

Characterization of Early Non-responders within Behavioral Weight Loss Treatment

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Objectives: Given that low early (4 weeks) weight loss (WL) predicts longer-term WL, the purpose of this study was to identify factors associated with poor early WL. **Methods:** We had 438 adults with overweight/obesity participating in an Internet-delivered behavioral WL program provide weights at baseline and 4 weeks. Participants were stratified by percent WL at 4 weeks: LOW: < 2% WL, MEDIUM: 2 to < 4% WL, HIGH: ≥ 4% WL and groups were compared on baseline variables (demographics, physical activity, and psychosocial measures) and 4-week intervention adherence. **Results:** Respectively, 37.4%, 40.9%, and 21.7% of participants had LOW, MEDIUM, and HIGH early WL. LOW was more likely to be female compared to HIGH and less likely to be non-Hispanic white compared to MEDIUM and HIGH (p 's < 0.05). After controlling for demographic differences, LOW had lower baseline physical activity compared to HIGH and watched fewer video lessons, self-monitored calorie intake and weight on fewer days, and were less likely to achieve the exercise goal compared to MEDIUM and HIGH (ps < .05). **Conclusion:** Findings can inform future adaptive interventions that tailor treatment based upon early WL to improve WL outcomes for more individuals.

Keywords: Stepped Care, Behavioral Weight Loss, Adaptive Intervention, Early Non-responder, Obesity.

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Rates of overweight and obesity remain alarmingly high and represent a significant public health concern.¹ As a result, in recent years, there has been a shift in behavioral weight loss (WL) treatment from primarily in-person programs to remote-based programs to promote dissemination and greater access for more individuals. This shift has been accelerated further by the COVID-19 pandemic, as many individuals now prefer fully remote programs over in-person treatment.^{2,3}

However, individual response to remote WL programs is variable – many individuals achieve clinically significant WL (e.g., ≥ 5%), whereas others fail to lose weight or even gain weight throughout treatment.⁴⁻⁶ Attempts to predict WL response to

behavioral treatment using baseline factors have not been uniformly successful.^{7,8} However, identification of factors that differentiate who succeeds with remote-WL treatment and who does not, could help inform the development of tailored, remote interventions to optimize WL outcomes for more individuals.

Prior research indicates that the amount of WL achieved early in a program (e.g., 4 weeks) is a consistent and robust predictor of post-treatment or longer-term WL within both in-person and remote treatment.^{5,9-16} For example, individuals who failed to achieve a ≥ 2% WL at 4 weeks were over 5 times less likely to achieve a clinically significant weight loss at one year¹⁰ and that this association remained through year 8.⁹ This is significant, as it suggests that

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it is possible to identify ‘at risk’ individuals early in treatment. Moreover, provision of extra support to these early non-responders could boost WL outcomes.^{17,18} For example, early non-responders (ie, 4-week WL < 2%) to an Internet-based WL program who received 3 consecutive weeks of individual coaching were nearly twice as adherent to the intervention and had double the amount of WL compared to early non-responders who did not receive coaching.¹⁷ These data suggest that early intervention for individuals with low initial WL could be one method for tailoring WL programs to improve outcomes for more individuals. However, to inform these future intervention efforts, it is important to identify factors that differentiate those with poor early WL from those with higher degrees of early WL. To date, there has been limited research conducted in this area.

The purpose of this study is to characterize early non-response to a fully automated, Internet-delivered WL program for adults with overweight and obesity. Specifically, we aim to assess the variability in 4-week WL by categorizing individuals into one of 3 early response categories (LOW: < 2%, MEDIUM: 2% to < 4%, and HIGH: \geq 4%) and then comparing these early WL groups on baseline factors (e.g., demographics, physical activity, WL goals, self-efficacy, motivation, etc) and intervention adherence during the first 4 weeks of treatment. Rationale for these early WL groupings was derived from prior research that examined the sensitivity and specificity of various early WL thresholds in predicting achievement of subsequent clinically significant WL.¹⁰ A 2% threshold is most commonly used to identify poor WL response^{11,15,19} and has high rates of specificity, whereas a 4% WL threshold has lower specificity but high sensitivity.¹⁰

