Supplemental materials for

Jay MR, Wittleder S, Vandyousefi S, et al. A Cluster-Randomized Study of Technology-Assisted Health Coaching for Weight Management in Primary Care. *Ann Fam Med*. 2024;22:392-399.

Supplemental Appendix:

Randomization: Randomization was stratified by healthcare systems (MMG and VA) and on number of care teams. This results in three "stratum:" the VA, MMG facilities with a single primary team, and MMG facilities with more than one primary care team. Within each stratum, block randomization was performed to ensure balance in treatment arms. For the VA and MMG sites with more than one primary care team, this involved blocks of size 4. Because the number of teams within strata were not always divisible by 4, teams within "incomplete" blocks were randomized with equal probability to study arms. Due to a limited number of randomization units at two of the MMG facilities that had one primary care team, these facilities/teams were randomized to separate arms to ensure balance of clinic size in each arm.

Presence of physicians and patients who had participated in GEM pilot study: We did not exclude PCPs or patients who had participated in the GEM pilot study [1] two to three years prior to the current study. In the pilot study, physicians had received a 20-minute training on the 5As model, and their patients were randomized to GEM vs. Control. Eight providers in this study also participated in the GEM pilot study –five providers in the GEM intervention arm (with 65 patients recruited into this study) and three providers in the EUC control arm (with 48 patients recruited into this study). Two of the patient participants (one in GEM and one in EUC) had participated in the pilot two to three years prior to enrollment in this current study.

Patient Inclusion and Exclusion Criteria:

Patients had to meet the following eligibility criteria: (1) 18-69 years of age; (2) BMI $\geq$ 30 kg/m^2 (obesity) or $\geq$ 25 kg/m^2 (overweight) with a weight-associated co-morbidity; (3) at least

one primary care visit in the prior 24 months; (3) telephone access; and (4) able to travel for in-person visits at baseline, 6-, 12-, and 24-month follow-up visits. We excluded patients who:

- Had a medical condition that could affect study participation or outcomes or who had a condition for which weight loss is contraindicated. These included metastatic cancer in the last 6 months, current chemotherapy or cancer treatment, active psychosis, psychoactive substance use, Parkinson's disease, or a health condition that may prohibit the patient from walking or physical activity such as chest tightness, a heart condition, or severe arthritis, or who had active psychosis or cognitive impairment that would keep them from being able to participate)
- Had participated in an intensive weight management program in the past year
- Had diabetes (because they were not eligible to attend the Diabetes Prevention Program (DPP) at Montefiore)
- Were enrolled in a weight loss study within the past year
- Were unable to read at the 5^{th} grade level (self-reported)
- Were unable to travel to study visits or receive telephone calls from health coaches.
- Did not want to lose weight
- Had a primary care provider that informed the research team prior to outreach that they should not participate
- Had a current prescription for anti-obesity medications to lose weight or antipsychotic medications
- Had a history of bariatric surgery
- Were ineligible for the MOVE! or Montefiore's DPP program (of note, the DPP program waived the requirement to have prediabetes for study participants).

Sample Size and Power Analysis Supplement:

We calculated the anticipated power we would have for the exploratory outcomes. Under this sample size, we would have at least 84% power to detect our hypothesized difference of 15% of GEM Intervention patients achieving clinically significant 5% weight loss [2,3], assuming 12% of patients in the EUC control arm achieved a 5% loss [4], using a two-sided chi-square with a significance level of 5%. We would also have at least 84% power to detect a hypothesized difference of 2.9-cm change (SD=7.7 cm) in waist circumference between two arms, using a two-sided t-test with significance level 5%. All outcomes were powered for and assessed under a two-sided hypothesis test framework. This decision was made for two reasons: (1) while we suspect that the GEM intervention would result in greater weight loss compared with EUC, we wanted to be able to detect any difference (positive or negative) in our analyses; (2) the two-sided test (as conducted) is more conservative in detecting positive effects than a one-sided test with the same type-I error rate. Power analyses were conducted in Microsoft Excel and confirmed using R (version 4.2.1). To account for within-clinic and within-provider clustering, sample size estimates were inflated based upon the variance inflation factor.[5]

Description of Goals for Eating and Moving (GEM) and Enhanced Usual Care (EUC) Intervention Arms

GEM Intervention Description**.**

After an initial pilot study at the VA,[1] the GEM intervention was adapted for use at the Montefiore Medical Center sites and with Spanish-speaking patients.

