HealthyMe Online Weight Management Education/HealthyMe at Home (HOME)

Protocol

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5.5.2. Specific Aims
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The Institute of Medicine report on comparative effectiveness research priorities notes that "Identifying effective methods for treating obese populations could significantly improve health in this country" and gives particular emphasis to high risk populations such as the urban poor.[7] Community Health Centers provide primary care to poor, often ethnic minority, populations.[8] Community health centers provide care to 20 million persons and this is expected to grow to 40 million in less than a decade.[8] Thus, obesity treatment through community health centers has the potential to reach millions of obese, poor persons, reduce disease disparities, and, possibly, reduce health care costs.

However, community health centers are chronically short-staffed[9] and have limited space thus mitigating their potential effectiveness.[10] Alternative weight loss solutions are needed.[11-13] In an editorial on obesity, James Hill and Holly Wyatt wrote "we need research with social networks and need to embrace new technology."[14]

We have conducted successful pilot tests of a socially interactive multiparty video-conference weight loss program delivered to community health center patients in their homes using ubiquitous hardware and Internet access supplied by the project. Video-conferencing enables two-way communication, interactive on-screen displays of text and images, group discussion, and behavior modeling. Video-conferencing helps overcome many barriers to participation including transportation, childcare, and the time and cost demands of traveling to and from group meetings conducted at a central location. Using this approach a single staff person can serve patients of multiple community health centers and patients can be located anywhere with broadband Internet.

For the proposed efficacy trial we will randomize 210 adult community health center patients with body-mass index ≥30 and <50 to either an in-person weight loss program, a video-conference delivered weight loss program, or to a usual care control group. Both active intervention arms will use the same protocol of the same services delivered by the same interventionists who will be trained and monitored following a treatment fidelity checklist[5] developed from an NIH workgroup's recommendations.[4] In-person sessions will be held at community health centers, and in public community spaces such as the public library conference and meeting rooms and church class rooms; and video-conference sessions will be conducted by interventionists located in community health centers or at Regenstrief Institute with participants accessing the program from home using project supplied hardware and Internet connection. Both active interventions will include nutrition education, support group discussion, and exercise classes tailored to the needs of obese community health center patients. These intervention programs were developed using principals of social cognitive theory, and have been modified for a participant population with a range of literacy and numeracy skills. All participants will receive their usual community health center medical care.

Primary aims are to compare weight loss in the two active treatment arms to the control condition at 6- and 12-months. We hypothesize that, compared to usual care, 30% more persons in each of the active arms will have a clinically significant weight loss (≥2 kg) at 6-months, and will maintain this weight loss at 12-months. We consider 2 kg a minimally clinically significant weight loss based on sound evidence that a 2 kg weight loss is associated with a 20% reduction in the 3yr risk of hypertension[15] and a 32% reduction in the 3yr risk of type 2 diabetes.[16]

Secondary aims are: 1) to compare the costs of the two active treatment arms and their cost-effectiveness to usual care, 2) to compare the two active treatment arms to the usual care arm in health outcomes (health-related quality of life, blood pressure, waist circumference) and 3) to assess processes of change (social support, enjoyment, attendance, nutrition literacy, self-efficacy, energy expenditure, and energy intake).

Summary of Impact: 1) Multiparty video-conferencing has the potential to become a new, more effective way of delivering behavioral interventions to a much wider base than is possible with in-person sessions. Access to video-conference weight loss resources could substantially reduce the opportunity costs of weight loss participation for all persons. 2) Our proposed work could form the foundation for a longer term trial in a more geographically and socially diverse sample. 3) This work could result in a cost-effective weight loss intervention that could be widely disseminated through either or both community health centers and broadband Internet. Our study will be conducted in community health centers operated by the 3rd largest safety-net health system in the U.S. Through the National Association of Public Hospitals and Health Systems this safety-net

system has the capacity to facilitate dissemination of model programs throughout the country and is currently doing so with recently developed care models.[17]

5.5.3 (a). Significance

a.1. Obesity disparities may be related to unequal access to resources. Obesity rates are higher among lower socioeconomic status and minority groups[13, 18] and disadvantaged subjects, particularly African-American women, have been less successful in weight loss interventions.[19-23] Culturally tailored interventions have had modest success[13, 23] leading some experts to conclude that unequal access to resources is a main factor in disparties.[11-12] In in-depth home interviews, we have heard lower income persons verbalize this hypothesis themselves.[24] In fact, it has been hypothesized that attention to information and counseling without attention to resource disparities will lead to even greater socioeconomic and ethnic disparities in obesity.[11-12]

a.2. Attendance and physical activity are critical to weight loss success. Both the Pounds off with Empowerment (POWER) trial [25] and the Weight Wise trial[26] adapted the core of the Diabetes Prevention Program (DPP) for delivery to lower income persons. Mean weight loss was 2.7kg to 3.7kg at 6 months but 63% (Weight Wise) and 27% (POWER) of participants attended one-half or fewer intervention sessions. In both studies, a strong relationship between attendance and weight loss was observed. Similarly, in the ongoing multi-site Look AHEAD trial, individuals in the highest quartile of program attendance were five times more likely than those in the lowest quartile to meet the 12-month, 7% weight loss goal.[21] And, the odds of reaching weight loss goal were nine times greater for persons in the highest vs. lowest quartile of physical activity minutes.[21] Similar findings have been reported elsewhere.[23, 25-29] Key goals of the proposed intervention are to improve opportunities for physical activity and reduce barriers to attendance.

a.3. Broadband Internet is rapidly becoming available and affordable. Although building an intervention for disadvantaged communities based on broadband Internet may at first seem counterintuitive, broadband is available in most all urban areas whereas resources such as gyms, community meeting rooms, transportation, comfortable weather, etc. are often limited or do not exist.[30-31] Currently 42% of lower income households,[32] 52% of African-American, and 47% of Hispanic households (English and Spanish speaking) have a home broadband Internet connection.[33] Internet access rates for low income people and minorities are growing by 10% per year [34] and the federal government has dedicated billions to broadband growth. On March 17, 2010, the FCC delivered a National Broadband Plan to Congress to bring greater high-speed Internet availability to improve education, energy, and health care. The FCC plan calls for Internet broadband to become a universal service like the telephone system of old. FCC objectives include: 1) broader adoption and innovation in e-care technologies, 2) assigning airwaves for reduced cost or free broadband service, and 3) service in 90% of U.S. homes. Thus, the proposed intervention will become increasingly relevant and applicable over time.

