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Evaluation of early weight loss thresholds for identifying non-responders to an intensive lifestyle intervention

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Abstract

Weight losses in lifestyle interventions are variable, yet prediction of long-term success is difficult.

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CONFLICTS OF INTEREST STATEMENT

Dr. Cheskin reported being the chair of the Scientific Advisory Board for Medifast, Inc. Dr. West is on the Scientific Advisory Board to Jenny Craig, Inc. The remaining authors have no conflicts of interest to report.

AUTHOR CONTRIBUTIONS: RN and PH had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. RJ, AK, FP, DSW, RW, LC contributed to the study design, GE-H, JN collected the data or assisted with the intervention, PH and RN performed the data analyses, and JU wrote the manuscript. All authors contributed to the discussion and interpretation of the data and reviewed and edited the manuscript.

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Objective—We examined the utility of using various weight loss thresholds in the first 2 months of treatment for predicting 1-year outcomes.

Design and Methods—Participants included 2327 adults with type 2 diabetes (BMI:35.8±6.0) randomized to the intensive lifestyle intervention (ILI) of the Look AHEAD trial. ILI included weekly behavioral sessions designed to increase physical activity and reduce caloric intake. 1-month, 2-month, and 1-year weight changes were calculated.

Results—Participants failing to achieve a ≥2% weight loss at Month 1 were 5.6 (95% CI:4.5,7.0) times more likely to also not achieve a ≥10% weight loss at Year 1, compared to those losing ≥2% initially. These odds were increased to 11.6 (95% CI:8.6,15.6) when using a 3% weight loss threshold at Month 2. Only 15.2% and 8.2% of individuals failing to achieve the ≥2% and ≥3% thresholds at Months 1 and 2 respectively, go on to achieve a ≥10% weight loss at Year 1.

Conclusions—Given the association between initial and 1-year weight loss, the first few months of treatment may be an opportune time to identify those who are unsuccessful and utilize rescue efforts.

Keywords

weight loss; behavioral treatment; lifestyle intervention

Introduction

Given the high prevalence of obesity, strategies for improving weight loss are needed (1). Currently, intensive lifestyle interventions yield an average weight loss of up to 10% at 1 year (2, 3). However, of concern is the large variability in response; with some individuals being highly successful while others lose very little weight or even gain weight from pre- to post-treatment (4, 5, 6). Baseline variables have not consistently predicted treatment weight loss. However, weight loss in as early as the first few weeks of an intervention is predictive of longer-term weight loss success (7, 8, 9, 10). In a sample of 262 obese women, individuals with the fastest rate of weight loss during the first month of treatment also had significantly larger weight losses at 6 and 18 months, compared to those with slower weight losses initially(10). Moreover, weight loss at the end of the intensive phase of lifestyle treatment predicts longer-term success (5, 11, 12). For example, in the Diabetes Prevention program, participants who achieved a ≥7% weight loss at 6 months were 3 times more likely to achieve this magnitude of weight loss at follow-up (mean 3.2 years) (5). Given the association between initial weight loss and subsequent outcomes, it may be important to try to identify early non-responders and provide additional assistance for these individuals.

Previously, non-empirically supported weight loss thresholds have been used to determine whether and when to provide ‘rescue efforts’ (i.e., a more intensive or different intervention approach) to non-responders or to suggest that treatment be discontinued in individuals who are not meeting weight loss goals (4, 13, 14, 15, 16). For example, in Look AHEAD, pharmacotherapy was offered to individuals who lost <5% at 6 months. This strategy had little effect on weight loss outcomes (4), suggesting that there was either poor compliance to the medication or the type or timing of this rescue intervention may not have been appropriate. The 6-month time point is also used in the new Medicare guidelines (14) where

individuals not achieving a ≥3kg weight loss after 6 months of intensive therapy are required to have their readiness to change reassessed before further treatment is provided. Other investigators have found no benefits of providing more intensive behavioral treatment at week 12 to those who were experiencing difficulty (13, 15). In contrast, a behavioral intervention offered at 6 weeks to those losing <2.5% of their body weight was found to be effective (16). Although investigators are beginning to evaluate whether changing the type or intensity of the intervention can 'rescue' non-responders, empirically-based weight loss thresholds have not been employed and it remains unclear how early these non-responders can be identified.

The purpose of this manuscript is to examine the association between early treatment response and 1-year weight change among overweight/obese individuals with type 2 diabetes randomized to the intensive lifestyle intervention (ILI) arm of the Look AHEAD trial and to identify specific weight loss thresholds at 1 and 2 months that can be used by clinicians to classify early non-responders to lifestyle treatment. In addition, this paper also examines the sensitivity and specificity of these initial weight loss thresholds for predicting 1-year weight loss outcomes. This information could be particularly valuable when choosing a weight loss threshold for initiating 'rescue efforts'. For example, the threshold chosen may differ depending upon whether the treatment goal is to minimize the cost of supplemental 'rescue' efforts or whether the goal to maximize the number of individuals receiving supplemental 'rescue' treatment.

