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A randomized trial of calorie labeling on menus

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ABSTRACT

Background. Food consumed outside the home accounts for a growing proportion of the North American diet and has been associated with increased obesity.

Purpose. To examine the effect of nutrition labeling on menus on awareness, use, and food consumption, including the impact of “traffic light” labeling and adding other nutrients.

Methods. Blinded, randomized trial with 635 Canadian adults conducted in 2010–2011. Participants ordered a free meal from one of four experimental menus: 1) no nutritional information shown, 2) calorie amounts only, 3) calorie amounts in “traffic lights”, and 4) calorie, fat, sodium, and sugar shown in “traffic lights”. Recall of nutrition information, knowledge of calorie content and nutrient consumption were assessed.

Results. Participants in the calorie conditions were more likely to recall the calorie content of meals and to report using nutrition information when ordering. The calorie content of meals was not significantly different across conditions; however, calorie consumption was significantly lower among participants in the *Calorie-only* condition compared to the *No information* condition (mean = −96 kcal, $p = .048$).

Conclusions. Menu labeling increased awareness and use of nutrition information and reduced consumption. Adding “traffic lights”, fat, sodium, and sugar amounts to menus had little impact compared to calorie-only labeling.

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Introduction

In Canada, approximately 25% of adult Canadians are obese and an additional 37% are overweight (Public Health Agency of Canada, 2011). Over the past 25 years, obesity in Canada has increased among all age groups and socioeconomic strata and in all geographic regions. However, socioeconomic disparities are apparent, with significantly higher levels of obesity among lower socioeconomic groups and aboriginal populations in particular (Public Health Agency of Canada, 2011). The economic burden of obesity in Canada is considerable: recent estimates suggest that the direct costs attributable to overweight and obesity exceed \$6.0 billion or 4% of health expenditures (Anis et al., 2010).

Increased energy intake is a primary determinant of rising obesity rates (Jeffery and Harnack, 2007). In North America, energy intake has increased dramatically as a result of greater portion sizes and greater consumption of energy-dense foods (Dietary Guidelines Advisory Committee, 2010; IOM, Institute of Medicine, 2010; Slater et al., 2009; Statistics Canada. Food Statistics, 2008, 2009). Increased energy intake has been driven in part by greater calorie intake outside the home at “fast-food” and other restaurants (DGAC, Dietary Guidelines Advisory

Committee, 2010; French et al., 2000; Slater et al., 2009). Approximately 60–70% of Canadians report eating out at least once a week, and the Canadian Restaurant and Foodservices Association (2012) estimates that restaurant food accounts for approximately one-fifth of the average Canadian’s daily diet (Joint Initiative of the National Institute of Nutrition and the Canadian Food Information Council, 2004; Reaman, 2010; Stewart et al., 2006). Food eaten outside the home is associated with higher calorie intake and fat intake, as well as lower intake of fiber, calcium, fruit, and vegetables (Canadian Restaurant Foodservice Association, 2010; Dietary Guidelines Advisory Committee, 2010; French et al., 2001; Kant and Graubard, 2004; Satia et al., 2004; Schmidt et al., 2005), and excess weight gain in prospective studies (Brownell, 2004; Mancino et al., 2009; Pereira et al., 2005; Thompson et al., 2004).

A recent scan of the nutrient profile of foods served at 85 of the leading restaurants in Canada indicated substantial variability in calorie levels even among the same types of food offerings (Powell et al., 2007). Given this variability, it is not surprising that most consumers are unable to accurately estimate the calorie level of restaurant foods (Burton et al., 2006; Scourboutakos and L’Abbé, 2012). A growing number of restaurants make nutrition information available online and in pamphlets available upon request. However, according to a 2007 survey, none of the 136 Canadian outlets surveyed provided nutrition information for standard items on menus or menu boards, where it is most visible prior to ordering (Centre for Science in the Public

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Interest, 2008; Wansink and Chandon, 2006). Therefore, although Canadians consume a substantial proportion of their energy intake outside the home, it remains unclear whether they are aware of the nutritional quality of the food they are consuming.

