

Workday Sitting Time and Marital Status: Novel Pretreatment Predictors of Weight Loss in Overweight and Obese Men

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Philip J. Morgan, PhD¹, Jenna L. Hollis, PhD^{1,2}, Myles D. Young, PhD¹,
Clare E. Collins, PhD¹, and Pedro J. Teixeira, PhD³

Abstract

The evidence base for weight loss programs in men is limited. Gaining a greater understanding of which personal characteristics and pretreatment behaviors predict weight loss and attrition in male-only studies would be useful to inform the development of future interventions for men. In December 2010, 159 overweight/obese men (mean age = 47.5 years; body mass index = 32.7 kg/m²) from the Hunter Region of New South Wales, Australia, participated in a randomized controlled trial testing the effectiveness of two versions of a 3-month gender-targeted weight loss program. In the current analyses, social-cognitive, behavioral, and demographic pretreatment characteristics were examined to determine if they predicted weight loss and attrition in the participants over 6 months. Generalized linear mixed models (intention-to-treat) revealed weight change was associated with education level ($p = .02$), marital status ($p = .03$), fat mass ($p = .045$), sitting time on nonwork ($p = .046$), and workdays ($p = .03$). Workday sitting time and marital status accounted for 6.5% ($p = .01$) of the variance in the final model. Attrition was associated with level of education ($p = .01$) and body fat percentage ($p = .01$), accounting for 9.5% ($p = .002$) of the variance in the final model. This study suggests men who spend a lot of time sitting at work, especially those who are not married, may require additional support to experience success in self-administered weight loss programs targeting males. Additional high-quality evidence is needed to improve the understanding which pretreatment behaviors and characteristics predict weight loss and attrition in men.

Keywords

obesity, predictor, weight loss, male, attrition

Obesity is a serious global health concern (Finucane et al., 2011) associated with multiple negative physical and psychological health conditions including cardiovascular disease (Guh et al., 2009), type 2 diabetes (Guh et al., 2009), depression (Luppino et al., 2010), anxiety (Garipey, Nitka, & Schmitz, 2010), and several cancers (Renehan, Tyson, Egger, Heller, & Zwahlen, 2008). Increases in obesity have affected both sexes (Finucane et al., 2011), but men are much less likely than women to participate in weight loss research (Pagoto et al., 2012). Although several innovative male-only weight loss programs have been conducted to address this imbalance in recent years (e.g., Hunt et al., 2014; Morgan et al., 2014), the evidence base to inform weight loss recommendations for men remains limited (Young, Morgan, Plotnikoff, Callister, & Collins, 2012).

Gaining a greater understanding of which personal characteristics and pretreatment behaviors predict weight

loss and attrition in male-only studies would be useful to inform the development of future interventions. Although sex-specific predictors of weight loss success likely exist (Stubbs et al., 2011), many studies do not analyze men and women separately or include sex as a covariate within analyses (Teixeira, Going, Sardinha, & Lohman, 2005), which may obscure important sex differences in results. There is a rationale to examine predictors in men

¹University of Newcastle, Callaghan, New South Wales, Australia

²University of Southampton, United Kingdom

³University of Lisbon, Lisboa, Portugal

Corresponding Author:

Philip J. Morgan, Priority Research Centre in Physical Activity and Nutrition, Faculty of Education and Arts, University of Newcastle, Callaghan, New South Wales 2308, Australia.
Email: philip.morgan@newcastle.edu.au

and women separately (Lovejoy, Sainsbury, & Stock Conference 2008 Working Group, 2009).

Importantly, predictor analyses should be guided by theory (Teixeira et al., 2005). Bandura's social cognitive theory (SCT) presents a causal framework of social and personal factors that are hypothesized to influence behavior including self-efficacy (i.e., confidence in ability to control health habits), outcome expectations (i.e., anticipated consequences), behavioral goals (i.e., intentions), and sociostructural factors (i.e., social and environmental barriers and facilitators; Bandura, 1986). Notably, SCT is one of the most widely examined theories for key weight loss behaviors including physical activity and healthy eating (Luszczynska & Schwarzer, 2005). A recent review of SCT in the physical activity domain noted that men were similarly underrepresented in the field (Young, Plotnikoff, Collins, Callister, & Morgan, 2014).