Methods

Participants

Look AHEAD enrolled 5,145 participants from 16 centers across the United States and inclusion/exclusion criteria have been previously reported (17). In short, participants had type 2 diabetes, were aged 45-76 years, had a BMI ≥25kg/m^2 (or ≥27kg/m^2 if taking insulin), HbA_{1c} ≤11%, triglycerides <600mg/dL, and systolic and diastolic blood pressure ≤160 and ≤100mmHg, respectively. All participants provided written informed consent, and study procedures were approved by each center's institutional review board.

Intervention

Look AHEAD participants were randomly assigned to an intensive lifestyle intervention (ILI; n=2570) or Diabetes Support and Education (n=2575), which served as the comparison group. During Months 1-6, ILI participants attended three weekly group sessions and one individual counseling session per month, which was reduced to two group and one individual session per month in Months 7-12.

Participants in ILI were prescribed a calorie goal of 1200-1800 kcal/day depending upon initial body weight and were instructed to consume <30% of total calories from dietary fat. Meal replacements were provided, and participants were instructed to replace two meals and one snack per day with a meal replacement product for months 1-6 and one meal and one snack per day during months 7-12. Participants were given a home-based physical activity

regimen designed to gradually increase structured activity to ≥175 min/week within the first 6 months.

Behavioral strategies such as regular self-weighing, daily self-monitoring, and stimulus control were discussed. To help unsuccessful participants meet the study goals, a "toolbox" strategy was implemented at 6 months. This "toolbox" has previously been described in greater detail (4). In short, it consisted of advanced behavioral strategies such as motivational interviewing, problem solving techniques, instrumental support (e.g., gym memberships, cookbooks, etc.), and the option to use orlistat. A total of 291 of the 722 participants losing <5% at month 6 were started on orlistat, which as previously reported did not improve their one-year weight losses (4).

Measurement of body weight and calculation of weight change

Weights were measured at each intervention visit by unmasked intervention staff using a digital scale to the nearest 0.2 lb (model BWB-800; Tanita, Willowbrook, IL). Baseline weight was considered the weight at the first intervention meeting. Annual assessment weights were obtained by a staff member masked to intervention assignment.

Percent weight change at Month 1 was calculated as follows: [(Session 5 weight – Session 1 weight)/Session 1 weight] × 100. If a participant did not attend the intervention meeting at Session 5 or complete a "make-up", but was present at *both* Sessions 4 and 6, the average of these two weights was used as their 1-month weight. If a participant was missing a Session 5 weight and had a weight at *either* Session 4 or 6, they were included in the analyses and their Session 4 or 6 weight was used as their 1-month weight. If a participant was absent at Sessions 4-6, they were excluded from the analyses. Similar procedures were employed to calculate 2-month weight change using weight measurements at Sessions 1 and 9.

Data analyses

2570 participants were randomized to ILI, 2327 of whom were included in the subsequent analyses: 2318 individuals (90%) had weights at Month 1 and Year 1, and 2303 (90%) had weights at Month 2 and Year 1.

Weight loss quartiles at Months 1 and 2 were calculated and rounded to the nearest whole integer. These values were used to group participants into categories based upon achievement of these various magnitudes of weight loss at Months 1 or 2. For example, the upper weight loss quartile at Month 1 was 3.97%, which rounded up to 4%. Participants were then stratified into one of two categories: 1) <4% weight loss or 2) ≥4% weight loss at Month 1. The proportion of individuals within each of these two groups achieving a ≥5% or ≥10% weight loss at Year 1 was calculated. A similar approach was taken for each quartile of weight loss at 1 and 2 months.

Logistic regression modeling assessed the relationship between early weight loss and 1-year weight loss, defining 1-year success as achievement of a ≥5%(18) or ≥10%(19) weight loss. These 1-year thresholds were chosen because they are often used to define clinically significant weight loss and have been shown to be associated with significant improvements in long-term health outcomes (18, 19, 20). Unadjusted models and models adjusting for

clinic site, gender, age, race/ethnicity, and initial BMI were performed. Since we were interested in identifying participants at risk of being unsuccessfully treated over the year period, we chose to model the probability of failing to reach these weight loss goals. The cut-points representing the quartiles of weight loss at Months 1 and 2 were entered as dichotomous predictors in separate models. For Month 1 the cut-points were 2%, 3%, and 4% weight loss; for Month 2, 3%, 5%, and 7% were used.

To examine the ability of the initial weight loss thresholds to correctly classify individuals based upon whether they were successful or unsuccessful at Year 1, four groups were created: 1) true positives: failed to achieve the weight loss threshold at Month 1 and Year 1, 2) false positives: failed to achieve the weight loss threshold at Month 1 but achieved the weight loss threshold at Year 1, 3) false negatives: achieved the weight loss threshold at Month 1 but failed to achieve the weight loss threshold at Year 1, and 4) true negatives: achieved the weight loss threshold at Month 1 and Year 1. Similar groupings were formed combining Month 2 and Year 1 weight loss thresholds. Sensitivity and specificity were calculated for each model: sensitivity = [true positives/(true positives + false negatives)] and specificity = [true negatives/(true negatives + false positives)].

Results

Baseline characteristics of the entire Look AHEAD cohort have been previously reported (17). The 2327 ILI participants who were included in the current analyses (Figure 1) had a mean BMI of 35.8±6.0kg/m^2, 59.7% were female, 63.6% were Caucasian, and the mean age was 58.6±6.8 years.