In Canada, nutrition labeling regulations are limited to pre-packaged food products and do not apply to foods served in restaurants (Health Canada, 2010; Health Canada, 2012; Joint Initiative of the National Institute of Nutrition the Canadian Food Information Council, 2004). Mandatory menu board labeling regulations have been implemented in a number of other jurisdictions. In 2008, New York City became the first jurisdiction in the world to require calorie information on menus at restaurants (US Food Drug Administration, 2011). The regulations require restaurant chains with 15 or more locations to list calories on menu boards, menus, or food item display tags. The font and format of the calorie number must be at least as large as the name or price of the menu item. Similar menu regulations have been implemented in six US states and several US cities, and federal regulations are under development (Center for Science in the Public Interest, 2010; New York City Department of Health Mental Hygiene and Board of Health, 2006).

Evidence on the impact of menu labeling is mixed. Among the studies that used experimental research designs to examine the impact on food ordering, eight studies reported a reduction in calorie intake (Bassett et al., 2008; Burton and Creyer, 2004; Davis-Chervin et al., 1985; Howlett et al., 2009; Mayer et al., 1987; Roberto et al., 2010; Stubenitsky et al., 2000; US Food and Drug Administration, 2011), two reported no effect (Harnack et al., 2008; Tandon et al., 2010), and one study reported increased intake associated with labeling (Hoefkens et al., 2011). It should be noted that the type of information presented in the menu labels, the study protocol, and the study setting varied widely across these studies. Research conducted in New York City suggests that consumer awareness and use of calorie information increased following menu labeling regulations (Aaron et al., 1995). Only five studies to date have examined the impact of mandatory calorie labeling regulations, including four studies in New York (Bollinger et al., 2010; Dumanovsky et al., 2010; Elbel et al., 2009, 2011) and one study in King County, Washington State (Finkelstein et al., 2011). Three of the studies did not detect any differences in average calories ordered (Elbel et al., 2009, 2011; Finkelstein et al., 2011), and one study reported mixed findings (Dumanovsky et al., 2011). The final study found that average calories per transaction in Starbucks outlets fell by 6% after calorie posting was implemented in New York City, compared to Starbucks with calorie posting in control jurisdictions (Bollinger et al., 2010). To date, two studies on calorie labeling have been published in Canada: both studies report an association between nutrient labeling on menus and lower calorie consumption (Girz et al., 2012; Vanderlee and Hammond, 2013).

Overall, few menu labeling studies have measured actual food consumption, as opposed to food ordering. Consumers may alter the amount of food they consume in response to calorie labeling; however, only five studies to date have assessed food consumption in response to menu labeling. One such study used direct observation to estimate intake (Howlett et al., 2009), another relied on self-report, while three studies collected food waste and calculated intake based on the weight of the food waste (Aaron et al., 1995; Harnack et al., 2008; Roberto et al., 2010). Finally, we are unaware of any studies that have empirically tested different formats of nutrition information on menus. Menu labeling studies have almost exclusively examined the display of calorie amounts on menus, with very few exceptions (Dumanovsky et al., 2011; Harnack et al., 2008). Research conducted on pre-packaged food labeling indicates that the use of prescriptive information, such as traffic lights to communicate “high”, “moderate”, and “low” levels of nutrients, reduces the cognitive burden on consumers and may increase comprehension and use (Thorndike et al., 2012). A single published study has examined the use of traffic light systems on menu displays and observed an increase in healthy food choices associated with traffic light menu labeling (Thorndike et al., 2012). Finally, most research to date has examined the presentation of calorie information on menus; it is

not known whether adding other nutrients might enhance or detract from this use of nutritional information.

The current study sought to examine the effect of menu labeling on food ordering and food consumption, including the effect of displaying calories along with other nutrients, such as sodium, fat, and sugar, as well as in different formats, such as traffic lights.

