



## Worksite environment intervention to prevent obesity among metropolitan transit workers

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### ABSTRACT

**Objective.** The results of an 18-month worksite intervention to prevent obesity among metropolitan transit workers are reported.

**Methods.** Four garages in a major metropolitan area were randomized to intervention or control groups. Data were collected during the fall of 2005 prior to the start of the intervention and during the fall of 2007, after the intervention ended. Intervention program components at the garage included enhancement of the physical activity facilities, increased availability of and lower prices on healthy vending machine choices, and group behavioral programs. Mixed model estimates from cross-sectional and cohort samples were pooled with weights inverse to the variance of their respective estimates of the intervention effects.

**Results.** Measurement participation rates were 78% at baseline and 74% at follow-up. The intervention effect on garage mean BMI change was not significant ( $-0.14 \text{ kg/m}^2$ ). Energy intake decreased significantly, and fruit and vegetable intake increased significantly in intervention garages compared to control garages. Physical activity change was not significant.

**Conclusion.** Worksite environmental interventions for nutrition and physical activity behavior change may have limited impact on BMI among transit workers who spend most of their workday outside the worksite.

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### Introduction

In the United States in 2006, there were 1500 bus agencies and approximately 221,302 bus operators driving 83,080 buses across 2494 million miles (American Public Transportation Association, 2008). In comparison with other occupations, transportation workers are at high risk for obesity and poor dietary intake (Tse et al., 2006; Winkleby et al., 1988; Ragland et al., 1998; Ragland et al., 1987).

Both individual behaviors and work environmental variables probably contribute to higher obesity prevalence and risk of excess weight gain in this occupational group (Tse et al., 2006; French, 2010). Long work hours, shift work, lack of scheduled breaks or meals, and lack of healthful food and physical activity options on the transportation routes or in the transportation hubs (e.g., bus or train garage) are some of the structural variables that make healthful food choices and physical activity difficult for transportation workers (Tse et al., 2006; Winkleby et al., 1988).

Worksite physical and social environments provide opportunities and exposures that influence individual food choices and physical activity behaviors (French, 2010; French et al., 2001; Bureau of Labor

Statistics, 2007). Previous worksite weight control and nutrition interventions have mainly focused on traditional worker populations at fixed worksites (French, 2010; Jeffery et al., 1993; Sorensen et al., 1999; Sorensen et al., 1996; Beresford et al., 2001; Tilley et al., 1999). Little descriptive or experimental research has specifically examined the eating and physical activity behaviors of transit worker populations (Tse et al., 2006).

The present paper describes and reports the results from a worksite obesity prevention intervention that targeted transit employees at four bus garages in a metropolitan area. This study (Route H) was one of several simultaneously funded by the National Institutes of Health to examine worksite environment obesity prevention interventions (Pratt et al., 2007).

### Methods

#### Study population and recruitment

The Route H study was conducted in 2005–2007 in collaboration with the Metropolitan Transit Council in Minneapolis. Four garages (two urban; two suburban) were randomized within pair to intervention or control. Table 1 shows the study design and participant sample sizes for each of the four garages (Murray, 1998; Stevens et al., 2005). The study was approved by the University of Minnesota IRB Human Subjects Protection Program.

Participants in each garage were recruited using a variety of methods, including paycheck distribution fliers, signs posted in the garages, fliers

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**Table 1**

Study design and participation across four bus garages for worksite obesity prevention intervention.

	Baseline, <i>n</i>	Follow-up, <i>n</i>
Drivers surveyed at one time only	406	244
Substudy		
Dietary recall	120	103
Accelerometry	132	131
Drivers surveyed at both times	696	696
New drivers (surveyed twice), combined sample	1123	1070

New drivers enrolled after the baseline data collection period.

distributed at health fair events, information in employee newsletters and instant text messaging on the buses. All garage employees who worked at each of the four garages were eligible to complete the evaluation measures.

Garage-level incentives were offered at all four garages to enhance individual participation rates in the evaluation measurements. Garages were offered a financial incentive that increased with the participation rate for the garage (incentive amounts ranged from \$2500 to \$6000).

#### Data collection methods

Data collection sessions were held at various times and dates in each of the four garages to accommodate day and night shifts. The survey and weight and height measures took about 45 minutes to complete. Employees received a \$20 incentive for completing the survey, weight and height measurements.