The mean weight change at each time point was as follows: Month 1 (−2.7±2.7%), Month 2 (−4.6±3.3%), and Year 1 (−8.8±6.7%). Month 1 and 2 weight change were significantly correlated with weight change at Year 1 (r=0.43 and r=0.61 respectively, $p<0.001$). This association is graphically depicted in Figure 2. Participants were categorized based upon their initial weight loss at Month 1 (Figure 2a) or Month 2 (Figure 2b) into one of six weight loss categories. These groupings were selected in 1% weight loss increments for visual purposes and the monthly weight change trajectory throughout the first year of the intervention was plotted for each group.

Table 1 presents the proportion of participants falling above or below several 1-month or 2-month weight loss thresholds, while also examining what percentage of participants achieve a ≥5% and ≥10% weight loss at Year 1, based upon these initial weight loss groupings. For example, 50.1% of individuals achieving a ≥2% weight loss at Month 1 achieved a ≥10% weight loss at Year 1, whereas only 15.2% of those who had a weight loss <2% at Month 1 reached this threshold at Year 1. A higher proportion of individuals meeting any of the criteria for successful weight loss initially, also met the criteria for a clinically significant weight loss at Year 1, compared to those who did not meet the criteria initially. In addition, the higher the initial weight loss threshold (e.g., ≥4% vs. ≥2%) the greater the proportion of participants who were “successful” at Year 1. The monthly weight loss trajectory for those falling above and below each of the weight loss thresholds at Month 1 and Month 2 is shown in the online Supplementary Figure 1.

Table 2 displays the odds of not achieving a ≥5% or ≥10% weight loss at Year 1 based upon failure to achieve an initial pre-defined weight loss threshold at Month 1 or 2 (e.g., <2%, 3%, or 4%) compared to the reference category (e.g., ≥2%, 3%, 4% weight loss). In all cases, failure to achieve a 1- or 2-month weight loss threshold significantly increased the likelihood of *not* achieving a clinically significant weight loss at Year 1. For example, participants with a 2-month weight loss <3% had 8.36 (95% CI: 6.81,10.26) and 11.58 (95% CI: 8.60,15.58) times greater odds of also not achieving a ≥5% and ≥10% weight loss respectively, compared to individuals achieving a ≥3% weight loss. These odds ratios remained highly significant even after adjusting for age, gender, race/ethnicity, clinic site, and BMI.

Table 3 examines the ability of the initial weight loss thresholds to correctly classify individuals on achievement or non-achievement of a ≥5% or ≥10% weight loss threshold at Year 1. The number of false positives (did not achieve weight loss threshold at Month 1 but achieved weight loss threshold at Year 1) was lowest using a 3% weight loss threshold at Month 2 to predict a ≥10% weight loss at Year 1 (n=53). This indicates that only 5.9% of participants who lost ≥10% at Year 1 (i.e., sum of false positives and true negatives; n=892) had a weight loss <3% at Month 2; thus specificity was high (94.1%). However, a 3% weight loss threshold at Month 2 also created the largest number of false negatives (n=815; achieved the weight loss threshold at Month 1 but did not achieve it at Year 1). This indicates that 57.8% of participants with a 1-year weight loss <10% (i.e., sum of true positives and false negatives; n=1411) had a 2-month weight loss ≥3%; thus sensitivity was low (42.2%). In general, as the initial weight loss threshold increased (e.g., ≥2% to ≥4%), sensitivity also increased, but specificity decreased.

Discussion

Findings from this study show that weight losses in the first two months of treatment are strongly correlated with weight loss following the first year of an intensive lifestyle intervention. Moreover, few individuals who lose <2% or <3% at months 1 and 2, respectively, go on to achieve clinically significant weight loss at Year 1. Thus, as illustrated in Figure 2, many individuals remain on the same weight change trajectory as established very early within treatment. This suggests that the first 2 months of treatment may be an ideal time to identify, and possibly intervene upon, those at greatest risk of not achieving clinically significant weight losses.

Although both 1- and 2-month weight losses significantly predicted 1-year outcomes, Month 2 weight loss was a stronger predictor than Month 1. Thus, if an intervention is designed to target and provide additional treatment to those at greatest risk of being unsuccessful in a standard behavioral program, waiting until Month 2 may improve the accuracy in predicting weight loss success. However, many of these individuals can actually be identified as early as Month 1; waiting until Month 2 or beyond may be too late to ‘rescue’ these early nonresponders, given that they may already be disengaged. For example, Carels et al. found that delivering a more intensive intervention to those failing to meet specific weight loss goals at week 12 was not effective (13), whereas one delivered at week 6 was successful(16). Moreover, Jakicic et al. (15) used a ‘stepped care’ intervention model (13,

15, 16, 21, 22) and offered participants who lost <5% at Month 3 (46% of sample) an additional 10-minute telephone contact monthly. This intervention only 'rescued' 8% of these participants. Thus, these findings suggest that both the timing and type of 'rescue' intervention are important to consider, and warrant further investigation.