a.4. Importance of keeping food diaries. The number of food records (diaries) kept is often correlated with weight loss [23, 26, 35] but the process of keeping food diaries is challenging for persons of lower health literacy. Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand health information[36] and is closely related to more general forms of literacy.[37] Among lower literacy populations, food records can be difficult to keep due to linguistic, graphic, and particularly numeric skills required for reading, measuring, calculating, and recording. A translation of the DPP in medically underserved urban locations found considerable resistance to and inaccuracy in recording fat grams and calories.[38] Among obese community health center patients in one of our prior studies, 81% tested inadequate in health literacy based on the New Vital Sign (NVS).[39,40] In reviewing audio-tapes of the administration of the NVS, it was clear that numeracy was a limiting factor—enough so that many subjects would not attempt the math required to answer the questions. There is emerging evidence that numeracy contributes to racial disparities in health behaviors[41-42] and Dr. Rothman, our consultant, has found a strong correlation between literacy and numeracy skills and the estimation and measurement of portion size.[43,44] The proposed protocol provides image-based education and portion control tools.

5.5.3 (b). Innovation

b.1. Simplified, tool-based nutrition protocol. Prior trials have taught nutrition label reading and reviewed food records with participants[21, 23, 26] but persons who lack numeracy confidence or ability may need assistance and practice to apply abstract nutrition concepts. The Diabetes Literacy and Numeracy Toolkit (DLNET) developed by Dr. Rothman contains education modules and tools with image-based and color-coded information for

persons with a 4th-6th grade reading ability.[45] We have modified the DLNET to develop a nutrition and portion size toolkit for persons without diabetes. Information and tools are designed to make it easier to eat less.

b.2. Innovative use of technology to deliver intensive weight loss services. Both community health centers and broadband Internet will be key resources in health care reform[46] and trials of Internet delivered weight loss services to community health center patients are currently underway.[10, 47-48] There are significant reach[49] and cost advantages of information technology weight loss interventions[50] but, to date, IT interventions have had less weight loss efficacy than in-person.[27, 29, 49, 51-57,58] The most effective elements of interventions have been social support and interactive communication[52, 59] but current and prior IT approaches have not had live communication or social interaction. Multiparty video-conference enables live, interactive communication, group interaction, supervision, and behavior modeling without travel. A trial of multiparty video-conference for exercise in older adults showed greater attendance and better outcomes when compared to individual exercise.[60] And, a 2009 randomized trial showed that satisfaction with primary care visits was similar across face-to-face and video-conference visits.[61]

b.3. Conceptual emphasis on costs of attendance, social support, and enjoyment. Social cognitive theory (SCT) is known best for its attention to internal factors such as self-efficacy (i.e., confidence), which has been the basis for the majority of behavior change interventions.[62] The DPP and Look AHEAD interventions, for example, helped participants establish realistic goals that are achievable and thereby contribute to increased self-efficacy.[63] SCT has its roots in social learning theory, which recognizes learning as a process resulting in part from direct observation and imitation of others.[64] Dr. Noreen Clark has shown the critical roles of social support and social networks in the social cognitive model.[65-66] Social networks represent the many social interconnections an individual may have. A recent study showed that friends of an individual who had become obese were 57% more likely to become obese themselves.[67] Another study showed through a path analysis that 40% of the variance in 18-month exercise adherence was accounted for in a model with perceived social support operating indirectly via self-efficacy.[68] These data also showed that perceived social support for exercise was associated with enhanced reports of enjoyment, which was also a strong predictor of adherence.

Lifestyle behavior change has been significantly greater in interventions with more frequent staff-subject communication either face-to-face or by telephone and one-on-one or group format.[21, 25, 27, 56] The content and length of interactions has varied across these trials with no apparent effect.[69] The more frequent the interaction, the greater the behavior change[70-71] and weight loss.[25, 27]

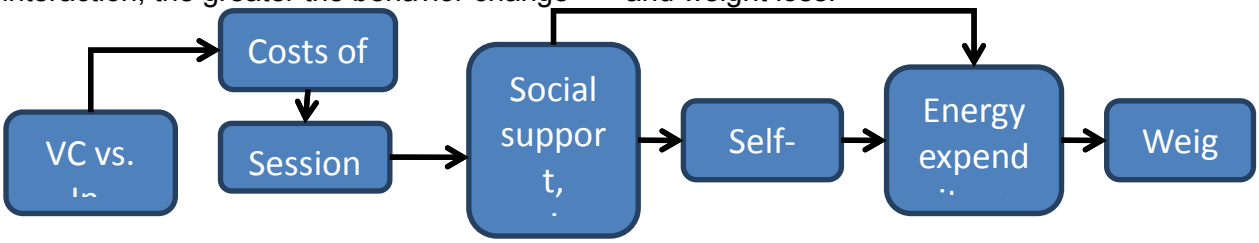

Figure 1 above shows that we are proposing to implement a program that can provide frequent social interaction and a sense of social support and enjoyment and that these will improve self-efficacy and increase performance and maintenance of weight loss behaviors. We expect this process to operate in both in-person and VC delivery arms although we expect VC delivery to reduce the costs of attendance. We will explore theoretically guided hypotheses regarding intervention mediators (see section c.22).

In sum, our proposed intervention is innovative in its use of: 1) literacy/numeracy sensitive nutrition materials and tools, 2) twice weekly social interaction, physical activity, and education, and 3) multiparty video-conference. Multiparty video-conference is an innovative and potentially cost-effective strategy that may overcome many barriers to weight loss participation for urban poor adults cared for in community health centers while also potentially preserving the critical elements of social interaction and support.

5.5.3 (c). Approach

c.1. Overview. Obese community health center patients will be randomly assigned to either in-person or VC weight loss program, or to a usual care control condition. The content and staff will be identical across active treatment arms. The primary aim is to compare weight loss outcomes in VC and in-person arms to usual care.

