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ORIGINAL ARTICLE

Outcomes of an RCT of videoconference vs. in-person or in-clinic nutrition and exercise in midlife adults with obesity

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Summary

Objective

New communication technologies have shown some promise in lifestyle weight loss interventions but may be most effective when leveraging face-to-face communications. The study reported here sought to test whether weight loss programme attendance and outcomes are greater when offered in-person at community sites or remotely via videoconference vs. in Federally Qualified Health Centers (FQHCs). In a three-arm randomized trial among 150 FQHC adults, intervention delivery in community-sites or via videoconference was tested against a clinic-based lifestyle intervention (enhanced usual care [EUC]).

Methods

Twice weekly, a nutrition topic was reviewed, and exercise sessions were held in a 20-week programme delivered either in community settings or via videoconference. The primary outcome was the proportion of participants losing more than 2 kg at 6 (end of treatment) and 12 months in intent-to-treat analyses.

Results

Mean (SD) age was 53 years, 82% were women, 65% were African–American, 50% reported $18,000 or less household income and 49% tested low in health literacy, and mean (SD) body mass index was 39 kg m^{-2}. The proportion losing more than 2 kg of weight in the community site, videoconference and EUC groups was 33%, 34% and 24%, respectively, at 6 months and 29%, 34% and 29% at 12 months. No differences reached significance. Attendance was poor in all groups; 45% of community site, 58% of videoconference and 16% of EUC participants attended at least one session.

Conclusion

Videoconference and community-based delivery were as effective as an FQHC-based weight loss programme.

Keywords: Adults, obesity, weight loss.

Introduction

Midlife obesity – a body mass index (BMI) of 30 kg m^{-2} or higher – is associated with an increased risk of morbidity from diabetes, cancer and cardiovascular disease, stroke and dementia (1–3). Recent estimates suggest that 40% of middle-aged adults (40–59 years) have obesity (4), but these rates are up to 50% higher among U.S. adults without a high-school diploma and 50% higher among those earning $15,000 or less per year (5).

The U.S. Preventive Services Task Force recommends that health care providers offer multicomponent behavioural interventions to patients with obesity (6,7). However, behavioural weight loss programmes delivered by providers have had limited impact in terms of clinically significant weight loss among patients with obesity (8),

and clinical trials have had limited impact among lower income and minority participants (7,8). For this reason, the task force also endorses referral of patients to interventions that are structured around evidence-based behavioural models (6).

Healthy Me is a weight management programme supported by one of the nation's five largest safety-net health systems and delivered inside its Federally Qualified Health Centers (FQHCs). Healthy Me combines the complementary models of the 5A's of behaviour change counselling (9) and motivational interviewing (10) in a health coaching strategy (11). Healthy Me was specifically designed to minimize barriers to provider referrals and patient participation, which includes electronic provider reminders and referrals to in-clinic coaches. Despite this, utilization has remained low: although 40% of patients with obesity receive a provider referral, fewer than 20% have even one Healthy Me visit (12).

Pounds off with Empowerment (POWER) (9) and Weight Wise (10) were successful weight-loss trials among lower income adults willing to participate in research and to be randomized. Both adapted the Diabetes Prevention Program for delivery in lower income clinical settings. Mean weight loss was 2.7 to 3.7 kg at 6 months, but 63% (Weight Wise) and 27% (POWER) of participants attended one half or fewer of the intervention sessions. In both studies, a strong relationship between attendance and weight loss was observed (11). Similarly, Healthy Me has shown that weight loss is far greater in adults with more visits (close to zero pounds with one to five visits, and near seven pounds in those with more than 10 visits over a 12-month period) (12).

Healthy Me participants' recommendations to improve session attendance have included offering sessions during times and at locations that reduce interference with work and family caregiving responsibilities. Participants also suggested addressing environmental barriers to exercise (e.g. safety concerns and few affordable options near home) and travel-related barriers (e.g. unable to afford fuel, or feeling uncomfortable driving in traffic) (13). Given this, our team turned to telehealth and community-based delivery as potential solutions.

