | 45 | 45 | 45 | (182) |
| Year 5 | 44 | Data analysis, report writing | | | (44) |
| | | | | | N=560 |

#### *7.1.1* Training and Certification

Study-specific training will take place regarding clinical and survey measures, and intervention protocol.

NU requires that all investigators and members responsible for the design and/or conduct of research provide evidence of adequate training in order to maintain IRB approval of a study. The names of the individuals who will be involved in conduct of the research have been provided. They have all completed the course required by Northwestern University for those who will participate in human subjects research, namely, the CITI web-based course in human subject protection and the NU HIPPA training course (www.research.northwestern.edu/research/oprs/irb/education/HIPAA_Presentation_2006.ppt.).

### *7.2 Potential Pitfalls*

The risks of participation in this study are small. Participants may experience discomfort due to the types of questions asked during the assessments, and some may find the questionnaires frustrating and time-consuming. The participants will not be required to answer questions or discuss topics that they do not feel comfortable with. There is a small risk that subjects might experience physical discomfort resulting from engagement in moderate physical activities. Project staff will be supervised by a licensed clinical psychologist (Dr. Bonnie Spring), and the team includes experts in exercise science (Dr. Christine Pellegrini) and psychology (Dr. Angela Pfammatter). Candidates who are judged based on screening measures to have medical or psychological conditions that might make participation injurious will not be enrolled. Participants are further encouraged to contact the PI at any time should they experience significant distress. The measures to be used have been tested in a variety of research programs and no problems have been reported due to their use. However, the participant may terminate questionnaires at any time and referrals may be made to the local psychological and medical services as needed.

# 8 Discussion of Next Steps

If successful, the trial will result in an innovative, highly disseminable technology-supported minimal by embedding expert decision supports on a phone with linkage to and brief intermittent telephone counseling from bachelors level coaches. OPT-IN reduces intervention cost and participant burden, overcoming access barriers and expanding population reach. If OPT-IN proves effective, the next step will be to reduce cost even further by fully automating the coaching system.

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# APPENDIX

## Opt-IN Research Study

### Permission to Contact Physician Form

Dear Participant,

As part of our study protocol, we require that your physician gives you medical clearance to participate in the Opt-IN study. In addition, you may be randomized to a group in which a report on your Opt-IN progress will be sent to your physician quarterly. In order to contact your physician for your medical clearance or to send your Opt-IN progress report, we ask for your permission to contact your primary care physician. Please note, we will not be obtaining any records from your physician. We will only ask that your physician signs off on a medical clearance form stating that you are medically eligible to participate in Opt-IN or with your Opt-IN progress report.

**Patient Information:**

| | |
|---|---|
| Name | |
| Date of Birth | |
| Address | |
| Phone Number | |

**Physician Information**:

| | |
|---|---|
| Name | |
| Address | |
| Phone Number | |
| Fax Number | |
| Type of Physician | |

Signing below signifies that you give the Opt-IN staff permission to contact your physician and obtain information about your medical eligibility for the Opt-IN study.

_____ _____

Signature Date

Please fax completed form to **312-503-0982**, or bring this completed form to your Baseline assessment**.** If you have any questions, please do not hesitate to contact Dr. Christine Pellegrini, the Opt-IN project coordinator (Opt-IN@northwestern.edu; 773-234-6711). Thank you for your cooperation!

**PI: Bonnie Spring, Ph.D., ABPP IRB#STU00066546**

## Physician Consent to Participate in the Opt-IN Research Study at Northwestern University

**To:**
Physician's Name: _____
Address: _____
City: _____ State: _____ Zip: _____
Telephone number: _____

Your patient, _____ DOB: _____, is interested in participating in the Opt-IN research study being conducted in the Department of Preventive Medicine at Northwestern University. Opt-IN is a behavioral telephone-based weight loss program that will encourage participants to follow a low-calorie, low-fat diet and to engage in a moderate level of physical activity. Brisk walking will be particularly emphasized. As part of the study, we may also send you quarterly reports on your patients' progress.
We are contacting you to ensure that your patient is medically stable and eligible to participate in a weight loss program that involves moderate diet and physical activity goals. In addition to any contraindications to physical activity, medical rule-outs of the Opt-IN study include: **uncontrolled hypertension, type-1 diabetes or uncontrolled type-2 diabetes, unstable angina pectoris, history of myocardial infarction, transient ischemic attack, cancer undergoing active treatment, or cerebrovascular accident within the past 6 months**. We ask that you review your patient's chart and determine his/her eligibility for our study. Please note, no participant will be allowed to participate without medical clearance from their physician.

☐ YES, I give this patient medical clearance to participate in Opt-IN.

☐ NO, I do not give this patient medical clearance to participate in Opt-IN because

_____

_____

Physician's signature*: Date:

_____ _____

*If Nurse Practitioner or Physician Assistant, **supervising MD or DO** must co-sign for form to be valid.

We greatly appreciate your time. Please fax this form back to Dr. Christine Pellegrini, the Opt-IN study program coordinator at (F) 312-503-0982. Please feel free to contact Dr. Pellegrini (Opt-IN@northwestern.edu; 773-234-6711) with any additional questions.
**PI: Bonnie Spring, Ph.D., ABPP IRB#STU00066546**

## Opt-In Physician Approval Form – Elevated Blood Pressure at Assessment

**Dear Dr. _____,**

Your patient, _____, DOB:_____ is currently participating in the Opt-IN clinical trial being conducted in the Department of Preventive Medicine at Northwestern University. Opt-IN is a 6-month behavioral telephone-based weight loss program that encourages participants to follow a low-calorie, low-fat diet and to engage in a moderate level of physical activity, such as brisk walking.

During an in-person screening session on _____, your patient's blood pressure was found to be elevated with an average reading of: _____/_____ mmHg. For your patient's safety, we request that you evaluate your patient and notify us about the results of your assessment (including blood pressure readings), and provide a treatment plan. Most importantly, we ask that you inform us about whether the participant can continue to participate in our study.

| Please provide the results of your assessment (including blood pressure readings): |
|---|
| |

| Treatment plan: |
|---|
| |

☐ YES, my patient may continue to participate in the Opt-IN trial, and is cleared to participate in moderate physical activity and a reduced fat and calorie diet.

☐ NO, my patient can no longer participate in the Opt-IN trial.