Methods

Participants

The study was conducted with 635 adults from South-Western Ontario, Canada. Subjects were recruited via newspaper, bus, and online advertisements. Eligible participants were 18 years of age or older, able to speak and read English, and self-reported no food allergies to gluten or other grain products. The participants were told that the study was related to “lifestyles” in the Waterloo Region; nutrition or diet was not mentioned in any recruitment materials to minimize self-selection bias. The participants received \$20 for completing the study. Target sample sizes of 150 participants in each of the four conditions were established prior to the study to provide 80% power to detect differences of 126 cal between groups, where $\alpha = .05$, 2-tailed. Means (825 cal in the control group) and standard deviations (400) were based on previous research using a similar protocol (Harnack et al., 2008) and equal variances between groups were assumed. Sample size calculations took into account that a conservative estimate of 20% of the study data will be unusable due to missing or invalid data. Ethics approval was provided by the Office of Research Ethics at the University of Waterloo. The study has been registered with ClinicalTrials.gov (Identifier: NCT01948752).

Study design

A between-groups experiment was conducted between November 2010 and June 2011. Prior to the study, all participants were informed that they would receive a free meal from *Subway* as part of the study. All sessions occurred at 6:00 pm to eliminate time effects and to justify the offer of a free meal. After ascertaining consent, the participants were provided with menus and asked to select their meal. The participants were informed that they could order one sandwich, one “side” (i.e., bag of chips), and one drink. The participants were also instructed that, due to study requirements, no food could be taken home or saved for later.

Experimental conditions

The participants were randomized to receive one of four menus: 1) menus with no nutritional information; 2) menus with calorie amounts next to each item; 3) menus with calorie amounts using the “traffic light” format, and 4) menus with calorie, fat, sodium, and sugar amounts in “traffic light” format (see Fig. 1). Traffic lights featured either a green, amber, or red light based on criteria adapted from the UK Food Standards Agency (2007) for pre-packaged food (see Table 1). Nutritional information for all menu items was collected

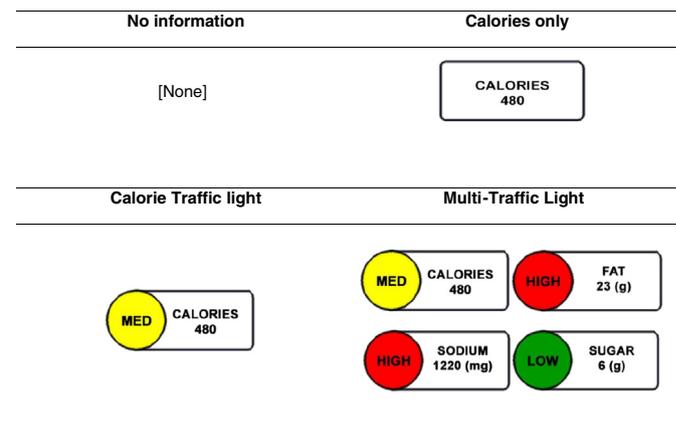


Fig. 1. Nutritional information displayed on menus by experimental condition*. *Example shown for “Cold Cut Combo”. Information was shown for all menu items individually. Full images of each menu are available at <http://www.davidhammond.ca/downloads/Papers/MenuStudy/>.

Table 1
Traffic-light categories for classifying food and beverages.

	Green	Amber	Red
Food			
Calories/portion			
Sandwich	≤450 kcal	>451 to ≤660 kcal	>661 kcal
Chips	≤100 kcal	>101 to ≤200 kcal	>200 kcal
Fat/100 g	≤3.0 g	>3.0 g to ≤20 g	>20.0 g
Sodium/100 g	≤120 mg	>120 mg to ≤600 mg	>600 mg
Sugar/100 g	≤5.0 g	>5.0 g to ≤12.5 g	>12.5 g
Beverages			
Calories	≤100 kcal	>100 to ≤199 kcal	>200 kcal
Fat/100 mL	≤1.5 g	>1.5 g to ≤10.0 g	>10.0 g
Sodium/100 mL	≤120 mg	>120 mg to ≤600 mg	>600 mg
Sugar/100 mL	≤2.5 g	>2.5 g to ≤6.3 g	>6.3 g

from the *Subway* website. Images of the full menu used in each condition are available at: <http://www.davidhammond.ca/downloads/Papers/MenuStudy/>. *Subway* was selected as the restaurant food source for several reasons: 1) *Subway* is the largest restaurant chain in the world in terms of number of outlets (Wall Street Journal, 2011); 2) *Subway* offers menu items with a range of nutritional values and allows patrons to tailor their meals; 3) a *Subway* outlet was located close to the study location, allowing for quick meal delivery to the participants.

