# Lifestyle Intervention for People With Severe Obesity and Serious Mental Illness

John A. Naslund, MPH,[1] Kelly A. Aschbrenner, PhD,[1,2] Emily A. Scherer, PhD,[3] Sarah I. Pratt, PhD,[1,2] Rosemarie S. Wolfe, MS,[2] Stephen J. Bartels, MD, MS[1,2,3]

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**Introduction:** People with serious mental illness experience elevated severe obesity rates, yet limited evidence documents whether lifestyle intervention participation can benefit these individuals. This study examined the impact of the In SHAPE lifestyle intervention on weight loss among participants with serious mental illness and severe obesity (BMI $\geq$40) compared with participants who are overweight (BMI 25 to $<$30) and have class I (BMI 30 to $<$35) or class II (BMI 35 to $<$40) obesity.

**Methods:** Data were combined from three trials of the 12-month In SHAPE intervention for individuals with serious mental illness collected between 2007 and 2013 and analyzed in 2014. In SHAPE includes individual weekly meetings with a fitness trainer, a gym membership, and nutrition education. The primary outcome was weight loss. Secondary outcomes were fitness, blood pressure, lipids, and program adherence.

**Results:** Participants (N=192) were diagnosed with schizophrenia spectrum (53.1%) or mood (46.9%) disorders. At 12 months, the overall sample showed significant weight loss, but differences among BMI groups were not significant (severe obesity, 2.57% [7.98%]; class II, 2.26% [8.69%]; class I, 1.05% [6.86%]; overweight, 0.83% [7.62%]). One third of participants with severe obesity achieved $\geq$5% weight loss, which was comparable across groups. More participants with severe obesity achieved $\geq$10% weight loss (20%) than overweight (2.9%, $p$=0.001) and class I (5.9%, $p<0.001$), but not class II (17.8%, $p$=0.974), obesity groups.

**Conclusions:** People with severe obesity and serious mental illness benefit similarly to those in lower BMI groups from lifestyle intervention participation.

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## Introduction

People with serious mental illness, including schizophrenia, schizoaffective disorder, major depressive disorder, and bipolar disorder, experience rates of obesity nearly double the observed rates within the general population,[1–3] as well as elevated prevalence of severe obesity (BMI $\geq$40).[1] This patient population is also disproportionately affected by comorbid medical conditions, increased cardiovascular risk, and poor health behaviors, which combined with elevated rates of obesity contribute to significantly reduced life expectancy up to 30 years fewer than the general population.[4,5] This is further exacerbated by numerous challenges in achieving weight loss among people with serious mental illness, including metabolic effects of psychoactive medications, the impact of symptoms on motivation, poor diet, and poverty.[2] Lifestyle interventions targeting fitness and diet may be an effective approach for addressing this serious public health concern.

In the general population, there is some evidence of the effectiveness and long-term benefit of behavioral weight management interventions for individuals with severe obesity.[6,7] Similar behavioral interventions may be well suited for people with serious mental illness given recent evidence supporting the use of fitness and diet interventions in this population.[8] For example, studies of

From the [1]The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, Lebanon, New Hampshire; [2]Department of Psychiatry, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire; and [3]Department of Community and Family Medicine, Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire

Address correspondence to: John A. Naslund, MPH, 46 Centerra Parkway, Suite 200, Lebanon NH 03766. E-mail: john.a.naslund@gmail.com.

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different lifestyle interventions have demonstrated effectiveness in achieving ≥5% weight loss in upwards of 47% of participants, or reduced cardiovascular risk in as many as half of participants with serious mental illness.[9–12] However, potential differential outcomes in different BMI groups are not known, and it is not clear whether people with severe obesity and serious mental illness benefit from participation in an intensive lifestyle intervention to the same extent as less obese individuals.

The purpose of this study was to examine the impact of the 12-month In SHAPE lifestyle intervention on weight loss among participants with serious mental illness who had severe obesity (class III) compared with participants who were overweight (BMI 25 to <30) and had class I (BMI 30 to <35) or class II (BMI 35 to <40) obesity. Secondary outcomes including fitness, blood pressure, lipids, and program adherence were also compared among the different BMI groups. Specifically, the aim of this study was to determine whether participants with severe obesity achieved differential outcomes when compared with lower BMI classes after participation in the In SHAPE lifestyle intervention.