Physician's signature*: Date:

_____ _____

*If Nurse Practitioner or Physician Assistant, **supervising MD or DO** must co-sign for form to be valid.

| Place office stamp within this box |
|---|
| |

Please fax this form to Dr. Christine Pellegrini, the Opt-IN Project Coordinator at **(F) 312-503-0982**. Please contact Dr. Pellegrini (Opt-IN@northwestern.edu; 773-234-6711) or Dr. Bonnie Spring (PI) (bspring@northwestern.edu, 312-908-2293) with questions. Thank you for your cooperation. NU IRB: STU00066546

# Opt-IN Buddy Instruction Sheet

In order to participate in the Opt-IN study, all participants must choose a "buddy," or an individual (friend, family member, etc.) who they believe would support them in their weight loss efforts throughout the 6-month study. In order for your buddy to be eligible to participate and support you, he/she must be 18 years of age or older, and must have access to a computer for the duration of the 6-month study.

All buddies will receive an informational email on providing support to you while you are participating in the Opt-IN study. In addition, if you are randomized to a condition that includes buddy training, your buddy will complete telephone training and a series of 4 webinars. Each webinar will last approximately 30-45 minutes and encompass both a lesson and discussion period about supporting the participant for the Opt-IN trial. Your buddy will be paid $5 in the form of an online gift card after participation in each of the 4 required webinars (up to $20). Also, if your buddy attends at least of the required webinars, he/she will receive an additional $20 online gift card.

## Please instruct your buddy to visit the following website:

www.optin.northwestern.edu. On this website, your buddy must click on the "Buddy Survey" button on the right-hand side of the screen, and fill out a short questionnaire to continue to be eligible for the next step of the screening process. Note: it is **CRITICAL** that your buddy fill out this web survey as soon as possible. Without your buddy's completed online survey, you as a potential participant cannot move on to the next step of the study. An email reminder will be sent to you after this orientation session; please direct your buddy to our website (www.optin.northwestern.edu, click on "Buddy Survey") so that they can complete the task soon!

After your buddy completes the web survey, a member of the Opt-IN team will be in contact with them via phone for the next step.

Thank you again for your interest in the Opt-IN study!

# Locator Person Instruction Sheet

You are receiving these instructions from someone that would like to participate in a research study in the laboratory of Dr. Bonnie Spring at Northwestern University. Every participant must choose a locator person. This individual must know how to contact the participant and will be asked for permission to be contacted in the event of an emergency or if the study team cannot contact the participant.

To protect participant confidentiality and privacy, it is our practice not to disclose details about the specific study in which the participant is enrolling. We thank you for your understanding.

**If you agree to be this participant's locator person, please visit the following website:**

**REDCAP LINK TO LOCATOR PERSON AGREEMENT**

Note: it is **CRITICAL** that you fill out this web form as soon as possible. Without your completed form, the participant cannot go on to the next steps of the study. If you do not wish to agree to serve as this person's contact, please let him/her know so that another person may be chosen.

Thank you for your help!

Dr. Bonnie Spring's Research Study Team

# General Psych Referrals

APA (American Psychological Association) Therapist Finder: http://locator.apa.org
Northwestern Memorial Physician Finder: http://www.nmh.org/nm/physician-finder

- You can select from Psychiatry (MDs that can prescribe psychotropic medications) or Psychology (PhD/PsyDs that specialize in therapy)
- Within those two categories you can narrow your search even more by searching for clinicians based on their clinical interests (i.e. depression, anxiety, eating disorders)
- Or call 877-926-6363
    - Department of Psychiatry
    - Northwestern University
    - 446 East Ontario, Suite 6-300
    - Chicago, IL 60611
    - Phone 312.926.8200

University of Chicago Physician Finder: http://www.uchospitals.edu/physicians/index.html

- Or call HealthLink toll-free at 1-888-UCH-0200.
- You can select from Psychiatry (MDs that can prescribe psychotropic medications) or Psychology (PhD/PsyDs that specialize in therapy)
- Within those two categories you can narrow your search even more by searching for clinicians based on their clinical interests (i.e. depression, anxiety, eating disorders)
- Office of Applied Psychological Services at UIC
    - University of Illinois at Chicago
    - Behavioral Sciences Building, Room 3011A
    - 1007 West Harrison Street
    - Chicago, IL 60607-7137
    - Phone 312.996.2540
    - Fax 312.413.7841
    - http://www.psch.uic.edu/clinicalcenters.asp?sm=clinical_centers

Rush University Medical Center Physician Finder: http://rush.photobooks.com/

- You can select from Psychiatry (MDs that can prescribe psychotropic medications) or Psychology (PhD/PsyDs that specialize in therapy)

- Within those two categories you can narrow your search even more by searching for clinicians based on their clinical interests (i.e. depression, anxiety, eating disorders)

# Chicago Area Weight Loss Options

## Commercial Weight Loss Programs

**Jenny Craig**
http://www.jennycraig.com

Now offering programs specifically designed for men, spouses, seniors, and teens. Programs allow you to meet with consultants and develop a weight-loss plan that fits your lifestyle for an affordable price. For more privacy, you can try Jenny Direct which allows a consultant to meet with you via telephone. Jenny Direct also delivers food to your house in 2- or 4-week increments. Jenny Craig will introduce you to a new, healthier lifestyle and offer you one-on-one coaching to keep you on track.
Wide variety of locations throughout Chicago and the surrounding areas; consult website for details.
Hours of operation and meeting times vary by location.
Instant callback from a Jenny Craig consultant when you call 1-800-597-5366

**Weight Watchers**
http://www.weightwatchers.com

Low cost option with an extremely wide range of weight loss programs and tips. Many of the options have free registration, and you can sign up online to attend a meeting for free to check it out.
Wide variety of locations throughout Chicago and the surrounding areas; consult website for details.
Hours of operation and meeting times vary by location. You can also choose to do Weight Watchers online where you can access to your plan info via your home, office and even your mobile device. Weight Watchers offers flexible food plans that allow you to eat what you like and can adapt to any lifestyle or unique needs. You are provided with the information on how to lose weight in a healthy way and how to keep the weight off for good. Weight Watchers stresses an integrated approach emphasizing good eating choices, healthy habits, a supportive environment and exercise. A diet plan is developed according to a points system, with each food you eat equal to a certain number of points.

**Curves**
http://www.curves.com

The Curves fitness program allows you to get a complete aerobic and strength training workout in just 30 minutes. The system is built around easy-to-learn hydraulic resistance machines, so there are no cumbersome weight stacks to change or manage. The machines are designed specially for women. New to Curves is the CurvesSmart program. CurvesSmart is a state-of-the-art personal coaching system that has been incorporated into the 30-minute circuit workout. Now every piece of equipment in the circuit is programmed with your body's information to give you moment-by-moment feedback.