The aim of the current study was to identify pretreatment predictors of weight loss and attrition in the male-only (Self-Help, Exercise and Diet using Internet Technology) SHED-IT Community Randomized Controlled Trial (RCT; Morgan et al., 2010; Morgan et al., 2013). In this secondary analysis, it was hypothesized that the SCT cognitions for physical activity and healthy eating would significantly predict changes in weight during the study, with self-efficacy exhibiting the strongest association. Given the poor understanding of pretreatment predictors of weight loss and attrition in men, a number of demographic and anthropometric variables were also examined as predictors, but no hypotheses were offered for this exploratory component.

Method

Participants

The study was conducted in the Hunter Region of New South Wales, Australia. Participants were men aged 18 to 65 years with a body mass index (BMI) between 25 and 40 kg/m². Eligibility criteria also included mobile (cell) phone ownership, access to Internet facilities, availability to attend all assessments, agreement to refrain from participating in other weight loss programs during the study, and no major weight loss (5% or more) in the previous 6 months (Morgan et al., 2010). Participants were predominantly recruited through advertisements (e.g., radio, newspaper), workplace e-mails/notices, and a university media release. The study received institutional ethics approval, all men provided written informed consent and the study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000699066). Detailed study methods are reported elsewhere (Morgan et al., 2010).

Design and Interventions

As noted previously, data for this secondary analysis were sourced from the SHED-IT Community RCT, which was a multiarm parallel, assessor-blinded trial investigating whether provision of a 3-month self-administered, gender-sensitized weight loss program could lead to significant weight loss in a community sample of overweight and obese men. Participants were randomized to (a) SHED-IT *Resources* (i.e., SHED-IT Program plus paper-based self-monitoring), (b) SHED-IT *Online* (SHED-IT Program plus online self-monitoring), or (c) a wait-list control. The SHED-IT *Resources* program included (a) a DVD on weight loss for men; (b) the *Weight Loss Handbook for Men*; (c) the *Weight Loss Support Book for Men* (for self-monitoring and completing key social-cognitive tasks); and (d) weight loss tools (e.g., pedometer, tape measure). The SHED-IT *Online* program included all of the SHED-IT *Resources* program components, but men completed their self-monitoring on a website (www.calorieking.com.au) and received seven individualized e-feedback reports.

Both programs were based on extensive qualitative and quantitative pilot work (Morgan et al., 2010) and operationalized SCT (Bandura, 1986) by targeting key mediators such as self-efficacy, outcome expectations, and social support. The resources were designed to appeal to men with attention given to surface-structure components (e.g., pictures of men, male-specific research) and deep-structure, value-based components (e.g., use of humor, a frank approach, and autonomy support; Morgan, Young, Smith, & Lubans, 2016; Resnicow, Baranowski, Ahluwalia, & Braithwaite, 1999).

Assessment of Predictors

Measure details for the potential psychological, social, physiological, and demographic predictor variables are summarized in Table 1. Comprehensive details are available elsewhere (Morgan et al., 2010).

Statistical Analysis

Analyses were conducted on all pretreatment variables of interest using generalized linear mixed models with weight (kg) as the outcome variable at 3 and 6 months (SPSS v20). Weight was analyzed as a continuous variable, expressed as the residualized value after the effect for the baseline dependent measures was removed. This method protects the dependent measure against an overcorrection of the post score by the prescore that occurs when calculating a change score through a standard subtraction method. Variables with a *p* value less than 0.2 in bivariate correlations were examined in an intention-to-treat forward

Table 1. Summary Details of the Potential Psychological, Social, Physiological, and Demographic Predictor Variables.

