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Enrollment Challenges: Recruiting Men to Weight Loss Interventions

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Abstract

Obese men are at an increased risk of chronic disease and are far less likely than women to attempt weight loss. There is a need to successfully recruit men to weight loss clinical trials. Overweight and obese men were recruited to a 6-month, randomized, controlled weight loss trial. Initial recruitment efforts were aimed at men in the workplace with less than or equal to 2 years of college education. After unsatisfactory interest from men and businesses alike, recruitment strategy shifted to enroll men outside the workplace with any educational background. Recruitment methods included word of mouth, email and website advertisements, printed posters in local businesses and doctors' offices, Facebook ads, and a 1-week newspaper ad campaign. Initial interest and enrollment was negligible with only 35 men enrolled in the first 7 months. The launch of a 1-week newspaper advertisement was the most useful recruitment technique and 102 overweight/obese men were successfully enrolled. Study retention remained high throughout the Gutbusters program, indicating targeted, effective recruitment, and not weight loss interest, may be the largest barrier to trial participation for overweight and obese men.

Keywords

obesity, behavioral issues, behavioral research, research, men's health interventions, nutrition, general health and wellness

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The number of overweight and obese men has steadily climbed in recent years, presenting a substantial public health problem (Centers for Disease Control and Prevention, 2016). Current prevalence estimates indicate that 33.7% of men and 36.5% of women in the United States are obese (BMI ≥30), resulting in over $190 billion in medical costs, annually (Ogden, Carroll, Kit, & Flegal, 2014). Men are currently underrepresented in the weight loss treatment literature. However, men have nearly the same prevalence of overweight and obesity as women and suffer greater levels of morbidity and mortality because of it (Sattar, 2013; The Global BMI Mortality Collaboration, 2016). Obese men are at an even greater risk than women of developing many chronic diseases such as heart disease, diabetes, and cancer, as men typically accumulate fat in the abdominal region, elevating the health risks related to visceral fat deposits (Jakicic, 2012; Westerterp, Meijer, Janssen, & Saris, 1992).

Research suggests that women enroll in weight loss interventions nearly four times as often as men do, both commercially and in research settings (Franz et al., 2007). Globally only 27% of weight loss trial participants are men, with even fewer men participating in the United States (22% of weight loss subjects; Franz et al., 2007; Pagoto et al., 2012). Men and women face different societal pressures related to weight, and women typically engage in more dieting behaviors (Pagoto et al., 2012). Men are also far less likely to identify themselves as overweight in the first place (Dorsey, Eberhardt, & Ogden, 2012), and are more likely to pursue weight loss as a result of an illness or health issue (Hankey, Leslie, & Lean, 2002; Klem, Wing, McGuire, Seagle, & Hill, 1997; Pagoto et al., 2012).

One widespread hypothesis for poor male participation in weight loss trials is that men are not being appropriately targeted during the recruitment process, leaving them unengaged and uninterested. The public image of the

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weight loss industry is primarily female, with Caucasian women making up the majority of weight loss participants. Consequently, when men join a weight loss intervention, they are often depending on approaches that have been designed for women (Lovejoy & Sainsbury, 2009). In order to moderate increased obesity and lessen the negative health consequences associated with excess weight in men, more efforts are necessary to accommodate the needs and preferences of men, in order to increase male enrollment in weight loss interventions (Aguiar et al., 2017; Hunt et al., 2014; Morgan et al., 2012; Morgan, Lubans, et al., 2011; Morgan, Lubans, Collins, Warren, & Callister, 2009; Morgan, Warren, Lubans, Collins, & Callister, 2011; Pagoto et al., 2012).

Research study recruitment can be a momentous challenge. Poor recruitment can result in an underpowered study, producing inadequate data and may also lead to a trial extension or termination, increasing costs. Some estimates suggest that less than half of clinical trials globally achieve their recruitment targets (Anna-Bettina & Ioannidis, 2001; Charlson & Horwitz, 1984; Foy et al., 2003; Sully, Julious, & Nicholl, 2013). An increasing number of studies have suggested that the strategy for recruitment, instead of a lack of suitable and interested participants, is the largest hurdle for enrolling participants in research studies (Sood et al., 2009; Sutton, Cain, Vallo, & Redman, 2017; Treweek et al., 2013). Unfortunately, there is extremely limited literature on successful recruitment techniques for weight loss interventions for men.