At baseline and again at follow-up, all current employees were randomly assigned, prior to the initiation of the primary data collection sessions, to receive an invitation to participate in either the 24-h telephone-administered dietary recall or the 4-day accelerometry substudy. Interested employees were enrolled in the substudies on a first-come first-served basis until 160 (40 per garage) had enrolled in each of the substudies. An additional incentive was offered to participants for completing the dietary recall measurement (\$10) or the accelerometry measurement (\$20). The agreement rate for the accelerometry substudy was 68% at baseline and 74% at follow-up. The agreement rate for the dietary recall substudy was 80% at baseline and 74% at follow-up. Numbers of completed accelerometry measures available for analysis were 132 at baseline and 131 at follow-up. Numbers of completed recalls available for analysis were 120 at baseline and 103 at follow-up.

#### Intervention program

##### Garage advisory groups

Garage advisory groups were formed at each of the four garages to provide feedback to the research team about intervention and measurement activities. Groups ranged from 6 to 10 employees and included drivers and bus maintenance mechanics. Study staff met monthly with intervention garage advisory groups and quarterly with control garage advisory groups. Advisory group members were paid their normal hourly rate by the research study for their advisory group participation time.

##### Intervention components

The intervention components focused on changing the physical and social environment at the garages to support more healthful food choices and higher levels of physical activity among garage employees. Specific program components are described below. Choice of components was based on our previous successful worksite interventions and advisory group feedback about employee preferences. Certain programs were offered one to three times, while others were implemented for the entire 18-month intervention.

##### Vending machines

The vending machine intervention increased the availability and lowered the price of healthful food and beverage vending machine choices (French et al., 2010). Vending machines in each intervention garage were reconfigured so that at least half of the items offered met specified calorie, fat and sugar requirements. Prices on these items were reduced by 10%. Nutrition information was displayed for the "Route H" healthy vending machine items on the side of the vending machines. The vending machine intervention was implemented continuously for the 18-month intervention duration.

##### Fitness facilities

Prior to the intervention, garages had limited fitness facilities (e.g., a small room with a limited selection of exercise equipment, such as a stationary bicycle, treadmill and or free weights). The two intervention garages elected to spend their garage incentive funds on new fitness equipment, such as a treadmill, exercise bicycle, and weight lifting machine. Other fitness room improvements were aesthetic, including new mirrors, better lighting, and wall murals. The control garages were not allowed to purchase physical activity equipment with their garage incentive funds.

##### Self-weighing team competition

New scales were purchased and placed in the intervention garage restrooms and fitness rooms. To increase awareness of the importance of daily self-weighing for weight gain prevention, a team competition for daily self-weighing was implemented. Employees configured their own teams and self-weighed daily for four consecutive weeks. Individuals tracked their own body weights by self-weighing and recording their weight daily on charts located in the locker rooms. Teams whose members did not gain weight during the 4-week competition period won incentive prizes. The self-weighing program was implemented twice in each intervention garage.

##### Behavioral food and physical activity programs

Several programs were offered during the intervention to improve food choices and physical activity behaviors: team walking competitions, fruit and vegetable intake challenges, and fitness classes with individualized instruction including yoga, tai chi and personal training using the fitness room equipment. Team walking programs were offered twice in each intervention garage. Each of the other behavioral programs was offered one time during the 18-month intervention.

##### Route H garage expo

A free, 1-day health and fitness expo was held twice at each intervention garage to increase awareness of and promote healthy eating and physical activity behaviors. It included free fresh fruit and vegetable samples, sign ups for walking team competitions, demonstrations of brief exercise routines appropriate for the driving route, fitness equipment demonstrations, bike rides, basketball demonstrations and tai chi classes.

##### Farmer's markets at garage

Mini-farmer's markets were held at each of the intervention garages during the summer months (June, July, and August, 2006) and were staffed by research staff. Low-priced fresh produce was offered for sale once a month for a 1-day period.

##### New driver weight gain prevention peer mentoring program

Anecdotal reports by the garage employees during the intervention development phase suggested that the initial six months of employment as a bus driver represented a very high-risk period for excess weight gain. To prevent excess weight gain during this high-risk period, new drivers were invited to participate in a peer-mentoring program. Incentives were provided for both the new drivers and for their peer mentors to encourage them to meet regularly. Peer mentors received training by research staff on how to implement the weight gain prevention behavioral messages with their new driver mentee and provide support for healthy eating and physical activity behaviors within the work environment. The peer-mentoring program was offered continuously throughout the 18-month intervention.