GEM Tool and Baseline Health Coach Counseling: At baseline, patients completed the GEM tool, an online software program delivered on tablet computers designed to facilitate goal setting and health coach counseling. The tool was designed to support 5As counseling (Assess, Advise, Agree, Assist, Arrange). [6,7] Using a 16-item survey, it assesses weight loss goals, dietary and physical activity behaviors, barriers to weight loss, and interest in various weight management resources. The tool was completed in about 20 minutes with the help of the health

coach, who then utilized an individualized GEM tool report and motivational interviewing to facilitate SMART goal setting, [8] and address barriers for approximately 30 minutes. The GEM tool also provided a report that was pasted into the electronic health record (EHR) to facilitate communication with the PCPs and health care team. Health coaches encouraged patients to attend MOVE! or DPP weight management programs and self-monitor their weight, diet, and physical activity, and referred patients to extended healthcare team members (e.g., health educators, dietitians) and/or other resources when needed, and communicated with PC providers through notes in the EHR.

Health Coaching Calls: GEM patients were then scheduled to have 12 telephone coaching calls, over the course of one year, which addressed self-reported weight and self-monitoring data, and attainment of SMART goals. Using a template, health coaches assessed self-reported weight change, health behaviors, and barriers. They used brief motivational interviewing to address barriers and help the patient set new goals as needed.

A sample coaching call schedule is shown in **Supplemental Table 1:**

Supplemental Table 1. Sample Phone Coaching Schedule				
11/16/2017 Thursday	Baseline			
11/30/2017 Thursday	call #1	2 reminder calls (3 and 1 day prior)	3 calls attempts (scheduled time, 10 and 30 minutes after)	2 rescheduling calls (1 and 3 days after)
12/14/2017 Thursday	call #2			
01/11/2018 Thursday	call #3			3 rescheduling calls (1,3, and 10 days after)
02/08/2018 Thursday	call #4			
03/08/2018 Thursday	call #5			
04/05/2018 Thursday	call #6			
05/03/2018 Thursday	call #7			
05/31/2018 Thursday	call #8			
06/28/2018 Thursday	call #9			
07/26/2018 Thursday	call #10			
08/23/2018 Thursday	call #11			
10/18/2018 Thursday	call #12			

During the course of the intervention, health coaches facilitated contact with other members of the healthcare team as needed to support weight management barriers and encourage enrollment and engagement in MOVE! or DPP. Of note, the MOVE! program was offered for the first year of enrollment as group classes at the Manhattan VA (in addition to 1:1 telephone visits) but then stopped due to low enrollment. After that, a MOVE! dietician offered the MOVE! program 1:1 via telephone to all patients enrolled in MOVE!.

Training of Health Coaches and PCPs:

Health coach and PCP training is detailed elsewhere and summarized here. [9] One full-time health lead health coach and a team of volunteer health coaches worked at each site and did not have prior formal clinical training. The volunteers worked 10-15 hours per week for a year to receive school credit and/or relevant experience. The coaches were trained for at least 40 hours to provide 5As counseling and brief motivational interviewing techniques using multimodal training techniques that included role-playing. They were trained to promote small lifestyle changes, provide empathic care, and communicate with healthcare teams. They were trained to identify potential clinical barriers and red flags (e.g. suicide ideation) where further help from the PC team and/or emergency services would be needed. Health coaching calls were recorded and regularly monitored for fidelity.

