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Early Weight Loss Success Identifies Nonresponders following a Lifestyle Intervention in a Worksite Diabetes Prevention Trial

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Abstract

Background—People with prediabetes are at increased risk for developing type 2 diabetes. Weight reduction through lifestyle modification can significantly reduce diabetes risk. Yet, weight loss varies among individuals and some people do not achieve clinically meaningful weight loss following treatment.

Objective—Evaluate the timepoint and threshold for achieving ≥ 5% weight loss following completion of a 16-week worksite, lifestyle intervention for diabetes prevention.

Design—Weight change before and after the behavioral intervention among participants randomized to the experimental group was examined.

Participants/setting—Individuals with prediabetes aged 18–65 years with a body mass index of 25–50 kg/m^2 at Ohio State University were eligible.

Intervention—The 16-week, group-based intervention, adapted from the Diabetes Prevention Program, was delivered to 32 participants in the experimental group.

Main outcome measures—Percent weight loss was assessed weekly during the intervention and at 4- and 7-month follow-up.

Statistical analyses performed—Linear regression modeled the relationship between percent weight loss during month 1 of the intervention and percent weight loss at 4 and 7 months. Logistic regression modeled failure to lose ≥ 5% weight loss at 4 and 7 months using weekly weight change during the first month of intervention.

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Results—Percent weight loss at intervention week 5 was significantly associated with percent weight loss at 4 and 7 months (all P<0.001). Only 11.1% and 12.5% of participants who failed to achieve a 2.5% weight loss threshold during month 1 achieved ≥ 5% weight loss at months 4 and 7, respectively.

Conclusions—The first month of lifestyle treatment is a critical period for helping participants achieve weight loss. Otherwise, individuals who fail to achieve at least 2.5% weight loss may benefit from more intensive rescue efforts or stepped care interventions.

Trial Registration—ClinicalTrials.gov identifier: NCT01682954

Keywords

prediabetes; diabetes prevention; weight loss success; sensitivity; specificity; predictive value

INTRODUCTION

People with prediabetes are at increased risk for developing type 2 diabetes mellitus (T2DM).[1] Weight reduction, through lifestyle modification, has been shown to prevent or delay the onset of T2DM and reduce cardiovascular risk in at-risk individuals.[2–4] For example, the Diabetes Prevention Program (DPP) found that for every kilogram of weight loss, there was a 16% reduction in diabetes risk.[5] The 7% weight loss goal in the DPP was achieved by 49% of participants at the end of the 16-session core intervention.[6] Similarly, less than half of participants achieved the 7% weight loss goal in translational studies of the DPP.[7–8]

Prior studies found that early weight loss during an intervention predicted greater weight loss at end of treatment.[6,9–11] In one study, participants who had a mean weight loss of 0.68 kg/week lost the most weight and maintained the most weight loss at 30-month follow-up compared to participants with a slower rate of weight loss.[12] These studies contradict the belief that rapid weight loss is associated with poorer long-term weight loss outcomes.[13] Given the relation between early weight loss and treatment success, the optimal timepoint and weight loss threshold for identifying individuals who will fail to achieve significant weight loss is critical. The identification of nonresponders provides an opportunity to offer “rescue” efforts or more intensive intervention procedures. One attempt to efficiently allocate treatment resources includes stepped-care interventions, in which participants are transitioned to more intensive treatment when a less intensive treatment is insufficient. In recent research, participants who received stepped care with additional therapist contact and counseling lost significantly more weight than participants who received a standard behavioral weight loss program.[14] Despite the potential advantages of a stepped-care approach, it is not clear how early nonresponders to weight loss treatment for diabetes prevention can be identified.

Therefore, the association between early treatment response and 4- and 7-month weight change among employees with prediabetes randomized to a 16-week lifestyle intervention during a worksite trial was examined. Individuals unlikely to achieve significant weight loss by the end of the study can be identified by determining the optimal timepoint and weight

loss threshold for successful respondents during early phases of the intervention to classify early nonresponders to treatment. The sensitivity and specificity of initial weight loss efforts for predicting 4- and 7-month weight loss outcomes were determined. The sensitivity and specificity findings suggest a timeline and threshold for initiating “rescue” efforts to optimize weight loss success.