CurvesSmart also automatically adjusts to your body's endurance level so you stay continually challenged and achieve your potential on every machine, during every workout. CurvesSmart then automatically computes all of your workout data to produce detailed progress reports that show your overall muscle strength, your calories burned and how close you are to reaching your goals
Wide variety of locations throughout Chicago and the surrounding areas; consult website for details. Hours of operation may vary by location.
Call 1-800-257-5332 to request a FREE personal fitness plan.

## Medically-Based Weight Loss Programs

**University of Illinois Medical Center (located in Chicago):**
http://uillinoismedcenter.org/Patient_Care_Services/Surgical_and_Transplant_Services.html

Weight Management Program: This program is a multidisciplinary, medically supervised weight loss program for overweight and obese patients. Our treatment programs are physician-monitored and designed to improve health through sustained weight loss based on reasonable long-term goals.To request an appointment, please call or 312.413.3631 or 800.842.1002.
New Hope: New Hope is a division of the Pediatric Department dedicated to treating severely overweight teenagers and their families. The program tailors psychological, nutritional and activity support according to the patient's individual needs.
To request an appointment or for more information, please call us at 312.413.5655.
Nutrition and Wellness Center: The Nutrition and Wellness Center provides advanced clinical expertise, specialized services and state-of-the-art technology. Specializing in bone health, diabetes, medical nutrition therapy, rheumatology and weight management, patients receive the highest quality personalized care possible. Phone: 312.413.3631

**Northwestern Comprehensive Center on Obesity:** http://www.ncco.northwestern.edu/index.html

The Center offers Energy Metabolism workshops as well as an Obesity Seminar series. For dates, topics and locations, please consult the website and look under the "News and Events" section.
Center for Lifestyle Medicine:
Health care professionals can help you
 manage your weight;
 determine if bariatric surgery would be a good option and then, if so, guide you through the surgery, follow-up care, and adjustment period;
 evaluate your risk factors for major life-threatening chronic diseases such as heart disease, diabetes, stroke; and
 counsel you using specific test results and recommend ways to change your behavior that suits your needs and personality

Our highly skilled interdisciplinary team includes physicians in various specialties, psychologists, nurses, dietitians, exercise specialists, and others who can help you achieve and maintain a healthier lifestyle.

Please call 312/695-2300 to schedule an appointment. The Center for Lifestyle Medicine is located on the 19th floor of Galter Pavilion, Northwestern Medical Faculty Foundation, 675 N. St. Clair, Chicago, IL 60611.

**Alexian Brothers Health System**
http://www.alexianbrothershealth.org/services/nutritionalassess/ourservices/nonsurgical/our-tests-treatments-and-therapies.aspx

**Outpatient Medical Nutrition Therapy**
Outpatient Medical Nutrition Therapy is designed to help you take control of your nutritional care. A Registered Dietitian (RD) will help you set personal goals and create a personalized plan to achieve weight management, reduce your risk of becoming ill, and improve your quality of life.

**Alexian Brothers Advanced Weight Solutions** is standing by to support and encourage you. Use your checklist below to direct your next steps.
Call us today! (847) 695-5362
Alexian Brothers Medical Group
One American Way
Elgin, IL 60120

**University of Chicago's Eating and Weight Disorders Program**
http://psychiatry.bsd.uchicago.edu/patientCare/adultSectionPrograms/adult_eatingDisorders.html

The Adult Eating and Weight Disorders program is a research and training clinic that specializes in the assessment and treatment of difficult-to-treat eating and weight disorders. Our research and clinical mission is to develop treatment for these individuals utilizing psychosocial treatments such as Dialectical Behavior Therapy and Cognitive-Behavior Therapy. These endeavors are funded by a variety of federal and foundation grants. In addition, our teaching mission is to train student therapists in the delivery of these treatments to individuals with eating and weight disorders and to train student assessors in the assessment of these problems.

The Eating Disorders Program at The University of Chicago Hospitals provides comprehensive outpatient and limited inpatient services for the assessment, treatment and follow-up of adolescents and adults with eating disorders. This includes:
- Adolescent anorexia and bulimia nervosa and related disorders
- Adult anorexia and bulimia nervosa and related disorders
- Binge eating disorder
- Childhood and adolescent obesity

Services include:
- Diagnostic evaluations
- Individual and/or group psychotherapy
- Parent participation in the treatment of children and adolescents
- Medication consultations and management

 Medical evaluation and follow-up

If you would like detailed information about the Eating Disorders Program, please contact Colleen Stiles-Shields at (773) 702-0789.

## Clinical Trials

**Current Diet and Nutrition Trials at Rush Medical Center:**
http://www.rush.edu/rumc/page-1099611527209.html
Contact Name: Clinical Trials at Rush
Contact Phone: (312) 942-5498
Contact E-mail: clinical_trials@rush.edu

**Current Clinical Trial at Northwestern University:**
http://www.ncco.northwestern.edu/index.html

Physicians at Northwestern University in Chicago are conducting an overnight research study on healthy weight and overweight people. If you are between 25-40 years old and are in either of these categories, you may be eligible to participate. This research study is measuring changes in body temperature using a swallowed gastrointestinal pill. The study will involve 2 visits, one of which will be overnight. Participants will be reimbursed for validated parking and will receive $150.00 for completion of the study.
For more information, please call Sarah at: (312) 503-3177

**University of Chicago: Treatment Study for Women with Binge-Eating Disorder**
Eunice Chen, PhD

The purpose of this research study is to determine how helpful different outpatient psychotherapy is for women with Binge-Eating Disorder. This study compares two outpatient treatments, Dialectical Behavior Therapy and Cognitive-Behavior Therapy. For more information about this study, please go to http://psychiatry.uchicago.edu/research/volunteers/BED.html

## Dieticians

**Allison B. Shudnow MS, RD, LDN**
www.eatingdisorderdietician.com

Allison specializes in Binge Eating Disorder, Night Eating Syndrome and Compulsive Overeating, in addition to Anorexia Nervosa, Bulimia Nervosa, and Eating Disorder-Not Otherwise Specified. She offers services in weight management, pre and post Bariatric surgery, diabetes and cardiovascular disease (cholesterol and blood pressure management). In the first hour-long consultation, you will determine your nutrition/health goals for treatment and how to implement small, realistic changes

into your dietary pattern. Basic nutrition education is provided and a meal plan may be designed, if indicated. Half-hour follow up sessions review your eating patterns and behaviors since the previous session. One very unique service Allison offers is her Restaurant Dining Group, designed for people who avoid restaurants because of anxiety and people who frequently find themselves alone at home eating only "safe" foods. The group meets about once a week at a different restaurant where members support each other while challenging their food choices and practicing normalized eating. After the meal, Allison and the members go to a local coffee shop and process how the meal went and learn new strategies for successful restaurant eating. Contact Allison to reserve a spot for the next outing!
77 W. Washington St.
Suite 1620
Chicago, IL 60602
Phone: 847-721-8030 email: Allison@shudnow.com