METHODS

Participants were enrolled in the DIAL Now Trial (Disseminating Internet-based Approaches to Lifelong change), a randomized controlled trial in which the primary aim is to examine the effect of brief or extended phone coaching provided to individuals enrolled in an Internet-delivered WL program with 4-week WL < 4%. A full description of this study protocol has been published previously.²⁰ Primary outcomes are percent weight change at 4- and 12-month follow-ups and a secondary aim examines for whom coaching is most effective (ie, those with LOW or MEDIUM early WL) and will be presented in a future paper. This manuscript focuses on early

treatment response, and thus, includes baseline data and intervention adherence data through week 4 of the trial. Although participants were randomized into one of 3 treatment arms at baseline (no coaching, brief, or extended coaching for those with 4-week WL < 4%), they were not informed of their randomization assignment (ie, whether they would receive phone coaching) until week 5 of the trial, nor were they informed of the criteria for determining who would receive coaching. Therefore, all participants received an identical intervention (Internet-based WL program) through week 4.

Participants

A total of 452 WL-seeking men and women enrolled in this trial. To be eligible, individuals needed to be between 18 and 70 years of age, have a BMI between 25 kg/m² and 45 kg/m², have daily Internet access, and complete all baseline study procedures. Individuals were excluded if they were enrolled in another WL program or taking WL medication, had a history of bariatric surgery, were unable to walk several blocks unassisted, had plans to become pregnant (or had a recent pregnancy) or to relocate outside the area within 12 months of enrollment, or presence of any medical condition for which WL or aerobic physical activity was contraindicated.

Internet-based WL Program

All participants enrolled in a rigorously tested, 12-month Internet-delivered WL and WL maintenance program and were given a WL goal of 10% of their initial body weight.^{4-6,17,21} To assist in achieving this goal, individuals were given a daily calorie intake goal based upon their initial body weight which ranged from 1200 to 1800 kcals/day. They were also given a moderate-intensity physical activity goal (e.g., brisk walking) starting at week 3 (ie, no prescribed exercise for weeks 1-2) which was 50 minutes/week (weeks 3-4) and gradually progressed to 150 minutes/week thereafter. Participants were instructed to record their body weight, calorie intake, and physical activity minutes daily during the first 4 months. This information could be entered on the study website or via a third-party tracking application that shared data with the study website. Computer-generated, personalized feedback, based upon the self-monitoring data, was provided weekly. Participants were also instructed to watch a weekly 10-15-minute video lesson, modeled after the behavioral weight

loss approached used in the Look AHEAD Trial.²² The first 4 lessons focused on an introduction to the program and study goals, instructions for following a low-calorie diet, strategies for increasing physical activity, and setting up one's environment for success (ie, stimulus control). In addition, the study website gave participants access to weekly recipes and tip sheets offering useful strategies for healthy eating and regular exercise and access to an individualized weight graph to track their progress over time.

Defining Early WL Response

Percent WL at the end of week 4 was used to classify individuals into one of 3 early WL categories: LOW (< 2%), MEDIUM (2 to < 4%), HIGH (\geq 4%). This was calculated using the self-reported weight that the participant entered on the study website on day one of the program and their self-reported weight at the end of the week 4. If a participant did not report a weight at week 4, a member of the research staff contacted the participant to obtain a weight. Participants who were still missing a 4-week weight after several contact attempts were unable to be classified, and therefore, not included in the analyses. Self-reported weight was chosen over objectively measured weight to enhance translation potential, as most individuals enrolled within Internet WL programs will not have access to smart scales and it also would not be feasible to have all participants go to a physical location for a weight after one month of treatment. Furthermore, self-reported weights have been shown previously to be highly correlated with objective weight measurements within Internet-based WL programs (ie, correlation coefficients of 0.98 and 0.99).^{23,24}

Baseline Measures

Prior to the start of the WL program, participants completed a series of questionnaires which included demographic information, physical activity, and psychosocial measures. They also were asked to report a realistic 4-week WL ("Thinking about the structure of this program, how many pounds do you think is realistic for you to lose in the first 4 weeks of this program") as a measure of early WL expectations (reported in pounds and converted to kilograms). In addition, height was measured to the nearest millimeter using a stadiometer, weight was measured to the nearest 0.1kg using a digital scale, and body mass index (BMI) was calculated.