##### Measures

Trained and certified research staff conducted all anthropometric measurements and administered the behavioral surveys at each of the garages.

##### Weight and height

Body weight was measured in street clothing without shoes using a calibrated electronic scale. Height was measured using a portable stadiometer. Two separate measurements were conducted for both the weight and the height measures. The average of the two values were used in statistical analyses. Body mass index was calculated as weight (kg)/height (m<sup>2</sup>).

##### Dietary intake

All participants completed a self-report food frequency questionnaire (adapted from Thompson et al., 2002; Thompson et al., 1998). Daily servings of fruit and vegetable items, high-fat snack food items and sugar sweetened

beverage items were calculated by multiplying the frequency of consumption per week by the servings consumed per eating. At baseline and follow-up, a subset of 40 bus drivers at each of the four garages were recruited to complete a single, telephone-administered 24-h dietary recall (Casey et al., 1999; Tran et al., 2000; Feskanich et al., 1988; Feskanich et al., 1989; Johnson et al., 1996; Beaton et al., 1983; Willett, 1998). Total energy was estimated.

#### Physical activity

Physical activity was self-reported using the Godin leisure time physical activity questionnaire (Godin and Shephard, 1985; Godin et al., 1986; Gionet and Godin, 1989). At baseline and follow-up, a subset of 40 bus drivers at each of the four garages were recruited for participation in accelerometry data collection (four consecutive days) (Freedson et al., 1998; Leenders et al., 1998; Matthews et al., 2002; Trost et al., 2000). The average daily number of minutes of strenuous, moderate, and light activity were calculated for each participant.

#### Perceived worksite environment and social support

Perceptions of the worksite environment regarding food choices, physical activity opportunities and weight management resources were self-reported using a series of 5-point Likert-response items. Content areas included barriers (4 items), ease of access to information (3 items) and social support from co-workers, friends and family (9 items). Frequency of use of the worksite vending machines and fitness room facilities, television viewing hours, and frequency of self-weighing were self-reported (Jeffery and French, 1999).

#### Statistical analysis

The primary outcome was change in (mean garage) body mass index. Secondary behavioral outcomes were behaviors or beliefs expected to mediate body weight or behavior change. All analyses were adjusted for age, gender, education, income, marital status, race, and smoking status. These demographic variables were significantly associated with BMI in the bivariate analyses or were related to BMI in the existing literature. At baseline, the mean intervention garage BMI was significantly lower than the control garages (by one BMI unit). There were no other significant differences between intervention and control garages at baseline on any of the demographic variables above.

Because employees can change garages, the amount of time each employee spent in each garage was calculated to create an intervention exposure score. This individual exposure score was used as a weighting variable in analysis.

To maximize yield from the collected data three component analyses were conducted. Participants with baseline and 18 months of data were analyzed as a baseline-adjusted nested member-cohort (participants nested within garages, garages nested within condition). New drivers were analyzed in a similar fashion but with a different exposure score to account for their later entry into the study. Finally, for the cross-sectional data, a two-stage analysis was performed on drivers with data only at baseline or 18 months. For this analysis, individual-level covariate-adjusted means were generated for each garage at baseline and 18 months. To estimate the intervention effect, a baseline-adjusted analysis of the follow-up measure was conducted. The standard error of the net difference is estimated on only two degrees of freedom. Finally, these three estimates (cohort, new drivers, cross-section) were combined, each weighted inverse of its variance to achieve a minimum variance pooled estimate. The intervention effect confidence intervals and *p*-values are calculated on 2 degrees of freedom. Analyses were conducted using SAS Version 8.2 (SAS/STAT Release 8.2, 2001).

Means presented in Tables 3 and 4 are adjusted and exposure-weighted, combining all data available at baseline and follow-up. Differences do not necessarily equal the intervention effect estimates due to the precision-weighting of the estimates coming from the three component-analyses. *p*-values are from the combined three sample minimum variance weighted analyses.