MATERIALS AND METHODS

Research Design and Participant Inclusion Criteria

A pretest/posttest research design was employed among participants randomized to the experimental group. The trial design, eligibility criteria, recruitment methods, and randomization procedures for the larger worksite trial are described elsewhere.[15] Following randomization, the experimental group proceeded through the intervention, completed a second assessment following implementation of the intervention, and completed a third assessment 3-months after the second data collection period, 7 months from baseline. Data collection began in October 2012 and was completed in May 2014.

Employees at Ohio State University aged 18 to 65 years with a body mass index (BMI) of 25–50 kg/m^2 and fasting fingerstick glucose levels of 100–125 mg/dl, indicative of prediabetes,[16] were eligible. All procedures were followed in accordance with the ethical standards of the Institutional Review Board at the University, and participants provided written, informed consent. There were no adverse effects reported by study participants.

Lifestyle Intervention

The experimental group received the 16-week Group Lifestyle Balance intervention adapted from the DPP.[2] Weekly 60-minute group sessions were held on campus and facilitated by a lifestyle coach. The intervention was goal-based with a goal of losing 7% of initial body weight, consuming ≤ 25% of energy from dietary fat, and achieving ≥ 150 minutes/week of moderate to vigorous physical activity. The first 8 sessions presented information about modifying energy and fat intake and increasing energy expenditure to promote weight loss. The last 8 sessions focused on barrier identification to achieving lifestyle goals, problem solving, relapse prevention, and motivational factors for sustaining behavioral change. Intervention staff had no contact with participants during the 3-month follow-up period.

Calculation of Percent Weight Change

Body weight was measured using a calibrated digital scale (Health-O-Meter® Professional, McCook, Illinois) with participants wearing light clothing and shoes removed. Participants were weighed at the beginning of each intervention session. If participants missed a session, they were encouraged to attend a make-up session prior to the next regularly scheduled group meeting and were weighed during the make-up session. For the purposes of this analysis, baseline weight was considered the weight at the first intervention session. Percent weight change from baseline was determined for each intervention session. For example, percent weight change for week 2 of the intervention was calculated as [(session 2 weight – session 1 weight)/session 1 weight] × 100. Percent weight change for subsequent weeks was calculated similarly. If a participant did not attend the intervention session at week 2 but was

present at both sessions 1 and 3, the average of these two weights was imputed and used as the session 2 weight. Average weights were calculated similarly for sessions 3 through 5 for absent participants. If a participant was absent for two consecutive weeks, a weighted average was imputed from the immediate prior week's weight and two weeks subsequent to the missed session using a weighted average with weights equal to 2/3 and 1/3, respectively. Participants also were weighed following completion of the intervention (4 months from baseline) and at 3-month follow-up.

Statistical Analyses

The distribution of outcomes was assessed for normality and outliers. Simple linear regression modeling and correlation analyses assessed the relation between percent weight loss at weeks 2 through 5 of the intervention and percent weight loss immediately following completion of the intervention (4 months from baseline) and at 3-months follow-up (7 months from baseline) at study end. Logistic regression modeling assessed the relation between early weight loss and percent weight loss success at 4 and 7 months. The magnitude of the relationship was measured with odds ratios and 95% confidence intervals (95% CI). Achievement of ≥ 5% weight loss at 4 or 7 months were defined as successes, consistent with the threshold often considered clinically significant and shown to be associated with significant improvement in risk for chronic disease and T2DM.[17] The probability of failing to reach ≥ 5% weight loss was modeled to identify the optimal timepoint and weight loss threshold for identifying participants at risk of being unsuccessfully treated. The threshold values chosen for early weight losses maximized the sum of sensitivity and specificity, and provided thresholds designed to evaluate diagnostic tests. Weekly estimates of the absolute and percent weight loss were computed using a mixed effects model with weeks as nominal fixed effects and subjects as random effects.