When using these empirically-derived weight loss thresholds and choosing the threshold to identify early non-responders, it is important to weigh the cost of providing supplemental 'rescue' treatment against the number of individuals that would be reached. For example, if the cost of the 'rescue' strategy is high, limiting the number of individuals receiving additional intervention unnecessarily may be of greatest interest (i.e., false positives). In this case, a 2% weight loss threshold at Month 1 would be ideal, given that only 116 participants (5% of total sample) would receive supplemental intervention when it was not needed; however, a large number of individuals who may actually need supplemental intervention would not receive it (false negatives; n=775; 33% of the total sample). If on the other hand, the cost of the supplemental intervention is low, the goal may be to maximize the number of individuals receiving supplemental treatment who really need it (true positives) and minimize the number of individuals not receiving supplemental treatment, but who might have benefited from it (false negatives). In this case, a 4% weight loss threshold at Month 1 would maximize the true positives (n=1231; 53% of the total sample) and minimize the false negatives (n=192; 8% of the total sample). However, the number of individuals receiving supplemental treatment unnecessarily (i.e., false positives) also substantially increases (n=517; 22% of total sample). Thus, clinicians, investigators, and policy makers should consider this potential trade-off when making treatment decisions.

Although this study is the first to examine the predictive accuracy of several initial weight loss thresholds on achievement of clinically significant weight losses at 1 year, the current findings are in agreement with Nackers et al (10), who reported that obese women losing weight at a rate of ≥0.68 kg/week (≥2.7% weight loss at 1 month) are 5.1 times more likely to achieve a ≥10% weight loss at 18 months compared to those losing weight more slowly, defined as <0.23 kg/week (approximately <1% weight loss at 1 month). These findings suggest that individuals losing <2-2.5% weight loss at Month 1 may be unlikely to go on to achieve a ≥10% weight loss at Year 1 and may require additional support or treatment. Alternatively, interventions could consider discontinuing treatment in these early nonresponders given their low likelihood of success.

There are many strengths of this study including the large sample size and the determination of clinical weight loss cut-points at 1 and 2 months for identifying individuals least likely to achieve clinically significant weight losses at Year 1. However, it is unclear whether these findings would hold true in healthier or younger cohorts or within treatment programs utilizing a less intensive intervention.

In conclusion, the current findings suggest that for overweight or obese adults with type 2 diabetes, weight loss in the first 2 months of a lifestyle intervention is predictive of 1-year weight loss. Moreover, of those individuals failing to meet specific weight loss criteria in the first 2 months, few go on to attain a ≥10% weight loss at Year 1. Therefore, the first few months of treatment may be an opportune time to identify individuals at greatest risk for

being unsuccessful at the conclusion of treatment and to provide additional intervention 'rescue efforts' before it is too late. Future studies should examine the efficacy and cost-effectiveness of using these empirically-based weight loss thresholds for early identification and 'rescue efforts' for these initially non-responsive individuals.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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REFERENCES

1. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. JAMA. 2012; 307:491–497. [PubMed: 22253363]
2. Wadden, TA.; Stunkard, AJ. Handbook of Obesity Treatment. The Guilford Press; New York: 2002.
3. Barte JC, ter Bogt NC, Bogers RP, Teixeira PJ, Blissmer B, Mori TA, et al. Maintenance of weight loss after lifestyle interventions for overweight and obesity, a systematic review. Obes Rev. 2010; 11:899–906. [PubMed: 20345430]
4. Wadden TA, West DS, Neiberg RH, Wing RR, Ryan DH, Johnson KC, et al. One-year weight losses in the Look AHEAD study: factors associated with success. Obesity (Silver Spring). 2009; 17:713–722. [PubMed: 19180071]
5. Wing RR, Hamman RF, Bray GA, Delahanty L, Edelstein SL, Hill JO, et al. Achieving weight and activity goals among diabetes prevention program lifestyle participants. Obes Res. 2004; 12:1426–1434. [PubMed: 15483207]
6. Jakicic JM, Marcus BH, Lang W, Janney C. Effect of exercise on 24-month weight loss maintenance in overweight women. Arch Intern Med. 2008; 168:1550–1559. discussion 1559-1560. [PubMed: 18663167]
7. Carels RA, Cacciapaglia HM, Douglass OM, Rydin S, O'Brien WH. The early identification of poor treatment outcome in a women's weight loss program. Eat Behav. 2003; 4:265–282. [PubMed: 15000970]