## Results

### Baseline demographic and behavioral characteristics

The average individual participation rate across the garages was 78% (69–84%) at baseline and 74% (71–79%) at follow-up (18

months). At baseline, 73% of the garage employees who completed the surveys were bus drivers; 16% were bus maintenance staff; 3% were managers; and 8% held other jobs (such as dispatchers). Below, the total sample is referred to as garage employees for simplicity of presentation.

Of the employees, the average age was 47 years (age range, 20–79 years), 79% were men, 63% were white, 49% had completed high school/vocational school or had less education, and 43% reported annual household incomes before taxes of less than \$50,000. Most workers had been employed with the transit company seven or more years; about one-third had been working with the transit company 15 years or longer. Overall, the prevalence of obesity among the garage employees was very high. The average BMI was 32.3 kg/m<sup>2</sup>; 87% were overweight or obese (BMI ≥ 25 kg/m<sup>2</sup>) and 56% were obese (BMI ≥ 30 kg/m<sup>2</sup>).

### Intervention fidelity: Implementation and participation

The intervention was well-implemented. Seven group behavioral programs were made available during the 18-month intervention. Six additional environmental programs were offered, including the health expos, farmers markets, fruit and vegetable day, healthy meal day and exercise with Route H staff day. In addition, vending machine and fitness room enhancements were continuously implemented for the 18-month intervention.

Participation in the intervention activities was modest to low. Overall, 55% of garage employees participated in at least one intervention activity and 25% participated in two or more activities. Among those who participated in at least one activity, 45% completed two or more activities during the 18 months. The largest participation in any single intervention program was 22% in the self-weighing programs, and 17% in the walking group competition programs.

The new driver peer-mentoring program had modest participation rates. Of the 75 new drivers invited to participate, 36% (*n* = 28) indicated interest, and of these interested people, 57% (*n* = 17) met with a Route H staff person about the program. Of those who met with a Route H staff person, 70% (*n* = 12) were paired with a trained bus driver mentor, and of those paired with a mentor, 75% (*n* = 9) met one or more times with their mentor.

### Primary outcome: Body mass index change

Relative to control garages, the intervention garage mean BMI change was -0.14 kg/m<sup>2</sup>, which was not statistically significant (see Table 2). With only 2 *df* available for error in this official analysis of a group randomized trial, and a SE of BMI change of 0.16, a BMI difference of -0.68 kg/m<sup>2</sup> would be required to achieve statistical significance.

### Weight-related behavior change: Dietary intake and physical activity

Compared to control garages, a significant decrease in energy intake and a significant increase in fruit and vegetable servings per day were observed in intervention garages (see Table 3). No significant intervention-related changes were observed for intake of sugar-sweetened beverages, snacks and sweets and physical activity.

### Perceived worksite environment change

Compared to employees in control garages, intervention garage employees reported significantly greater increases in perceived ease of access to fruits and vegetables, healthy foods, opportunities for physical activity at work and information and resources for weight control at work (see Table 4).

**Table 2**  
Change in body mass index and body weight over 2 years among metro transit garage employees.

	Baseline, n = 1063	Follow-up, n = 832	Intervention effect <sup>a</sup>	95% Confidence interval <sup>b</sup>
Body mass index (kg/m <sup>2</sup> )				
Intervention	31.6	31.5	-0.14	(-0.84, 0.57)
Control	33.0	32.9		
Weight (kg)				
Intervention	95.9	95.6	-0.49	(-2.68, 1.71)
Control	99.2	99.4		

Means adjusted for gender, age, education, income, marital status, race, smoking status.

<sup>a</sup> Change estimate from combined three sample exposure-weighted estimates.

<sup>b</sup> Based on 2 df.

## Discussion

The results of the present study showed that after 18 months of environmental intervention in the 2 garages, the changes in body mass index, eating behaviors or physical activity that were observed among employees in intervention garages compared to control garages were slight. Although the intervention effects on BMI were not statistically significant, the size of the changes in body mass index and dietary changes were comparable to previous worksite weight control and nutrition interventions that included 28–32 worksites. For example, the Healthy Worker Project was a 2-year weight control intervention that included 32 worksites and observed an intervention effect for BMI change of -0.04 in the cross-sectional sample and +0.10 in the cohort sample (not statistically significant) (Jeffery et al., 1993). The intervention effect for BMI change for the Route H study was -0.14. Worksite nutrition interventions for fruit and vegetable increase have observed statistically significant intervention-related increases in daily fruit and vegetable servings between +0.5 (Sorensen et al., 1999) to +0.2 (Sorensen et al., 1996; Beresford et al., 2001; Tilley et al., 1999) with the number of worksites ranging from 22 to 108. The intervention effect for FV intake in the Route H study was +0.25 FV servings per day. Although the changes observed in Route H and the other worksite weight control and nutrition interventions are small, they are meaningful from a population perspective (Rose, 1985;

Jeffery, 1989). Small changes at the population level can produce meaningful decreases in risk by shifting the population distribution on the risk behavior toward a more healthful direction (Rose, 1985; Jeffery, 1989).