PCPs received training (30-60 minutes) prior to the start of study recruitment during faculty meetings and/or using an academic detailing approach. Training covered 1) A GEM study overview, 2) How to support participant goals and address barriers (e.g. pain, depression), 3) The role of the health coach. The PCPs were asked to discuss goals and address barriers, communicate with health coaches, and document weight counseling. They were offered at least one follow up training session within 2 years after the start of the study.

EUC (Control) Intervention Description

The EUC intervention components included weight management and general health education materials delivered by research assistants. Handouts were based on the VA-developed "Healthy Living Messages" and MOVE! program handouts on weight management that were adapted for use at the MMG sites. Topics included screening tests and immunizations, being involved in healthcare, managing stress, being tobacco-free, limiting alcohol, being safe, striving for a healthy weight, being physically active, and eating wisely. EUC patients also received information about MOVE! and DPP weight management programs. Patients in the EUC arm were advised to follow up with their healthcare teams as needed. Providers in the EUC arm received information about the GEM study aims but were not trained in weight management counseling.

Supplemental Table 2: Data Collection and Survey Measures.

Supplemental Table 2 details the measures. This was adapted from a table from the protocol paper [9].

Supplemental Table 2. Data Collection and Survey Measures

Measure	Baseline	Month 6	Month 12	Month 24
Anthropomorphic Measures				
Height	X			
Weight (BMI)	X	X	X	X
Waist circumference	X	X	X	X
Blood pressure	X	X	X	X
Weight-loss Behaviors				
Intensive program attendance	X	X	X	X
Nonwalking physical activity (IPAQ-S) (16)	X	X	X	X
Healthy dietary changes (11-14): See Description Below.	X	X	X	X
Other Measures: Covariates				
Sociodemographics (age, gender, race and ethnic group, employment, marital status, primary language at home)	X			
Food Security [10]	X		X	X

Depression (CES-D-7)[11]	X	X	X	X

Abbreviations: IPAQ-S, International Physical Activity Questionnaire short form; FBC, Food Behavior Checklist; REAP-S, Rapid Eating Assessment for Participants; LDBQ, Latino Dietary Behaviors Questionnaire; CES-D-7, Brief Center for Epidemiologic Studies Depression Scale

Description of Measures and Measurement Procedures: Weight, height, waist circumference and blood pressure monitoring procedures were adapted from the National Health and Nutrition Examination Survey (NHANES) [12] and collected by RAs, who were blinded to the patient's study arm assignment to limit measurement bias. We used standardized survey measures in both English and Spanish to assess specific dietary changes addressed by the GEM tool and health coaches including fruit and vegetable intake, [13] sweets and salty snack intake, [14,15] and changes in portion sizes and unhealthy food choices. [16] Fruit and vegetable intake of participants was measured using the Food Behavior Checklist (FBC), a scale that has been validated to measure fruit and vegetable intake in low-income, low-literacy population. [17] Sweets and salty snack intake of participants was measured using two questions from the Rapid Eating Assessment for Participants (REAP-S). [14,15] Six items from the Latino Dietary Behaviors Questionnaire (LDBQ) was used to assess changes in portion sizes and unhealthy food choices. [16]

We also assessed nonwalking physical activity using the International Physical Activity Questionnaire short form (IPAQ-SF),[18] and food security using the short form of the household food security scale.[10] A full list of measures is published.[5]

Remote Data Collection after March 2020**:**

After March of 2020, during the COVID pandemic lockdowns, we switched to remote measurement with patients, providing information via telephone. We sent all participants who had yet to complete study visits bathroom scales (Greater Goods) and a tape measure with written and pictorial instructions on how to take waist circumference measurements. RAs called participants to collect data and ensure measurements were taken properly. During this time,

blood pressure measurements were extracted from the electronic medical record when available.