A number of studies have used videoconference technology to deliver health coaching interventions (14–18). In observational analyses of commercial weight loss participants, a 2017 study reported that videoconference participants were more likely to complete the 11-week programme but not more likely to lose weight (19). Most recently, a study team reported from two randomized trials (one of 25 and one of 30 adults with obesity) that those randomized to videoconference arms had significantly greater 12-week weight loss than those randomized to either in-person or usual care arms (20,21). These two trials provided individual health coaching, and the 2018 trial also provided participants with a wireless watch and weight scale. We are aware of three videoconferencing interventions focused on weight loss in adult populations that successfully provided group-based coaching (22–24). In each of these, videoconference resulted in similar or greater weight loss compared to in person. In small samples, these studies have demonstrated that videoconferencing allows two-way communication, group discussion and the ability to see and hear class facilitators and other remote participants concurrently. Videoconferencing also permits the class facilitators to deliver programming simultaneously to multiple participants who are at different locations. Most importantly, these studies provide evidence that videoconferencing can be used to address the barriers to participation described to us by participants who did not attend Healthy Me.

In a randomized trial among middle-aged FQHC adults with obesity, nutrition education and exercise supervision delivered in person at community sites or via Internet-based videoconference were tested against enhanced usual care (EUC). The in-person and videoconference sessions followed a nutrition and exercise protocol similar to the Diabetes Prevention Program but adapted for use with adults who have lower literacy and numeracy.

We hypothesized that compared to usual care, 30% more persons in each of the active arms (in-person community site and videoconference) will have a clinically significant weight loss (≥2 kg) at 6 months and will maintain this weight loss at 12 months. We considered 2 kg a minimally clinically significant weight loss based on evidence that a 2-kg weight loss is associated with a 20% reduction in the 3-year risk of hypertension (25) and a 32% reduction in the 3-year risk of type 2 diabetes.

Methods

This trial was approved by the Indiana University-Purdue University Indianapolis Institutional Review Board, registered in Clinical Trials (NCT02057952), supported by the National Institute of Diabetes and Digestive and Kidney Diseases (DK092377) and conducted from 2011 to 2016. All participants provided written informed consent. The study participants were recruited from eight FQHCs operated by Eskenazi Health, a tax-supported health system of Marion County, Indiana. Participants must have had a visit to a health care provider in one of the FQHCs within 12 months of the study, an electronic medical record (EMR) indication of age between 40 and 64 years, BMI of 30 to 50, home address within Marion County, English speaking, and a primary care provider referral to

Healthy Me (the programme described earlier). Providers granted study permission to contact participants for study screen and enrolment but did not refer or recruit patients into the study. Exclusion criteria were EMR evidence of cardiovascular event within 6 months, current diagnosis of congestive heart failure, psychosis or bipolar affective disorder, asthma or type 2 diabetes mellitus. People with type 2 diabetes mellitus were excluded to minimize the need for individualized nutrition education in the context of the group classes. Psychosis, bipolar affective disorder and asthma were exclusions due to the potential for these patients to be taking weight-affecting medications, such as antipsychotic drugs or corticosteroids. Violent criminal background, including harassment, was added as an exclusion criterion following an adverse event, which is reviewed in the discussion section.

Participants who did not have EMR evidence of the earlier conditions were telephoned by practice-based research assistants, to complete further eligibility screener. Patients were excluded if not English speaking, lacked regular access to telephone or residence, missed one or more items on a six-item cognitive screener (26), had or planned bariatric surgery, responded 'yes' to a query about eating or substance use disorder or reported were receiving disability insurance.

Randomization was carried out immediately following the baseline assessment. Due to weight loss success differences for black and white adults in many weight loss trials, randomization was stratified by race.

Participants in all three study groups had access to EUC (i.e. Healthy Me) embedded within the FQHCs (12,27). Participants randomized to EUC had access to the Healthy Me programme only.

As noted, the Healthy Me programme is structured around the 5A's of behaviour change (28) and implemented by a FQHC-employed coach (29). The EMR system creates a note to providers about a patient's Healthy Me eligibility when the patient's BMI is 30 or greater. FQHC providers may refer their adult patients with obesity to Healthy Me. Health coaches certified in behaviour change counselling and fitness instruction are present on at least 2 days per week in each FQHC. Participants can meet with coaches to have their current weight-related behaviour assessed and to receive assistance in solving problems and setting an action plan. The action plan is entered into a Healthy Me database that becomes part of the patient's medical record. Dietary and physical activity self-monitoring instruction and logs are provided. A 'passport to wellness' incentive programme gives participants points for participation that earn them modest rewards (e.g. T-shirt, coupons to purchase produce and gym trial). Healthy Me coaches stress increased physical activity, healthful food choices and portion control. If desired, patients can also meet with the FQHC dietitian for nutritional guidance. Specific weight loss objectives are not provided.