Before presenting details of the proposed trial, we present our trial experience, recruitment of minority and socioeconomically disadvantaged persons, intervention development and implementation experience in community health centers, and video-conference pilot work. We have organized a team with complementary expertise. Drs. Clark, Weiner, Marrero, Miller, and Stevens all have experience directing large study teams. Drs. Clark, Weiner, Marrero, Morrison, Keith, and Li all have office space in the Health Information and Technology Sciences building on the Indiana University School of Medicine campus. Drs. Stevens, Rothman, and Mauskopf will participate in study meetings via teleconference and will travel to Indianapolis multiple times throughout the study. Drs. Rothman and Mauskopf have an ongoing working relationship through another project and the Indiana faculty has ongoing working relationships that span from four to 17 years.

c.2. Trial Experience. Dr. Clark has worked with multidisciplinary teams in the completion of several recent randomized trials among primary care patients, including behavioral interventions for medication adherence in hypertension[72] and congestive heart failure[73] and clinical interventions in the collaborative care of elders.[74] As noted earlier, Dr. Weiner has experience with a video-conference trial.[3] Dr. Stevens has been a leader of a number of large behavioral weight loss trials, including PI of the coordinating center for the weight loss maintenance trial.[35, 50] He was also PI of the coordinating center for the PREMIER trial, which assessed the effects of weight loss and dietary change on hypertension.[15] Dr. Marrero has decades of experience in behavioral interventions and was the Indiana University (IU) site PI of the DPP. The IU DPP site recruited 192 subjects (second largest cohort among 27 participating centers) with 58 assigned to the intensive lifestyle condition. For the follow-up DPP Outcomes Study, IU kept over 89% of subjects and continues to study them after 15 years. Our consultant Dr. Rothman and colleagues recently completed two randomized controlled trials to test the efficacy of the DLNET.[45,75] Dr. Li is an experienced clinical trials biostatistician and Dr. Mauskopf has decades of experience in cost-effectiveness in randomized trials.

c.3. Recruitment of Disadvantaged Persons. Our research team has recruited and retained socioeconomically disadvantaged participants in a number of recent trials with careful attention to the protection of human subjects.[74, 76-77] The GRACE trial randomized 951, low income older adults to usual care or collaborative care. We completed 850 out of 951 24-month assessments.[74] The mean Rapid Estimate of Adults Literacy in Medicine-revised (REALM-R) score was 4.7.[24,74] A score of six on the REALM-R corresponds to a sixth-grade reading level, below which individuals have difficulty understanding written instruction.[78] A majority (58%) of the sample was African-American. Dr. Miller's African-American Health (AAH) project is a population-based cohort study of non-institutionalized African-Americans born between 1936 and 1950 and living in St. Louis, Missouri. There were 998 subjects enrolled in 2000-2001, with an overall enrollment rate of 76%. The AAH has completed six assessments in eight years; only 79 have refused further participation (190 have died).

c.4. Evaluation and Needs Assessments of Obese Community Health Center Patients. In an effort to further improve the reach and effectiveness of our weight loss program, our team recently completed in-depth home interviews with community health center women (n=10 African-American; n=9 Mexican-American interviews conducted in Spanish; n=11 non-Hispanic white) who were *eligible but did not participate in the TCL weight loss program*. Negative themes that emerged included: 1) exercise is pain, 2) frustration with a primary focus on education, particularly repetitious education based on food guide pyramids, and 3) strong dislike of food diaries and monitoring. As we mentioned, women had great difficulty interpreting nutrition label information as indicated by the NVS and it seemed due less to word recognition difficulty than to numeracy limitations. We also learned that, for varied reasons, it is very difficult for most of these women to get to central meeting locations. Strong positive themes were that patients wanted: 1) more discussion with community health center providers about their weight, 2) more support at home for weight management, 3) exercise options, and 4) help with portion size control.

A survey assessment of 141 obese female, English speaking community health center patients aged 40 to 64 who were non-Hispanic white (n=77) or African-American (N=64) showed that 71% have 12 or fewer years of education, 43% have inadequate health literacy, and 76% have annual household incomes of less than $25,000. In health behavior, 39% smoke, 49% have very high fat diets, and 48% have very low fruit and vegetable consumption.

c.5. Community Health Center Weight Management Program: Take Charge Lite (TCL). Dr. Clark is PI of TCL, a weight management program for obese English and Spanish speaking adults that was implemented in five

community health centers operated by Wishard Health Services.[40, 79] TCL was developed following principles of community-based participatory research and implemented as a quality improvement project. To date, TCL has provided weight loss services to over 4,700 obese patients. TCL is based on the five 'A's of behavior change counseling (for more details see http://medicine.iupui.edu/IUCAR/roybal/dissemination.asp). Our team of patient advisors, clinicians, and scientists completed multiple plan-do-study-act (PDSA) cycles in the process of adapting established protocols for local implementation of each 'A' (assess, advise, agree, assist, arrange). Written materials are simple and kept to a minimum to address low health literacy. This program has provided crucial insights for the trial proposed in this application, particularly the need to address health literacy and numeracy and the critical importance of and barriers to physical activity and program attendance.[79]

c.6. Video-Conference Pilots. As noted, our co-investigator Dr. Weiner piloted computer-enabled video-conference for clinical evaluations of patients in nursing homes.[3] We have now piloted multiparty video-conference for home-based exercise and weight loss education and discussion.

Our experience with five separate video-conference pilots—three exercise only pilots and two exercise plus education and discussion pilots—demonstrates: 1) ability of users with no prior computer experience to participate fully, 2) exercise, education, and discussion feasibility, 3) no adverse events related to the protocol, 4) high satisfaction (3.5 out of 4.0), 5) high attendance (85% to 94%), and 6) highly reliable technology.