## Methods

The analyses in this study used data from participants who received the In SHAPE lifestyle intervention in three separate clinical trials in people with serious mental illness. Two were randomized trials and the third was an implementation study. The first randomized trial (N=133), conducted from April 2007 to November 2011, compared In SHAPE to gym membership at one community mental health center in Concord, New Hampshire.[12] The second randomized trial (N=210), conducted from April 2008 to May 2013, compared In SHAPE to gym membership in people receiving services at one of three community mental health centers in Boston, Massachusetts.[11] The third evaluation (N=122), conducted between December 2009 and March 2013, compared In SHAPE implemented in two community mental health centers with usual care in two additional centers from rural and urban settings in New Hampshire.

The current analytic sample consisted of data from the 192 participants who completed the 12-month In SHAPE intervention. Forty participants completed baseline assessments but did not complete the 12-month intervention. These dropouts were not included in the analyses and did not differ from participants who completed the intervention on any baseline characteristics.

Participants across all three studies were aged ≥21 years; had serious mental illness defined by an axis I diagnosis of major depressive disorder, bipolar disorder, schizoaffective disorder, or schizophrenia (based on the Structured Clinical Interview for DSM-IV), and persistent impairment in multiple areas of functioning (e.g., work, school, self-care)[13]; had BMI >25; and provided informed consent for participation. Participants were on stable pharmacologic treatment defined as receiving the same psychiatric medications over the prior 2 months. Detailed inclusion and exclusion criteria are described elsewhere.[11,12] Committees for the Protection of Human Subjects at Dartmouth College and specific to each site approved the study procedures.

In SHAPE is a fitness intervention consisting of a gym membership, weekly individual meetings with a certified fitness trainer, and instruction on healthy eating and nutrition.[11,12,14] The fitness trainers completed a 1-week In SHAPE training consisting of instruction in motivational interviewing, fitness goal setting, healthy nutrition, tracking eating and exercise, and strategies for health behavior change in people with serious mental illness such as addressing mental health symptoms that interfere with exercise and healthy eating. Prior to enrollment, participants obtained medical clearance from their primary care provider. After conducting lifestyle and fitness evaluations, the fitness trainer developed personalized fitness plans for each participant using shared goal setting. Thereafter, they met with participants individually each week for 45–60 minutes at a local gym (YMCA) and provided fitness coaching, support, and reinforcement for exercise. The nutrition component consisted of individualized instruction emphasizing healthy eating during each session. Throughout the program, the fitness trainers received ongoing supervision from a health psychologist, personal fitness trainer, and registered dietitian.

### Measures

Assessments were conducted at baseline and at 12-month follow-up for all study outcome measures. The primary outcome was weight (pounds) reported as the change in body weight over time and as the percentage change in weight. The proportion of participants who achieved ≥5% weight loss was calculated because modest weight loss is associated with improvements in cardiovascular risk factors in overweight and obese individuals in the general population[15,16] and with diabetes.[17] The proportion of participants who achieved ≥10% weight loss was also calculated because this widely used metric contributes to well-documented clinical benefits.[18] These measures are considered clinically significant weight loss. Additional measures of obesity included BMI, calculated as weight (kg)/height $(m)^2$, and waist circumference measured in inches.

The 6-Minute Walk Test (6-MWT) measures the distance in feet that an individual can walk in 6 minutes, and was used to evaluate participants' fitness. In obese adults in the general population, the 6-MWT is considered a reliable and valid measure of fitness.[19,20] Change in this measure was reported both as a change in feet and as a percentage change in feet. Two different measurement criteria for clinically significant improvement in fitness were used. First, an increase in distance >50 meters (about 164 feet) on the 6-MWT is considered clinically meaningful in terms of reduced cardiovascular risk among people with medical conditions including heart failure, chronic obstructive pulmonary disease, and pulmonary arterial hypertension.[21] Among obese individuals in the general population, a >80-meter (about 263 feet) increase is considered clinically significant.[19] Therefore, the proportion of participants who achieved >80-meter increase on the 6-MWT is reported; however, given the numerous challenges in promoting positive lifestyle change and the disproportionate burden of chronic disease affecting people with serious mental illness, the broader >50 meter criteria was also applied.

Blood pressure was measured after completing the 6-MWT. Serum lipids were measured using the CardioChek PA Analyzer,