In addition to the access to Healthy Me, participants randomized to videoconference or in-person study intervention groups received a nutrition and physical activity booklet entitled, *Tip the Calorie Balance*, as well as portion-control plates. The booklet content was adapted from the Diabetes Literacy and Nutrition Education Toolkit (30)and the Diabetes Prevention Program (31). Our team obtained input from FQHC coaches and Healthy Me participants to design lessons from these toolkits that would be accessible to adults with low literacy and numeracy. We contracted with a visual-design expert to coordinate the logos, colours and shapes of the portion plates and the booklet. The custom-designed plates included pictures of vegetables (one-half plate), grains (one-quarter plate) and proteins (one-quarter plate) that were colour-matched to the *Tip the Calorie Balance* lessons.

Instructors followed the booklet content and led exercises that progressed from seated to standing, with increasing intensity. Sessions were conducted two times per week for 20 weeks. The first session of the week introduced a new nutrition lesson. The second session of the week was a discussion of participants' experiences with implementing that lesson. The nutrition lessons lasted about 20 min and were then followed by 30 to 45 min of exercise. The exercise was a multimodal routine (i.e. involved stretching, strength and aerobic exercises) developed by the team. For safety and adherence, participants' progression was determined by the research staff's assessment of participants' readiness to progress. The intention was to have participants progress to both standing and seated exercises by 6 weeks, and only standing exercises by 10 weeks. Starting in week 4, participants were encouraged to gain an additional 60 min of physical activity per week outside of the sessions. At the end of 20 weeks, the twice-weekly sessions were tapered slowly; brief discussions of nutrition, and continued exercise sessions, were provided once per week during weeks 21 to 23, every other week during weeks 24 to 39 and monthly during weeks 40 to 52.

The earlier described educational lessons and exercise protocols were not followed in Healthy Me but were identical in the videoconference and in-person arms. Participants randomized to the in-person group had the option to attend sessions with two to six other participants at community sites (e.g. a community centre). Those assigned to the videoconference group were able to participate in study sessions via Internet-based videoconference from their home, where an all-in-one Dell

desktop computer with 17″ display and cellular Internet card was set up for the 12-month study. Computers were programmed to limit uses beyond the videoconference study sessions.

Data collection

Eligibility data were obtained via EMR and telephone screener, as noted earlier. Baseline and 6- and 12-month follow-up assessments were completed in participants' homes. At each in-home data collection, weight was measured to the nearest 0.1 lb using a Scale-Tronix 5125 portable scale. Height was measured using a portable stadiometer, and shoes were removed. Participation data were collected by observation of attendance. Demographic characteristics retrieved from the EMR were confirmed during the baseline home visit, and the New Vital Sign (NVS) (32) for literacy and Patient Health Questionnaire (PHQ-8) (33) for depression were administered. At follow-up assessments, weight was measured using the same procedures and equipment as baseline. For those with a missing study weight, we used values from the Eskenazi Health EMR system if obtained within 2 months of the due date of an assessment.

Sample Size

For the determination of the sample size, we considered more than 2 kg a clinically significant weight loss, based on evidence that a 2-kg weight loss leads to a 20% reduction in hypertension and a 32% reduction in type 2 diabetes over 3 years (25,34). With weight-loss data from the POWER trial, we expected 40% of participants in the in-person and videoconference groups and 10% of participants in the EUC group to achieve a weight loss of more than 2 kg. Assuming 90% follow-up, we needed to randomize 50 persons into each treatment group to have 80% power to detect a difference of 30% in the proportion achieving weight loss of more than 2 kg, at a two-sided alpha level of 0.025 for the two comparisons of an intervention arm to the EUC arm.