Physical Activity: A modified version of the *Paffenbarger Physical Activity Questionnaire*²⁵ was used

to capture self-reported PA. Using this interviewer-administered questionnaire, participants were asked to think about the last 7 days and were queried on their time spent brisk walking in bouts \geq 10 minutes in duration, and time spent engaging in sports and recreational activities that were \geq 10 minutes in duration (excluding occupational or job-related activities). Minutes per week spent walking and performing sports and recreational activities of at least moderate intensity were summed up and compared between early WL groups.

Psychosocial Measures: Both dietary and physical activity self-efficacy were assessed using previously validated questionnaires: the *Weight Efficacy Lifestyle (WEL) Questionnaire* Short Form for diet²⁶ and the *Self-Efficacy for Exercise Scale (SEE)*.²⁷ The WEL is an 8-item questionnaire that assesses one's self-efficacy related to their ability to avoid overeating when faced with certain situations (e.g., availability of food, negative emotions, physical discomfort, etc). The SEE is a 9-item questionnaire that evaluates an individual's confidence to exercise when faced with a variety of barriers which include factors such as fatigue, emotional discomfort, lack of social support, and time. Higher values on both measures are indicative of greater self-efficacy.

Motivation was measured using the *Treatment Self-Regulation Questionnaire for Weight Management*,²⁸ which assesses the degree to which an individual's motivation for weight management behaviors is relatively autonomous and self-determined. This questionnaire asks individuals to respond to a series of questions related to reasons why they would engage in behaviors to manage their weight (ie, 'Because I feel that I want to take responsibility for my own health' or 'Because others would be upset with me if I did not'). Motivation was characterized using 2 subscales: autonomous motivation (ie, engaging in behaviors because they are consistent with intrinsic goals; 6 items) and controlled motivation (ie, engaging in behaviors for external reasons; 6 items), with higher scores on each subscale indicative of greater levels of that type of motivation.

Perceived stress was measured via the 10-item *Perceived Stress Scale*²⁹ which assesses the degree to which situations in one's life are appraised as stressful. A total score was computed, and higher scores are indicative of greater perceived stress.

Intervention Adherence Measures

Adherence to the intervention was assessed using data obtained from the study website and was quantified over the initial 4-week period using several metrics – the number of video lessons viewed (out of a possible 4), the number of days that weight and calorie intake were reported by the participant (out of a possible 28 days), average daily calorie intake over the first 4 weeks, and total physical activity minutes reported over the first 4 weeks. Instances when weekly caloric intake was < 500 kcals (n = 4, n = 1, n = 3 in weeks 2-4 respectively) and when total physical activity was > 900 minutes/week were excluded from the analyses (n = 4, n = 5, n = 7, n = 10 in weeks 1-4 respectively). The percentage of participants achieving the exercise goal of > 100 minutes over the first 4 weeks was also computed.

Data Analysis

Baseline demographics, psychosocial variables, and adherence metrics were summarized and compared among the 3 early WL groups (LOW, MEDIUM, HIGH) using one-way analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical variables. When overall tests were statistically significant (at a 5% level of significance), subsequent pairwise comparisons between groups were made and p-values adjusted using the Bonferroni

method. To control for differences in demographic factors when comparing early WL groups, a series of analysis of covariance (ANCOVA) calculations were used for continuous dependent variables and logistic regression for categorical variables. Analyses were run in SPSS 25 (IBM Corp, Armonk, NY) and an *a priori* significance level was set at .05.

RESULTS

A total of 452 individuals enrolled in this study; of these, 438 (96.9%) had 4-week weight data and were classified into one of 3 early WL categories: WL < 2% (LOW; n = 164, 37.4%), 2% to < 4% (MEDIUM; n = 179, 40.9%), and ≥ 4% (HIGH; n = 95, 21.7%). On average, participants were 50.9±11.4 years of age, had a BMI of 34.6±5.0 kg/m², 69.9% were female, and 75.6% were non-Hispanic white. Comparison of demographic characteristics among early WL groups revealed statistically significant differences in biological sex and race/ethnicity (Table 1). The percentage of females with 4-week WL categorized as LOW was significantly greater than that in the HIGH group ($\chi^2 = 31.95, p < .001$). Furthermore, a lower percentage of non-Hispanic white individuals had LOW early WL compared to MEDIUM or HIGH ($\chi^2 = 10.78, p = .005$). There were no differences in baseline weight, BMI, age, or education level across early WL groups ($p > .16$).