Study protocol

The study was conducted on weeknights in groups of up to ten participants per night. Prior to the study session, groups were assigned to parallel groups to receive menus designed according to one of the four study conditions, described below. Allocation to groups alternated each evening beginning with conditions 1 to 4, and then beginning again with condition 1 on the 5th day of the study. The participants were blinded to the study condition: they could view the menu to which they were assigned but were unaware of the nature of the study or the presence of other conditions. After placing their order with the research assistant, the participants were provided with a self-completed “lifestyle” survey, which consisted of socio-demographic questions, as well as a brief passage on the design of a city park and several questions related to their opinion of the proposal. While the participants completed the survey, research assistants purchased the *Subway* orders from a nearby location and delivered the orders to the lab. All food items were weighed using a digital scale prior to being delivered to the participants. Meals were provided upon completion of the “lifestyle” survey and the participants notified the research assistant when finished. All remaining food and beverage items were collected and weighed to estimate the proportion of each item that was consumed. The participants completed an additional survey that assessed recall, knowledge, and use of nutrition information presented on the *Subway* menus, as well as its degree of influence on meal selection. The height and weight of the participants were measured in a private room in order to calculate BMI.

Measures

Socio-demographic information

A socio-demographic survey was administered after meal selection. Questions included sex, age, presence of children under 18 in the home, and ethnicity (recoded as 1 = White/Caucasian, 0 = Other). Education level was coded as 1 = High school or less, 2 = Some/completed college or university, and 3 = Graduate or professional school). Body Mass Index (BMI) was categorized as “underweight” (<18.5), “normal weight” (18.5–24.9), “overweight” (25–29.9), and “obese” (30+).

Recall & use of nutrition information

Recall of nutrition information on menus was measured using an unprompted recall task after the meal was eaten; approximately 20 min after the time of ordering. The participants were asked, “Was there any nutritional information provided on the *Subway* menu you were given?” Participants who reported “yes” were asked: “What information did you notice?” Responses were recorded verbatim and subsequently recoded based on any mention of “calories”, “sodium”, “sugar” or “fat”.

Perceived influence of nutrition information

The participants were asked: “How much, if at all, did the nutritional information shown on your menu influence what you ordered for your meal?”

Response options were: “I did not notice any nutrition information on the menu”/“Not at all”/“A little”/“A lot”. The question was asked of all respondents, including respondents in the “no information” condition, to control for any social-desirability bias across conditions.

Calorie knowledge

The participants were asked: “Approximately how many calories were in your *Subway* sandwich?” Responses were coded as “correct” if they were within 50 cal of the actual total. The participants were asked to try their best to estimate; “Don’t know” responses were thus coded as incorrect.

Calories ordered and consumed

The calorie content of all food and beverage items ordered by each participant was calculated using information provided by *Subway*. All items were weighed immediately prior to delivery to the participants. After the participants indicated that their meal was completed, the research assistants collected and weighed any leftover food or beverage portions. A consumption variable was calculated for calorie, fat, sodium, and sugar consumption for each participant by subtracting the estimated number of calories in food and beverage waste from the total for the meal, based on differences in weight.

Statistical analyses

All analyses were conducted using IBM SPSS Version 20.0 (New York, NY). A total of 666 participants began the study. Twenty-six participants did not order a meal and were excluded from the analysis; 5 additional participants were excluded for missing data/failing to complete the study protocol. Chi-square tests were used to test for differences in sample profile between experimental conditions, as well as to test differences in recall, knowledge and use of nutrition information between experimental conditions. Linear regression models were conducted to test differences between experimental conditions in the mean number of calories ordered and consumed by the participants. Experimental condition was entered as an indicator variable with the following covariates: age, sex, education, ethnicity, and BMI. A level of $p < .05$ was considered statistically significant.

Results

Sample characteristics

Sample characteristics are shown in Table 2. There were no significant differences in socio-demographic factors across experimental conditions.

