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Readiness Redefined: A Behavioral Task during Screening Predicted 1-Year Weight Loss in the Look AHEAD Study

Adam G. Tsai[1], **Anthony N. Fabricatore**[2], **Thomas A. Wadden**[3], **Allison J. Higginbotham**[3], **Andrea Anderson**[4], **John Foreyt**[5], **James O. Hill**[1], **Robert Jeffery**[6], **Marci E. Gluck**[7], **Edward W. Lipkin**[8], **Rebecca S. Reeves**[5], **Brent Van Dorsten**[9], and **the Behavioral Run-in Ancillary Study Group of the Look AHEAD Research Group**

[1]University of Colorado School of Medicine, Aurora, Colorado, USA

[2]Nutrisystem Inc, Fort Washington, Pennsylvania, USA

[3]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA

[4]Wake Forest University, Winston-Salem, NC

[5]Baylor College of Medicine, Houston, TX

[6]University of Minnesota, Minneapolis, MN

[7]National Institute of Diabetes and Digestive and Kidney Diseases, Phoenix, AZ

[8]University of Washington, Seattle, WA

[9]Center for Behavioral Medicine, Denver, CO

Abstract

Objective—Predicting outcome in weight loss trials from baseline characteristics has proved difficult. Readiness to change is typically measured by self-report.

Design and Methods—We assessed performance of a behavioral task, completion of food records, from the screening period in the Look AHEAD study (n = 549 at 4 clinical centers). Completeness of records was measured by the number of words and Arabic numerals (numbers) recorded per day, the number of eating episodes per day, and days per week where physical activity was noted. The primary outcome was weight loss at one year.

Results—In univariable analysis, both the number of words recorded and the number of numbers recorded were associated with greater weight loss. In multivariable analysis, individuals who recorded 20–26, 27–33, and ≥34 words per day lost 9.12%, 11.40%, and 12.08% of initial weight, compared to 8.98% for individuals who recorded less than 20 words per day (p values of 0.87, 0.008, and <0.001, respectively, compared to <20 words per day).

Corresponding Author: Adam G. Tsai, Anschutz Health and Wellness Building, University of Colorado, 12348 E. Montview Ave, Room 4108; Aurora, CO 80045, Telephone: 303-724-9053; Fax: 303-724-9976, adam.tsai@ucdenver.edu.

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Conclusions—Participants who kept more detailed food records at screening lost more weight after 1 year than individuals who kept sparser records. The use of objective behavioral screening tools may improve the assessment of weight loss readiness.

Currently, 34% of U.S. adults are obese.[1] The U.S. Preventive Services Task Force recommends that all adults with a body mass index ≥ 30 kg/m^2 be offered intensive counseling for weight loss, or be referred to programs that offer it.[2] However, it is not practical to provide intensive counseling to such a large number of individuals. If patient selection could be improved, weight loss programs might achieve lower attrition rates and improved weight losses.

The NIH guidelines on evaluation and treatment of obesity state that readiness for weight loss should be assessed in persons presenting for treatment, while noting that such assessment is "easier said than done."[3] However, a recent review challenged the notion that weight loss readiness – a person's self-reported desire and willingness to make changes to lose weight – is important to assess in clinical settings.[4] Self-reported readiness, the review concluded, predicted neither treatment adherence nor the magnitude of weight loss among persons pursuing a variety of weight control methods. The authors suggested that the lack of significant findings may be a function of the limited range of readiness among people who voluntarily engage in weight loss programs. Another explanation may be the limitation of self-report assessments of readiness. Individuals may overestimate their readiness because they do not clearly understand what behaviors are needed to make them successful, or because they greatly desire the outcome of weight loss.

We examined the ability of a behavioral task at screening to predict weight loss, session attendance, and physical activity at 1 year among participants who received an intensive lifestyle intervention in the Look AHEAD study.[5] Look AHEAD's careful screening procedures included a 2-week run-in period, in which candidates were required to record (but not required to alter) their food intake for at least 12 of 14 days.[6] Look AHEAD investigators believed that participants' keeping food records during the run-in would predict record keeping during treatment. Keeping food records during treatment, in turn, is positively correlated with weight loss.[7–12] Thus, in the current study, we assessed performance of a specific behavior, expected to be related to weight loss, rather than asking about general readiness to lose weight. We specifically sought to determine whether the completeness of record keeping during the screening period would predict weight loss outcomes at 1 year.