**Dawn Jackson-Blatner RD, LDN**
http://dawnjacksonblatner.com
773.208.5777

Dawn offers a variety of services including wellness consultations, medical nutrition therapy, experiential nutrition sessions (including hands-on cooking and grocery shopping trips), 12-week weight management, couples nutrition counseling and the ultimate 7-day diet plan. She also offers healthy cooking demonstrations which are held at:
The Chopping Block Cooking School
222 Merchandise Mart, Suite 107
Chicago, IL 60654

Sessions are $40 each and you can register at www.thechoppingblock.net or call 312-644-6360. Dawn delivers a variety of workshops touching on topics including: The Flexitarian Diet, Ultimate Makeover: Refrigerator Edition, Eat and Drink Your Way to Longevity, Nutrition Tune-Up, and the Environmental Diet. Contact Dawn for details regarding pricing and location.

**Jennifer Vimbor, MS, RD, LDN, CDN:**
http://www.chicagonutritionist.com/

Licensed dietician and founder of "Nutrition Counseling Services".
*Office Address:*
410 South Michigan Avenue, Suite #631
Chicago, IL 60605
*Telephone:*
(312) 235-0050
*Email Address*:
info@ChicagoNutritionist.com

## Surgical Options

***Recommend When:***
***BMI ≥ 40 OR BMI ≥ 35 and patient has significant medical comorbidity***

**Alexian Brothers Health System**
http://www.alexianbrothershealth.org/weight-solutions/

The two most commonly performed procedures are **adjustable gastric banding** and **gastric bypass**. Both surgeries are usually performed laparoscopically, which is a minimally invasive technique compared to regular open surgery. Consult the website for a more in-depth description of the surgical procedures as well as to register for a free informational seminar.
Alexian Brothers Advanced Weight Solutions is standing by to support and encourage you. To learn more, please call 800-433-3130, e-mail weightsolutions@alexian.net

**Alexian Brothers Medical Center**
800 Biesterfield Road
Elk Grove Village, IL 60007
Phone: 847-437-5500

**St. Alexius Medical Center**
1555 Barrington Road
Hoffman Estates, IL 60169
Phone: 847-843-2000

**Rush University Medical Center: Bariatric Surgery Program:**
http://www.rush.edu/rumc/page-1116006426150.html

Services Provided:
- Laparoscopic Roux-en-Y Gastric Bypass (RYGBP)
- Laparoscopic Vertical Banded Gastroplasty (VBG)
- Laparoscopic Adjustable Gastric Banding (LAGB)
- Conventional (open) RYGBP
- Conventional (open) VBG
- Revision interventions for failed or unsafe operations

Rush University Medical Center
1653 W. Congress Parkway, Suite 785 Jelke-Southcenter
Chicago, IL 60612
(888) 352-RUSH

**University of Chicago's Center for the Surgical Treatment on Obesity:**
http://www.uchospitals.edu/specialties/general-surgery/obesity/

**The University of Chicago Medical Center offers the following procedures:**
Roux-en Y gastric bypass (RYGB)
Adjustable gastric banding (Lap-Band®)
Biliopancreatic diversion with duodenal switch (DS)
As a multidisciplinary team, the surgeons at the University of Chicago Hospitals have more than 12 years experience and have performed more than 2,000 weight loss procedures. Because of our experience with all bariatric surgery options, our experts can accurately recommend the best surgical treatment for each patient. Our experienced surgeons have better outcomes--and lower mortality rates--than most medical centers. Our team approach uses the latest research, technology, and ongoing nutritional, behavioral, and psychological support to give our patients the best care possible. The University of Chicago Hospitals team includes: board-certified surgeons who are specialists in minimally invasive surgery and bariatric surgery, certified nurse practitioner, nurse clinician, registered dietitians, psychologist, and insurance coordinator.
Because of our team approach, our patients have easy access to numerous experts in other specialties--including endocrinology and cardiology--if they need treatment for obesity-related problems. We also recognize that surgery may not be the best option for every patient. Together, the doctor and patient come to a decision about the treatment that best fits the patient's needs.

**Bariatric Surgery Information Sessions:**
Second and third Tuesday of every month: 9:00 a.m. to 10:30 a.m.
Fourth Tuesday of every month: 4:00 p.m. to 6:30 p.m.
Center for Advanced Medicine
5758 S. Maryland Avenue
Chicago, IL
Room 1402

**University of Illinois Medical Center (located in Chicago):**
http://uillinoismedcenter.org/Patient_Care_Services/Surgical_and_Transplant_Services.html

*Surgery:* The University of Illinois Medical Center has one of the country's most advanced centers for minimally invasive surgery. We offer robotic assisted bariatric procedures including laparoscopic gastric bypass, open gastric bypass and laparoscopic lap band procedures. We also provide body contouring procedures to reduce baggy skin and reshape the body after significant weight loss. These procedures include tummy tucks, circumferential lifts, thigh lifts, breast lifts/reductions, arm lifts, face and neck lifts.
Our multidisciplinary weight loss team provides care for both adults and adolescents. The team includes board-certified internists, registered dietitians, nurse practitioners, highly-experienced bariatric and pediatric surgeons, and plastic surgeons specializing in body contouring procedures. Psychological and psychiatric support services are also available. Visit our Weight Management page for information about solutions for weight loss

# Chicago-Area Alcohol and Substance Abuse Services

*Chicago Area Alcoholics Anonymous* http://www.chicagoaa.org
The Chicago Area Service Office
180 N Wabash Ave.
Suite 305
Chicago, IL 60601
Toll Free: 800-371-1475 (Illinois only)
Phone: 312-346-1475
Fax: 312-346-5477

*New Hope Recovery Center*
Intake and assessment Office
2451 North Lincoln Ave
Chicago, Illinois (IL) 60614
www.new-hope-recovery.com
773-883-3916/888-707-HOPE

Services include:

- 28 day residential drug treatment
- Residential day treatment program
- Outpatient drug treatment program
- Extended care rehabilitation program

*Chicagoland Region of Narcotics Anonymous* http://www.chicagona.org
Help Line: 708-848-4884
Phone: 708-450-1880
Fax: 708-450-1885

Chicagoland Service Office
C/O Public Information
Eisenhower Tower, Ste. 508A
1701 S First Ave
Maywood, Illinois 60153