Communication via video-conference can be described as live, interactive television. Multiple persons can be in the same conference creating a group or multiparty conference. A conference "call" is answered in a way similar to a telephone in that one hears an incoming call and "clicks" the answer button on the screen at which time one joins the conference. Everyone in the conference can hear and be heard, and see and be seen. Off-the-shelf equipment is set up wherever the participant prefers in their home. We have used several different base desktop computer models (Compaq Presario or HP 500B; $325). We attach a webcam (we used Logitech c200; $23) to the top of a 19" monitor (Asus VH192D; $109) and we use external speakers with volume control (Logitech s120; $11). The speakers can be turned up so adults who can hear a television can hear the conference session. The instructor's unit is similar but with a larger screen; we use a 40" LED model. A basic DSL or cable broadband Internet service is used for all participants (just 200 Kbps speed is needed which is well below standard DSL or cable modem speeds). There are many options for picture-in-picture views. We use a view where each subject sees a larger image of the interventionist and slightly smaller images of the other participants. Each person's name is visible at the bottom of his/her picture-in-picture image. We have tested several off-the-shelf video-conference software products, including Skype, Oovoo, Polycom, and Movi. These all work for multiparty video-conference. We will use Movi for this trial because in our experience the audio quality with Movi is a little better than with the other products. Our most recent pilot (n=6) had no technical difficulties across four weeks of twice weekly multiparty video-conference sessions; all participants used the system error free and reported high satisfaction with the exercise, education, and discussion content, audio and video quality, and usability. Our pilots have included adults with no prior computer experience and all have been able to participate fully.

In our first three pilots of video-conference among obese community health center patients, we conducted exercise classes only to establish the exercise and safety protocols. No dietary or weight loss education or discussion was completed. The number of class participants ranged from 4 to 8. All three pilots had both non-Hispanic white and African-American participants. This was a 2-day per week progressive exercise program as described in Section c.16. We ran these classes for 2 months each—16 total classes in each pilot. There were no adverse events. Overall attendance was 85%. Nine subjects completed 15 or more of 16 sessions.

Table 2. Two month physical performance outcomes in exercise via video-conference pilot study.

Measure	Baseline	2-month	Change
Chair stands in 30 seconds, mean (n=16)*	11.4	14.1	24%
Steps in 2 minutes, mean (n=16)*	74.7	97.7	31%

*Baseline values carried forward for one subject.

In a fourth pilot (n=6; 2 African-American and 4 white) and a fifth pilot (n=6; 5 African-American and 1 white), we conducted exercise (45min) followed by nutrition education and discussion (30min) twice weekly for one month. The purpose of these two pilots was to demonstrate feasibility of education and discussion following exercise and the reliability and usability of the technology. The details of the pilot recruitment, enrollment,

baseline assessment, and intervention protocol were the same as the proposed trial and are presented in Sections c.11, c.12, c.16, c.17 and c.18 below. We consented and enrolled 1 in 4 eligible patients. Attendance in both pilots was 94% (90/96 person-sessions attended). Education sessions and discussion were completed to the high satisfaction of participants. At the completion of the pilot, participants were asked what they liked or didn't like about the program in an open-ended question. The negative comments were: "better time", "earlier in the day", "more education", "increase intensity", and "include a session about support group." Positive comments were: "I love it--the girls are very detailed", "very educational and helpful", "it is at home but still other people to do it with", "community like aspect; comfortable in home and still have group in home; feel safe in home; no self-image insecurities at home", "convenience", "fellowship." Satisfaction with the program was also assessed using questions on a Likert-type scale ranging from (4) very satisfied to (1) very dissatisfied. Mean satisfaction was 3.55. No one reported that the system affected their doctor-patient relationship. All reported ease of use and total satisfaction with answering the "call" and audio and visual quality. In the fourth pilot, an electrical storm disrupted service for one class session. In the fifth pilot, there were no technical errors or difficulties.

c.8. Weight Loss In-Person. Through TCL we have conducted hundreds of in-person weight loss, nutrition, exercise and discussion groups over 4 years in five different community health centers. Community health center meeting rooms have been used for this program. Retention of coaches has been good with 4 current coaches. We have had to replace 3 coaches over the 4 years who have moved on to other things.

c.9. Overview of Experience. We have the infrastructure and experience for: 1) recruiting and retaining low socioeconomic status and ethnic minority adults, 2) running behavioral weight loss randomized trials using both the DLNET and the DPP protocols, 3) developing and operating weight loss interventions through community health centers, and 4) designing and operating video-conference interventions.

PROPOSED Design

c.10. Study Setting and Population. The setting will be community health centers located around Indianapolis—an area consisting of mainly African-American and lower income non-Hispanic white persons. We have full support of Wishard Health Services (see letter of support from Dr. Harris, CEO). The target population is English speaking patients aged 40 to 69 years without type 2 diabetes and a BMI ≥30<50. The age range is where obesity is most prevalent. We exclude persons with diabetes to avoid multiple nutrition messages for the same class (Drs. Rothman and Marrero have evolving protocols and projects for persons with diabetes that could serve as video-conference models for this subgroup). Less than 5% of the Wishard population has a BMI of 50 or higher and intensive medical interventions may be necessary for this group.[80] Exclusion criteria are modeled after weight loss trials under way at this time.[10, 47-48] Changing location of residence will be ok; we had one pilot participant do this. However, persons will need a physical space with utility services available.

Inclusion Criteria	**Exclusion Criteria**
EMR/Physician report: 1. Aged 40 to 69 years. 2. One or more community health center visits in the past 12 months 3. Body-mass index of ≥30<50. *Self-report:* 4. English speaking. 5. Access to telephone. 6. A residence. 7. Willingness to be randomized. 8. Willingness to have computer installed in home.	*EMR/Physician report:* 1. Current diagnosis of type 2 diabetes. 2. Any serious medical condition likely to hinder accurate weight measurement, or for which weight loss is contraindicated or could cause weight loss (e.g., cancer). 3. Cognitive Impairment based on the 6 item screener. 4. Current diagnosis of psychosis or bipolar disorder. 5. Unstable or recent onset of cardiovascular disease within 6 months or presence of congestive heart failure. 6. Illness that might be associated with weight change, such as asthma (because of treatment with corticosteroids), psychosis 7. Use of medications that might cause weight gain such as hypoglycemic oral medicines or insulin, anti-depressants, and weight loss medications. 8. One no show to a primary care visit in the past 12 months. *Self-report:* 9. Unwilling or unable to provide informed consent. 10. Receiving or plans to obtain disability insurance at enrollment. 11. Pregnant or nursing in past 6 months, or plans to become so within 12 months. 12. Enrolled in a weight loss program or member of household enrolled in study. 13. Residence outside of Marion County, Indiana(a PO box will not be counted as a Marion County address. 14. Residence relocation plans within 12 months. 15. Planned or prior bariatric surgery.