8. Dutton CA, Jakicic JM, Goodpaster BH, Otto AD. Is initial weight loss associated with longer-term weight loss in obese adults? Medicine and Science in Sports & Exercise. 2008; 40:S111.
9. Elfhag K, Rossner S. Initial weight loss is the best predictor for success in obesity treatment and sociodemographic liabilities increase risk for drop-out. Patient Educ Couns. 2010; 79:361–366. [PubMed: 20223613]
10. Nackers LM, Ross KM, Perri MG. The association between rate of initial weight loss and long-term success in obesity treatment: does slow and steady win the race? Int J Behav Med. 2010; 17:161–167. [PubMed: 20443094]
11. Wadden TA, Neiberg RH, Wing RR, Clark JM, Delahanty LM, Hill JO, et al. Four-Year Weight Losses in the Look AHEAD Study: Factors Associated With Long-Term Success. Obesity (Silver Spring). 2011
12. Elfhag K, Rossner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. Obes Rev. 2005; 6:67–85. [PubMed: 15655039]
13. Carels RA, Young KM, Coit CB, Darby LA, Clayton AM, Spencer AC, et al. The failure of therapist assistance and stepped-care to improve weight loss outcomes. Obesity (Silver Spring). 2008; 16:1460–1462. [PubMed: 18356835]
14. Centers for Medicare and Medicaid Services. Final Coverage Decision Memorandum for Intensive Behavioral Therapy for Obesity. 2011. [August 8, 2013]. Available from: http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&bc=ACAAAAAAIAAA&NCAId=253
15. Jakicic JM, Tate DF, Lang W, Davis KK, Polzien K, Rickman AD, et al. Effect of a stepped-care intervention approach on weight loss in adults: a randomized clinical trial. JAMA. 2012; 307:2617–2626. [PubMed: 22735431]
16. Carels RA, Wott CB, Young KM, Gumble A, Darby LA, Oehlhof MW, et al. Successful weight loss with self-help: a stepped-care approach. J Behav Med. 2009; 32:503–509. [PubMed: 19521759]
17. Pi-Sunyer X, Blackburn G, Brancati FL, Bray GA, Bright R, Clark JM, et al. Reduction in weight and cardiovascular disease risk factors in individuals with type 2 diabetes: one-year results of the look AHEAD trial. Diabetes care. 2007; 30:1374–1383. [PubMed: 17363746]
18. Blackburn G. Effect of degree of weight loss on health benefits. Obes Res. 1995; 3(Suppl 2):211s–216s. [PubMed: 8581779]
19. National Heart L, and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: The evidence report. Obes Res. 1998; 6(Suppl.):51S–210S. [PubMed: 9813653]
20. Wing RR, Lang W, Wadden TA, Safford M, Knowler WC, Bertoni AG, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. Diabetes Care. 2011; 34:1481–1486. [PubMed: 21593294]
21. Brownell KD. Public health approaches to obesity and its management. Annu Rev Public Health. 1986; 7:521–533. [PubMed: 3718654]
22. Carels RA, Darby L, Cacciapaglia HM, Douglass OM, Harper J, Kaplar ME, et al. Applying a stepped-care approach to the treatment of obesity. J Psychosom Res. 2005; 59:375–383. [PubMed: 16310019]

What is already known about this subject?

- ○ There is large variability in weight loss response to an intensive lifestyle intervention.
- ○ Baseline variables do not consistently predict who will be successful following a lifestyle intervention.
- ○ Weight loss in the first several months of treatment may be associated with greater long-term weight loss.

What this study adds:

- ○ This study examines the association between month 1 and month 2 weight loss and 1-year weight loss among participants enrolled in a lifestyle intervention, using the largest cohort to date.
- ○ This study identifies empirically-based weight loss thresholds at months 1 and 2 of a lifestyle intervention which can be used by clinicians to classify early non-responders to lifestyle treatment.
- ○ This study is the first to examine the predictive accuracy of several initial weight loss thresholds on achievement of clinically significant weight loss at 1 year.