METHODS

Participant Sample

We acquired food records for 549 individuals who were assigned to the Intensive Lifestyle Intervention (ILI) arm of the Look AHEAD study. Look AHEAD is a 16-center NIH-funded trial (N = 5,145) of weight loss among individuals with type 2 diabetes, with an age range of 45–76 at randomization. Participants were randomized either to ILI or to a control group of Diabetes Support and Education (DSE). ILI participants were assigned to an intensive lifestyle change program that involved individual and group counseling, striving to attain

goals with respect to energy intake, macronutrient intake, and use of meal replacements, as well as engaging in ≥ 175 min/week of aerobic activity (e.g., brisk walking). The target of the lifestyle program was to lose at least 7% of initial body weight. To qualify for participation in Look AHEAD, potential participants were required to monitor their food intake and physical activity for 2 weeks, just as they would be required to do during treatment. Potential participants were not asked to modify food intake during the 2 week run-in or to count calories. If they failed to keep these records for at least 12 of 14 consecutive days, they were excluded from participation in the trial. [Out of 9,045 individuals who attended a clinic screening visit, 434 were excluded for not keeping adequate food records.[13]] The treatment prescription in the first year of Look AHEAD included: 1) attendance at 42 individual and group sessions during the first year of treatment [24 in the first 6 months, 18 in the second 6 months]; 2) self-monitoring of food intake, including amounts of food, number of calories, and grams of fat; and 3) self-monitoring of daily physical activity, listing only bouts of exercise that were at least 10 minutes in duration, with a goal of achieving 175 minutes per week of activity by month 6 of the first year.

The Look AHEAD intervention was stopped in September 2012 because of the failure to observe a significant difference between groups on the primary end point of cardiovascular disease morbidity and mortality.[14] However, a number of health benefits have been observed in ILI participants, compared with DSE, including improvements in mood, sleep apnea, medication use, mobility, and overall health-related quality of life.[15–19]

Run-in food records from Look AHEAD were scored for completeness to determine whether a reasonably simple scoring algorithm could predict success in weight loss during the trial. Because we were interested in the association of food records with adherence to the intervention, we examined only participants in the ILI group. Food records for the current analysis were obtained from 4 of the 16 Look AHEAD centers. These were University of Pennsylvania, University of Colorado, Baylor College of Medicine, and University of Minnesota.

Outcomes and Predictors

The primary outcome of this analysis was weight loss, defined as percentage reduction in initial weight at 1 year. There were two secondary outcomes, attendance at treatment sessions and minutes of physical activity per week. These two secondary variables were two of the three behavioral variables that have previously been shown to predict weight loss at 1 year in the overall trial.[20] (The third variable was meal replacement use, which was not required during the run-in period.) Attendance was verified by study staff, whereas food intake and physical activity were self-reported by study participants. Attendance was quantified as the percentage of sessions (0–100%) attended during the first year. Physical activity was quantified as average minutes per week from month 6 to year 1, when participants were expected to have reached their exercise goal. If a participant did not turn in a monitoring booklet in a given week, he/she was given a zero for minutes of physical activity that week.

Predictor variables—Demographic and clinical predictor variables tested for the current analysis included the following: age; gender; race/ethnicity; education level; baseline body mass index; and baseline insulin usage. Of these, all except education level and baseline BMI were associated with weight loss at 1 year in previous analyses.[20]

Self-monitoring variables—From participants' run-in food records, we extracted four variables which constituted the predictors of greatest interest to the present study; these were words, Arabic numerals (i.e., numbers), episodes of food or beverage intake ("eating episodes"), and performance of daily exercise. These variables were chosen for face validity; the food records that appeared the most complete seemed to have more words and numbers. Words and numbers, respectively, were simply the number of words and numerals that participants wrote per day in their food record. The number of eating episodes was the number of times per day that participants recorded eating or drinking something other than water. To qualify, an episode of eating/drinking had to be marked with a time on the food record or had to be separated by one blank line in the record. Performance of exercise was whether the participant noted any purposeful activity in the exercise section of the self-monitoring booklet. We counted the number of days that the participant recorded any physical activity (range, 0–14 days). All four self-monitoring variables were extracted manually from patients' food records, which were handwritten. In pilot testing, we found very high inter-rater reliability (interclass correlations > 0.97) for all of the predictor variables.

Statistical Analyses

All outcome variables (weight loss, physical activity, and treatment attendance) were analyzed as continuous variables. Predictor variables were analyzed as categorical variables for ease of interpretation. Separate models were developed for each outcome. Linear regression was used for all analyses. We first conducted univariable analysis with each independent variable. If that variable had an overall association with the outcome with a p value of < 0.2, it was included in the multivariable regression analysis. In the multivariable analysis, variables were retained only if they had a final p value of < 0.05.