The Route H study was unique in several respects. First, an atypical approach to the analysis of these complex data was used. (Murray, 1998) Typically employees (individuals) are measured at one or more points in time. While the unit of evaluation is the worksite (group-level), individuals are measured to create the group-level measure for the intervention effect estimate. Employees can join or leave the worksite, thus cross-sectional and cohort data are typically collected and separately analyzed to estimate intervention effects. The combined and weighted analysis of the cross-sectional and cohort data that was used in the present study afforded a more precise estimate of the intervention effect, as reflected by a greater weighting of the cohort sample intervention effect estimate. The weighting using the inverse variance approach reflects the greater precision of estimate for the baseline-adjusted cohort sample, and acknowledges the less precise estimate of the cross-sectional data, which are based on a relatively small number of different individuals at each point in time. Thus, although Route H is a typical example of a community group randomized trial, the approach to the analysis of these complex data is comprehensive and illustrates an efficient use of the data collected from all individuals.

Second, a single employer was used, and employees could transfer between sites, thus potentially being exposed to the condition different from their original assignment. Data on employee garage transfers obtained from the employer afforded the opportunity to create an intervention exposure score for each employee based on the number of days he or she operated from an intervention garage. The use of the intervention exposure scores and the combined cross-sectional and cohort-weighted analysis offer sophisticated techniques to approach the analysis of complex data from community group randomized trials.

Possible reasons for the low participation rates and the weak intervention effects include the non-centralized location of the transit employees' work, mobile nature of the employee population, and the work schedule constraints (i.e., lack of flexibility in work time and lack of control over scheduled work hours and time of day worked). The

**Table 3**  
Mean change in food choice and physical activity behaviors over 2 years among metro transit employees.

	Intervention		Control		Intervention effect <sup>a</sup>	95% Confidence interval <sup>b</sup>
	Baseline	Follow-up	Baseline	Follow-up		
<b>Food choices</b>						
Fruit and vegetable (svg/day)	2.2	2.2	2.0	1.9	0.25 <sup>c</sup>	(0.01, 0.49)
Sugar beverages (svg/day)	0.6	0.5	0.5	0.5	0.04	(-0.13, 0.21)
Snacks/sweets (svg/day)	1.2	1.0	1.3	1.1	-0.12	(-0.35, 0.11)
Fast food meals (times/week)	1.2	1.0	1.1	1.1	-0.31 <sup>d</sup>	(-0.66, 0.04)
kcal/day	2363	1864	2424	2328	-407 <sup>d</sup>	(-778, -36)
Vending machine use (% any/month)	85.8	80.7	88.4	85.4	-0.03	(-0.14, 0.07)
<b>Physical activity</b>						
Godin physical activity						
Moderate/vigorous (episodes/week)	4.4	4.7	4.2	4.2	-0.25	(-2.04, 1.55)
Mild (episodes/week)	3.4	3.6	3.3	3.5	-0.05	(-1.34, 1.23)
Accelerometry						
Moderate/vigorous (min/day)	15.8	17.0	18.6	17.0	2.7	(-5.2, 10.6)
Light (min/day)	234	242	228	232	4.2	(-12.6, 21.0)
Garage fitness room use (% any/year)	34.6	43.5	24.3	27.0	0.02	(-0.31, 0.34)
Exercise on driving route (% any/year)	49.5	64.0	41.3	46.6	0.13 <sup>d</sup>	(-0.02, 0.30)
Television viewing (h/day)	2.0	1.9	2.0	1.9	-0.09	(-0.35, 0.18)
Self-weighing (1 = less than once per year; 5 = daily)	3.5	3.7	3.4	3.5	0.09	(-0.18, 0.36)

Means adjusted for age, education, income, marital status, race, gender, smoking status.

