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## Comparison of people with serious mental illness and general population samples enrolled in lifestyle interventions for weight loss

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### Dear Editors

Elevated obesity rates are a major contributor to the dramatic gap in life expectancy affecting people with serious mental illness (SMI) (Allison et al., 2009). Recent trials of lifestyle interventions targeting this group have achieved modest weight loss of 5% in upwards of 47% of participants, or reduced cardiovascular risk in roughly half of participants (Bartels et al., 2013; Bartels et al., 2015; Daumit et al., 2013; Green et al., 2015). Despite the promise

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#### Conflict of interest

Dr. Pratt received payments from Ken Jue Consulting to provide training in the In SHAPE program at community mental health centers (non-research sites). The other authors report no conflicts of interest.

#### Contributors

Conceived, designed, and prepared the current manuscript: JAN.

Performed the analyses and interpreted the data: JAN and KAA.

Collected the data and conducted the clinical trials: KAA, SIP, and SJB.

Wrote and revised the manuscript: JAN, KAA, SIP, and SJB.

of these interventions, many are resource intensive, and there remain considerable barriers to implementation in real world settings.

In contrast, the Diabetes Prevention Program (DPP) in the general population is the most widely replicated model for behavioral weight loss in the United States (Ali et al., 2012). The DPP focuses on achieving 7% weight loss through a healthy low-calorie, low-fat diet, and increasing physical activity to 150 min each week. The DPP trial, in which half of participants receiving the lifestyle intervention achieved over 7% weight loss (Diabetes Prevention Program Research Group, 2002), and subsequent Look AHEAD (Action for Health in Diabetes) trial, in which over 55% of participants receiving the intensive lifestyle intervention modeled after the DPP achieved over 7% weight loss (The Look AHEAD Research Group, 2007), are considered gold standards in behavioral weight management research.

In spite of the high prevalence of obesity among people with SMI (Allison et al., 2009), both the DPP and Look AHEAD trials systematically excluded people with schizophrenia, other psychotic disorders, bipolar disorder, hospitalization for depression in the past six months, self-reported psychiatric hospitalization, use of psychoactive medications, or other psychiatric or behavioral factors that could interfere with compliance, study participation, or ability to follow the intervention protocol (Diabetes Prevention Program Research Group, 2001; The Look AHEAD Research Group, 2012). The exclusion of people with SMI is consistent across most large weight loss studies due to challenges in achieving weight loss in this group, such as metabolic effects of psychoactive medications, impact of symptoms on motivation and ability to complete the studies, and consequences of poverty, low health literacy, societal stigma of having a mental illness, and social isolation on study retention (Allison et al., 2009).

Identifying differences in these target populations may highlight specific considerations for tailoring scalable and economically sustainable lifestyle interventions developed for the general population for adults with SMI or provide insights for scaling existing intensive weight loss interventions targeting this group. We compared characteristics of N = 465 participants with SMI enrolled in three trials of the evidenced-based In SHAPE lifestyle intervention with those of N = 3234 participants enrolled in the DPP and N = 5145 participants enrolled in the Look AHEAD trials in the general population.

## 1. In SHAPE program

The 12-month In SHAPE lifestyle intervention consists of a gym membership and weekly individual meetings with a certified fitness trainer who helps participants develop personalized fitness plans, provides fitness coaching, instruction on healthy eating, and support for managing mental health symptoms that interfere with exercise and healthy eating (Bartels et al., 2013; Bartels et al., 2015). Between 2007 and 2013, N = 465 participants with SMI were enrolled across three trials (2 in New Hampshire, and 1 in Boston, MA) of the In SHAPE program delivered in community mental health settings. Inclusion and exclusion criteria are reported elsewhere (Bartels et al., 2013; Bartels et al., 2015). Study procedures

were approved by Committees for the Protection of Human Subjects at Dartmouth College and specific to each site.

## 2. Findings and implications

Table 1. compares baseline characteristics of participants in the In SHAPE trials with those of participants in the DPP and Look AHEAD trials. The proportion of participants in the In SHAPE trials with annual household income under \$25,000 was nearly 6 times greater, with less than 13 years of education was about double, who were unemployed was 8 to 17 times greater, and who were never married was up to 8 times greater. Participants with SMI were at increased cardiovascular risk, with rates of smoking 5 to 8 times higher and severe obesity 1.5 to 2 times higher compared to DPP and Look AHEAD trial participants.

These findings illustrate many of the challenges for implementing and scaling behavioral weight loss interventions targeting this group. To date, effective behavioral weight loss in people with SMI has been resource-intensive and has required individualized support and counseling, often in combination with supported exercise or group nutrition education. Providing additional support increases costs and limits intervention scalability, but is likely necessary for overcoming the combined effects of socioeconomic instability and mental health symptoms that contribute to low-motivation, poor functioning, and social isolation. By contrast, lower intensity interventions of short duration have shown limited effectiveness in this group, as they likely are insufficient for overcoming these health disparities and complex social factors.