Variable	Measure
Weight and height	Objectively measured using standardized procedures (Morgan et al., 2010).
Body mass index	Calculated using the standard equation (weight [kg]/height [m] ²).
Waist circumference	Measured at the umbilicus with a nonextensible steel tape (KDSFI0-02, KDS Corporation, Osaka, Japan).
Body composition	Bioimpedance was used for the assessment of body composition, including fat mass percentage and skeletal muscle mass and visceral fat area using the InBody720 (Biospace Co., Ltd., Seoul, Korea) which has shown to be valid and reliable (Gibson, Holmes, Desautels, Edmonds, & Nuudi, 2008).
Physical activity	Objectively measured over 7 days with valid and reliable Yamax SW200 pedometers (Yamax Corporation, Kumamoto City, Japan; Steeves, Silcott, Bassett, Thompson, & Fitzhugh, 2011).
Sedentary behavior	Workday and nonworkday sitting time measured with the Sitting Questionnaire (Marshall, Miller, Burton, & Brown, 2010).
Energy intake	Assessed using the Australian Eating Survey, which is a validated 135-item semiquantitative food-frequency questionnaire (Collins et al., 2014).
Portion size	Assessed using portion size photographs from the Dietary Questionnaire for Epidemiological Studies Version 2, food-frequency questionnaire from the Cancer Council Victoria (Giles & Ireland, 1996).
Hazardous alcohol score	Measured with the validated Australian Government Department of Veteran Affairs, Alcohol Use Disorders Identification Test (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993).
SCT cognitions	Assessed using validated instruments (Morgan et al., 2010): PA self-efficacy ($\alpha = 0.87$; $n = 5$ items); PA outcome expectations ($\alpha = 0.87$; $n = 3$ items); PA social support ($n = 1$ item); PA intention ($n = 1$ item); Healthy eating self-efficacy ($\alpha = 0.87$; $n = 6$ items); Healthy eating outcome expectations ($\alpha = 0.91$; $n = 6$ items); Healthy eating social support ($n = 1$ item); Healthy eating intention ($n = 1$ item).
Demographic characteristics	Collected via questionnaire and consisted of age, marital status, ethnicity, educational level, gross annual family income, postcode, and socioeconomic status ^a .

Note. SCT = social cognitive theory; PA = physical activity.

^aSocioeconomic status was derived from postcode of residence using the Index of Relative Socioeconomic Advantage and Disadvantage from the Australian Socio-Economic Indexes for Areas.

stepwise multiple linear regression analysis (weight) or logistic regression (attrition). The baseline observation carried forward method was used to impute missing data. Attrition was analyzed as a binary categorical variable and coded as “1” if the participant attended the 6-month assessment and “2” if they did not.

Results

The flow of men through the trial and study results have been reported elsewhere (Morgan et al., 2013). Briefly, 159 overweight and obese men were recruited from the Hunter Region of New South Wales, Australia. The mean (SD) age and weight of the sample were 47.5 years (11.0) and 103.4 kg (14.0), respectively. Ninety-one percent was born in Australia and 73% was obese. Table 2 presents a summary of baseline characteristics for the sample and, as reported previously (Morgan et al., 2013), these characteristics were similar between groups. There were no significant differences in withdrawal rates between treatment groups during the study. At 6 months, significantly greater weight losses were observed in the *Online* group (−4.7 kg; 95% CI [−6.1, −3.2]) and *Resources* group (−3.7 kg; 95% CI [−4.9, 2.5]) compared with the control

(−0.5 kg; 95% CI [−1.4, 0.4]), with no difference between interventions (1.0 kg; 95% CI [−0.7, 2.6]). The average weight change by 6 months for all men ranged from −22.3 kg to +6.9 kg, with a mean (SD) of −3.6 kg (5.0).

Predictors of Change in Weight

As seen in Table 3, the bivariate analysis revealed that weight change was significantly associated with fat mass ($\beta = 0.14$, $p = .045$), workday sitting ($\beta = 0.23$, $p = .03$), nonworkday sitting ($\beta = 0.22$, $p = .046$), highest level of education ($\chi^2 = 7.6$, $p = .02$), and marital status ($\chi^2 = 4.5$, $p = .03$). Men who were married, had a smaller initial fat mass percentage or reported a lower sitting time on a workday or nonworkday, lost more weight. There was a nonlinear relationship between highest level of education and weight loss, with men with a trade/diploma qualification losing the most weight, followed by university qualified men and then men with a school education only. The stepwise multiple linear regression analysis revealed that total sitting time per workday ($\beta = 0.20$) and marital status ($\beta = 0.19$) were significant predictors of weight loss, explaining 6.5% of the variance at 6 months (adjusted R^2 , $F = 5.5$, $p = .01$).

Table 2. Baseline Characteristics for Men Participating in the SHED-IT Community Weight Loss Trial (n = 159).