Email us at info@chicagona.org

*Gateway Alcohol and Drug Rehab* http://www.recovergateway.com
1-877-RECOVER
Gateway Alcohol & Drug Rehab
Headquarters
55 East Jackson Blvd.
Suite 1500
Chicago, IL 60604

Phone: 312-663-1130
Fax: 312-663-0504

Facilities located in: Aurora, Belleville, Carbondale, Caseyville, Chicago Kedzie, Chicago Northwest, Chicago Westside, Lake Villa, Springfield

Free Confidential Screening and Assessments: Drug Rehab and Alcohol Rehab

Gateway accepts most insurance plans as well as credit card and check.
Services:

- Intensive after-work/after-school outpatient
- Day treatment
- Inpatient treatment

## Opt-IN Lesson Topics

Lesson Topics (12a):
Lesson 1: Getting started with Activity and Healthy Eating
Lesson 2: Be a Fat and Calorie Detective
Lesson 3: Healthy Eating
Lesson 4: Move Those Muscles
Lesson 5: Tip the Calorie Balance
Lesson 6: Taking Charge of Cues
Lesson 7: Problem Solving
Lesson 8: Four Keys to Healthy Eating Out
Lesson 9: Slippery Slope of Lifestyle Change
Lesson 10: Jump Start Your Activity Plan
Lesson 11: Make Social Cues Work for You
Lesson 12: Ways to Stay Motivated

Lesson Topics (12b):
Lesson 1: Balance Your Thoughts
Lesson 2: Food Cravings
Lesson 3: More Volume, Fewer Calories
Lesson 4: Stand Up for Your Health
Lesson 5: My Time, My Values
Lesson 6: Preparing for the Holidays
Lesson 7: Stress Management
Lesson 8: Mindful Eating
Lesson 9: Weight Loss Plateau
Lesson 10: Strength and Flexibility
Lesson 11: Strategies for Grocery Shopping
Lesson 12: Exercise Motivation

**Potential Additional Handouts (dependent on Randomization):**

- Portion Size Handout (from WebMD)
- "What is RPE and Moderate Physical Activity?" Form
- "What is a Meal Replacement?" Form

**Opt-IN Participant Contact Information Form**

Participant Name: _____

Old Address: _____

City: _____ State: _____ Zip Code:

Date of changes: _____

New Home Address: _____

City: _____ State: _____ Zip Code:

_____

**Has any of your contact information changed since the last assessment?**

☐ Yes ☐ No

If so, please write them below.

Home Phone: _____
Cell Phone: _____
Work Phone: _____

Preferred Contact Number: ☐ Home ☐ Cell ☐ Work

Would it be ok for us to leave a message at the numbers you have listed above?

☐ Yes ☐ No

Email Address: _____

**PARTICIPANT CERTIFICATE – Opt-IN**

This is to certify that I participated as a research subject in the OPT-IN STUDY on _____/_____/_____ and I am to be reimbursed for my participation as follows:

| | | |
|---|---|---|
| Participant Payment | = | 20.00 |
| Total Payment | = | 20.00 |

_____
Signature of Participant

_____
Date

Mailing Address (PLEASE PRINT):

NAME: _____

ADDRESS: _____

_____

_____

Staff Use Only:

APPROVED: _____
Project Coordinator

DATE: _____

Invoice ID: _____

Date Check Received: _____
Date Check Mailed: _____

**Opt-IN PCP Letter – 3-month no weight lost**

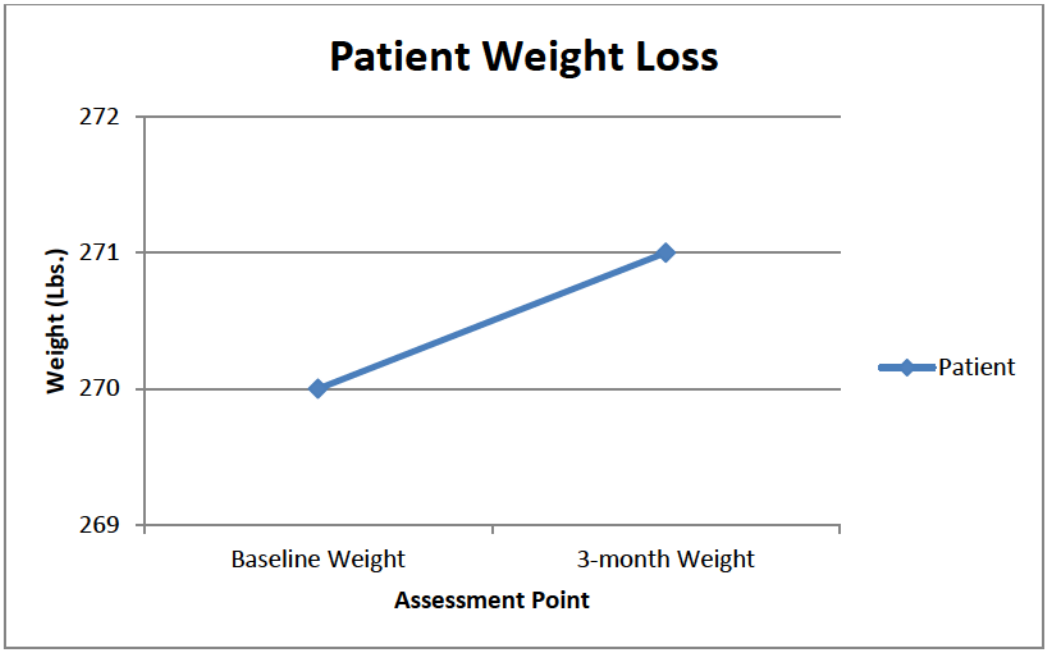
**Date**

**«Physician_Name»**
**«Address»**
**«City», «State» «Zip»**

**RE: Primary Care Provider Progress Report for Opt-IN Research Study (IRB#STU00066546) at Northwestern University**
Dear «Physician_Name»,

Your patient, «Patient_Name» DOB: «Patient_DOB», is participating in the Opt-IN research study being conducted in the Department of Preventive Medicine at Northwestern University. Opt-IN is a 6-month behavioral telephone-based weight loss program that encourages participants to follow a low-calorie, low-fat diet and to engage in a moderate level of physical activity, such as brisk walking. As part of the study, we are sending you quarterly reports on your patients' progress.

At the beginning of our study, «Patient_Name» weighed «Patient_Initial_Weight» pounds. As of the 3-month assessment, «Patient_Name» now weighs «Patient_3month_Weight» pounds. Please refer to the graph below for a more specific outline of weight loss progress over this time frame.