Sample size and power—We did not have any preliminary data on which to base a power calculation. However, a pilot analysis of 103 patients randomly selected from the 549 in the overall sample revealed an association between weight loss at 1 year and number of words, and an association between weight loss at 1 year and number of numbers.[21] We estimated that evaluation of records from all 549 ILI participants at the four Look AHEAD centers would provide > 99% power to examine our hypotheses.

RESULTS

Participants' Characteristics

Participants' characteristics are shown in Table 1, as compared to the characteristics of the overall Look AHEAD sample. Overall, Look AHEAD had 5% Native-American participants, who were largely concentrated at two sites that were not included in this study; thus the percentage of "other" race/ethnicity is higher in the overall sample. Otherwise, the

sub-sample used for this analysis was very representative of the overall ILI group in Look AHEAD. Women in this sub-sample had a higher baseline weight, compared to the overall study, but a similar BMI.

Correlation among Self-Monitoring Variables

All four self-monitoring variables (i.e., number of words recorded, number of numbers, number of eating episodes per day, and days of exercise) were significantly associated with each other (all p values < 0.01). However, none of these associations met the criterion for co-linearity (correlation coefficient of ≥ 0.8). Thus, we tested all variables separately in each model.

Primary Outcome: Weight Loss

Univariable analysis—Among socio-demographic and clinical variables, only race/ethnicity and insulin use at baseline were associated with 1-year weight loss with a $p < 0.2$. Non-Hispanic whites lost 10.2% of initial weight, while African-American, Hispanic-American, and participants of mixed/other race lost 7.3%, 6.6%, and 5.5% of initial weight, respectively. Participants using insulin at baseline lost 7.3% of initial weight, compared to 9.6% for those not using insulin. Among self-monitoring variables, greater numbers of words recorded and of numbers recorded were strongly associated with greater weight loss at 1 year ($p < 0.001$ for both). Greater number of eating episodes and more days of exercise during the run-in period both were associated with greater weight loss at 1 year, but the associations did not reach statistical significance (p values of 0.10 and 0.15, respectively).

Multivariable analysis—Non-white race/ethnicity, insulin use, and number of words recorded in the food record remained associated with weight loss at 1 year in the multivariable model. The strength and direction of the association for all three variables was similar to that in the univariable analysis. For the number of words recorded, being in the second quartile was not associated with greater weight loss, but being in the third or fourth quartile was associated with significantly greater weight loss. When the number of numbers recorded was put into the multivariable model, it was no longer significant, but the number of words remained significant.

Secondary Outcomes

Treatment attendance—Race/ethnicity and gender were the only variables associated with treatment attendance at 1 year. Hispanic ethnicity and female gender were associated with lower attendance at treatment.

Physical activity—Race/ethnicity, gender, and age all were associated with the outcome of physical activity. African-American race was associated with less exercise, while the oldest age category (age 65–75, as compared to the youngest age category of 45–54) and male gender were associated with greater amount of physical activity at 1 year (Table 5). The number of days of physical activity during the run-in was strongly associated with frequency of physical activity at 1 year.

Exploratory analysis—In post hoc analysis, we examined whether the average number of words recorded for a shorter period of time (than the 14 days assessed in the present study) would predict weight loss at 1 year. We found that the average number of words recorded during the first 3 days of the screening period significantly predicted 1-year weight loss in the multivariable model (data not shown).

DISCUSSION

In this analysis of data from run-in food records, a very simple measure of the completeness of an individual's food record (i.e., the number of words recorded) was strongly associated with weight loss at 1 year. Individuals in the highest two quartiles of self-monitoring lost 11.4% and 12.1% of initial weight, compared to 9.0% and 9.1% for those in the lower two quartiles. Our methods are novel in that we sought to predict outcomes with performance on a behavioral task (completing food records for 14 days), rather than with a self-report measure of weight loss readiness, as previous studies have done.[22–24] The task of keeping a food record is simple and inexpensive to perform, and the performance measures (the number of words, numbers, and eating episodes that appeared in those records) can be assessed with near-perfect reliability. The exploratory analysis suggests that it may be possible to assess the completeness of food records over a shorter duration.