	16. Substance abuse. 17. History of treatment for eating disorder. 18. Unstable weight with loss or gain of ≥ 10% in last 3 months.

c.11. Recruitment. First, an electronic medical records review will identify initial demographic, clinic visit, medical, and BMI eligibility. Second, community health center providers will be given a list of their potentially eligible patients and asked to exclude persons they do not want approached for this study. Providers will be given a list of contraindications to exercise and asked to exclude any persons who have these contraindications. Third, potentially eligible patients will be met in person before a clinic visit or receive a telephone call from the Practice-Based Research Network (PBRN) research assistant (RA)inviting the patient's participation in the study. Those indicating interest will receive further screening at this time.

c.12. Enrollment, Baseline Assessment, and Randomization. Final screen, consent, baseline assessment, and randomization will follow the telephone screen. Baseline assessments will be completed in patients' homes, community centers, or community health centers prior to randomization. Random assignment to study arms will occur after at least three assessments have been completed. We will stratify randomization by race (we expect that all Hispanics in our sample will be white). We will also stratify randomization by Patient Health Questionnaire (PHQ) scores (a score of 10 or higher indicates major depression). The biostatistician (Dr. Li) will provide one stack of sealed envelopes for each of the strata and the research assistants will take the next available envelope from the appropriate stack. Each of the planned recruitment, enrollment, assessment, and randomization steps were used successfully in our VC pilot studies. Subjects in all arms will receive a $100 gift card for completion of the baseline and 6 month assessment. A research assistant will travel to participants' homes, inform them of their arm assignment, give them the materials, if needed, for their assignment, and take an additional weight measurement. If the first assessment occurs in community center, health center or similar location, randomization may occur at the same time as the assessment if space and staffing allows. Arrangements may be made at that time for the computer to be installed for those randomized into the video conference arm.

c.13. Final Assessment and Close-out. The follow-up assessments will be completed in patients' homes, community center, health center, or similar location 6 and 12 months after the start of the intervention. To achieve blinded final assessments, the 12-month assessment will be completed by assessors who did not carry-out 6-month assessments and only after equipment has been retrieved from the VC arm participants' homes by research assistants. Every effort will be made to retrieve equipment within 2 days of the final meeting. Compensation for completing the 12-month assessment will be a $50 gift card for subjects of all arms.

c.14. In-person Arm. Participants assigned to the in-person arm will have access to weight loss services at set times in community health center meeting rooms or in nearby community rooms in churches, community centers, SoBeFit or other similar exercise facilities and public libraries. The structure, size, goals, and content of the sessions will be the same as that for the VC group.

c.15. Video-Conference (VC) Arm. Participants assigned to VC treatment will have a windows-based desktop computer with broadband Internet installed in their home. Computers will be setup in kiosk mode and Internet browsing will not be possible. Participants are shown what they will see and need to "click" to answer the video-conference call.

c.16. Treatment Fidelity Strategies. The study will use two interventionists and each will deliver in-person and VC sessions. Detailed protocols exist and allow consistent delivery and replication of DPP sessions, modified DLNET sessions, and physical activity movements and progression. Treatment fidelity and monitoring strategies follow the NIH Behavior Change Consortium Strategies[4] and checklist[5] as detailed in the table below.

Five Treatment Fidelity Categories and Associated Strategies	**Active Arms (video-conference arm and in-person)**
1. Treatment design	
a) specify theory, content, and dose	See sections b.1, b.3, and c.17
b) specify provider credentials	Bachelor's degree in exercise science or nutrition
2. Training providers	
a) describe and standardize provider training	Trained according to revised DPP (Dr. Marrero) and DLNET (Dr. Rothman) protocols and

	physical activity (Dr. Keith) protocol; Listed investigators are very experienced in training interventionists according to their respective protocols.
b) conduct posttraining evaluations	Each interventionist will lead and be rated in 2 practice sessions (one session in-person and video-conference) with investigators as participants; investigators will independently rate and critique on dietary and behavioral recommendations and physical activity instruction; retraining as needed; rating measure based on protocol fidelity across delivery modes
3. Treatment delivery	
a) provide delivery manual and checklists	Manuals established for DPP and DLNET sessions, and physical activity protocol; procedural and safety checklists created and approved by team and IRB
b) assess provider adherence to treatment plan	Ratings of protocol compliance following method described under "posttraining evaluations" based on random, approximately biweekly evaluations of audio and video recorded sessions (digital recording of video-conference sessions is an option in Movi that we have tested; for in-person sessions we will have a digital video-camera setup for all sessions— research shows that recording-induced effects disappear after three data-gathering sessions[82-83])
4. Receipt of treatment	
a) assess subject understanding	Discussion and review of prior session lesson and homework; practice nutrition label reading
b) assess subject ability to use skills taught in the treatment	Observation of physical activity movements; nutrition and physical activity logs; New Vital Sign (NVS) test for nutrition literacy
5. Skill enactment	
a) assess subject performance of intervention outside of treatment setting	2-week accelerometry for energy expenditure and 24-hour dietary recall for energy intake (see section 5.5.3.c.19)

c.17. Weight Loss Session Content: ***Both In-Person and VC Treatment Arms***. A weight loss goal of 1lb per week will be suggested however we will not prescribe specific goals. Lasting motivation is more likely to develop when individuals set their own goals and receive support for their goals.[84-85] The primary focus is reduction in energy intake through portion control and increased energy expenditure. Very recent, high quality trials confirm that the most effective weight loss strategy is a combination of reduced caloric consumption and increased exercise.[86-87] The first five months of the intervention schedule is shown below. Lesson content is based on modified material from the DPP and DLNET and discussion groups are structured similar to Look AHEAD. Through week 19, one session per week is a DPP or DLNET lesson and the other session that week is a discussion of that lesson. At every session, exercise will fill the first 45 minutes. The sessions will take place for 75 to 90 minutes twice per week. We acknowledge the comparative high frequency of meetings but as discussed earlier trials have shown that more frequent contact leads to greater weight loss and there is no evidence that adherence is less in more frequent programs. We may have a focus group of participants that have attended at least 25% of their sessions. Participants will have completed at least 50% of the study. The focus group will be a conversation style asking questions pertaining to what could make the classes more enjoyable and ways to increase the participant's attendance.