Statistical Analysis Supplement:

Implementation of Mixed Effects Modelling:

We used mixed effects modeling for multivariate analyses taking into account correlation between (1) patients seen by the same providers and (2) patients seen within the same clinics. Mixed effects models were fit using the *lme4* package in R version 4.2.1. Mixed effects models included the following variables as fixed effects: sex, age, race, employment status, food insecurity, depression, year of enrollment, and indicators of whether baseline visits and final measurements occurred post-March 2020. These covariates were chosen based on their expected prognostic ability for weight change outcomes. Inclusion of variables which have prognostic ability for the outcome of interest may improve power over unadjusted alternatives.[19] We initially included random intercepts for provider teams and for clinic. After adjustment for covariates and within team correlation, there was no evidence of between clinic variability and we dropped the clinic-level random intercept in subsequent analyses. This model assumes an exchangeable correlation structure between patients within the same provider team. To account for missing observations, we used a multiple imputation by chained equations (implemented using the *mice* package in R) procedure that imputed data using predictive mean matching. The number of imputed datasets (50 datasets) was selected using a two-stage approach based upon the fraction of missing information [20]. The specified mixed effects model was fit on each of the 50 datasets and results were combined using Rubin's Rules through the *miceadds* package in R.

Adjusting for COVID 19 Effects and Sensitivity analyses:

Because weight management and many other PCMH services were temporarily discontinued during the COVID-19 pandemic, affecting 213 (43.6%) of patients, we adjusted for time effects

by (1) including indicators of whether or not outcome measurements occurred post-March 2020 in analytic models, and (2) performing stratified sensitivity analyses on patients whose 12-month outcomes occurred post-March 2020. Stratified analyses were fit using the mixed effects model described above (removing indicators of whether measurements occurred post-March 2020, as these would be equal to 1 or 0 for all units within the same strata) within strata defined by date of 12-month measurements. These stratified sensitivity analyses showed similar results to the primary analyses.

Details of Software Used for Statistical Modeling:

The following R packages were used for the multivariate models: (1) *lme4*[21] was used to estimate the mixed effects models, (2) *mice*[22] was used to perform multiple imputation with predictive mean matching, (2) *mitools*[23] and *miceadds*[24] were used to combine results of the linear mixed effects models across imputed data sets, and (4) *tidyverse*[25] packages were used in the construction of figures.

Results Supplement:

Supplemental Tables 3 and 4 detail exploratory outcomes at 6 and 24 months.

Supplemental Table 3. Adjusted changes in weight and other measurement outcomes between baseline and 6 and 24 Months.

	GEM	EUC	Difference (GEM-EUC)	95% CI Difference
Weight Change (kg)				
6 months	-0.89 (0.56)	-0.69 (1.14)	-0.2(0.65)	(-1.5, 1.1)
24 months	-0.75 (0.77)	-0.93 (1.53)	0.18(0.9)	(-1.6, 1.9)
Weight Change (%)				
6 months	-0.85 (0.56)	-0.61 (1.14)	-0.23(0.64)	(-1.5, 1)
24 months	-0.38 (0.75)	-0.71 (1.48)	0.33(0.87)	(-1.4, 2)
Proportion with Weight Loss ≥5% (%)				
6 months	13.45 (15.24)	10.73 (31.8)	2.72(17.77)	(-32.1, 37.6)
24 months	23.98 (17.13)	24.01 (35.7)	-0.04(19.98)	(-39.2, 39.1)
BMI (kg/m^2)				
6 months	-0.5 (0.33)	-0.35 (0.68)	-0.16(0.38)	(-0.9, 0.6)
24 months	-0.42 (0.44)	-0.38 (0.91)	-0.04(0.51)	(-1.1, 1)
Waist Circumference (in)				
6 months	-0.14 (3.86)	0.19 (2.74)	-0.32(1.71)	(-3.8, 3.2)
24 months	-1.48 (0.5)	-0.47 (1.04)	-1.01(0.57)	(-2.1, 0.1)
Diastolic Blood Pressure (mmHg)				
6 months	1.07 (1.31)	0.53 (2.39)	0.54(1.53)	(-2.5, 3.5)
24 months	6.15 (2.85)	4.45 (3.68)	1.7(3.23)	(-4.8, 8.2)
Systolic Blood Pressure (mmHg)				
6 months	-0.47 (1.47)	2.3 (2.54)	-2.77(1.76)	(-6.3, 0.7)
24 months	11.64 (4.51)	12.69 (4.77)	-1.05(4.73)	(-10.7, 8.6)