Continuous variables	Mean (SD)	Categorical variables	N (%)
Age	47.5 (11.0)	Highest level of education	
BMI (kg/m ²)	32.7 (3.5)	School	42 (26)
Waist (cm)	113.3 (9.5)	Trade/Diploma	78 (49)
Fat mass (%)	32.2 (5.2)	University	39 (25)
Visceral fat area (cm ²)	169.2 (31.8)	Marital status	
Skeletal muscle mass (kg)	40.0 (5.2)	Married	117 (74)
Quality of life (SF-12)		Unmarried	42 (26)
Mental subscale	48.1 (9.4)	Country of birth	
Physical subscale	49.1 (7.4)	Australia	144 (91)
Total energy intake (MJ/day)	11.5 (3.5)	United Kingdom	8 (5)
Saturated fat score		Other	7 (4)
Portion size	1.2 (0.3)	Weekly household income (\$)	
Hazardous alcohol score	7.8 (2.9)	Unknown	5 (3)
Steps (1000/day)	6.9 (2.9)	<1,000	20 (13)
Sitting time (hour/day)		1,000 to <1,500	28 (18)
Workday	10.3 (3.7)	≥1,500	105 (67)
Nonworkday	8.5 (3.3)	Socioeconomic status	
Physical activity cognitions		1-2 (most disadvantaged)	9 (6)
Self-efficacy	3.9 (0.8)	3-4	25 (16)
Social support	3.4 (1.2)	5-6	58 (37)
Outcome expectations	4.5 (0.6)	7-8	47 (30)
Intention	4.7 (0.6)	9-10 (most advantaged)	20 (13)
Nutrition cognitions		BMI category	
Self-efficacy	3.6 (0.7)	Overweight	43 (27)
Social support	3.8 (1.1)	Obese I	76 (48)
Outcome expectations	4.4 (0.6)	Obese II	40 (25)
Intention	4.6 (0.6)		

Note. SHED-IT = Self-Help, Exercise and Diet using Internet Technology; SF-12 = Short Form 12; MJ = Megajoule; BMI = body mass index; SEIFA = Socio-Economic Indexes for Areas.

Predictors of Attrition

At 6 months, 30 men (19%) were considered noncompleters. The best model for program completion was statistically significant and indicated that highest level of education and baseline fat mass reliably predicted attrition (Wald's $\chi^2 = 15.3$, $df = 3$, $p = .002$). This model accounted for between 9.5% (Nagelkerke R^2) and 15.3% (Cox and Snell R^2) of the variance, indicating a weak association between prediction and attrition. In this model, 98.4% of completers was correctly classified to *remaining in the study* but only 6.9% of nonattenders was correctly classified to *dropping out of the study*. Overall 81% of participants was correctly classified. For a one-unit change in the predictor variable of body fat percentage, the odds of dropping out by the end of the study increased by 1.1. Men who had completed "school education only" were three times more likely to drop out than men with a university education. The odds of dropping out of the study for men who had completed a trade or diploma were 0.8 times the odds of those with a

university education and 0.3 times the odds of those that had completed school education only.

Discussion

The aim of this study was to identify pretreatment predictors of weight loss and attrition after a weight loss program targeting overweight and obese men. In the final model, being married and reporting a lower sitting time on a workday significantly predicted greater 6-month weight loss. Contrary to the study hypotheses, SCT variables at baseline were not associated with weight loss during the study. Lower initial fat mass and level of education significantly predicted a lower level of attrition. Men with a trade/diploma were more likely to complete the study than those with university degrees or those who did not achieve additional postschool qualifications.

The results for weight loss success suggest that additional support, or alternative strategies, may need to be considered for men in weight loss programs who are seated for long periods of time at work. Given the large

Table 3. Predictors of Change in Weight and Attrition at 6 Months.