Based on your patient's progress, we propose several behavioral recommendations to support his/her weight loss efforts.

- Encourage your patient to self-weigh regularly.
- Encourage your patient to regularly track caloric intake using the provided Opt-IN Study application.

- Encourage your patient to engage in regular, short bouts of moderate intensity physical activity such as brisk walking.

We greatly appreciate your time. We will send you another progress report in regard to «Patient_Name»'s weight loss progress at the 6-month assessment. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

Sincerely,

Bonnie Spring, Ph.D., ABPP
Professor of Preventive Medicine, Psychology, and Psychiatry
Director, Center for Behavior and Health
Co-Program Leader for Cancer Prevention
Principle Investigator of the Opt-IN Research Study

**Date**

**«Physician_Name»**
**«Address»**
**«City», «State» «Zip»**

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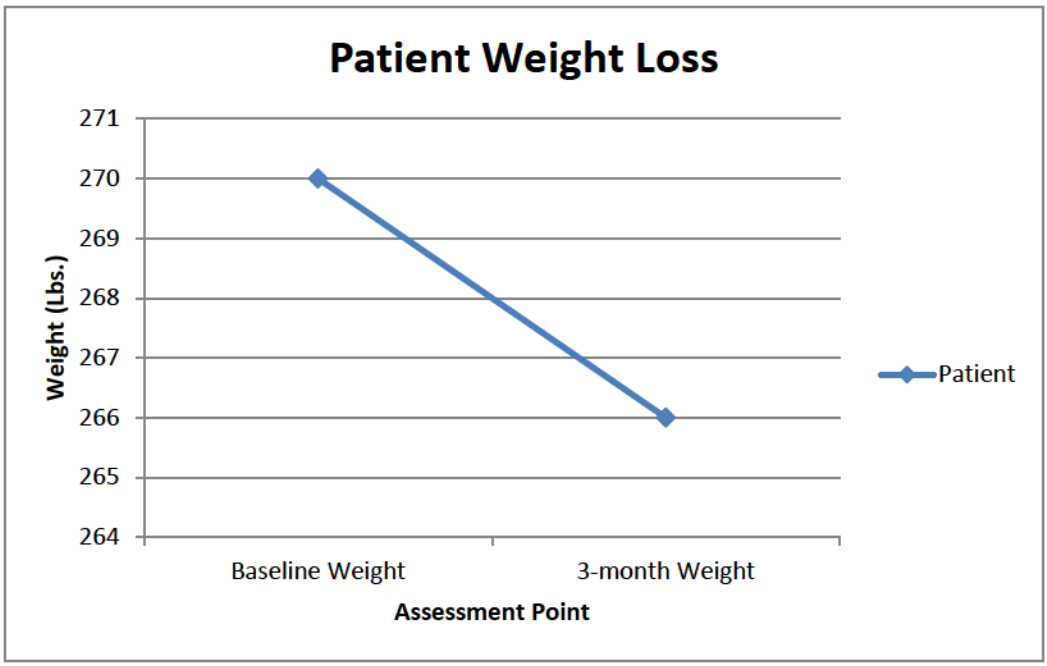


Based on your patient's progress, we propose several behavioral recommendations to support his/her weight loss efforts.

- Encourage your patient to continue self-weighing regularly.
- Encourage your patient to continue monitoring caloric intake using the provided Opt-IN Study application.

- Encourage your patient to continue engaging in moderate intensity physical activity such as brisk walking.

We greatly appreciate your time. We will send you another progress report in regard to «Patient_Name»'s weight loss progress at the 6-month assessment. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

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Director, Center for Behavior and Health
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**Wednesday, March 04, 2020**

**«Physician_Name»**
**«Address»**
**«City», «State» «Zip»**

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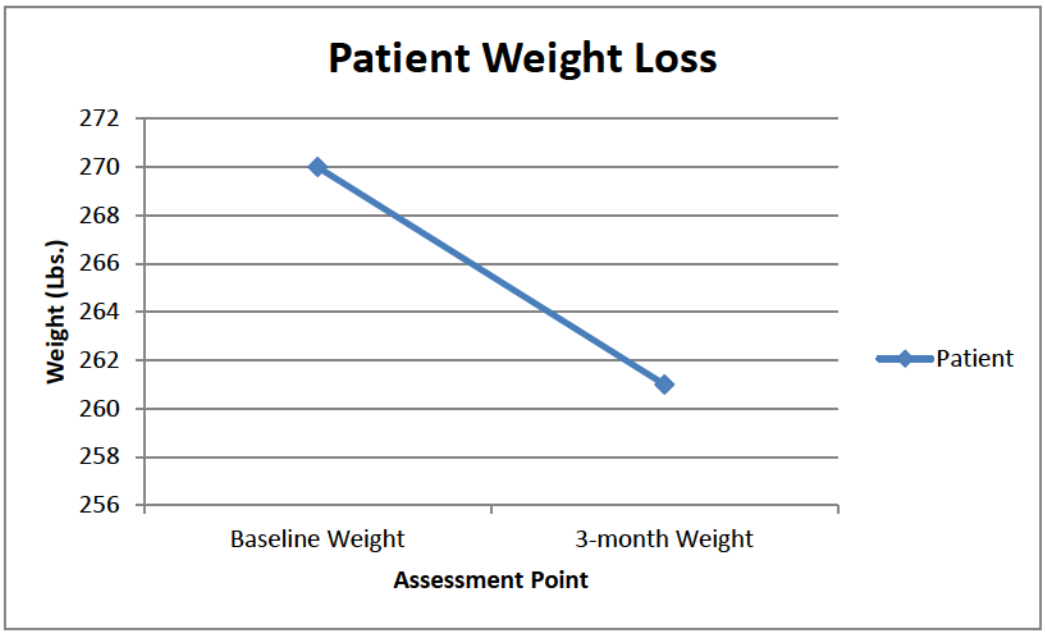


Based on your patient's progress, we propose several behavioral recommendations to support his/her weight loss efforts.

- Encourage your patient to continue self-weighing regularly.
- Encourage your patient to continue monitoring caloric intake using the provided Opt-IN Study application.

- Encourage your patient to continue engaging in moderate intensity physical activity such as brisk walking.