Statistical analysis

Baseline participant characteristics across treatment groups were summarized using frequency and proportion for categorical variables. For continuous variables, mean and standard deviation were reported for normally distributed variables, and median and interquartile range were reported for skewed variables. Intent-to-treat analyses were performed where baseline weight was carried forward for participants with no available weight data at 6 or 12 months, assuming no weight loss. The primary outcome, proportion of participants achieving a weight loss of more than 2 kg, was compared among study groups using Pearson's chi-squared test. Analysis of variance was used to compare the mean weight loss among the three treatment groups. Secondary analyses of the weight loss outcome were performed to examine whether treatment effect varied by depression (with or without major depressive disorder) or literacy level (low vs. high). All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Figure 1 shows an enrolment flow diagram: 1,598 persons were determined by EMR scans, conducted approximately every 6 months over the course of the study period, to be potentially eligible; 420 (26%) refused to complete the screener, primarily due to lack of interest. Another 747 (47%) did not meet eligibility requirements, leaving 431 (27%) eligible. Of the 431 eligible, 281 (65%) cancelled or never scheduled a home visit. One hundred fifty (35%) completed a home visit and were consented, assessed and randomized.

Among the 150 randomized participants, mean age was 53 years, and most (82%) were women (Table 1). Two thirds reported themselves to be black or African–American. Mean years of education were 13. The median reported annual household income was $18,000. Just under one half (49%) scored below adequate on the NVS literacy test, and nearly one third (32%) had a PHQ score indicative of major depression. Mean BMI was 38.9.

Following baseline and randomization, weight measures were obtained for 136 (91%) and 126 (84%) of the participants at 6- and 12-month follow-up, respectively. Due to an adverse event unrelated to the intervention, eight participants in the videoconference group were lost to follow-up. Consequently, the percentage of participants with completed weight measures was lowest for the videoconference group; 82% at 6 months and 70% at 12 months.

Table 2 shows the percentage of participants in each treatment group achieving a weight loss of more than 2 kg at 6 and 12 months using available weight data (study or EMR value) and baseline observations carried forward (BOCF). Among participants with an available 12-month weight measurement, 32% of EUC, 32% of in-person and 49% of videoconference participants achieved a weight loss of more than 2 kg. With BOCF, these values were 29%, 29% and 34%, respectively.

A Healthy Me class was attended at least once by eight (16%) EUC participants, five (10%) in-person participants and two (4%) videoconference participants. Similarly, session participation was poor in both active

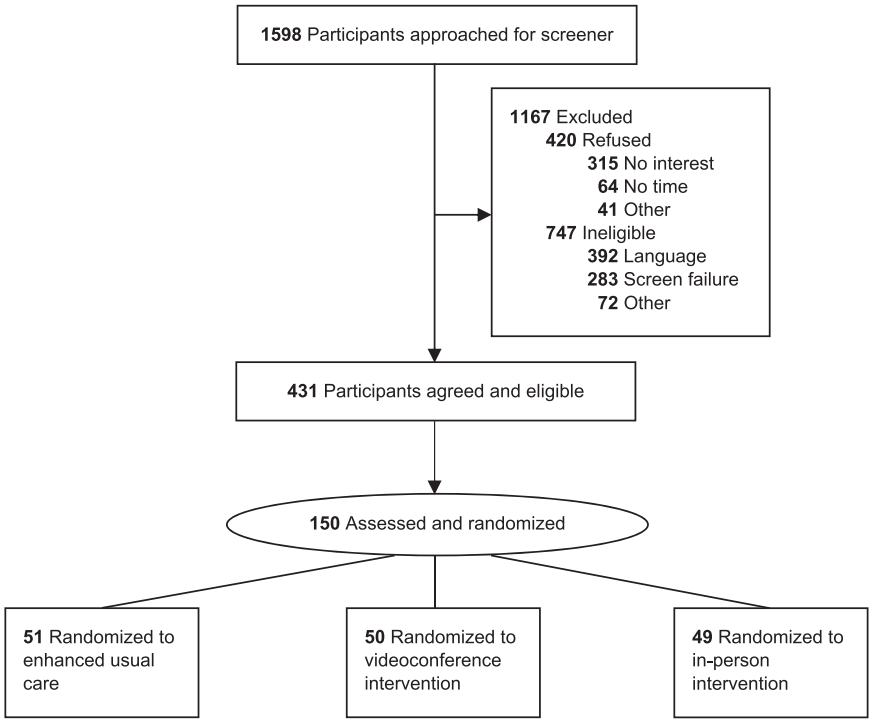

Figure 1 Flow of participants in randomized clinical trial comparing videoconference and in person interventions to enhanced usual care.

treatment groups, with 29 (58%) of the participants in the videoconference group and 22 (45%) of the participants in the in-person group attending at least one training session. Among the 29 participants with training in the videoconference group, the number of training sessions attended ranged from 1 session to 44 sessions, with a median of 15 sessions. Among the 22 participants with training in the in-person group, the number of training sessions attended ranged from 1 to 48, with a median of 19.