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; CI, Confidence Interval; EUC, Enhanced Usual Care; GEM, Goals for Eating and Moving intervention**.**

Mean (SD) of adjusted outcomes in each treatment arm are provided for continuous variables and the % in each treatment arm for dichotomous outcomes. Ninety-five percent confidence intervals for the tests that the difference in outcomes between treatment arms are equal to zero are provided.

Supplemental Table 4. Adjusted Changes In Behavioral Outcomes Between Baseline and 6 and 24 Months

	GEM	EUC	Difference (GEM – EUC)	95% CI Difference
Went to Weekly MOVE! or DPP				
6 months	15.03(32)	10.04(15)	4.99(18.39)	(-31.06, 41.04)
24 months	12.34(31)	9.87(16)	2.48(16.54)	(-29.94, 34.89)
Proportion achieving >150 minutes of Moderate to Vigorous nonwalking physical activity				
6 months	61.87(38.34)	57.28(18)	4.59(22.17)	(-0.39, 0.48)
24 months	47.23(37.51)	41.13(18)	6.1(21.6)	(-0.36, 0.48)
Change in Fruit and Vegetable consumption (cups/day),				
6 months	0.27(0.76)	-0.03(0.39)	0.31(0.41)	(-0.49, 1.1)
24 months	0.35(0.89)	0.06(0.52)	0.29(0.43)	(-0.55, 1.13)
Change in Fruit consumption (cups/day),				
6 months	0.06(0.54)	0.01(0.26)	0.05(0.31)	(-0.55, 0.65)
24 months	0.08(0.63)	0.06(0.34)	0.02(0.33)	(-0.63, 0.67)
Change in Vegetable consumption (cups/day)				
6 months	0.21(0.66)	-0.05(0.35)	0.26(0.34)	(-0.42, 0.93)
24 months	0.27(0.71)	0(0.4)	0.27(0.35)	(-0.43, 0.96)
Change in REAP-S[a]				
6 months	0.37(0.72)	0.21(0.35)	0.17(0.4)	(-0.62, 0.96)
24 months	0.47(0.61)	0.47(0.29)	0(0.35)	(-0.69, 0.69)
Change in LDBQ[b]				
6 months	3.01(2.32)	1.86(1.32)	1.16(1.07)	(-0.96, 3.27)
24 months	2.58(2.24)	2.36(1.45)	0.23(0.96)	(-1.67, 2.12)
Change in minutes of Moderate to Vigorous nonwalking physical activity per week				
6 months	31.28(42.01)	4.2(21.15)	27.09(37.01)	(-47.14, 101.32)
24 months	-102.08(113.1)	-161.74(77.13)	59.66(42.66)	(-25.91, 145.22)

Abbreviations: CI, Confidence Interval; DPP, Diabetes Prevention Program; EUC, Enhanced Usual Care; GEM, Goals for Eating and Moving intervention.

Note: Mean (SD) of adjusted outcomes in each treatment arm are provided. Ninety-five percent confidence intervals for the tests that the difference in outcomes between treatment arms are equal to zero are provided.

[a] Rapid Eating Assessment for Participants (REAP-S) scores were 1=Rarely/ Never, 2=Sometimes, 3= Usually/ Often and were based on two questions about the frequency of sweets and salty snack.