<sup>a</sup> Change estimate from combined three sample exposure-weighted estimates.

<sup>b</sup> Based on 2 df.

<sup>c</sup>  $p < 0.05$ .

<sup>d</sup>  $p < 0.10$ .

**Table 4**  
Mean change in perceived worksite environment over 2 years among metro transit employees.

	Intervention		Control		Intervention effect <sup>a</sup>	95% Confidence interval <sup>b</sup>
	Baseline % reporting	Follow-up% reporting	Baseline % reporting	Follow-up % reporting		
<i>Work environment support</i>						
Easy to get FV at work	31.0	40.1	28.7	32.3	4.7	(-13.1, 22.6)
Information on healthy eating at work	32.9	57.1	31.9	37.1	18.6 <sup>c</sup>	(3, 34.2)
Easy to eat healthily at work	15.1	28.2	16.5	17.7	12.2 <sup>c</sup>	(0.2, 24.2)
Information on physical activity at work	29.6	53.5	37.5	36.5	19.5 <sup>d</sup>	(-4.5, 43.4)
Easy to be physically active at work	28.9	39.4	31.7	30.7	9.4	(-17.4, 36.2)
Information on weight control at work	24.1	42.5	29.3	29.4	17.5 <sup>d</sup>	(-3.3, 38.2)
Easy to control weight at work	20.3	28.1	16.6	21.4	7.4	(-6.1, 20.9)
<i>Social support</i>						
<i>Healthy eating</i>						
Friend	25.8	29.9	30.0	29.6	2.5	(-14.5, 19.5)
Co-workers	15.7	18.3	14.8	14.8	2.2	(-12.5, 17.0)
Family	44.9	51.8	51.3	48.6	4.3	(-7.7, 16.3)
<i>Physical activity</i>						
Friend	30.9	31.9	30.3	30.5	2.0	(-13.6, 17.6)
Co-workers	15.7	16.4	13.5	13.9	-3.2	(-14.8, 8.4)
Family	44.3	47.2	46.6	47.8	-1.9	(-10.6, 6.8)
<i>Weight control</i>						
Friend	25.2	28.1	21.8	28.4	-0.1	(-16.1, 15.9)
Co-workers	12.3	16.1	9.5	13.8	-1.8	(-15.2, 11.6)
Family	41.2	46.2	45.8	49.6	-0.8	(-15.5, 14)

Adjusted for age, education, income, marital status, race, gender, smoking status. FV = fruits and vegetables.

<sup>a</sup> Change estimate from combined three sample exposure-weighted estimates.

<sup>b</sup> Based on 2 *df*.

<sup>c</sup> *p* < 0.05.

<sup>d</sup> *p* < 0.10.

fact that transit workers work away from the garage may have limited the potential effectiveness of a (garage) worksite intervention, no matter how intensive the intervention. This limits the effects of a garage-based environmental intervention on behavior change. For example, only 18% of the bus drivers' total daily energy intake occurred at work, and of this, only 20% was from the vending machines (i.e., about 90 kcal/day).

#### Study strengths and limitations

Strengths of the present study included a strong environmental intervention, with multiple intervention components, and high levels of research staffing and active employee advisory group participation. Limitations were the availability of only four garages, thus limiting statistical power; the mobile nature of the employee population, thus limiting exposure to the garage environment; our inability to change route schedules or policies about break times for meals or physical activity; lack of trust between bus operators and management, which might have limited participation in the program components; and the prevalence and severity of the obesity in the garage employee population. The relatively short duration of the intervention limited the ability to address broader institutional changes, such as policies regarding schedules and breaks, that could potentially have sustained effects on behaviors related to body weight. Intervention-related reporting bias may have increased the likelihood of observing significant results for the food choices (Caan et al., 2004; Harnack et al., 2004). The use of body mass index as the sole measure of body composition is a study limitation, as is the fact that workers had different work schedules.

#### Conclusions

Worksite environmental interventions for nutrition and physical activity behavior change may have limited impact on BMI among transit workers who spend most of their workday outside the worksite. Obesity prevention strategies that target transit workers

may need to include policy changes that provide incentives for behavior change and that address larger infrastructure issues such as work schedules and break policies.

#### Conflict of interest statement

The authors declare that there are no conflicts of interest. This project was initiated and analyzed by the investigators.

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