Four participant groups were created for the 4 and 7 month assessments to examine the ability of initial weight loss to correctly classify participants based upon whether they were successful or unsuccessful at achieving ≥ 5% weight loss. These four groups included: (a) true positives (TP): failed to achieve the weight loss threshold at week 5 of the intervention and at 4 months; (b) false positives (FP): failed to achieve the weight loss threshold at week 5 of the intervention but achieved ≥ 5% weight loss at 4 months; (c) false negatives (FN): achieved the weight loss threshold at week 5 of the intervention but failed to achieve ≥ 5% weight loss at 4 months; and (d) true negatives (TN): achieved the weight loss threshold at week 5 of the intervention and at 4 months. Similar groupings were created to examine percent weight loss at week 5 of the intervention and achievement of ≥ 5% weight loss at month 7 (study end). Also, similar groupings were formed based on percent weight losses at weeks 2 through 4.

Sensitivity and specificity were calculated for each model as: sensitivity (percentage of true nonresponders correctly identified as nonresponders) = TP/(TP+FN) and specificity (percentage of true responders correctly identified as responders) = TN/(TN+FP). These metrics characterize the accuracy of the predictive model. The threshold producing the maximum sum for sensitivity and specificity was chosen as the optimal cut-off value. Corresponding positive and negative predictive values (PV) were computed: positive PV =

TP/(TP+FP) and negative PV = TN(TN +FN).[18] These measures represent the precision of the predictive model at an individual level.

The area under the receiver operating characteristic (ROC) curve also was calculated, which represents the average measure of prediction success. The optimal area under the curve is 1; a random classifier has sensitivity, specificity, positive and negative PV of 0.5 and also an area under the ROC curve of 0.5.[19] All analyses were completed using the SAS statistical software package JMP version 10 (release date March 2012, SAS Institute, Inc., Cary, NC). Statistical significance was determined with an alpha = 0.05.

RESULTS

Participant demographic characteristics and the flow of participants from screening to analyses for the randomized trial are reported elsewhere.[15] Forty participants were randomized to the experimental group, and 32 had sufficient number of weekly weights recorded for the current analyses. There was no significant difference in baseline participant characteristics or body mass index (BMI) between those who did and did not complete the study (all $P > 0.05$). Participants were primarily Caucasian (78.1%) women (84.4%) who were employed full-time at the University (93.7%) and married (68.8%) (Table 1). The mean (SD) BMI of the intervention group was 35.1 (5.8) kg/m^2 at baseline. Age, gender, and BMI were not significant predictors of weight loss at months 4 or 7 and hence, were not used as predictors in this analysis.

The mean (SD) cumulative weekly weight change during the first month of the intervention for all participants combined was: week 2 (−0.5% ± 0.8%; n=32), week 3 (−1.0% ± 0.8%; n=31), week 4 (−1.6% ± 0.9%; n=31), and week 5 (−2.0% ±1.2%; n=31). Table 2 provides mixed-model based estimates, adjusted for week and subject effects, of the weekly absolute and percent weight change for participants who lost ≥ 5% weight at 4 months compared to those who lost < 5%.

There was no significant association between percent weight change at weeks 2 or 3 of the intervention and percent weight change at months 4 or 7. There was a significant association between percent weight change at week 5 of the intervention with percent weight change at month 4 (slope $\beta = 2.1$ (SE 0.46); 95% CI: (1.2–3.1); Pearson correlation $r = 0.65$) and percent weight change at month 7 (slope $\beta = 2.6$ (SE 0.76); 95% CI: (1.1–4.2); $r = 0.54$) (see Figures 1 and 2). Thus, about a 2.1% change in weight at month 4 and 2.6% change at month 7 for every 1% change in weight at week 5 is expected. Percent weight change at week 4 was significantly associated with percent weight change at month 4 ($r = 0.75$) and at month 7 ($r = 0.60$); however, these associations were not significantly different from those observed at week 5. Further, these correlations reflect large effect sizes, the threshold being 0.5.[20]

The predictive power, as seen by the sum of sensitivity and specificity or the sum of positive and negative PV, increased from week 2 to week 4 and then stabilized (Table 3). The areas under the ROC curve showed a similar pattern and were highest for weeks 4 or 5 and were in the range of ≥ 0.70. The positive PV (62–69) were moderate while the negative PV (80–

100) were high for decision rules based on week 4 and week 5 thresholds. Thus, early weight loss success was highly predictive of long-term success; the early failure was not a strong predictor of future failure.