Each week as has two sessions; first weekly session introduces a topic and second weekly session is a discussion of that topic
Every session starts with 45 minutes of supervised, group exercise; progressing to 60 minutes

Week	Session 1 Lesson Topic	Source	Session 2 Discussion Topic	Notes
1	Tip the calorie balance	DPP	Tip the calorie balance	
2	Use your plate (Dry food)	Revised DLNet	Use your plate (Dry food)	
3	Use your cup (Liquid food)	"	Use your cup (Liquid food)	
4	Being Active: A way of life	DPP	Being Active: A way of life	Add PA minutes
5	Carbohydrates	Revised DLNet	Carbohydrates	outside of class
6	Protein	"	Protein	
7	Fats and oils	"	Fats and oils	
8	Nutrition label-how to count calories	"	Nutrition label-how to count calories	Progress to 1/2
9	Nutrition label-how to count fat	"	Nutrition label-how to count fat	standing exercise
10	Nutrition label-how to count fiber	"	Nutrition label-how to count fiber	
11	Nutrition label-how to count sodium	"	Nutrition label-how to count sodium	
12	Eating out	DPP	Eating out	Progress to all
13	Snack ideas	Revised DLNet	Snack ideas	standing exercise
14	Budget shopping	New	Budget shopping	
15	Take Charge of What's Around You	DPP	Take Charge of What's Around You	
16	Social cues	DPP	Social cues	
17	Slippery Slope	DPP	Exercise/brief discussion	Progress to 60 minute
18	Stay motivated	DPP	Exercise/brief discussion	exercise class
19	Nutrition label-booster session	Revised DLNet	Exercise/brief discussion	
20	Interventionist led support/exercise		Maintenance information	

Exercise. Physical activity is critical to weight loss maintenance but obese adults often report functional limitations and discomfort with traditional exercise.[88] Thus, the initial exercise training session includes a

series of movements for which the participants remain seated. The Ratings of Perceived Exertion scale will be introduced and subjects will receive a copy. Subjects will be advised to exercise at the intensity level of five to six on a 10 point scale. For adults over the age of 40 years, moderate-intensity is five to six on a 10-point exertion scale.[89] The session includes flexibility but emphasizes muscular and cardiovascular fitness. Each exercise is performed in sets of two or three and the exercise leader counts out loud to maintain appropriate movement pace. There is a focus on proper breathing techniques and good posture and the exercise leader gives feedback and encouragement to the participants during the session. Brief interactive games woven into the exercise sessions give an opportunity for exertion checks (e.g., "talk test").[90]

In the first three weeks, exercise recommendations will be limited to participation in the supervised, seated group exercise sessions. Starting in week 4, participants will be encouraged to progress over weeks four and five to achieving a minimum of at least 60 additional (i.e., outside of class) minutes of moderate-intensity (e.g., brisk walking) physical activity per week for a total of 150 minutes. We will give subjects maps and details of exercise programs that operate throughout the city, including walking trials. In addition, the seated exercise progresses in pace each week as participants become familiar with the routine. At the end of six weeks, the exercise sessions will progress to ½ seated and ½ standing although the movements stay the same—seated movements are repeated in the standing position. At the end of 10 weeks, the exercise sessions will be standing aerobic movements (any subject who wishes to remain seated can do so). Starting in week 17, the sessions will be 60 minutes of standing exercise followed by 15 minutes of cool down and discussion. Community health center patients have progressed from seated to standing exercise in TCL program classes.

Exercise Safety. While large scale home based exercise programs have reported few adverse events,[91] we will nonetheless have a detailed plan for any potential emergencies that might occur. We have incorporated exercise program elements that are associated with lower risks of cardiovascular complications and musculotendinous injury, such as employing a warm up, flexibility exercise, using moderate intensity exercise, and a gradual progression of exercise intensity and duration.[92-93] Supervised exercise programs, even in persons with known cardiovascular disease, also have a low rate of complications[80] suggesting that the use of trained exercise instructors will also provide a margin of safety to the participants. Detailed staff and patient emergency protocols are in the Human Subjects section and a Data Safety and Monitoring Plan is provided that includes an NIH Project Officer ex officio.

DPP/DLNET Lessons and Look AHEAD Discussion Group. In weeks 1 through 18, exercise will be followed by a 30-minute lesson in the first session of the week and a 30-minute discussion of that lesson will be held in the second session of the week. This format was met with high satisfaction in our pilot trial. Subjects will receive a binder that has participant handouts clearly marked by session number. The education lesson content will follow core DPP sessions excluding nutrition lessons that will follow modified DLNET content as shown in the box above. Nutrition lessons incorporate the use of portion size tools—plate, bowl, and tumbler. Each lesson handout presents subjects with a take home message and action plans related to the content. The DPP and DLNET artwork and content have been extensively reworked to coordinate with one another, as well as self-monitoring forms and portion size tools. The coordinated DLNET, DPP and portion size tools can be viewed at http://medicine.iupui.edu/IUCAR/roybal/tools.asp.

Discussions will be carried out following the support group structure and rules of the Look AHEAD study (https://www.lookaheadtrial.org/public/dspMaterials.cfm). Action plans and take home messages from the prior session will be used in the discussion group session as a way of providing review and support, and discussion of barriers and solutions. The interventionists will lead the discussion with the goal of creating peer interaction and support. Look AHEAD training materials state that "rather than lecturing the group or interviewing individual participants, you should encourage participants to interact freely with each other; participants should pose questions to each other, offer suggestions, and share experiences."

Self-Monitoring. Many lower literacy subjects desire simplified food consumption and activity monitoring. From the first session, subjects will receive portion size tools and instruction in their use as well as supervised exercise. Self-monitoring forms will be included with the program binder but subjects will not be asked to use the activity log until after the DPP Being Active a Way of Life lesson in week 4 and will not be asked to use the food log until after the fifth DLNET nutrition lesson in week 7. In weeks 5 through 7, subjects will be asked to bring their activity logs to share with the group. In weeks 8 through 11, which cover nutrition label use,

subjects will be asked to bring their food logs to review, ask questions, and discuss at meetings. The logs will be used for behavior support and reinforcement as well as supplemental teaching.

6 to 12-month Tapered Intervention. Our maintenance schedule is modeled after the intensive arm of the POWER trial. For both intervention arms, in the 6th through 9th months we will hold twice monthly meetings and in months 10 through 12 we will hold monthly meetings. The meetings will include an exercise session, review lesson concepts from the core 5-month program, and allow subjects to discuss their successes and setbacks. Subjects will keep their binders and portion size tools and be reminded of these tools.

