RESEARCH
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Early Weight-Loss Success Identifies Nonresponders after 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 mellitus. 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 after treatment.

Objective Our aim was to evaluate the time point and threshold for achieving ≥5% weight loss after 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 to 65 years with a body mass index (calculated as kg/m^2) of 25 to 50 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.

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.

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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/wk 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 relationship between early weight loss and treatment success, the optimal time point and weight-loss threshold for identifying individuals who will fail to achieve significant weight loss are 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 time point 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] After randomization, the experimental group proceeded through the intervention, completed a second assessment after 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; calculated as kg/m^2) of 25 to 50 and fasting fingerstick glucose level of 100 to 125 mg/dL (5.6 to 6.9 mmol/L), which is 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 $\leq$25% of energy from dietary fat, and achieving $\geq$150 min/week of moderate to vigorous physical activity. The first eight sessions presented information about modifying energy and fat intake and increasing energy expenditure to promote weight loss. The last eight 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) 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 before the next regularly scheduled group meeting and were weighed during the makeup 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]$\times$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 2 consecutive weeks, a weighted average was imputed from the immediate prior week's weight and 2 weeks subsequent to the missed session using a weighted average with weights equal to two-third and one-third, respectively. Participants also were weighed after 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 after 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 relationship 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 (CIs). Achievement of $\geq$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 $\geq$5% weight loss was modeled to identify the optimal time point 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 on whether they were successful or unsuccessful at achieving $\geq$5% weight loss. These four groups included the following:

1. True positives (TP): failed to achieve the weight-loss threshold at week 5 of the intervention and at 4 months;
2. False positives (FP): failed to achieve the weight-loss threshold at week 5 of the intervention but achieved $\geq$5% weight loss at 4 months;
3. False negatives (FN): achieved the weight loss threshold at week 5 of the intervention but failed to achieve $\geq$5% weight loss at 4 months; and