Future efforts must focus on increasing intervention reach without sacrificing impact or effectiveness. Successes of the DPP and Look AHEAD trials offer valuable insights for informing the dissemination of weight loss programs targeting people with SMI. Through new collaborations between mental health services researchers and behavioral scientists, existing behavioral weight loss interventions tailored to meet the needs of this at-risk group could incorporate components of successful programs delivered in the general population to lower costs and increase scalability. Continued efforts across medicine and social science disciplines are needed to address this serious public health concern in the form of significantly reduced life expectancy affecting people with SMI.

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**Table 1**

Baseline demographic and clinical characteristics of participants in the In SHAPE trials compared to participants in the Diabetes Prevention Program (DPP) and Look AHEAD trials.

Characteristics	In SHAPE trials total sample		DPP trial		Look AHEAD trial		p-Value for comparison between In SHAPE and Look AHEAD trials <sup>a</sup>	
	N	465	3234	5145				
<i>Demographic characteristics</i>								
Gender								0.049
Male		210 (45.2%)	1043 (32.3%)	2082 (40.5%)				
Female		255 (54.8%)	2191 (67.7%)	3063 (59.5%)				
Mean Age (years)		44.4 (11.3)	50.6 (10.7)	58.8 (6.9)				<0.001
Race								0.009
Black		76 (16.3%)	645 (19.9%)	803 (15.6%)				
Hispanic		38 (8.2%)	508 (15.7%)	677 (13.2%)				
Non-Hispanic white		320 (68.8%)	1768 (54.7%)	3246 (63.3%)				
Other		31 (6.7%)	313 (9.7%)	406 (7.9%)				
Employment status								<0.001
Full- or part-time		100 (21.5%)	2426 (75.0%)	3232 (71.2%)				
Not employed		324 (69.7%)	126 (3.9%)	381 (8.4%)				
Other		41 (8.8%)	682 (21.1%)	925 (20.3%)				
Education								<0.001
<13 years		225 (48.4%)	834 (25.8%)	1024 (20.4%)				
13–16 years		185 (39.8%)	1556 (48.1%)	1912 (38.0%)				
>16 years		55 (11.8%)	844 (26.1%)	2093 (41.6%)				
Household Income < \$25,000 <sup>b</sup>		364 (79.0%)	446 (13.8%)	589 (12.7%)				<0.001
Current smoker		167 (36.4%)	226 (7.0%)	228 (4.4%)				<0.001
Marital status								<0.001
Never married		282 (60.7%)	420 (13.0%)	386 (7.5%)				
Currently married/living together <sup>c</sup>		37 (8.0%)	2124 (65.7%)	3461 (67.3%)				
Previously married		146 (31.4%)	690 (21.3%)	1293 (25.2%)				
<i>Clinical characteristics</i>								

Characteristics	In SHAPE trials total sample	DPP trial	p-Value for comparison between In	
			SHAPE and DPP trials <sup>a</sup>	SHAPE and Look AHEAD trials <sup>a</sup>
N	465	3234	Look AHEAD trial	5145
BMI (kg/m <sup>2</sup> )				
25 to <30	88 (19.0%)	1046 (32.3%)	765 (14.9%)	<0.001
30 to <40	221 (47.7%)	1639 (50.7%)	3220 (62.6%)	
> = 40	154 (33.3%)	549 (17.0%)	1146 (22.3%)	
Blood pressure (mm Hg)				
Systolic blood pressure (mm Hg)	128.4 (18.1)	123.7 (8.5)	128.8 (11.0)	0.482
Diastolic blood pressure (mm Hg)	83.2 (11.6)	78.3 (5.8)	70.2 (6.3)	<0.001
Lipids (mg/dL)				
Total cholesterol (mg/dL)	182.7 (48.0)	203.7 (37.5)	191.0 (23.4)	<0.001
LDL (mg/dL)	108.4 (38.0)	125.0 (34.9)	112.3 (19.9)	<0.001
HDL (mg/dL)	42.9 (16.4)	43.9 (18.0)	43.5 (6.4)	0.258
Triglycerides (mg/dL)	173.4 (114.5)	159.1 (88.5)	181.7 (80.2)	0.002

<sup>a</sup>P-values were calculated using chi-square tests for categorical variables and one-way ANOVAs for continuous variables computed using summary statistics extracted from published reports for the DPP and Look AHEAD trials because raw data were not available (Diabetes Prevention Program Research Group, 2002; The Look AHEAD Research Group, 2007). STATA 14.0 was used for all analyses.

<sup>b</sup>Medicaid eligibility was used to approximate annual household income for participants in the In SHAPE trials because no income information was collected, and most participants (79%) were Medicaid recipients. Average annual household income for Medicaid eligibility in 2008 (first year of enrollment for participants in the In SHAPE trials) was \$20,650. Income values from the DPP and Look AHEAD trials were converted to 2008 dollars using the United States Department of Labor Bureau of Labor Statistics inflation calculator.

<sup>c</sup>In the DPP and Look AHEAD trials, currently married, marriage-like living situation, and living together were combined. In the In SHAPE trials, marital status was measured only as never married, currently married, or previously married.