Predictor variable	Category	Weight (kg)		Attrition		
		Effect size (slope) [95% CI]	<i>p</i>	Assessed at 6 months	Wald's χ^2	<i>p</i>
Highest level of education	School	1.74 [-0.27, 3.74]	.02*	-1.33 [-2.46, -0.20]	9.81	.01*
	Trade/diploma	-0.67 [-2.44, 1.09]		0.00 [-1.15, 1.15]		
	University	Referent		Referent		
Marital status	Married	-1.78 [-3.41, -0.14]	.03*	0.22 [-0.65, 1.10]	0.24	.62
	Unmarried	Referent		Referent		
Country of birth	Australia	-0.92 [-4.48, 2.64]	.67	1.22 [-0.33, 2.78]	2.61	.27
	The United Kingdom	0.38 [-4.38, 5.14]		1.66 [-0.92, 4.23]		
	Other	Referent		Referent		
Weekly household income (\$)	Unknown	1.20 [-3.38, 5.79]	.46	-0.21 [-2.22, 1.80]	6.18	.10*
	≥1,500	-1.12 [-3.35, 1.12]		1.03 [-0.03, 2.08]		
	1,000 to <1,500	-0.09 [-2.77, 2.59]		1.50 [-0.01, 3.01]		
	<1,000	Referent		Referent		
Age (years)	—	-0.01 [-0.08, 0.05]	.69	0.02 [-0.01, 0.6]	1.38	.24
SEIFA index	—	-0.00 [-0.02, 0.01]	.65	0.00 [-0.01, 0.01]	0.20	.66
BMI (kg/m ²)	—	0.16 [-0.05, 0.36]	.14*	-0.12 [-0.24, -0.01]	4.50	.03*
Waist (cm)	—	0.04 [-0.04, 0.12]	.32	-0.03 [-0.07, 0.01]	2.02	.14*
Fat mass (%)	—	0.14 [0.00, 0.28]	.05*	-0.12 [-0.21, -0.03]	7.58	.01*
Visceral fat (cm ²) ^a	—	0.01 [-0.01, 0.03]	.36	-0.01 [-0.02, 0.00]	2.59	.11*
Skeletal muscle (kg) ^b	—	-0.11 [-0.25, 0.04]	.14*	0.03 [-0.05, 0.11]	0.65	.42
Quality of life (SF-12) ^c						
Mental subscale	—	-0.07 [-0.15, 0.01]	.08*	0.02 [-0.02, 0.06]	0.97	.32
Physical subscale	—	-0.03 [-0.13, 0.07]	.55	-0.04 [-0.10, 0.02]	1.84	.18*
Total energy intake (MJ/day)	—	0.04 [-0.17, 0.25]	.69	0.01 [-0.10, 0.13]	0.03	.86
Saturated fat score	—	0.03 [-0.01, 0.08]	.17*	-0.00 [-0.03, 0.02]	0.03	.87
Portion size	—	-1.65 [-4.57, 1.27]	.27	-0.72 [-2.34, 0.91]	0.75	.39
Hazardous alcohol score ^c	—	0.03 [-0.22, 0.28]	.82	0.06 [-0.07, 0.20]	0.90	.34
Steps (1,000/day) ^d	—	-0.26 [-0.53, 0.01]	.06*	0.03 [-0.13, 0.18]	0.12	.73
Sitting time (hour/day) ^e						
Workday	—	0.23 [0.03, 0.43]	.03*	0.02 [-0.09, 0.14]	0.17	.68
Nonworkday	—	0.22 [0.00, 0.44]	.05*	0.05 [-0.07, 0.18]	0.75	.39
Physical activity cognitions						
Self-efficacy	—	-0.31 [-1.20, 0.58]	.50	0.00 [-0.48, 0.49]	0.00	.99
Social support	—	0.06 [-0.56, 0.68]	.85	0.19 [-0.14, 0.53]	1.27	.26
Outcome expectations	—	0.21 [-0.95, 1.37]	.73	0.29 [-0.31, 0.89]	0.91	.34
Intention	—	-0.10 [-1.41, 1.22]	.88	0.36 [-0.28, 1.00]	1.24	.27
Nutrition cognitions						
Self-efficacy	—	0.38 [-0.62, 1.39]	.46	-0.24 [-0.80, 0.32]	0.69	.41
Social support	—	0.29 [-0.36, 0.94]	.38	0.26 [-0.07, 0.60]	2.35	.13*
Outcome expectations	—	0.89 [-0.41, 2.19]	.18*	0.25 [-0.44, 0.94]	0.51	.48
Intention ^c	—	0.22 [-0.92, 1.35]	.70	-0.21 [-0.90, 0.48]	0.37	.55

Note. SF-12 = Short Form 12; MJ = Megajoule; BMI = body mass index; SEIFA = Socio-Economic Indexes for Areas.

^a*n* = 154. ^b*n* = 153. ^c*n* = 158. ^d*n* = 143. ^e*n* = 152.

**p* < .2 therefore was included in the multiple linear regression or logistic regression model (values in bold).

proportion of waking hours that men spend at work, those with highly sedentary jobs may find it difficult to accumulate the necessary physical activity required for sustainable weight loss. This is particularly problematic

given that a recent mediation analysis of the SHED-IT Program revealed that physical activity changes in the first 3 months mediated the largest proportion of the intervention's effect on weight at 6 months (Young et al.,

2015). Although the evidence for effective strategies to reduce sitting in the workplace is limited, recent reviews have provided preliminary evidence that multicomponent interventions that include education in addition to environmental restructuring are likely to be most effective (Chu et al., 2016; Gardner, Smith, Lorencatto, Hamer, & Biddle, 2016). It is possible that men with highly sedentary jobs may require weight loss interventions that include these components to increase their likelihood of success.