Table 1
Demographic Characteristics Stratified by 4-week Weight Loss Category

	Total	4-wk WL <2%	4-wk WL 2 to <4%	4-wk WL ≥4%	p-value*
N (%)	438 (100%)	164 (37.4%)	179 (40.9%)	95 (21.7%)	
4-week weight change (%)	-2.63 ± 1.75	-0.90±0.87 ^a	-2.89±0.55 ^b	-5.10±0.88 ^c	< .001
4-week weight change (kg)	-2.5±1.8	-0.9±0.9 ^a	-2.7±0.8 ^b	-5.1±1.3 ^c	< .001
Demographics					
Baseline weight (kg)	96.6±18.0	97.0±18.0	94.9±17.4	99.1.0±18.7	.164
Body mass index (kg/m ²)	34.6±5.0	35.2±5.4	34.3±4.9	34.2±4.6	.158
Age (years)	50.9±11.4	50.2±11.3	50.8±11.3	52.0±11.8	.471
Female (n,%)	306 (69.9%)	125 (76.2%) ^a	137 (76.5%) ^a	44 (46.3%) ^b	< .001
Non-Hispanic White (n,%)	331 (75.6%)	111 (67.7%) ^a	139 (77.7%) ^b	81 (85.3%) ^b	.005
College education or higher (n,%)	293 (66.9%)	109 (66.5%)	119 (66.5%)	65 (68.4%)	.938

Note.

* p-value for comparison across early WL groups; values with different superscripts are significantly different from one another (p < .05).

Table 2 compares the early WL groups on various baseline variables, including physical activity levels, realistic WL goals, and psychosocial measures. On average, the LOW early WL group had significantly lower physical activity levels, expected to lose less weight at 4 weeks, and had lower exercise self-efficacy and higher perceived stress compared to HIGH (p

< .05), but not the MEDIUM group. However, after controlling for baseline demographic differences (biological sex and race/ethnicity), differences in realistic WL ($p = .49$), exercise self-efficacy ($p = .23$), and perceived stress ($p = .12$) were no longer significant. No differences were observed between early WL groups on dietary self-efficacy or motivation for WL.

Table 2
Comparison of Early Weight Loss Categories on Psychosocial Variables and Adherence Metrics

	Total	4-wk WL <2%	4-wk WL 2 to <4%	4-wk WL ≥4%	p-value*
Baseline Variables					
Physical activity (min/wk)	107.4±160.4	87.0±131.3 ^a	99.5±152.4 ^a	157.4±206.0 ^b	.002
Realistic 4-wk WL (kg)	-3.8±1.9	-3.6±1.7 ^a	-3.7±1.7 ^a	-4.2±2.3 ^b	.029
Self-efficacy for diet	45.3±15.2	43.6±16.3	45.8±14.7	47.4±13.9	.108
Self-efficacy for exercise	56.4±17.9	54.4±18.8 ^a	55.8±17.1 ^a	61.2±17.2 ^b	.010
Motivation – autonomous	39.0±3.8	39.4±3.3	38.7±4.4	38.9±3.3	.256
Motivation – controlled	17.1±7.0	17.3±6.9	17.0±7.2	16.8±6.8	.800
Perceived stress	23.0±6.1	23.3±6.1 ^a	23.5±6.3 ^a	21.3±5.2 ^b	.011
4-Week Adherence Metrics					
# of video lessons viewed (out of 4)	3.6±0.9	3.5±1.0 ^a	3.7±0.8 ^b	3.8±0.7 ^b	.002
Watched all lessons (n,%)	351(80.1%)	118 (72.0%) ^a	147 (82.1%) ^b	86 (90.5%) ^b	.001
Days weight was logged (out of 28)	23.3±6.7	21.2±7.9 ^a	24.0±5.7 ^b	25.5±5.0 ^b	< .001
Days kcals were logged (out of 28)	26.2±4.4	24.7±6.1 ^a	26.9±3.1 ^b	27.6±1.1 ^b	< .001
Average daily calorie intake (kcals)	1372.4±264.8	1382.4±303.6	1372.5±242.4	1354.9±234.0	.727
Total exercise during weeks 1-4 (minutes)	535.2±520.9	466.9±535.4 ^a	531.2±479.4 ^{a,b}	660.6±552.2 ^b	.015
Achieved exercise goal (n,%)†	347 (79.2%)	115 (70.1%) ^a	148 (82.7%) ^b	84 (88.4%) ^b	.001
Note.					
* p-value for comparison across early WL groups; values with different superscripts are significantly different from one another (p < .05).					
† Achieved exercise goal was defined as ≥ 100 min over the 4-week period.					