While the optimal thresholds at week 4 and week 5 produced a similar sum for sensitivity and specificity in predicting outcomes at months 4 and 7 and similar areas under the ROC curves, week 5 produced a stable threshold of 2.5% weight loss (Table 3). With this threshold, a high sensitivity (over 90%) for predicting weight change at both months 4 and 7 was obtained. Only 7.1% of participants who failed to achieve 5% weight loss at month 4 achieved > 2.5% weight loss at week 5 of the intervention; only 6.2% of participants who failed to achieve 5% weight loss at month 7 achieved > 2.5% weight loss at week 5.

Among participants who achieved > 2.5% weight loss at week 5, 90% achieved ≥ 5% weight loss at month 4 and 89% achieved this at month 7 (Table 3). The near equal thresholds based on week 5 produced the highest, near equal, sum of sensitivities and specificities for predicting both 4 and 7 month outcomes (at 1.46 and 1.47, respectively). The corresponding sum of the sensitivities and specificities for the best thresholds based on weight loss at week 4 came close (at 1.49 and 1.40); thus, week 4 (after 3 weeks of intervention) also could be used as a potential timepoint for identifying at-risk participants for weight loss failure. However, the divergence of the thresholds, −1.7% for predicting the month 4 and −2.1% for the month 7 weight loss, makes the use of 4-week weight loss less desirable.

The odds ratio of not achieving a ≥ 5% weight loss at month 4 based upon failure to achieve an initial weight loss of 2.5% at week 5 was 14.6 (95% CI: 1.4–138.2; P=0.009), and a similar odds ratio for month 7 failure was 8.0 (95% CI: 1.3–48.2; P=0.023).

DISCUSSION

The study findings illustrate that the first month of intervention is highly correlated with and predictive of weight loss after 4 months of treatment and 3-months of follow-up. Failure to achieve a weight loss threshold of 2.5% at the beginning of week 5 was predictive of failure to achieve clinically significant weight loss. Thus, participants who fail to achieve 2.5% weight loss by week 5 of the intervention are at risk and may benefit from additional intervention while the intervention is actively underway. Furthermore, the areas under the ROC curves were fairly high (0.71 – 0.76) indicating the ability of the threshold to correctly classify participants who did or did not achieve ≥ 5% weight loss. While estimates of the odds ratio for long-term failure were large (14.6 and 8.0), the small sample size resulted in wide confidence intervals. However, the lower limits of the confidence intervals (1.4 and 1.3) were not close to the threshold value of 1.0, indicating strong evidence for successful prediction and differentiation between the two weight change groups.

The current findings are consistent with the findings from the Look AHEAD study conducted among overweight or obese adults with T2DM (n=2,294). In the Look AHEAD study, weight loss in the first two months of treatment was highly correlated with weight loss at 1-year.[21] Of those who failed to achieve 2% weight loss at month 1 of the intervention, 57.9% failed to achieve ≥ 5% weight loss at 1-year, while 77.8% of

participants in Look AHEAD who achieved 2% weight loss at month 1, achieved ≥ 5% weight loss at 1-year. When considering the current and Look AHEAD studies, the findings suggest that participants with prediabetes or T2DM who achieve < 2.0% weight loss at month 1 are at high risk for failing to achieve 5% weight loss at treatment end. The percentage of participants who achieved weight loss success in the Look AHEAD study was greater (67–70% depending on level of obesity)[22] than the percentage of participants in the current study (53%). However, the Look AHEAD intervention was longer in duration (1 year), included monthly individual counseling sessions, and provided meal replacement products free of charge.

In addition, participants who experience minimal weight loss early during a treatment program often drop out of treatment. For example, obese women in a 6-month weight reduction program who dropped out of the program (16%) experienced a 2% weight gain, on average, prior to dropping out.[23] An additional 14% of women failed to lose at least 1% of body weight by the sixth week of the intervention, and these women lost, on average, < 2% of their weight by program completion. Thus, unsatisfactory early weight loss was an early indicator of unfavorable treatment outcome and program attrition.