Marital status was also associated with weight loss; married men lost weight than unmarried men. This effect may be explained by the social support provided by partners, which was targeted explicitly in the SHED-IT interventions. Indeed, men have previously reported that their wives are important sources of nutrition information, social support, and accountability during weight loss (Wirth, James, Fafard, & Ochipa, 2013). These findings indicate that unmarried men may require additional support or strategies to engage other family members or friends, though further exploration of this hypothesis is required.

In the current study, higher fat mass at baseline and level of education were significant predictors of attrition in men. It is somewhat difficult to place these findings into context, as the evidence for pretreatment predictors of attrition in weight loss programs has been mixed (Teixeira et al., 2004) with considerable heterogeneity evident in study samples, program types, and study designs (Moroshko, Brennan, & O'Brien, 2011). As noted previously, men have also been greatly underrepresented in weight loss research and many studies adjust for sex in the analyses, which may obscure important sex differences that exist in the population (Lovejoy et al., 2009). When reviewing the available evidence, Moroshko et al. (2011) noted that the association between weight status and attrition was null in 18 studies, positive in five, and negative in four. However, it is important to note that this study determined that body fat percentage was a stronger predictor of attrition than BMI in men, which may be considered a better measure of adiposity, given the lack of distinction between muscle mass and fat mass when using BMI or weight.

Findings for the association between level of education and attrition have also been mixed. In their systematic review of the literature, Moroshko et al. (2011) retrieved five weight loss studies reporting that lower education level was associated with higher attrition and 10 studies reporting no association between the two variables. In the current study, the odds of dropping out of the study were lowest for men who had completed a trade or diploma. Notably, despite being an at-risk subgroup, these findings highlight that blue-collar men engaged with the self-administered, gender-targeted approach to

weight loss used in the current study. Future research into the sex-specific predictors of attrition in men is needed to build on these preliminary findings.

Although SCT was used to guide the analysis within an ecological model that included other demographic and biological variables, no psychosocial variables predicted weight change. These null findings may be due to limited variability in the measures at baseline, which was likely the result of recruiting a highly motivated sample. This motivational bias may reduce the predictive utility of these constructs. In addition, the predictive utility of social-cognitive variables is reduced when participants do not have previous experience with the behavior in question (Ajzen, 2001). As the sample of men recruited were mostly sedentary and demonstrated poor eating habits at baseline, it is possible that they were unsure of the difficulty or requirements needed to achieve regular physical activity or follow a healthy eating plan. This suggestion is supported by previous research indicating that men generally demonstrate poorer "health literacy" compared with women (Person & Saunders, 2009), and may require gender-tailored education to improve their knowledge, skills, and motivation to understand and apply health information to improve their quality of life (Davey, Holden, & Smith, 2015). In this context, much more empirical research is needed to study men's health cognitions and health competencies in the context of weight loss, diet, and physical activity. Despite self-efficacy being the pivotal predictor of behavior change in SCT (Bandura, 1986), and that some studies have identified that dietary and physical activity self-efficacy are associated with success (Teixeira et al., 2002; Teixeira et al., 2004; Young et al., 2014), neither predicted weight loss success in the current study. This finding has also been observed in previous research (Fontaine & Cheskin, 1997; Stubbs et al., 2011; Teixeira et al., 2002).

This article addressed several limitations of previous predictor analyses (Teixeira et al., 2005). The study examined a comprehensive range of biological, behavioral, and psychological predictors in an underrepresented subgroup, included objective measures of weight, body composition, and physical activity and conducted an intention-to-treat analysis. The study data were also drawn from a rigorous RCT that adhered to the CONSORT statement. Limitations include a moderate sample size, limited power to detect smaller associations, and the lack of longer term follow-up.

This study suggests that unmarried males who spend a lot of time sitting at work may require additional support to experience success in self-administered weight loss programs. These predictors may be used in future hypothesis testing or in more complex prediction models. However, as this is the first evidence in men, replication in other male samples is required.

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Authors' Note

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study. The funding body did not have any input into the design of the study of the study, the collection or analysis of data, the preparation of this article, or the decision to submit this article for publication.

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