[b]Latino Dietary Behaviors Questionnaire (LDBQ) subscores ranged from 0 to 24 and were based on a 6-item questionnaire concerning frequency of eating behaviors in several domains. Scores for questions about fried foods, regular white rice or white bread, soft drinks or soda pop were 6=never, 5=less than once a week, 4=about once a week, 3=2–5 times per week, 2=about once a day, and 1=2 or more times per day. Scores for portion control and change to make healthier choices were 1=Rarely or never, 2=Sometimes, 3=Many times, and 4=All of the time. Scores for frequency of eating at restaurants were coded as 1=3 or more times per month, 2=2–3 times per month, 3=1 time per month, and 4=Almost never or less than 1 time per month.

Supplemental Figure 1 shows percent weight loss at 6-, 12-, and 24-months in the GEM arm by quartile of completed health coaching calls, demonstrating that patients in the top 2 quartiles had greater weight loss.

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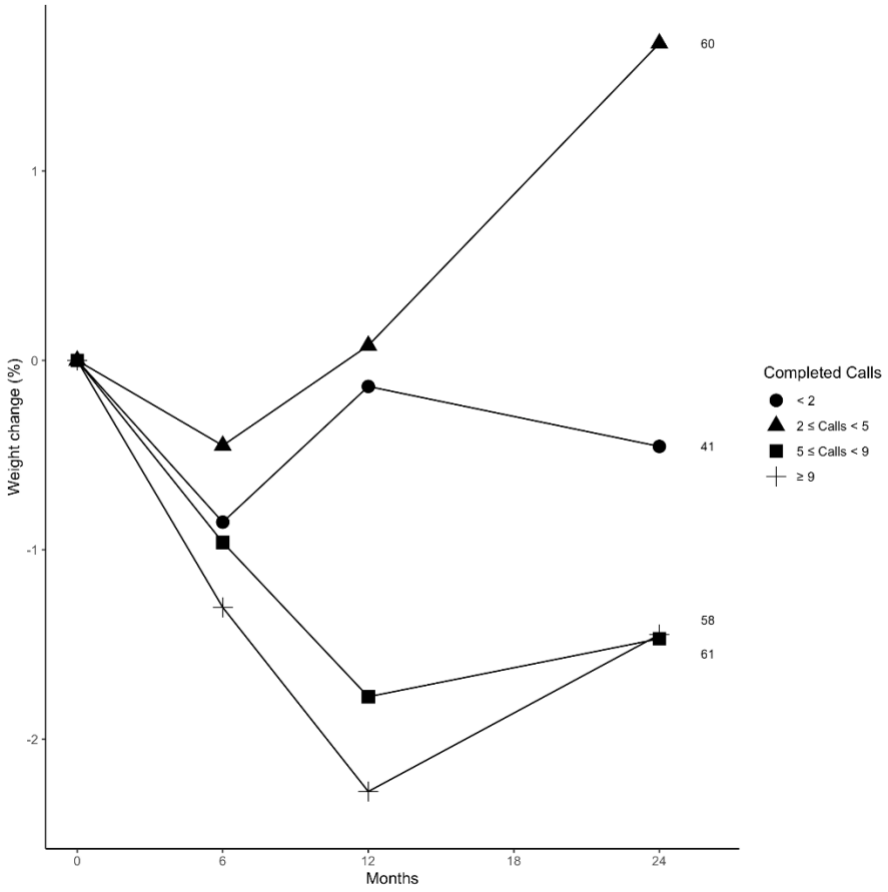
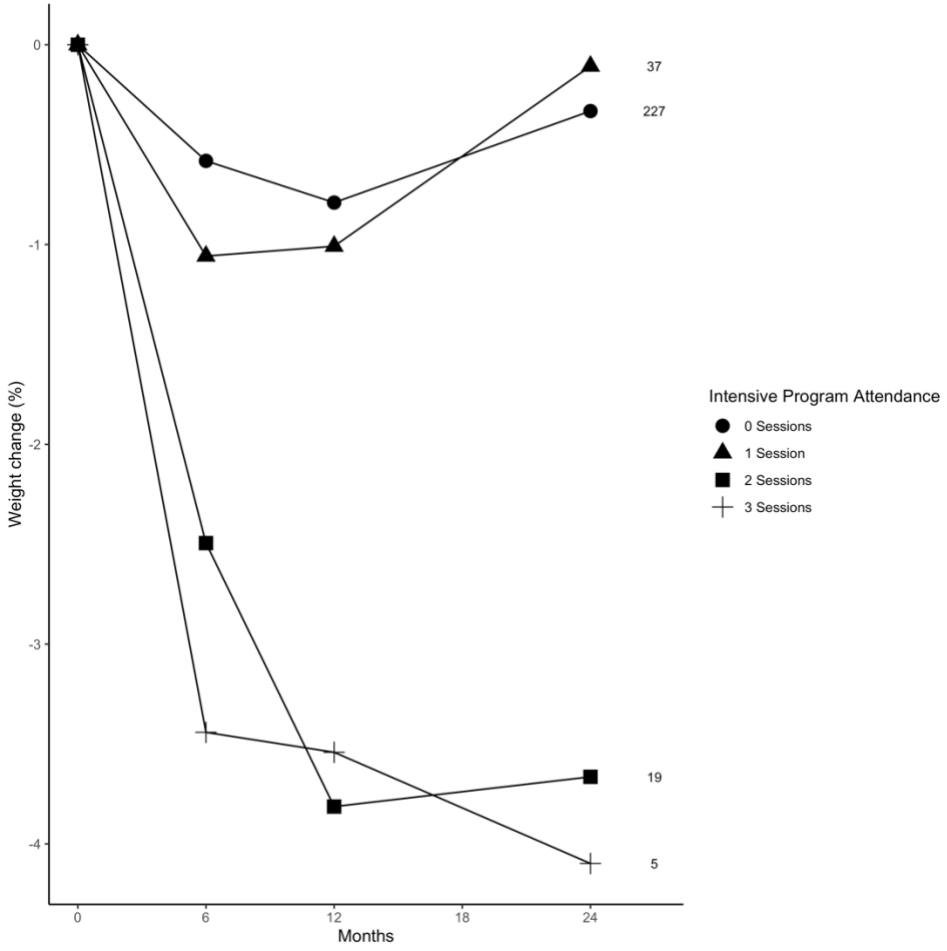
Supplemental Figure 1: Association of GEM calls with weight outcomes.



Supplemental Figure 2 shows percent weight loss at 6-, 12-, and 24-months for patients in both arms who self-reported regular weekly attendance at MOVE! or DPP programs during each 6-month period. Participants who reported regular attendance during 2 or 3 of the 6-month periods exhibited greater weight loss than those with more infrequent attendance

Supplemental Figure 2. Association of MOVE! or DPP program attendance with weight outcomes.



Missing data:

During follow-up, weight outcomes were recorded for 438 participants (89.6%) at 6 months, 418 participants (85.5%) at 12 months, and 393 participants (80.4%) at 24 months. There was slightly more missing follow-up data among participants who were seen during the COVID period (post-March 2020). At 12 months of follow-up, 16.0% of participants whose 12 month visit was after March 2020 did not record weight information, whereas 13.4% of participants whose 12 month visit was before March 2020 had missing weight information. [26]

Adverse Events:

There were 90 adverse events reported in the GEM arm and 127 adverse events in the EUC arm (p=0.19). None were coded as “definitely related” and seven were coded as “possibly related”, which occurred during physical activity (e.g., foot and wrist injuries, pain in shoulder, difficulty breathing during exercise, low sugar levels). There were four deaths, which were unrelated to the intervention (1 in GEM, 3 in EUC).

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