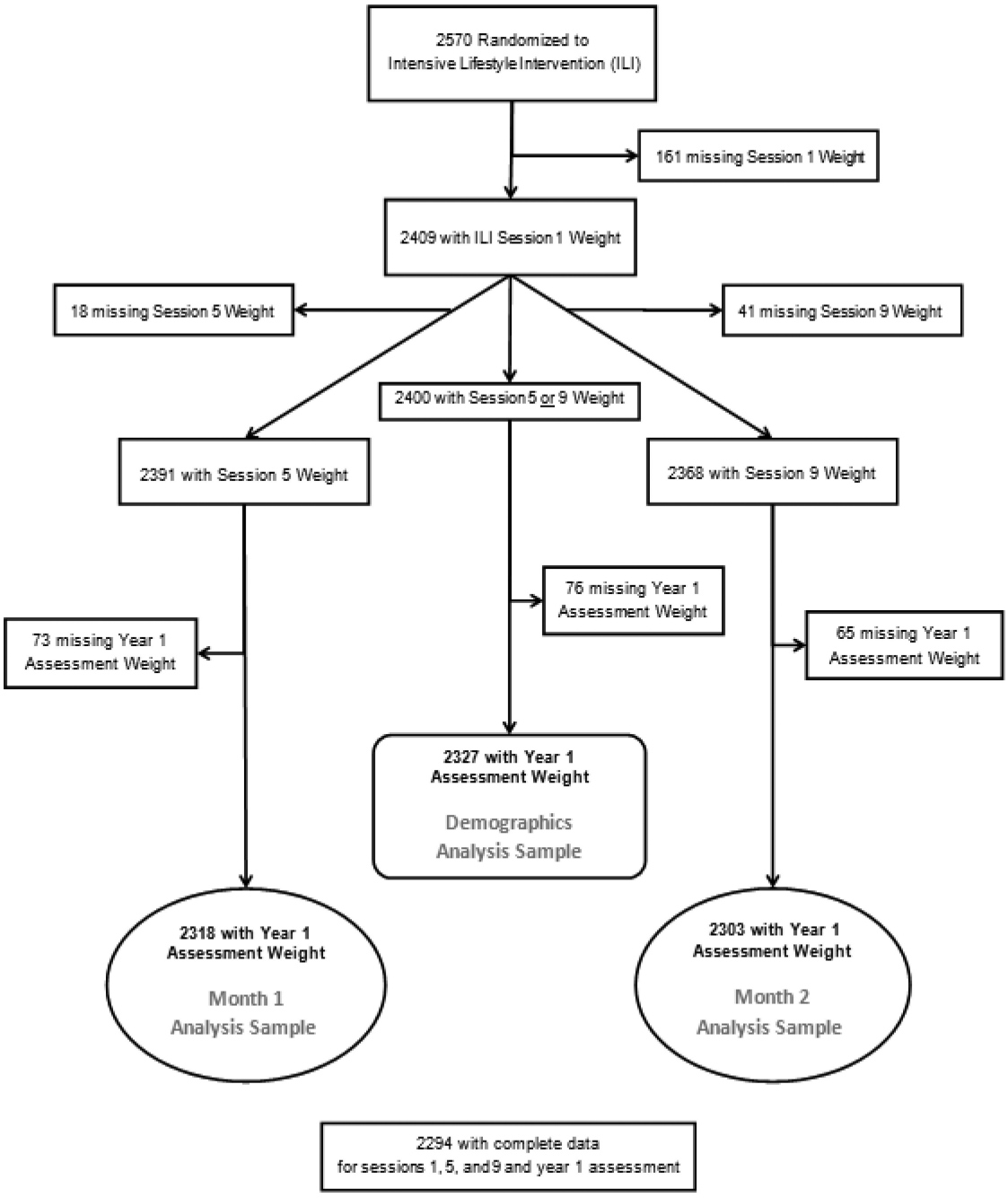
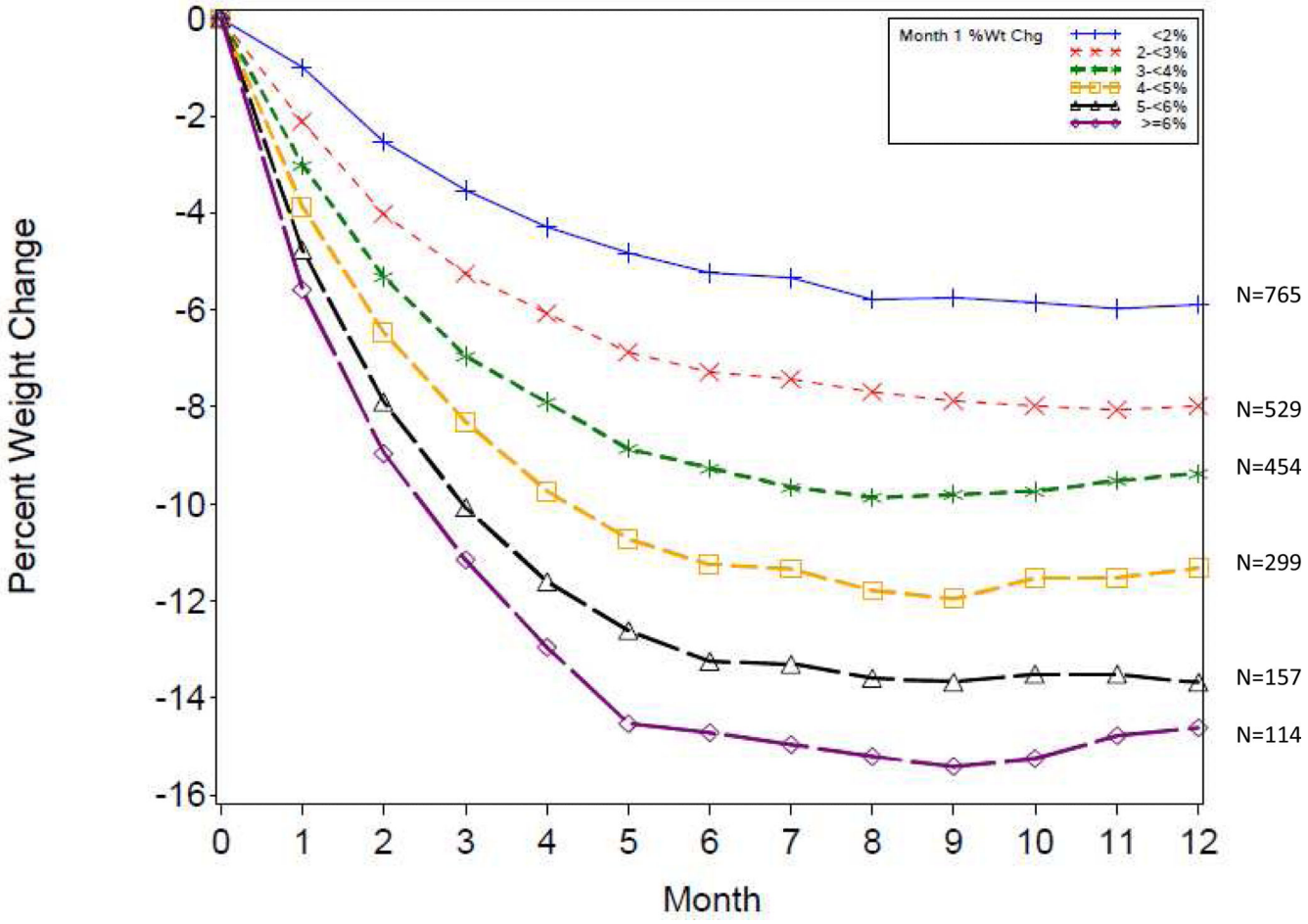