Given high rates of depression and low literacy within the sample, in secondary analyses, we compared weight loss by low (≤3 on the NVS) vs. adequate literacy, and PHQ consistent with depression (≥10 on the PHQ) vs. not consistent with depression. With EMR weight data included and BOCF, at 6- and 12-month follow-up times, fewer of those with PHQ consistent with depression achieved a weight loss of more than 2 kg, but this association did not differ by treatment arm. Similarly, fewer of those with low literacy achieved a weight loss of more than 2 kg, but no differences by treatment arm were significant. Finally, for the in-person arm, a weight loss of more than 2 kg was achieved by 41% at 6 months among those with any attendance and by 26% among those with no attendance. At 12 months, these percentages were 23% and 33%, respectively. In the videoconference arm, 48% of those with any attendance and 14% of those with no attendance achieved a weight loss of more than 2 kg at 6 and 12 months. The differences were not statistically significant.

Discussion

The proportion achieving more than 2 kg of weight loss at 6 and 12 months in the videoconference and community-based treatments did not differ from the clinic-based treatment (EUC) in this randomized trial among urban poor participants. Contrary to our expectations that about 10% of the EUC group would achieve a weight loss of more than 2 kg, nearly one third in the EUC group achieved the targeted weight loss. It may be important to note that mean weight change at 6 and 12 months, although not statistically significant between groups, was approximately 1.4 kg in the videoconference arm, no change in the in-person and −0.6 kg in the EUC. Videoconference and in-person treatment groups had twice-weekly access, either in person or via videoconference, to nutrition education and exercise classes. These participants also received portion plates and supportive educational materials in addition to coaching. The EUC programme classes were up to three times per week, and one-on-one coaching sessions could be scheduled as needed.

Although our study did not show a specific benefit of the remote sessions, with the caveat that study retention was lower in the videoconference compared to other

Table 1 Participants' characteristics at baseline by study group

Characteristic	Total (*N* = 150)	Enhanced usual care (*N* = 51)	Videoconference (*N* = 50)	In person (*N* = 49)
Age, mean (SD), year	53.4 (6.8)	53.9 (6.1)	53.2 (6.1)	53.2 (8.1)
Female, no. (%)	123 (82.0)	39 (76.5)	46 (92.0)	38 (77.6)
Race, no. (%)				
White (%)	45 (30.0)	14 (27.5)	14 (28.0)	17 (34.7)
Black or African–American (%)	97 (64.7)	32 (62.7)	34 (68.0)	31 (63.3)
American Indian or American Indian or Alaska Native (%)	6 (4.0)	4 (7.8)	1 (2.0)	1 (2.0)
Asian (%)	1 (0.7)	0 (0)	1 (2.0)	0 (0)
Refused (%)	1 (0.7)	1 (2.0)	0 (0)	0 (0)
Years of education, mean (SD), year	13.1 (2.2)	13.2 (2.4)	12.6 (1.7)	13.6 (2.4)
Education $<$12 years, no. (%)	19 (16.8)	7 (18.4)	7 (19.4)	5 (12.8)
Total household income in thousand dollars, median (Q1–Q3)	18 (12.9–30)	17.2 (12–44)	18 (13.6–22.5)	18 (13–26)
Waist circumference, mean (SD), cm	118.1 (13.5)	118.7 (14.5)	117.1 (10.7)	118.6 (15)
Weight, mean (SD), kg	105.5 (19.1)	107.2 (19.8)	103.2 (16.1)	106.2 (21.2)
Height, mean (SD), cm	164.5 (8.3)	164.8 (8)	163.8 (8.3)	164.9 (8.8)
Body mass index, mean (SD), kg/m^2	38.9 (5.8)	39.4 (6.2)	38.5 (5.5)	38.9 (5.8)
New Vital Sign (NVS) score, mean (SD)	3.4 (1.9)	3.8 (2.0)	3.0 (1.6)	3.3 (2.0)
Low literacy (NVS score $\leq$ 3), no. (%)	73 (48.7)	20 (39.2)	26 (52)	27 (55.1)
Self-rated health, no. (%)				
Excellent (%)	5 (3.3)	1 (2.0)	3 (6.0)	1 (2.0)
Very good (%)	8 (5.3)	1 (2.0)	3 (6.0)	4 (8.2)
Good (%)	48 (32.0)	14 (27.5)	17 (34.0)	17 (34.7)
Fair (%)	67 (44.7)	26 (51.0)	20 (40.0)	21 (42.9)
Poor (%)	22 (14.7)	9 (17.6)	7 (14.0)	6 (12.2)
SF-36 general health, mean (SD)	56.1 (19.8)	52.8 (19.0)	56.5 (21.8)	59.2 (18.4)
Patient Health Questionnaire (PHQ) score, mean (SD)	7.3 (5.6)	7.6 (6.0)	7.3 (5.3)	6.9 (5.5)
Score consistent with major depressive disorder (score $\geq$ 10), no. (%)	48 (32.2)	16 (32.0)	15 (30.0)	17 (34.7)