Session Reminder and Technical Assistance Calls. Subjects in either study group who miss a session will receive a 1 to 2-minute telephone call from an interventionist with the opening script "I missed you, is everything okay?" and the closing script "I look forward to seeing you (day and time of next session)." If persons in the VC group receive calls or visits for technical assistance, the same number of randomly selected persons in the in-person group will receive a brief telephone call with the script "I am just calling to check that everything is going okay for you in the program." All calls will be documented for subject, length, and reason.

c.18. Data Collection Procedures. Our team has decades of experience collecting field data from vulnerable middle and older aged adults. The assessors will have laptop computers with a database that is distinct from that used for monitoring safety. They will each have a scale, blood pressure cuff, and any other necessary equipment. Regenstrief Institute, Inc has two separate sets of office buildings on opposite ends of the IU School of Medicine campus. We will house assessors and interventionists in different locations. We will schedule the retrieval of study computers prior to final assessment. We will check assessor blinding by asking them to guess at subject assignment. This will allow a reporting of the extent to which assessors remained masked to assignment. Dr. Miller will lead the training of assessors. Dr. Miller will accompany each assessor to at least their first three assessments to observe procedures and review safety protocols.

c.19. Measures. All measures will be taken at baseline, 6, and 12 months. Age, gender, ethnicity, health literacy, chronic disease diagnoses, height, goals, activity plans, telephone contacts, and attendance are all recorded and captured in web tracking and electronic medical records. We will include questions about tobacco use at the baseline and follow-up assessments. At baseline, persons will also be asked to report their marital status, household size, and their weight history including frequency of weight cycling (change of 20 lbs or more) and number of previous weight loss attempts. The baseline assessment for the exercise plus nutrition education and discussion via video-conference pilots used the measures below and averaged 40 minutes. To address literacy issues, all survey measures are interviewer-administered. At the start of the intervention an additional weight measurement will be taken.

Primary Measure: Body Weight**.** We will measure body weight to the nearest 0.1 lb using the Scale-Tronix 5125 portable scale that has a capacity of 660lbs. It is accurate to within 0.1lbs. Subjects will stand flat footed, shoes removed, and light clothing. We will take two separate measurements and average the two; if they differ by more than 0.2lbs, a third measurement will be taken and the least congruent measurement dropped.

Secondary Measures: ACTIVE ARMS ONLY:

Attendance. Session attendance will be documented by visible video-conference attendance (VC arm) or physical presence (in-person arm). Research staff will keep a record of the time, date, and study subject for each session. Partial sessions will be counted based on the proportion of the session time completed.

Program Costs and Cost-Effectiveness. The one year cost of the first year of the individual-based DPP intervention was $1400 per subject.[94] The cost per subject of the group-based Weight Wise intervention was $242 over 5 months.[95] We are proposing meeting twice as frequently for 2.4 times as long. We estimate the fixed personnel and material intervention costs, whether in-person or VC, would be around $400 per subject over the first 5 months and $140 per subject over the remaining 7 months. Computer and broadband service costs add to the VC arm but clinic space and staff and subject time are likely greater in the in-person arm.

Participant and Societal Costs. Our piloted resource use questionnaire will be completed at 6 and 12 months to collect patients' costs to participate in the weight loss interventions (i.e., attendance costs). These costs include transportation costs, travel time, time off of work, and dependent care. Cost of participation will be

estimated by multiplying patients' reported time by age-appropriate national wages from the Bureau of Labor Statistics (BLS). Intervention costs consist of non-research fixed and variable costs of administering the intervention. Personnel costs will be calculated from interventionist's time logs and national median wages for registered dietitians or certified fitness instructors available online from the BLS. Space cost charges will be prorated for size of space and time in use from the clinic cost accounting system. Actual computer equipment and broadband service costs will be used. All costs will be adjusted for inflation, if necessary, using the Consumers' Price Index (U.S. city average, all items) from the BLS. The societal costs will be estimated by adding the participant costs to the clinic space, computer/broadband, and intervention staff costs to estimate the incremental costs from the societal perspective of VC vs. in-person interventions. Average intervention costs will be the sum of intervention costs divided by the number of subjects in the study group. As was done in the cost-effectiveness analyses of the Weight Wise intervention,[95] we will assume the incremental costs associated with the intervention for the usual care group are zero.

Cost-Effectiveness Analysis. Cost-effectiveness estimates will be generated; we will estimate the cost-effectiveness of each active treatment arm compared to usual care and to one another. For each comparison, the cost-effectiveness estimates will be generated by dividing the incremental costs—the difference between the costs associated with the intervention for the treatment arms—by the differential proportion achieving 2 kg weight loss at 6 months and maintaining to 12 months. Secondary analysis will use, as the denominator of the cost-effectiveness ratio, QALYs calculated by mapping from the SF-36 to the SF-6D and then to utility weights during the 12 month trial period.[96] We will use intention-to-treat analysis. Baseline observations will be carried forward for any subject not completing a 6-month or 12-month assessment. Additional sensitivity analyses will include 95% confidence limits for the estimated delivery and resource use costs and computer and broadband access costs. For the latter, we will complete an analysis in which the costs of computer and broadband access are discounted by the proportion of persons in the target age and ethnicity groups shown in the latest Pew Internet and American Life Project survey to have home computer and broadband Internet. Finally, we will estimate duration of effectiveness assuming 1) one-half of weight regained by 24 months and 2) all of weight regained by 24 months.[95] Health care costs related to obesity are substantial[97] however we do not expect significant impact on health care use or costs over a one year time frame in a relatively small sample and so health care use and costs will not be compared for the two intervention groups or for the control group.