Additional intervention could be provided to early nonresponders to treatment. In a stepped-care approach to treatment, more intensive treatment is provided when less intensive treatments are insufficient. In a recent study, participants in a weight loss program received individual counseling in addition to the group-based intervention sessions, if they did not achieve: > 1% weight loss by week 3; > 1% weight loss between weeks 3 and 6; > 2% weight loss between weeks 6 and 12; or > 2% weight loss between weeks 12 and 18 of the intervention.[14] Participants who received stepped care counseling lost significantly more weight compared to participants who only received the group-based intervention sessions. Thus, additional intervention could be provided or alternatively, treatment could be discontinued in early nonresponders given their low likelihood of success. More research is needed, however, to identify the participants who would benefit from a stepped care approach vs. those who are not ready to engage in behavioral weight loss treatment.

Moreover, the cost of providing supplemental stepped care, or “rescue” treatment, should be weighed against the number of participants that would be reached, especially from an employer’s perspective in a worksite trial. For example, limiting the number of employees who receive stepped care unnecessarily may be of greatest interest to an employer, if the cost of the stepped care is high (i.e., false positives). However, employees who may benefit from stepped care (i.e., false negatives) would not receive it, if treatment is only provided to those who fail to meet the weight loss threshold. In contrast, if the stepped care approach is low cost, the employer may want to maximize the number of employees who receive supplemental treatment who need it (i.e., true positives) and reduce the number of employees who do not receive stepped care who might benefit from it (i.e., false negatives). Employers should consider the potential trade-off when making intervention treatment decisions.[21]

Despite the strengths of this study, several limitations should be noted. First, the sample consisted primarily of women and the weight loss thresholds may vary for a sample with a

greater number of men or among a sample that is more ethnically diverse. Second, even though the predictive findings were significant, the findings were obtained among a relatively small sample. Future research should evaluate whether the thresholds are confirmed for a study with a larger sample. Third, the study was conducted at a university worksite setting and application of the intervention to alternate worksites may result in different outcomes. Finally, whether the weight loss thresholds hold true for other translational studies of the DPP intervention beyond the worksite is not known.

CONCLUSIONS

The first month of treatment among adults with prediabetes who receive the group-based intervention adapted from the DPP may be a critical window for identifying participants at risk for poor treatment weight loss outcome at program end. Individuals with a weight loss threshold of ≤ 2.5% following the first month of intervention should be identified and potentially offered stepped care, or “rescue” treatment. Future research should evaluate whether stepped care interventions improve intervention efficacy beyond what is achieved from the DPP intervention alone, and the characteristics of participants who benefit from stepped care should be examined. Whether a stepped care approach is cost effective also warrants further investigation.