We greatly appreciate your time. We will send you another progress report in regard to «Patient_Name»'s weight loss progress at the 6-month assessment. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

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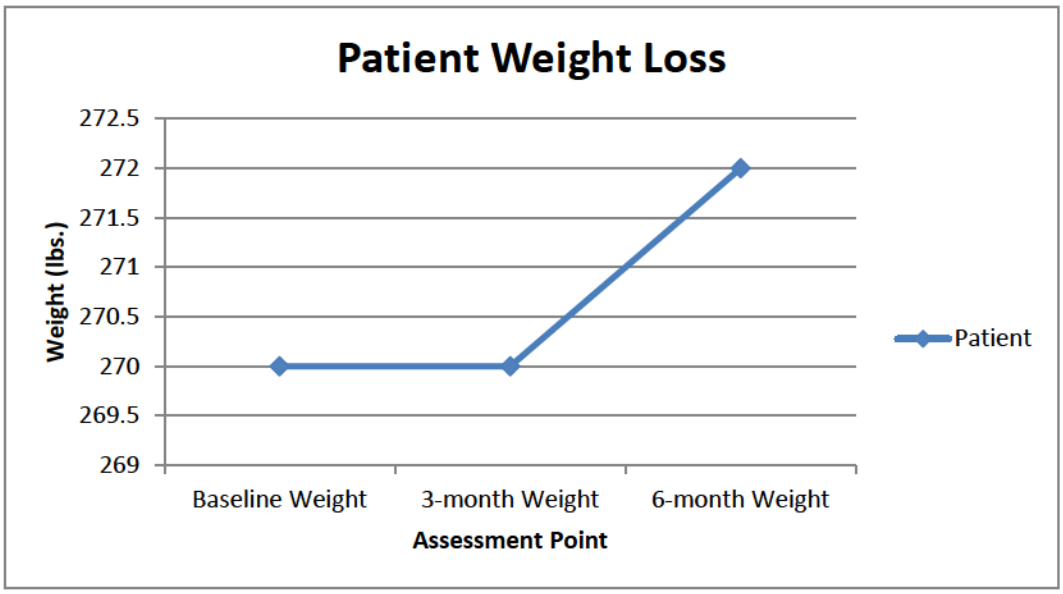
At the beginning of our study, «Patient_Name» weighed «Patient_Initial_Weight» pounds. As of the 6-month assessment, «Patient_Name» now weighs «Patient_6month_Weight» pounds. Please refer to the graph below for a more specific outline of weight loss progress over this time frame.




Based on your patient's progress, we propose several behavioral recommendations to support his/her continued weight loss efforts.

- Encourage your patient to self-weigh regularly.
- Encourage your patient to track caloric intake using a paper diary, website, or smartphone application.

- Promote engaging in regular, short bouts of moderate intensity physical activity such as brisk walking, to encourage weight loss in the future.

Your patient has completed the Opt-IN research study and we greatly appreciate your time. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

Sincerely,

Bonnie Spring, Ph.D., ABPP
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**Date**

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**«City», «State» «Zip»**

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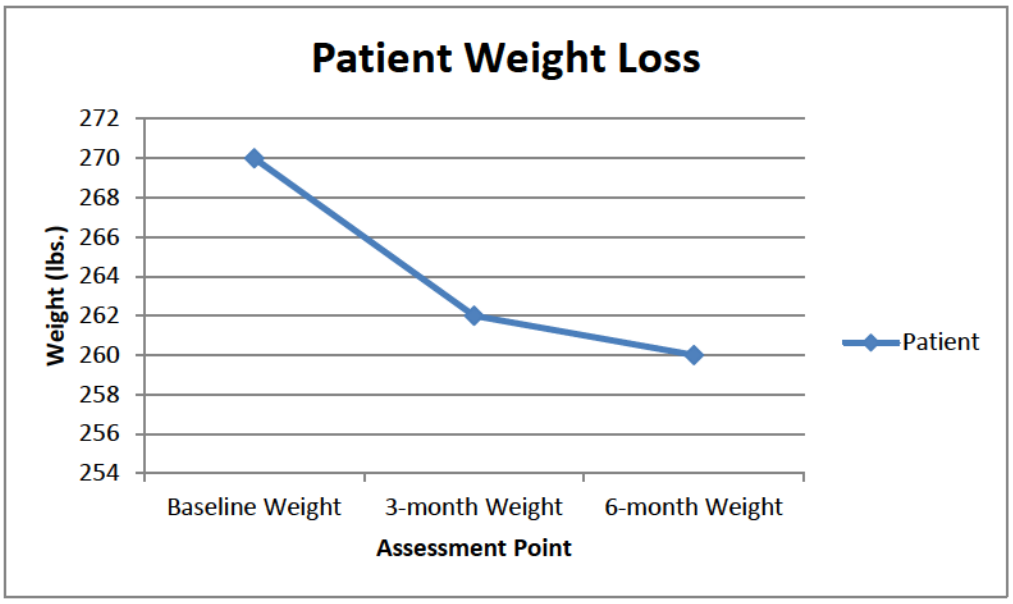


Based on your patient's progress, we propose several behavioral recommendations to support his/her continued weight loss efforts.

- Encourage your patient to continue self-weighing regularly.
- Encourage your patient to continue monitoring caloric intake using a paper diary, website, or smartphone application.

- Encourage your patient to continue engaging in moderate intensity physical activity such as brisk walking.

Your patient has completed the Opt-IN research study and we greatly appreciate your time. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

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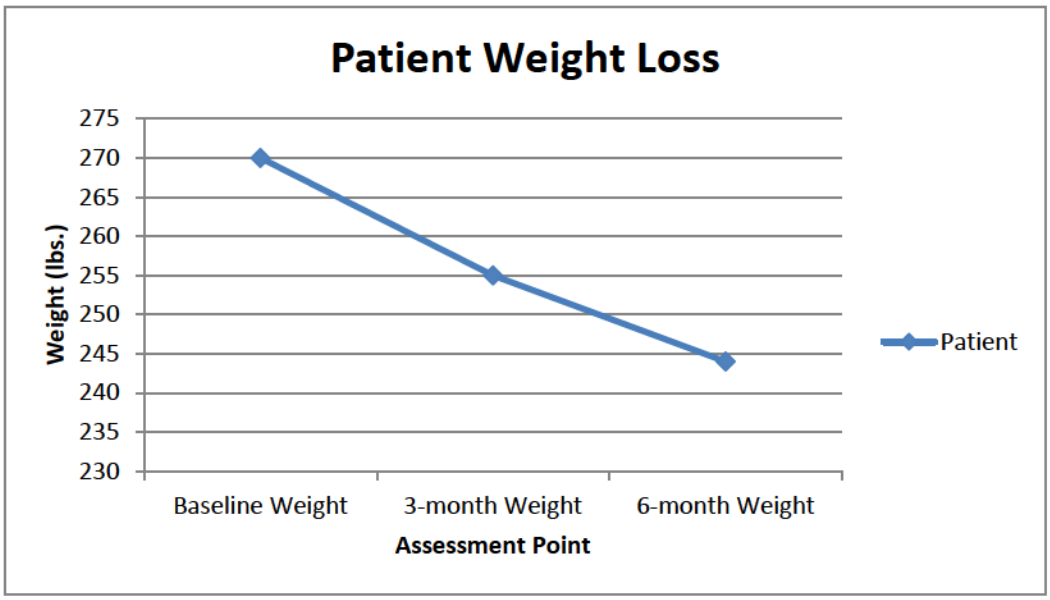
At the beginning of our study, «Patient_Name» weighed «Patient_Initial_Weight» pounds. As of the 6-month assessment, «Patient_Name» now weighs «Patient_6month_Weight»pounds. Please refer to the graph below for a more specific outline of weight loss progress over this time frame.