Figure 1.
CONSORT Diagram

a



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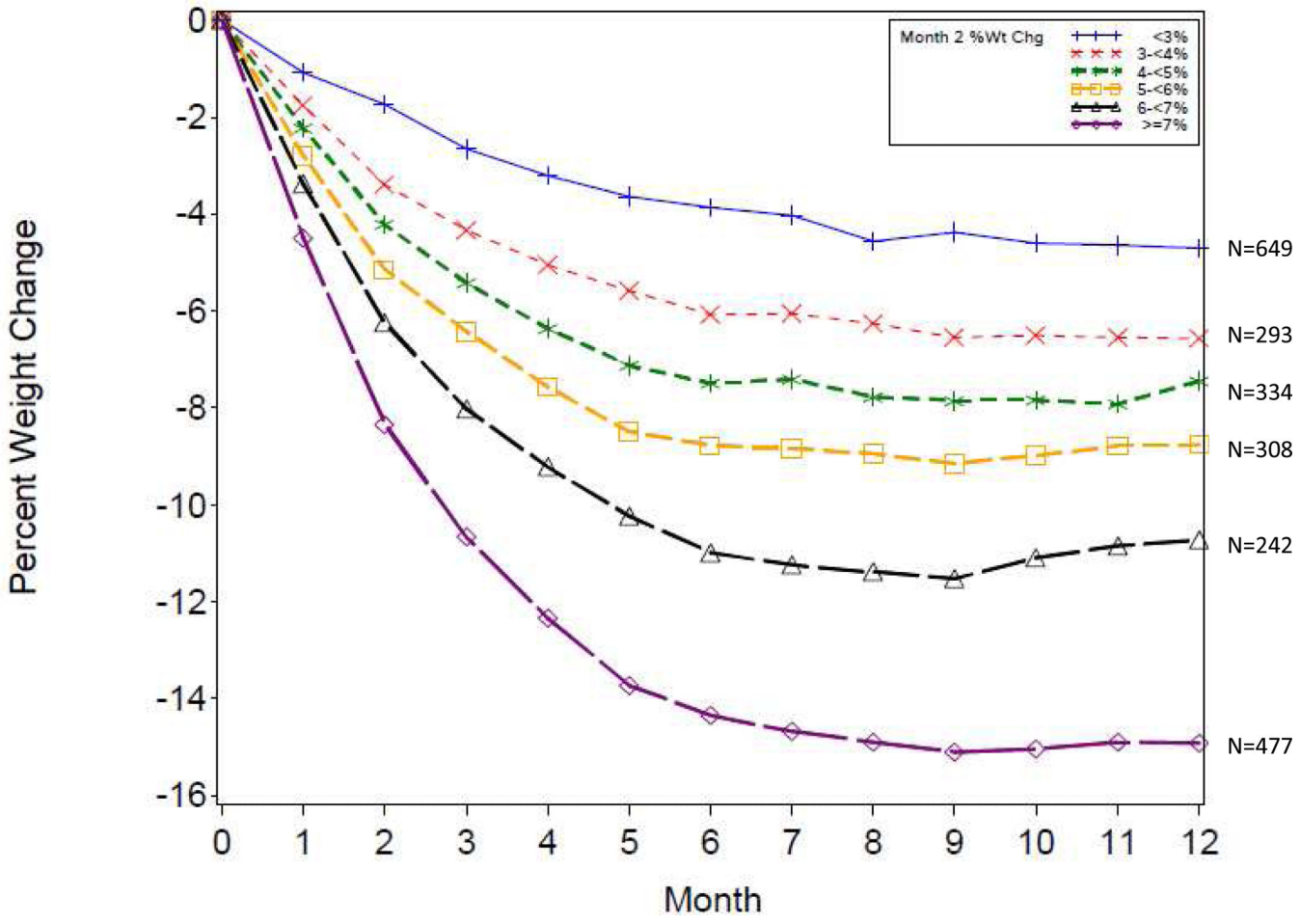

Figure 2.