Four-week adherence to the intervention was compared between early WL groups (Table 2). LOW watched significantly fewer lessons and logged their weight and calorie intake on fewer days compared to MEDIUM and HIGH and had fewer exercise minutes over the first 4 weeks compared to HIGH ($p < .05$). In addition, the percentage of those in the LOW group who watched all 4 video lessons or achieved the exercise goal over the first 4 weeks was significantly less than MEDIUM AND HIGH. All differences remained after controlling for significant baseline demographic differences except for total exercise minutes, which was no longer significant ($p = .18$).

DISCUSSION

Early WL (e.g., 4 weeks) within behavioral WL treatment is associated with longer-term outcomes;^{5,9-12} however, factors differentiating those with low, versus higher degrees of early WL have been largely unexplored. The current study compared early WL groups on demographic factors, weight-related baseline variables, and program adherence among a large sample of adults enrolled in Internet-delivered WL treatment. Results revealed that individuals with low early WL (< 2%) were more likely to be female compared to those with high early WL and more likely to be from an underrepresented racial or ethnic group compared to those with a 4-week WL greater than 2%. After controlling for these demographic differences, those with low early WL also had lower baseline physical activity compared to those with high early WL and watched fewer video

lessons, self-monitored calorie intake and weight on fewer days, and were less likely to achieve the exercise goal compared to those with a 4-week WL greater than 2%. Thus overall, when significant differences were observed among the 3 weight loss categories, the low early WL group always differed significantly from HIGH, and on variables related to adherence, low differed from both medium and high early WL groups.

The current findings indicate that 37% of participants had low early WL, defined as < 2% at week 4, and this proportion is in line with previous reports which have sought to identify the prevalence of early non-responders within both in-person and Internet-based behavioral WL treatment.^{5,10,11,13,30} Whereas studies tend to define early non-response using slightly different WL criteria, the current criterion (< 2% WL) has been commonly used^{10,11,15,19} and is strongly associated with achievement of clinically significant WL post-treatment.^{5,10} Using a threshold to identify early non-responders has important clinical implications, as preliminary data suggest that the provision of extra support to early non-responders may improve treatment outcomes.^{17,18} Furthermore, the current findings indicate that over one-third of individuals have low early WL, and thus, a significant proportion of participants enrolled in Internet-delivered WL treatment are at risk for poor post-treatment WL and may benefit from additional early intervention efforts.

Although little research has focused on examining baseline predictors of early WL in behavioral WL treatment, prior studies assessing demographic

characteristics have had mixed results. Two studies reported that those with low early WL were more likely to be female;^{9,31} however, one smaller study ($n = 89$; 76.4% female) reported no differences by biological sex.³⁰ In the current study, low and medium early WL groups had a similar proportion of females, but the high early WL group had significantly more males. Also in the current study, those with low early WL were less likely to be non-Hispanic white, which also has been reported previously in a large, multi-site study,⁹ but not in smaller, less diverse samples.^{30,31} Although preliminary, these findings suggest that females and non-Hispanic white participants may have lower initial WL, supporting the argument for early intervention adaptations for these subgroups. However, these findings should be interpreted with caution and replication in more demographically diverse cohorts and types of WL interventions is warranted.