There is a significant need to identify effective recruitment techniques to entice overweight and obese men to join weight loss interventions in order to initiate necessary weight loss and sustain successful long-term weight loss maintenance. Therefore, the purpose of this evaluation was to describe the methods that were, and were not productive, in recruiting men to an intervention designed specifically for males.

Methods

Intervention

With this in mind, a targeted recruitment strategy was developed to enroll 107 men to the Gutbusters weight loss intervention, conducted at the University of Vermont. Upon initial project design, the study was modeled after a previously successful intervention, Rethinking Eating and FITness (REFIT), completed at the University of North Carolina (UNC) (Crane, Lutes, Ward, Bowling, & Tate, 2015). The REFIT curriculum was used as a template for the Gutbusters trial. REFIT was a 6-month randomized controlled trial that compared an active intervention to a waitlist control group (Crane et al., 2015).

The plan with Gutbusters was to use the template intervention in a slightly different population of men with the addition of incentives for successful weight loss. The REFIT intervention targeted all men aged 18–65 years with a BMI between 25 kg/m^3 and 40 kg/m^3 without any known medical condition that would put them at risk when losing weight, changing their diets, or participating in physical activity. Men were excluded if they had weight loss greater than 10 pounds in the previous 6 months, were currently participating in another weight loss program, had plans to leave Vermont in the 6 months following recruitment, had a significant mental illness diagnosis or hospitalization, were currently being treated for cancer, or reported heavy alcohol or drug use. In contrast, for the Gutbusters study, eligibility criteria remained the same except recruitment efforts were originally aimed at men with 2 years or less of college education. The original intention was to conduct all in-person research activities at each participant's place of business in an attempt to make the intervention convenient for participants, as men have reported a desire for programs that provide little disruption to their daily routines (Egger & Mowbray, 1993; Wolfe & Smith, 2002). By implementing these changes to the eligibility criteria, the goal was to recruit a unique population of men, with 2 years of college education or less, that are not often enrolled in behavioral weight loss interventions, as the REFIT program primarily followed college-educated men (83.2%) who were employed full-time (88.8%; Crane et al., 2015).

Gutbusters

Gutbusters was a randomized controlled trial comparing two arms: intervention plus incentives for successful weight loss (defined as losing one pound per week) and intervention alone. The goal of the Gutbusters intervention was to reduce daily caloric intake by making six 100-calorie adjustments to their typical daily diet (for a total of 600 fewer calories per day, or 4,200 fewer calories per week). In order to guide participants in how to make these 100-calorie adjustments, a Gutbusters website was developed with 13 separate lessons focusing on different eating behaviors and activities, such as portion size, caloric beverages, eating in restaurants, and so forth. The majority of the lessons focused on behavioral changes related to diet, and one lesson provided information on walking as a way to create a calorie deficit (walking one mile burns approximately 100 calories). Participants were given the option each week to select two to three behaviors/lessons to focus on in order to meet their calorie-adjustment goals.

The Gutbusters program included three assessment time points (baseline, 12 weeks, and 24 weeks), as well as

Figure 1. Original Gutbusters recruitment posters.

a weekly in-person weight collection and online check-in for the first 12 weeks. Questionnaires, weight, body fat, and waist circumference were collected at each assessment time point. Weights were collected in person each week for 12 weeks on campus at the University of Vermont. The online check-in was completed using the Gutbusters website and an online survey platform, LimeSurvey. Participants were asked each week to report the number of daily diet changes from the previous week, as well as select the two to three Gutbusters lessons they wanted to focus on for the subsequent week, in order to meet their calorie reduction goals.

Participants repeated assessment measurements at 12 and 24 weeks. Between the 12-week and 24-week assessments, participants had access to the Gutbusters website with the 13 lessons. An email check-in was sent at week 18 to all participants in an attempt to maintain contact and encourage subject retention.