Based on your patient's progress, we propose several behavioral recommendations to support his/her continued weight loss or maintenance efforts.

- Encourage your patient to continue self-weighing regularly.

- Encourage your patient to monitor caloric intake using a paper diary, website, or smartphone application if/when weight regains occurs.
- Encourage your patient to continue engaging in moderate intensity physical activity such as brisk walking to prevent weight regain.

Your patient has completed the Opt-IN research study and we greatly appreciate your time. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

Sincerely,

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Director, Center for Behavior and Health
Co-Program Leader for Cancer Prevention
Principle Investigator of the Opt-IN Research Study

**Opt-IN PCP Letter – Incomplete Assessment, 3-month**

**Wednesday, March 04, 2020**

**«Physician_Name»**
**«Physician_Address»**
**«Physician_City_State_Zip»**

**RE: Primary Care Provider Progress Report for Opt-IN Research Study (IRB#STU00066546) at Northwestern University**

Dear «Physician_Name»,

Your patient, «Patient_Name» DOB: «Participant_DOB», is participating in the Opt-IN research study being conducted in the Department of Preventive Medicine at Northwestern University. Opt-IN is a 6-month behavioral telephone-based weight loss program that encourages participants to follow a low-calorie, low-fat diet and to engage in a moderate level of physical activity, such as brisk walking. As part of the study, we are sending you quarterly reports on your patients' progress.

Unfortunately, your patient has not completed the 3 month follow-up assessment, so we are unable to provide you with a weight loss progress report. There are documented benefits from weight loss, physical activity and a healthy diet. The aim of our study is to find an effective way to increase these behaviors and outcomes. The participation of your patient in this study will help us achieve our goal. We hope that you will encourage the patient to do so.

We greatly appreciate your time. We will send you another progress report in regard to «Patient_Name»'s weight loss progress at the 6-month assessment. Please feel free to contact Dr. Christine Pellegrini, the Opt-IN study program coordinator (Opt-IN@northwestern.edu; 773-234-6711) with any questions.

Sincerely,

Bonnie Spring, Ph.D., ABPP
Professor of Preventive Medicine, Psychology, and Psychiatry
Director, Center for Behavior and Health
Co-Program Leader for Cancer Prevention
Principle Investigator of the Opt-IN Research Study

**Opt-IN PCP Letter – Incomplete Assessment, 6-month**

**Wednesday, March 04, 2020**

**«Physician_Name»**
**«Physician_Address»**
**«Physician_City_State_Zip»**

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Principle Investigator of the Opt-IN Research Study

Opt-IN Study
Department of Preventive Medicine
Suite 1400
680 N. Lake Shore Drive
Chicago, IL 60611
773-234-6711
opt-in@northwestern.edu

PARTICIPANT NAME/ADDRESS

DATE

Dear NAME,

I hope this letter finds you well! We want to thank you for being a participant in the Opt-IN study and your contribution to our research knowledge about health and weight loss!

I don't know if you have received my messages, but I've been trying to reach you for coaching calls through e-mail and telephone. Since I haven't heard back from you yet, I'm becoming a little concerned. I would really like for us to touch base about how you've been and to talk about your ongoing participation in the Opt-IN study. Your enrollment in Opt-IN means a lot to our team! First and foremost we want to be able to support you as best we can in your effort to make these healthy changes and reach your personal goals.

Could you please give me a call as soon as you can, or let me know what the best way to reach you at this time would be? I would really like to speak with you directly in order to ensure your safety and I am open to discussing modified participation if the study is too demanding or challenging for you right now. We are here to help. Remember that it is just as important for us to know what is not working for our participants so we can go on to create better treatments!

I am also attempting to reach out to you by contacting the Locator Persons you provided at the beginning of the study. I will make several attempts to reach these individuals unless we hear from you before that time. Our offices are open from 8:00 am to 5:00 pm, Monday through Friday. Please feel free to e-mail or to call. My direct line is LINE, or you can call the Opt-IN main line at 773-234-6711. If I'm not available, you're welcome to coordinate a time to chat with any member of our team.

I look forward to hearing from you soon!

Sincerely,
Coach name and direct line

## Missed Contact Protocol and Checklist

**After missed coaching call appointment:**

- ☐ Attempt call 48 workday hours later (2nd attempt)
  Result:_____
- ☐ Email immediately if second attempt fails
  Result:_____

**After one week of no contact:**

- ☐ Call indicating 48 hours notice (exclusive of weekends and holidays) of attempt to contact Locator Persons (3rd attempt)
  Result:_____
- ☐ Email indicating 48 hours notice of attempt to contact Locator Persons
  Result:_____

**After expiration of 48 hour notice (make up to two attempts, 1 week apart):**

- ☐ Call Locator Persons, Leave message OR email if no answer
  Result:_____

**After failure to respond from steps above:**

- ☐ Send letter "Missed Contact Letter 4.11.2014"
  Results:_____
- ☐ Call one week after letter sent. Leave message OR email (4th attempt)
  Results:_____

**Two weeks prior to 3 month assessment due if contact was lost prior to 12th week:**

- ☐ Call once to attempt to make an assessment appointment (5th attempt)
  Results:_____
- ☐ Email if no answer
  Results:_____

**Two weeks prior to 6 month assessment due:**

- ☐ Call once to attempt to make an assessment appointment (5th or 6th attempt depending on when contact was lost)
  Results:_____
- ☐ Email if no answer
  Results:_____

# Opt-IN Study: Self-Report Weight Record

**Participant ID: _____**
**Date: _____/_____/_____**
**Time: _____:_____**

The participant was not able to come in for the **3-MONTH/6-MONTH** (circle one) follow-up assessment and self-reports his or her weight as _____ lbs today. This record is to be used in place of the follow-up weight taken in the Department of Preventive Medicine Clinic.

_____

Research Assistant Signature