To our knowledge, only 2 prior studies have investigated non-demographic pre-treatment factors associated with early WL and these studies included some similar as well as different measures from ours. The first study found no association between 4-week WL and dietary behaviors and psychological factors, including dietary self-efficacy, which was similar to the current findings.¹⁵ The second study found that greater eating disorder psychopathology and depressive symptoms at baseline were associated with lower early WL, with no association observed between early WL and emotional eating, physical activity, or exercise self-efficacy.³⁰ Whereas findings related to exercise self-efficacy were similar to the current findings, the null finding related to physical activity was in contrast to the current study, which found that those with low early WL were engaging in approximately 70 minutes/week fewer than those with high early WL. The sample sizes of these prior 2 studies were smaller than the current study and the intervention mode also differed from the current study (e.g., in-person individual treatment, treatment within primary care); thus, follow-up studies are needed to determine whether there are consistent predictors of early WL across treatment types and to also examine whether additional measures, beyond those assessed in this prior work, are also related to early WL.

In the current study, positive associations were also observed between early WL and adherence to the Internet program. Adherence is consistently linked to post-treatment or longer-term WL outcomes,^{4,32,33} but findings to date have been mixed as to whether early adherence differs by early WL response.^{5,15,34} A possible explanation for mixed findings across studies could be attributed to the limited variability in intervention

adherence, as compliance is generally high early in WL treatment. In the current study, those with low early WL watched fewer video lessons and self-monitored their weight and caloric intake on fewer days compared to those with a $WL \geq 2\%$ at week 4. Although statistically significant, the clinical relevance of these findings often can be difficult to interpret or vary depending upon what is of greatest interest to the reader. For example, those with low early WL watched 3.5 lessons on average and those with high early WL watched 3.8 lessons. It can be debated whether this difference of 0.3 lessons is clinically meaningful. For this reason, we also examined achievement or non-achievement of targeted goals as this could potentially produce more clinically interpretable data. In this instance, fewer participants with low early WL watched all 4 video lessons (72.0%) compared to those with higher levels of early WL (82.1% and 90.5%); thus, failure to comply to program recommendations in the first 4 weeks increases the likelihood of poor early WL. These data suggest that close monitoring of even small lapses in prescribed goals (e.g., not viewing one video lesson) may be an important clinical indicator of those at risk for suboptimal WL outcomes.

This study is strengthened by a large sample size and use of a rigorously tested, remote-based WL program. However, it is not without limitations. First, although more demographically diverse than some behavioral WL trials, the study sample was predominately female (70%), non-Hispanic white (76%), and college educated (67%); thus, the generalizability of these findings to other populations is uncertain. This study was also limited to baseline predictors that were measured as part of the parent study, and therefore, other factors which may differ between early WL groups were not measured. It is also important to note that 4-week weight was self-reported, but we felt that the enhanced dissemination potential of using self-reported weight to classify early WL, far outweighed the use of objective weight measurements which would significantly reduce dissemination potential. Finally, assessment of caloric intake and exercise minutes during the first 4 weeks of the intervention were self-reported, which is often prone to error.

CONCLUSION

Given that early WL is predictive of longer-term outcomes, a greater understanding of factors associated with early treatment response is important for informing future stepped care or adaptive interventions (e.g., Sequential Multiple Assignment Randomized Trials; SMART) targeting early non-responders. Findings from

the current study add to the scant literature highlighting baseline and early adherence differences observed among those with varying degrees of initial WL. Future studies should focus on replicating study findings and exploring additional factors that may contribute to the variability in early WL outcomes. Identification of such factors could lead to greater personalization in WL programs via tailored early intervention efforts, and thereby, serve as a strategy for increasing the percentage of individuals who achieve clinically significant WL post-treatment.

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Human Subjects Approval Statement

This Research was approved by The Miriam Hospital's Institutional Review Board and participants signed informed consent prior to participating in the study.

Conflict of Interest Disclosure Statement

Drs. Unick and Thomas are on the Scientific Advisory Board of Medifast. Dr. Thomas reports participation on the scientific advisory board and consulting fees from Lumme Health, Inc., and Dr. Wing is on the Scientific Advisory Board of NOOM. All remaining authors have no relevant financial or non-financial conflicts of interest to report.

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