arms (70% vs. 90%), we also did not find that the remote sessions performed worse than on-site methods in the proportion achieving more than 2 kg of weight loss. This finding seems important because the remote option may ultimately meet some patients' needs (e.g. transportation problems) more effectively than on-site treatment. In fact, a patient preferences trial that allowed patients to choose the method best for them might yield better participation, which is a potentially useful future study. Some companies have started to market remote exercise and weight loss sessions, leveraging the flexibility of time and location as advantages. Although these products might not provide measurable clinical advantages over more conventional approaches, if the products yield similar outcomes with greater satisfaction or lower out-of-pocket costs (fuel, parking at a gym, etc.), then perhaps these should be seriously considered as a way to promote healthful behaviours while preserving or improving quality of life. Participants in these programmes and previous studies have found the videoconferencing interventions to be enjoyable and reported the technology to be relatively easy to use (24,35). Participants in these prior videoconference studies, however, were mostly white, often college educated and selected through advertisement and sometimes included meeting run-in requirements prior to randomization.

A systematic review of randomized trials conducted with primary care patients showed weight loss differences between intervention and control arms ranged from 0 to 4 kg; however, unlike Healthy Me, usual care in these trials did not approximate the Centers for Medicare and Medicaid Services definition of intensive lifestyle counselling (36). A similar review of all National Institutes of Health supported multicentre weight loss trials showed that African–American participants have lost up to 50% less weight in these trials (37). As noted, two in three of our participants were African–American, one in three had PHQ scores consistent with depression, and poverty was the norm.

We pursued videoconferencing as a pathway to improving access to weight-loss services in patients receiving care in a FQHC. By design, FQHCs are located in

Table 2 Weight loss at 6 and 12 months, assessed using available data and baseline observations carried forward (BOCF)

	Usual care	Videoconference	In person	*P* value
6 months				
No. of participants with available data	49	41	46	
Weight loss more than 2 kg				
Available data (%)	12 (24.5)	17 (41.5)	16 (34.8)	0.22
BOCF (%)	12 (23.5)	17 (34)	16 (32.7)	0.46
% weight loss relative to baseline				
Available data	−0.67 (−1.87, 0.52)	1.38 (0.06, 2.7)	0.09 (−1.17, 1.35)	0.071
Multiple imputation	−0.66 (−2.03, 0.71)	1.41 (−0.03, 2.84)	0.05 (−1.41, 1.50)	0.11
Mixed model	−0.67 (−2.05, 0.7)	1.26 (−0.23, 2.75)	0.08 (−1.33, 1.49)	0.17
≥5% weight loss relative to baseline				
Available data (%)	5 (10.2)	8 (19.5)	9 (19.6)	0.35
BOCF (%)	5 (9.8)	8 (16)	9 (18.4)	0.46
12 months				
No. of participants with available data	47	35	44	
Weight loss more than 2 kg				
Available data (%)	15 (31.9)	17 (48.6)	14 (31.8)	0.22
BOCF (%)	15 (29.4)	17 (34)	14 (28.6)	0.82
% weight loss relative to baseline				
Available data	−0.11 (−1.51, 1.29)	1.59 (−0.45, 3.62)	−0.41 (−2.2, 1.39)	0.24
Multiple imputation	−0.22 (−1.60, 1.17)	1.81 (0.32, 3.31)	−0.44 (−1.95, 1.06)	0.062
Mixed model	−0.25 (−1.64, 1.14)	1.64 (0.08, 3.2)	−0.43 (−1.86, 1)	0.11
≥5% weight loss relative to baseline				
Available data (%)	7 (14.9)	8 (22.9)	6 (13.6)	0.55
BOCF (%)	7 (13.7)	8 (16)	6 (12.2)	0.92