A recent report on "myths" surrounding obesity concluded that the use of weight loss readiness tools did not improve the prediction of weight loss in clinical trials.[4] Our findings suggest that a behavioral test of readiness in which potential participants are asked to take the first steps towards behavior change, by recording their food intake and physical activity, may have greater predictive value than the questionnaire-based measures that have been employed to date. Indeed, a previous review reported that a run-in period was associated with lower attrition in trials of pharmacotherapy for obesity.[25] The run-in period in pharmacotherapy trials lasted an average of 2.5 weeks, usually involved single blind administration of a placebo, and often included a low calorie diet prescription. The recent report on obesity myths did not cite a recent study which showed level of motivation was associated with successful weight loss (≥5% of initial weight).[26]

Previous studies have demonstrated that certain baseline socio-demographic and clinical characteristics are associated with weight loss.[20,27–34] A 2005 review of pre-treatment predictors of weight loss, plus one small trial conducted since then, focused on behavioral (e.g., number of previous weight loss attempts) and psychological variables (e.g., cognitive style, mood).[35,36] A more recent review on predictors of weight loss noted the methodological problems of assessing weight loss predictors and cited the need for greater standardization.[37] None of these studies assessed a behavioral task, as was done in the current study. As described above, the behavioral task assessed was a key component of the therapy provided during the intervention. At least six studies have shown that self-monitoring during the treatment phase is positively correlated with greater weight loss.[7–12] Of these studies, three studies simply counted the number of food records completed/turned in, and showed that more records completed was associated with greater weight loss.[7,9,10] Three other studies, all by Kirschenbaum and colleagues, evaluated the quality of food records (e.g., number of eating occasions recorded, time food was eaten).[8,11,12] All three of

these studies found that higher quality of record keeping was associated with greater weight loss. Our study is the first to look at the completeness of record keeping as a potential screening tool.

The results of this analysis inevitably raise the question of how these findings should be applied to clinical care (or for screening into research studies). We do not believe that an incomplete food record, by itself, should be used to reject or postpone an individual from participating in a weight loss program. However, a sparsely completed food record, taken together with other evidence that an individual's attention may be consumed by life stressors or other obstacles, may be a good reason to delay participation in a time and resource intensive intervention.[38] It is important to acknowledge that an incomplete food record may be attributable to other causes, such as low health literacy or poor planning skills on the part of the individual seeking treatment, rather than low motivation. If an individual is unable or unwilling to complete self-monitoring as part of screening, then clinicians or researchers would ideally collect other information (e.g., clinical interview) to indicate that the individual is ready to undergo treatment. (See Wadden & Sarwer, 2006, for a discussion of the importance of assessing temporal factors in individuals who seek clinical management of their obesity.)[39]

Our study has at least three important limitations. First, Look AHEAD participants were a highly selected group who received a very intensive lifestyle intervention to induce weight loss. Thus, weight losses across the sample were excellent. Despite this limitation, we were able to detect a substantial additional effect of the completeness of the run-in food record. Second, our measure of food record completeness was admittedly somewhat crude. We originally devised what we believed to be a more sophisticated scoring system for assessing food record "quality," but we found an unacceptably low level of inter-rater agreement for this method. Third, completion of the behavioral task can be interpreted either as a personality trait (i.e., being detail-oriented) or as a behavioral state (i.e., readiness to pursue weight loss). Lack of completion of the task also could also be attributable to low health literacy, which was not assessed in Look AHEAD. In the context of screening for a clinical trial, we believe that completion of the food record represents willingness and motivation to self-monitor, which are conceptually similar to readiness. However, in other contexts, readiness may need to be assessed with different methods (e.g., attendance at screening visits).

In conclusion, we found that a simple behavioral measure– the number of words recorded in a pre-treatment food log – was strongly associated with weight loss at one year. Individuals who kept detailed run-in food records lost a clinically meaningful greater amount of weight after 1 year, as compared to individuals who complete less detailed records. We believe that this measure is one reasonable proxy for success in an intensive lifestyle intervention. Future studies should seek to define additional behavioral methods of assessing readiness to implement significant health behavior changes.

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Adam G. Tsai had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Written permission has been obtained from all persons named in the acknowledgment.