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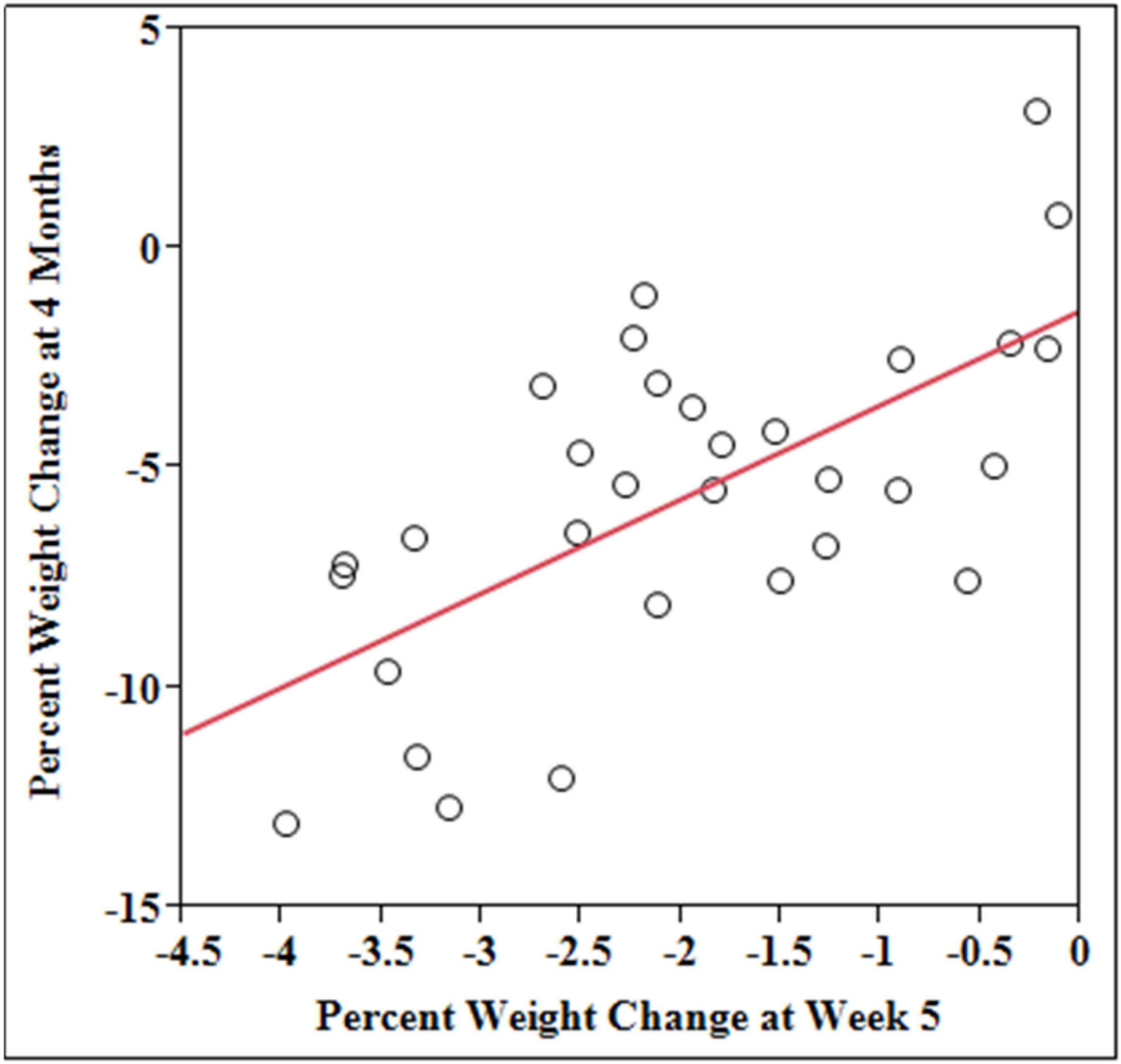

Figure 1.

The relationship between percent weight change at week 5 of the intervention and percent weight change at 4-month follow-up among employees enrolled in a worksite lifestyle intervention (n=31)