Secondary Measures: ALL GROUPS:

Energy Expenditure and Energy Intake. *Total and Physical Activity Energy Expenditure (via accelerometry)*. We will estimate physical activity EE and total EE using the Actigraph Accelerometer We will use a 2-week period requiring at least 7 days of continuous wear Assessors will give instructions and observe the participant putting on the accelerometer. Persons may be asked to wear the accelerometer on the right wrist and will be instructed not to remove the band for reasons other than showering/bathing/water immersion. The assessor will call the next day to ask about any difficulties. At 2 weeks, the assessor will make a visit to recover the accelerometer. It is important to note that these accelerometers will not have a display for participants to view and monitor their physical activity or EE. We successfully used similar devices for one week in an exercise intervention among community health center women[66] and have ongoing experience with accelerometers in an ancillary study to the DPP Outcomes Study. *Energy Intake (via 24-hour dietary recall).* At baseline, 6, and 12 months, we will complete the 2010 National Cancer Institute (NCI) web-based 24-hour dietary recall (ASA24) during the main assessment and again two weeks later when the assessor returns to recover the accelerometer (6 total dietary recalls). The ASA24 uses voice tutorial and navigation assistance for use in persons of all literacy levels that takes 20 minutes to complete online. The ASA24 is based on the US Department of Agriculture Automated Multiple Pass Method (AMPM) instrument currently used in the National Health and Nutrition Examination Survey. The AMPM method is among the most valid approaches to dietary recall.[102] A researcher web site allows researchers to register participants, set study parameters (e.g., number of recalls, time to complete a recall), and obtain analysis files. NCI scientists have created algorithms for combining recalls to estimate "usual intake" that we will use.[103-104] The output enables computation of total EI. Importantly, participants do not view data from the ASA24. We have NCI approval and registration to use the ASA24 and have tested it with 6 obese community health center patients using a laptop computer with network card and Internet service.

Nutrition Literacy and Numeracy. We will measure nutrition label competency at baseline and 6 months using the NVS. For re-test at follow-up we will use an alternative ice cream nutrition label but all questions will

remain the same. We will also use the Subjective Numeracy Scale which correlates 0.6 and higher with objective numeracy scales and takes only a few minutes.[105-106] Dr. Rothman recently administered this to over 600 patients and found good internal reliability and strong correlation with the more burdensome WRAT-4.

Health. *Blood pressure* will be the average of two measures taken from the right arm using an automatic device after the participant has been resting 5 minutes in an upright, seated position. Waist circumference will be measured to the nearest 0.1 cm at the midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. *Health-Related Quality of Life* will be measured using the SF-36. The SF-36 is well established, both on national populations[107-108] and in our patient population.[74] Test-retest reliability has been consistently in the 0.70 to 0.85 range.[109] *Adverse Events*. An adverse event is any unwanted outcome. An adverse event is considered serious if it is life or disability threatening or requires significant medical treatment. In all study arms, both non-emergent and serious adverse events will be recorded and handled as soon as they become known to study staff. The Data Safety and Monitoring Board will address adverse events and review existing safety protocols. Note that our IRB reviewed and approved the training and safety protocols that were used for the video-conference pilots. In addition to ongoing reports, and in a distinct database, blinded assessors will document medical events as part of the assessments.

Psychosocial. *Social support for dietary and exercise behavior* will be measured using the Social Support and Eating Habits Survey and the Social Support and Exercise Survey.[110] *Exercise Enjoyment* will be captured using the physical activity enjoyment scale.[111] This scale has 18 items that range from "I enjoy it" to "It's no fun at all." Internal consistency has been around 0.9 and test-retest reliability 0.60 to 0.90. *Self-efficacy*. The Weight Efficacy Lifestyle (WEL) questionnaire asks participants to rate their confidence in their ability to control eating in different situations—negative emotions, availability, social pressure, physical discomfort, and positive activities. WEL has Cronbach alpha coefficients from 0.70 to 0.90 and has been established in seven weight loss studies.[112] Low-fat diet self-efficacy will be measured using a validated 16-item scale.[113] A 5-item, validated exercise self-efficacy scale will be used to measure confidence in ability to exercise in various situations, representing negative effect, resisting relapse, and making time for exercise.[114]

c.20. Data Management. As in our prior studies, assessors will have laptop computers with Microsoft Access software carrying the data collection instruments. Access programs allow data to be input once, response restrictions to be set, data checks that are real time, and facilitate skip patterns. The data are backed up onto the data manager's computer at each day's end. Access data will be in SAS files for editing and analyses. All computers are password-protected so they can be accessed only by authorized personnel. ASA24 data are stored on the NCI maintained site and will be merged into the local study dataset. Assessors will give collected accelerometers to the data manager for data downloads within one business day of retrieval.

c.21. Power and Sample Size. Based on evidence that a 2kg weight loss leads to a 20% reduction in hypertension[15] and a 32% reduction in type 2 diabetes over three years,[16] 2kg is a minimally clinically significant weight loss. We have drawn on weight loss data from the POWER trial which was conducted through a community health center and provided 12 month weight change data. Based on these data, we expect 40% in the in-person and VC arms and 10% in the usual care arm to achieve a 2kg or greater weight loss. The POWER trial obtained a 12 month weight measurement on 81% of randomized subjects but required a visit to the community health center for this measurement. We have achieved 90% follow-up at 12-months in our prior trials where we have conducted home assessments. Assuming 90% follow-up, we need to randomize 50 persons per arm to have 80% power to detect a difference of 30% in the proportion achieving 2kg or more weight loss at a two-sided alpha level 0.025 for the two comparisons of an intervention arm to usual care arm.

c.22. Study Limitations and Design Rationale.
This is an efficacy trial of weight loss services delivered via video-conference and in-person. We have modified protocols successfully evaluated in prior trials for ease of use in community health center populations. Piloting shows high participant satisfaction. The use of home broadband Internet has pros and cons. Many barriers to participation in the target population are addressed by this technology. But, increased broadband access and affordability as laid out by the FCC is a key for reaching socially and medically vulnerable populations. Our team elected not to limit the sample to persons who currently have home broadband because it would limit generalizability to a subset that will not exist in the years ahead. In the very near future, through video-conference and broadband Internet, a central interventionist could serve patients of multiple

community health centers located virtually anywhere in the nation. For persons with equipment and broadband service, we estimate that $400 per participant would cover the costs to run the proposed 5-month core program with a group size of eight. With health care costs for an obese adult averaging $1,429 more *per year* than for a non-obese adult[97] this may be a reasonable cost to pay. Following a successful trial of what is proposed here, future work would include tests of maintenance strategies and costs, including peer support models that have been successful in other formats.[116] Dr. Stevens' vast experience in weight loss maintenance will be critical to these next steps.