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APPENDIX

The Behavioral Run-in Ancillary Study Group of the Look AHEAD Research Group

Clinical Sites

University of Colorado Anschutz Medical Campus

Adam G. Tsai, MD, MSCE; James O. Hill, PhD; Brent Van Dorsten, PhD; Marsha Miller, MS RD; Debbie Bochert

Baylor College of Medicine

John P. Foreyt, PhD; Rebecca S. Reeves, DrPH, RD; Molly Gee, MEd, RD

University of Minnesota

Robert W. Jeffery, PhD; Kerrin Brelje, MPH, RD; Therese Ockenden, RN; Carolyn Thorson, CCRP

University of Pennsylvania

Anthony Fabricatore, PhD; Thomas A. Wadden, PhD; Barbara J Maschak-Carey, MSN, CDE

VA Puget Sound Health Care System / University of Washington

Edward Lipkin, MD, PhD

Coordinating Center

Wake Forest University

Andrea Anderson, MS

Sponsor

National Institute of Diabetes and Digestive and Kidney Diseases

Marci Gluck, PhD

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What is already known about this subject?

Predicting outcome in weight loss trials from baseline clinical and demographic characteristics has not yielded a set of characteristics that is reliably associated with weight loss. A recent review article (Cassaza, NEJM, 2013) concluded that weight loss readiness was not associated with weight loss.

Most studies have measured readiness to change based on participant self-report, which is potentially biased.

Researchers and clinicians would benefit from knowing which individuals are truly "ready" to lose weight.

What does this study add?

In this analysis, individuals who kept more detailed food records during the screening period lost more weight after 1 year than individuals who kept sparser records.

The use of food records as a screening tool is low cost, objective, and can be reliably assessed.

The assessment of a behavioral task may improve the assessment of weight loss readiness among individuals seeking treatment for obesity.

Table 1

Demographic characteristics of participants*

	Current Study	Overall Look AHEAD**
Age	59.0 (6.8)	58.6 (6.8)
Race/ethnicity		
Non-Hispanic white	71.0%	63.1%
African-American	17.1%	15.5%
Hispanic-American	8.0%	13.2%
Mixed/other	3.8%	11.1%
Gender		
Female	54.8%	59.3%
Male	45.2%	41.7%
Education		
High school or less	14.2%	20.2%
Some college	38.5%	37.5%
College graduate	47.3%	42.3%
Weight (kg)	Women: 100.0 (18.6)	Women: 94.8 (17.9)
	Men: 108.7 (19.8)	Men: 108.9 (19)
Body mass index (kg/m^2)	Women: 36.8 (6.1)	Women: 36.3 (6.2)
	Men: 36.7 (5.7)	Men: 35.3 (5.7)
Insulin use		
No	85.4%	85.2%
Yes	14.6%	14.8%

* Mean (sd) unless otherwise stated

** Characteristics of ILI participants; From Table 1 of Pi-Sunyer et al (Diabetes Care, 2007)[13]

Table 2

Univariable associations of baseline characteristics and self-monitoring with weight loss at 1 year*

Variable	Percent Weight Loss, Absolute	Percent Weight Loss, Between-Group Difference (95% CI)	P value**
Race/ethnicity			<0.001
Non-Hispanic white (referent)	10.24%		
African-American	7.31%	−2.93% (−1.29, −4.57)	
Hispanic-American	6.69%	−3.55% (−1.20, −5.90)	
Mixed/other	5.52%	−4.72% (−1.48, −7.97)	
Age			0.36
45–54 (referent)	8.72%		
55–64	9.23%	0.51% (−1.01, 2.04)	
65–75	10.07%	1.35% (−0.51, 3.20)	
Gender			0.64
Female (referent)	9.15%		
Male	9.45%	0.30% (−0.96, 1.55)	
Education			0.31
High school or less (referent)	8.72%		
Some college	9.29%	0.57% (−1.41, 2.55)	
College graduate	9.79%	1.07% (−0.30, 2.44)	
Baseline BMI			0.34
25–29.9 kg/m^2 (referent)	7.82%		
30–34.4 kg/m^2	9.27%	1.45% (−0.66, 3.55)	
35–39.9 kg/m^2	9.77%	1.95% (−0.18, 4.08)	
≥ 40.0 kg/m^2	9.45%	1.63% (−0.53, 3.79)	
Insulin use			0.012
No (referent)	9.61%		
Yes	7.34%	−2.27% (−0.50, −4.04)	
Average words ⊣			<0.001
5–19 (referent)	7.65%		
20–26	7.95%	0.30% (−1.49, 2.09)	
27–33	10.23%	2.58% (0.75, 4.40)	
≥34	10.99%	3.34% (1.57, 5.11)	
Average numbers ⊣			<0.001
<3 (referent)	7.74%		
3–4	9.19%	1.45% (−0.48, 3.38)	
5–7	8.46%	0.72% (−1.00, 2.43)	
≥8	11.24%	3.50% (1.87, 5.13)	
Average eating episodes ⊣			0.10
<4 (referent)	8.47%		
4	9.33%	0.86% (−0.67, 2.39)	