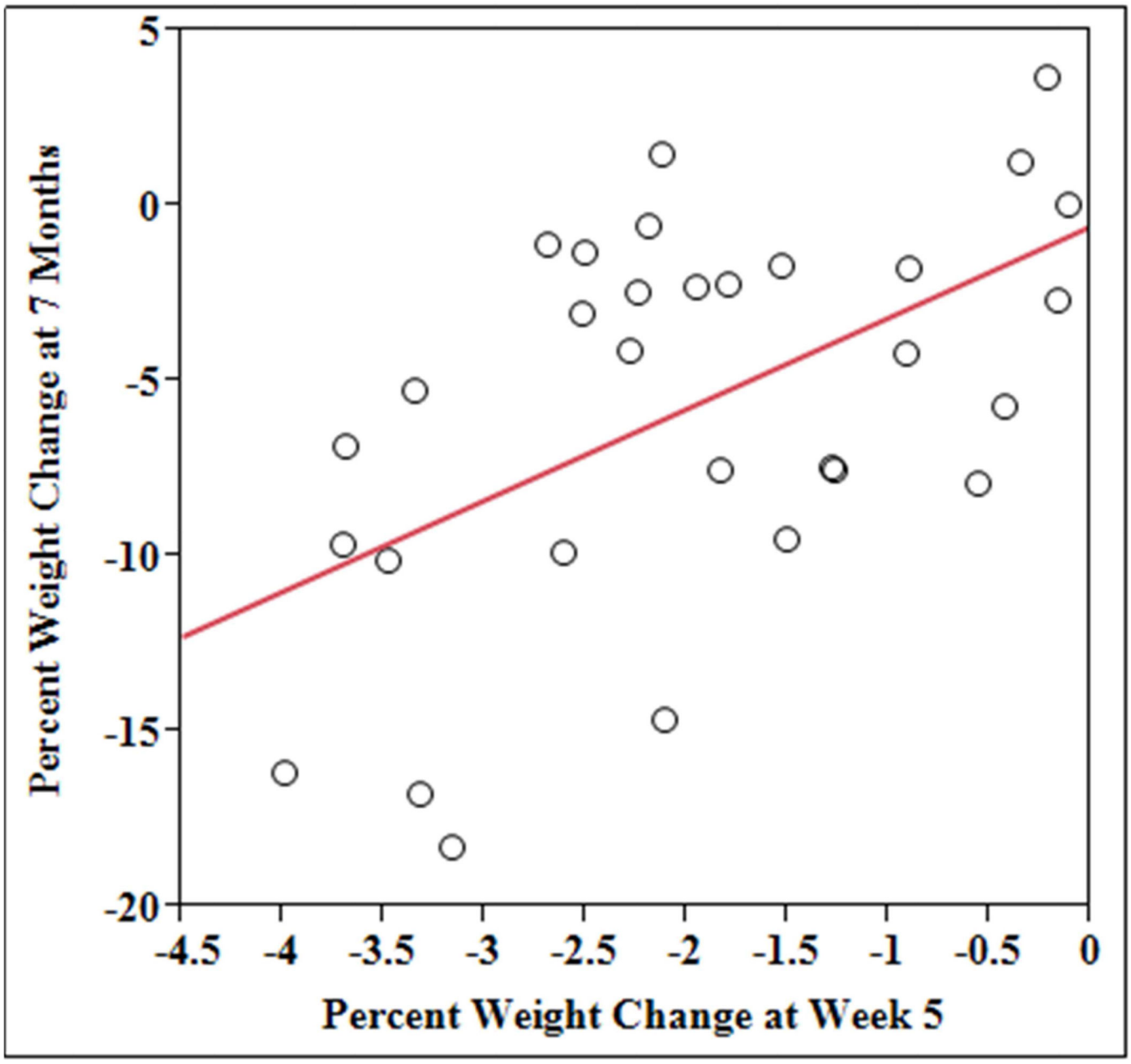

Figure 2.

The relationship between percent weight change at week 5 of the intervention and percent weight change at 7-month follow-up among employees enrolled in a worksite lifestyle intervention (n=31)

Table 1

Baseline characteristics of intervention participants with prediabetes who received a lifestyle intervention for weight loss (n=32) in a worksite trial

Characteristic	Mean (SD)
Age (years)	52.3 (9.0)
Body mass index (kg/m^2)	35.1 (5.8)
	n (%)
Race	
White	25 (78.1)
Black	5 (15.6)
Asian	2 (6.3)
Ethnicity	
Non-Hispanic/Latino	32 (100.0)
Gender	
Male	5 (15.6)
Female	27 (84.4)
Education	
Less than Bachelor's Degree	13 (40.6)
Bachelor's Degree	11 (34.4)
Advanced Degree	8 (25.0)
Employment	
Full-time	30 (93.7)
Part-time	2 (6.3)
Marital Status	
Married	22 (68.8)
Not Married	10 (31.2)
Occupation[a]	
Professional	11 (35.5)
Clerical	9 (29.0)
Other (i.e. clinical, technology, physical labor)	11 (35.5)
Years at Current Job	
1–5 years	12 (37.5)
6–10 years	12 (37.5)
11–15 years	3 (9.4)
≥ 20 years	5 (15.6)
Current Student	
No	29 (90.6)
Yes, full-time student	2 (6.3)
Yes, part-time student	1 (3.1)
Number of People in Household	
1	5 (15.6)

Characteristic	Mean (SD)
2	17 (53.1)
3	4 (12.5)
4	4 (12.5)
≥ 5	2 (6.3)
Annual Household Income[a]	
$20,000–39,999	7 (22.6)
$40,000–59,999	3 (9.7)
$60,000–79,999	5 (16.1)
$80,000–99,999	9 (29.0)
≥ $100,000	7 (22.6)

[a] One participant did not provide this information.