Monthly weight change trajectories for 1-month (a) and 2-month percent weight loss categories (b)

Table 1

Year 1 weight loss across initial (1 month and 2 month) weight loss categories

Initial weight loss category	N	Mean initial % weight loss (SD)	Mean 1-year % weight loss (SD)	≥ 5% weight Loss(%)	≥ 10% weight Loss (%)
1-month weight loss					
< 2%	765	0.32 (2.74)	5.00 (5.31)	47.0%	15.2%
≥ 2%	1553	3.84 (1.65)	10.69 (6.48)	81.1%	50.1%
< 3%	1294	1.21 (2.37)	6.30 (5.66)	56.2%	22.6%
≥ 3%	1024	4.52 (1.64)	11.98 (6.52)	87.0%	58.8%
< 4%	1748	1.80 (2.27)	7.33 (5.97)	63.0%	29.6%
≥ 4%	570	5.36 (1.79)	13.34 (6.70)	90.9%	66.3%
2-month weight loss					
< 3%	649	0.95 (2.59)	3.98 (4.30)	37.0%	8.2%
≥ 3%	1654	6.04 (2.19)	10.75 (6.41)	83.1%	50.7%
< 5%	1276	2.47 (2.44)	5.72 (4.80)	53.2%	18.5%
≥ 5%	1027	7.26 (1.90)	12.72 (6.55)	91.0%	63.8%
< 7%	1826	3.51 (2.60)	7.09 (5.44)	63.1%	28.0%
≥ 7%	477	8.82 (1.70)	15.55 (6.51)	96.7%	79.9%

SD denotes standard deviation.

Table 2

Odds (95% Confidence Interval) of failing to achieve a ≥5% and ≥10% weight loss at Year 1 based upon change in body weight at Months 1 and 2

		Failure to achieve a 5% weight loss at Year 1	Failure to achieve a 10% weight loss at Year 1
1 month			
	≥ 2% WL at 1 month	1.0 (ref)	1.0 (ref)
	< 2% WL at 1 month		
	Unadjusted	4.84 (4.00, 5.85)	5.61 (4.50, 7.00)
	Adjusted	4.77 (3.90, 5.84)	5.53 (4.39, 6.98)
	≥ 3% WL at 1 month	1.0 (ref)	1.0 (ref)
	< 3% WL at 1 month		
	Unadjusted	5.22 (4.22, 6.46)	4.90 (4.09, 5.87)
	Adjusted	4.98 (4.00, 6.20)	4.71 (3.90, 5.68)
	≥ 4% WL at 1 month	1.0 (ref)	1.0 (ref)
	< 4% WL at 1 month		
	Unadjusted	5.85 (4.33, 7.91)	4.69 (3.83,5.73)
	Adjusted	5.58 (4.10, 7.59)	4.55 (3.68, 5.61)
2 months			
	≥ 3% WL at 2 months	1.0 (ref)	1.0 (ref)
	< 3% WL at 2 months		
	Unadjusted	8.36 (6.81, 10.26)	11.58 (8.60, 15.58)
	Adjusted	8.30 (6.68, 10.31)	11.07 (8.17, 14.99)
	≥ 5% WL at 2 months	1.0 (ref)	1.0 (ref)
	< 5% WL at 2 months		
	Unadjusted	8.83 (6.94, 11.22)	7.76 (6.42, 9.39)
	Adjusted	8.76 (6.83, 11.23)	7.90 (6.46, 9.67)
	≥ 7% WL at 2 months	1.0 (ref)	1.0 (ref)
	< 7% WL at 2 months		
	Unadjusted	16.82 (10.13, 27.93)	10.21 (7.99, 13.06)
	Adjusted	16.27 (9.75, 27.17)	10.75 (8.29, 13.94)

Adjusted models include age, race/ethnicity, gender, clinic site, and baseline BMI

Table 3

Sensitivity and specificity using a ≥5% and ≥10 % weight loss threshold at Year 1 based upon several weight loss thresholds at Months 1 and 2

Month	Weight loss threshold	Sensitivity or true positive rate (N)	Specificity or true negative rate (N)	False negative rate (N)	False positive rate (N)
		Using a ≥5% weight loss threshold at Year 1			
1	2%	57.9% (405)	77.8% (1260)	42.1% (294)	22.2% (359)
1	3%	81.0% (566)	55.1% (892)	19.0% (133)	44.9% (727)
1	4%	92.6% (647)	32.0% (518)	7.4% (52)	68.0% (1101)
2	3%	59.4% (409)	85.1% (1374)	40.6% (280)	14.9% (240)
2	5%	86.5% (596)	57.9% (935)	13.5% (93)	42.1% (679)
2	7%	97.7% (673)	28.6% (461)	2.3% (16)	71.4% (1153)
		Using a ≥10% weight loss threshold at Year 1			
1	2%	45.5% (648)	87.0% (779)	54.5% (775)	13.0% (116)
1	3%	70.3% (1001)	67.4% (603)	29.7% (422)	32.6% (292)
1	4%	86.5% (1231)	42.2% (378)	13.5% (192)	57.8% (517)
2	3%	42.2% (596)	94.1% (839)	57.8% (815)	5.9% (53)
2	5%	73.6% (1039)	73.5% (656)	26.4% (372)	26.5% (236)
2	7%	93.2% (1315)	42.7% (381)	6.8% (96)	57.3% (511)

Sensitivity rate is defined as the percentage of participants failing to achieve ≥5 or ≥10% weight loss at Year 1 who are correctly identified using the initial weight loss threshold [true positives/(true positives + false negatives)], while false negative rate is the percentage of those incorrectly identified [false negatives/(true positives + false negatives)]. Specificity rate is defined as the percentage of participants achieving a ≥5% or ≥10% weight loss at Year 1 who are correctly identified using the initial weight loss threshold [true negatives/(true negatives + false positives)], while false positive rate is the percentage of those incorrectly identified [false positives/(true negatives + false positives)].