disadvantaged communities and must serve patients regardless of their ability to pay. Obesity in the urban poor is a crisis that the Institute of Medicine identified as a high priority for research (38), but engaging members of this population in lifestyle-oriented weight-loss behaviours involves significant challenges. Both the videoconference and community-based in-person interventions of our trial had very limited participation as did Healthy Me. The POWER and Weight Wise trials noted earlier also had low attendance. The primary barrier reported by staff and participants was participant availability for scheduled sessions. Sessions had to be scheduled to meet the availability of four to six participants and a coach. This resulted in times that were not ideal for some, but this is also a population with very frequent situational difficulties and schedule changes due to work, family and living arrangements that are not under their control. Periodic homelessness and food insecurity are serious issues; one in five participants reported 'often', and another one in five reported 'sometimes', to the question, 'How often in the past 12 months did you worry that your food would run out before you had money to buy more?' Participants often experienced food shortages in the latter half of a month as that month's money was running out. Food and housing insecurity, variable employment and work schedules, and caregiving needs in this population are often accompanied by emotional difficulties like depressive symptoms. For these most vulnerable, better engagement in health-focused lifestyle programmes likely requires concomitantly addressing living situations and security, as well as socio-emotional factors. As noted, we had one adverse event in the videoconference group. We classified this as a serious event unrelated to the intervention: the participant threatened study staff and other participants with violence. Over one dozen recorded messages including threats to staff and others were investigated by police, and the participant was prosecuted for harassment. As it turned out, this participant had a violent criminal record. This event resulted in a 1-month suspension of the study and the determination IRB that the study participants exposed to this event must be withdrawn. The study team had multiple discussions regarding what likely was a rare event, including discussions with university legal staff and health system administrators. Two changes were made: (1) prior criminal prosecution was added as a study exclusion criterion, and (2) a group 'ground rules' contract was developed for all participants to sign prior to randomization. The contract included instructions to listen to others, use kind words, have clean dress and language, turn off televisions and radios and not to talk on a telephone while in videoconference. The contract also made clear that two reminders would be followed by dismissal from the group. No further significant disruption issues were experienced.

A major limitation of this trial was low and uneven completion of follow-up assessments among treatment groups, partly due to the earlier event that excluded six videoconference participants from further participation. In most cases, we were able to supplement missing weight measurements with EMR values. Another limitation was the poor participation in the interventions due, in part, to a lack of attention to social and emotional factors and the fixed scheduling of the intervention sessions. Strengths of this trial included studying a vulnerable target population and testing an innovative intervention that addressed common, practical challenges for the target population.

We did provide a dell all-in-one desktop computer ($240) and Internet service ($41/month) for the 6-month trial. However, in the time since the trial began, Internet access via desktop computers has been largely supplanted by mobile devices, including in minority and low-income populations (39). We are now testing a customized mobile application that is tailored to an individual's daily routine which sends timely supportive messages created by the participants, coaches, health providers or family (40). We are optimistic that mobile interventions such as this will be helpful to urban poor adults with obesity, but we also know that lifestyle health interventions in this population must include attention to basic needs such as emotional, housing and food support. Geisinger, for example, is providing home-delivered meals with food education in its Fresh Food Farmacy trial (41). Similarly, we have a pending proposal in which we would work with Eskenazi Health to provide its home delivered meals to obese adults. We anticipate that future obesity trials in those living in poor households and communities will more aggressively address basic needs.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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