Table 2

Model based estimates[a] of mean weekly weight change from baseline during the 16-week intervention for participants who achieved ≥ 5% weight change compared to participants who achieved < 5% weight change at 4-month follow-up

Week	Mean weekly weight change for those who achieved ≥ 5% weight loss[b] (n=17)		Mean weekly weight change for those who achieved < 5% weight loss[b] (n=15)	
	Pounds	Percent	Pounds	Percent
2	−1.53	−0.73	−3.14	−0.47
3	−2.41	−1.20	−0.68	−0.74
4	−3.96	−1.97	−1.41	−1.11
5	−4.95	−2.44	−2.28	−1.29
6	−5.91	−2.91	−2.70	−1.80
7	−6.79	−3.31	−3.74	−1.80
8	−7.87	−3.86	−3.65	−2.11
9	−9.35	−4.55	−4.34	−1.90
10	−9.74	−4.80	−3.92	−2.22
11	−10.48	−5.14	−4.61	−2.59
12	−11.79	−5.76	−5.38	−2.88
13	−11.29	−5.57	−6.04	−2.85
14	−12.43	−6.15	−6.07	−2.87
15	−13.25	−6.59	−6.12	−3.22
16	−14.85	−7.33	−7.03	−3.14
Weight change at 4 months	−16.72	−8.16	−5.57	−2.53

[a] Estimates were based on a mixed effects model that treated absolute or percent change from week 1 as the response, weeks as nominal fixed effects, and participants as random effects.

[b] Body weight was imputed to calculate percent weight change for three participants at week 2, two participants at week 3, three participants at week 4, and two participants at week 5 of the intervention.

Table 3

Sensitivity and specificity using ≥ 5% weight loss threshold at 4- and 7-month assessment during the first 5 weeks of the lifestyle intervention among employees with prediabetes enrolled in a worksite trial

Intervention Week	Optimal Cutpoint or Threshold[a]	True Positive (TP)[b]	True Negative (TN)[b]	False Positive (FP)[b]	False Negative (FN)[b]	Sensitivity[c] (%)	Specificity[c] (%)	Positive Predictive Value[d] (%)	Negative Predictive Value[d] (%)	Area under curve[e]
Using ≥ 5% weight loss threshold post-intervention (4 months from baseline)										
2 (n=32)	−0.47	11	10	7	4	73.3	58.8	61.1	71.4	0.66
3 (n=31)	−0.47	6	16	1	8	42.9	94.1	85.7	66.7	0.69
4 (n=31)	−1.74	11	12	5	3	78.6	70.6	68.8	80.0	0.76
5 (n=31)	−2.50	13	9	8	1	92.9	52.9	61.9	90.0	0.76
Using ≥ 5% weight loss threshold at study end (7 months from baseline)										
2 (n=32)	−0.47	11	9	7	5	68.8	56.3	61.1	64.3	0.59
3 (n=31)	−1.03	11	10	5	5	68.8	66.7	68.8	66.7	0.70
4 (n=31)	−2.08	16	6	9	0	100.0	40.0	64.0	100.0	0.72
5 (n=31)	−2.51	15	8	7	1	93.8	53.3	68.2	88.9	0.71

[a] The optimal cutpoint maximizes the sum of sensitivity and specificity in predicting < 5% percent weight loss at 4 and 7 months.

[b] True positives failed to achieve the weight loss threshold at week 5 of the intervention and at follow-up. True negatives achieved the weight loss threshold at week 5 and at follow-up. False positives failed to achieve the weight loss threshold at week 5 but achieved ≥ 5% weight loss at follow-up. False negatives achieved the weight loss threshold at week 5 but failed to achieve ≥ 5% weight loss at follow-up.

[c] Sensitivity rate is defined as the percentage of participants failing to achieve ≥ 5% weight loss at the end of the specified period who are correctly identified using the initial weight loss threshold [TP/(TP +FN)]. Specificity rate is defined as the percentage of participants achieving ≥ 5% weight lost at the end of the specified period who are correctly identified using the initial weight loss threshold [TN/(TN +FP)].

[d] Positive predictive value is the percentage of participants who achieved < 5% weight loss at months 4 and 7 among participants who had initial weight loss that was below threshold [TP/(TP+FP)]. Negative predictive value is the percentage of participants achieving ≥ 5% weight loss at months 4 and 7 among participants who had initial weight loss that was above threshold [TN/(TN+FN)].

[e] The area under the receiver operating characteristic (ROC) curve is an average measure of accuracy of prediction of the diagnostic test; a perfect test has an area of 1.0.