All study procedures were reviewed and approved by the University of Vermont Institutional Review Board for human research in the behavioral and social sciences.

Recruitment

Burlington, VT has a population of 42,417, with approximately 20,619 men and a median household income of $46,754 (U.S. Census Bureau, 2017). According to the Vermont Department of Health, 60% of adults in Vermont (623,657 inhabitants) are currently overweight or obese, which provides a substantial subject pool for a weight loss intervention.

Worksites. Seventeen medium to large-sized companies were approached in the greater Burlington, VT area over the course of 3 months. Companies were targeted from a list of Vermont's largest employers that had 150 to 6,500 employees and also had a large proportion of men employed. For each business, an email was sent to a member of Human Resources or to a Human Resources representative through an employee familiar with the study and/or a member of our research team. A maximum of two follow-up emails were sent if we received no response after our initial communication. Out of the 17 companies, seven responded (41.2%) and of the seven, four (23.5%) were willing to meet to further discuss the Gutbusters study. Two companies decided not to participate after the meeting, and of the final two, one was a governmental organization that learned they could not allow the study at the worksite; the other allowed us to present the study to their employees during a regularly scheduled team meeting. After 3 months of minimal interest and few potential participants, we opened our eligibility to reflect that of the initial REFIT study, which meant including men from all educational backgrounds. Additionally, more "traditional" recruitment methods were employed including word of mouth, an email newsletter distributed to the University faculty and staff, and 75 printed recruitment posters. The study was advertised on the University Clinical Trials website, as well as distributed to both the University graduate student and first year medical students email Listserv. Recruitment posters were hung around the University campus, in local restaurants, bars and shops, several local gyms, and three separate physician's offices.

Table 1. Recruitment Methods and Totals.

Worksites	Email newsletter/ UVM clinical trials	Recruitment posters	Facebook	Newspaper
Initial outreach/enrollment				
17 businesses contacted	3 email newsletters, 1 online link	75 posters displayed	4,642 unique ads shown	432 screening website visits
7 business responses (41.2%)			43 ad clicks (0.92%)	251 completed screening questionnaire (58.1%)
4 meetings (23.5%)				69 scheduled for orientation (16.0%)
1 business participated (5.8%)				
Enrollment				
6 men enrolled	10 men enrolled	16 men enrolled	3 men enrolled	67 men enrolled

Recruitment materials directed potential participants to a study website which contained a brief study description and screening questionnaire. As recommended in previous research, all recruitment materials were designed using entertaining language and graphics and focused on the benefits of participation (Morgan, Warren, et al., 2011). The brief questionnaire took approximately 5 min to complete and collected basic demographic information, self-reported height and weight, major exclusion criteria based on health history, and contact information. After completion of the screening questionnaire, all eligible participants were contacted via telephone for final screening and to schedule an in-person study orientation and consent form review. Sixteen Gutbusters participants reported learning about the program through these printed recruitment posters.

Social media and newspaper. In an attempt to recruit individuals who regularly use technology, we posted a Facebook advertisement for 1 month beginning in September 2017. The ad was shown to 4,642 unique, targeted Facebook visitors (male, aged 18–65 in Burlington, VT) and resulted in only 43 clicks (0.92%) to the screening website. In total, after 7 months of recruitment, only 35 men were consented and enrolled into the Gutbusters program. After little community buy-in, few interested participants, and minimal success advertising online, a newspaper advertisement campaign was launched for 1 week in two local newspapers with statewide distribution (one free and one delivered to paid subscribers). After the 1-week advertisement period, a total of 432 visits to the screening website were recorded, and 251 (58.1%) men completed the initial screening questionnaire. Sixty-nine men (16.0%) were scheduled for orientation and 67 (15.5%) men consented and joined the Gutbusters program, for a total of 102 subjects.