Variable	Percent Weight Loss, Absolute	Percent Weight Loss, Between-Group Difference (95% CI)	P value**
≥5	10.11%	1.64% (0.12, 3.15)	
Exercise±			0.15
0–2 days (referent)	8.53%		
3–6 days	8.66%	0.12% (−1.69, 1.92)	
7–10 days	9.56%	1.03% (−0.70, 2.76)	
≥ 11 days	10.32%	1.79% (0.08, 3.50)	

*Each row shows the mean weight loss within the subgroup (referent and comparator groups). The rows for the subgroups show the absolute weight loss within that group, followed by the difference between the referent category and the comparator subgroup, and the 95% confidence intervals of the difference

**P value for overall F test

+Categories for words and numbers are in quartiles, categories for eating episodes are in tertiles

±Days of exercise recorded during run-in period (range, 0–14)

Table 3

Multivariable associations of baseline characteristics and self-monitoring with weight loss at one year*

Variable	Percent Weight Loss, Absolute	Percent Weight Loss, Between-Group Difference (95% CI)	P value
Referent	8.98% (7.59, 10.37)		<0.001
Race/ethnicity			
Non-Hispanic white	Referent		
African-American	6.24%	−2.74% (−1.13, −4.35)	0.001
Hispanic-American	5.2%	−3.78% (−1.46, −6.10)	0.002
Mixed/other	4.82%	−4.16% (−0.95, −7.36)	0.011
Insulin use			
No	Referent	Referent	
Yes	7.17%	−1.81% (−0.08, −3.54)	0.04
Average words			
5–19	Referent	Referent	
20–26	9.12%	0.14% (−1.62, 1.91)	0.87
27–33	11.4%	2.42% (0.63, 4.21)	0.008
≥34	12.08%	3.10% (1.37, 4.82)	<0.001

* Percent weight loss for each subgroup is displayed as the absolute weight loss within that group, followed by the difference between the referent and comparator groups, and the 95% confidence intervals of the difference.

Table 4

Multivariable associations of baseline characteristics and self-monitoring with treatment attendance at one year*

Variable	Percent Attendance, Absolute	Percent Attendance, Between-Group Difference (95% CI)	P value
Referent	79.6 (75.1, 84.0)		<0.001
Race/ethnicity			
Non-Hispanic white	Referent	Referent	
African-American	80.58	0.98 (−3.82, 5.78)	0.69
Hispanic-American	71.62	−7.98 (−14.93, −1.02)	0.025
Mixed/other	77.12	−2.48 (−11.93, 6.96)	0.61
Gender			
Female	Referent	Referent	
Male	74.7	4.90 (1.27, 8.52)	0.008

* Percentage (0–100) of sessions attended during the first year of treatment, relative to referent category. Percentage attendance for each subgroup is displayed as the absolute percentage attendance within that group, followed by the difference between the referent and comparator groups, and the 95% confidence intervals of the difference.

Table 5

Multivariable associations of baseline characteristics and self-monitoring with physical activity at one year*

Variable	Minutes per Week, Absolute	Minutes per Week, Between-Group Difference (95% CI)	P value
Reference	73.47 (46.91, 100.04)		<0.001
Race/ethnicity			
Non-Hispanic white	Referent	Referent	
African-American	30.7	−42.77 (−66.95, −18.60)	0.001
Hispanic-American	76.46	2.99 (−32.52, 38.49)	0.87
Mixed/other	76.07	2.60 (−44.75, 49.95)	0.91
Age			
45–54	Referent	Referent	
55–64	82.64	9.17 (−13.23, 31.57)	0.42
65–75	121.22	47.75 (20.52, 74.97)	0.001
Gender			
Female	Referent	Referent	
Male	114.32	40.85 (22.64, 59.07)	<0.001
Exercise**			
0–2 days	Referent	Referent	
3–6 days	106.1	32.63 (6.80, 58.45)	0.013
7–10 days	129.36	55.89 (30.62, 81.16)	<0.001
≥ 11 days	160.59	87.12 (62.33, 111.91)	<0.001

* Minutes of exercise recorded per week, relative to referent category. Exercise minutes for each subgroup is displayed as the absolute number of minutes within that group, followed by the difference between the referent and comparator groups, and the 95% confidence intervals of the difference.

** Days of exercise recorded during run-in period (range, 0–14)