Discussion

In summary, while we knew recruiting men to a weight loss intervention could pose some challenges, it was far more difficult than initially envisioned. Based on previous recruitment literature, a more active recruitment technique, utilizing direct interaction with potential participants, was originally attempted with men at worksites in an attempt to minimize barriers to participation (Morgan et al., 2012; Sutton et al., 2017). However, with such minimal worksite buy-in, we hit a roadblock to active recruitment that was not anticipated and instead, a more passive recruitment technique was ultimately most effective. Further, attempts to reach a population of men with 2 years of college education or less was surprisingly unsuccessful. In the end, of 102 enrolled subjects, only 20 (19.6%) had not completed 2 years of college. This presents an area for future research, as men with less education are at increased risk for obesity and associated comorbidities related to excess weight (Paeratakul, Lovejoy, Ryan, & Bray, 2002). Using recruitment posters and email newsletters, Crane and colleagues were able to engage 277 men in online screening with 107 (38.6%) enrolling in the REFIT intervention over a period of 8 months. It's important to note that the vast majority of the enrolled subjects had completed a college education, were employed full-time, and were married or living with their partner.

Newspaper advertising for clinical trials has shown inconsistent results. While some studies have demonstrated newspaper advertisements are a cost-effective and successful recruitment technique (Butt, Lock, & Harvey, 2010; Garrett et al., 2000), others have documented poor efficacy (Hapca et al., 2014). It is suspected that newspaper advertising success is significantly influenced by the cost of the advertisement (free local papers with high distribution and low cost advertising versus largely distributed subscription newspapers with more expensive ads). Recruitment via newspaper advertisement has also been more successful in trials with very broad inclusion criteria and few exclusion criteria, making the study appeal to more individuals (Hapca et al., 2014). Newspaper ad recruitment was our most successful recruitment technique. Interestingly, the average age of participants enrolled

from the newspaper was higher than the average age of participants recruited through other means (51 versus 39), suggesting newspaper recruitment may be more effective in a slightly older population, who are possibly more likely to read the newspaper than obtain the news through online outlets or social media platforms (Frandsen, Walters, & Ferguson, 2014; Piantadosi et al., 2015). Throughout the course of the study, our retention rate remained fairly high (75 of the original 102 participants, 73.5%, completed the full 24 weeks of the intervention). In comparison, some weight loss trials report dropout rates of one-third to one-half of participants in 1 year (Delahanty et al., 2016) and similarly long weight loss trials for men have reported retention rates of 81.0%–90.3% (Crane et al., 2015; Morgan, Collins, et al., 2011; Morgan, Lubans, et al., 2011; Morgan et al., 2009) supporting the notion that once enrolled, men frequently remain active participants (Robertson et al., 2017). One potential reason for study attrition was the majority of the study was conducted during the winter in Vermont. Many of our subjects were coming from far away and driving to the University of weight collection was challenging some weeks. In addition, dropout in the nonpayment group could be attributable to frustration about not being compensated for equal levels of study participation as paid participants.

While implementing a weight loss intervention solely for men positively contributes to the current literature, there are limitations to our recruitment strategy that could be addressed in future studies. To begin, newspaper advertisements qualify as a passive recruitment strategy and were the most successful Gutbusters recruitment technique. However, there are a variety of other active recruitment strategies (besides the workplace recruitment model used) that have the potential to be highly effective. Because we know that men are often motivated to lose weight after a poor health diagnosis or other illness, recruiting through a primary care physician's office could be advantageous, and has been utilized in other studies (Thomas, Leahey, & Wing, 2015). Additionally, offering a recruitment referral "incentive" has been utilized at a number of Universities and could be a way to entice men to encourage and refer other men to participate in upcoming interventions. Finally, the examination of the role of spouses/partners in male weight loss could be a promising future direction. When advertisements for weight loss programs are placed in environments accessible to both men and women, such as the newspaper (versus a bulletin board at work), who is initiating participation in these programs: the overweight man, or their romantic partner?

In the end, we were able to successfully recruit 102 men to a weight loss intervention, indicating that there are indeed men interested in losing weight. Our recent experience suggests that the recruitment strategy, rather than male interest in weight loss itself, may be the foremost challenge when it comes to enrolling men in a weight loss clinical trial.

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