Recall of nutritional information on menu

Fig. 2 indicates the proportion of participants who recalled seeing nutritional information on menus, including recall of calories, fat, sodium and sugar. There was an overall effect of experimental condition ($\chi^2 = 50.1, p < .001$), in which awareness of “any” nutritional information was significantly higher for all three experimental conditions compared to the control condition (*Calorie Only*: $\chi^2 = 109.3, p < .001$; *Calorie Traffic Light*: $\chi^2 = 118.2, p < .001$; *Multi-Traffic Light*: $\chi^2 = 65.1, p < .001$) (Table 3). Recall of calorie information was significantly different by condition ($\chi^2 = 18.4, p < .001$). As shown in Fig. 2, recall of calorie information was significantly higher in all experimental conditions compared to the *No Information* control condition ($p < .001$ for all), and significantly greater in the *Calorie Only* ($\chi^2 = 14.8, p < .001$) and *Calorie Traffic Light* ($\chi^2 = 16.1, p < .001$) conditions compared to the *Multi-Traffic Light* condition. Recall of sodium, fat, and sugar information was significantly greater in the *Multi-Traffic Light* condition compared to all other conditions ($p < .001$ in all cases).

Perceived influence of nutritional information

Significant differences were observed between conditions in the proportion of participants who reported that the nutrition information on menus influenced what they ordered ($\chi^2 = 18.4, p < .001$). Participants

Table 2
Sample characteristics.

Experimental condition						
Variable	No information (control) (n = 162)	Calories only (n = 165)	Calorie traffic light (n = 156)	Multi-traffic light (n = 152)	Overall (n = 635)	
Sex						
Female	49.1%	58.8%	58.3%	57.2%	55.8%	$\chi^2 = 4.4, p = .22$
Age						
18-24	21.0%	17.0%	23.7%	15.1%	19.2%	$\chi^2 = 15.2, p = .09$
25-34	16.0%	13.3%	16.0%	20.4%	16.4%	
35-64	43.2%	58.8%	46.2%	48.0%	49.1%	
65+	19.8%	10.9%	14.1%	16.4%	15.3%	
Ethnicity						
White/Caucasian	74.7%	70.3%	66.0%	73.0%	71.0%	$\chi^2 = 3.3, p = .35$
Other	25.3%	29.7%	34.0%	27.0%	29.0%	
Education						
High school or less	20.4%	14.0%	18.1%	15.9%	17.1%	$\chi^2 = 12.0, p = .68$
College/University	61.1%	67.1%	64.5%	63.6%	64.1%	
Post-graduate	18.5%	18.9%	17.4%	20.5%	18.8%	
BMI^a						
Underweight	1.2%	2.4%	0.6%	2.0%	1.6%	$\chi^2 = 8.1, p = .52$
Normal weight	46.0%	38.8%	43.9%	41.4%	42.5%	
Overweight	27.3%	37.6%	32.3%	28.3%	31.4%	
Obese	25.5%	21.2%	23.2%	28.3%	24.5%	

^a Includes "Did not notice nutrition information" and "Don't know" responses.

in the *No Information* control condition were less likely to report that they were influenced "A little" or "A lot" compared to those in the *Calorie Only* ($\chi^2 = 40.2, p < .001$), *Calorie Traffic Light* ($\chi^2 = 68.8, p < .001$) and *Multi-Traffic Light* ($\chi^2 = 63.0, p < .001$) conditions. Participants in the *Calorie Traffic Light* ($\chi^2 = 6.5, p = .011$) and *Multi-Traffic Light* conditions ($\chi^2 = 4.5, p = .034$) were also more likely to report being influenced than participants in the *Calorie Only* condition.

Calorie knowledge

Overall, 24.4% of the participants were able to identify the calorie content of their *Subway* sandwich within 50 cal of the actual caloric total. Significant differences were observed between conditions ($\chi^2 = 18.4, p < .001$): a greater proportion of participants in the *Calorie Only* (32.1%) and the *Calorie Traffic Light* condition (30.1%) correctly recalled the calorie content, compared to the *No Information* control condition (14.2%; $p < .001$ for both). No significant differences were observed with the *Multi-Traffic Light* condition (21.1%).

Calorie ordering & consumption

Fig. 3 shows the mean number of calories ordered and consumed by the participants in each condition. Linear regression models were conducted adjusting for age, sex, education, ethnicity and BMI. No significant differences were observed in the number of calories ordered between conditions: *No Information* (mean = 903.4, SD = 318.5), *Calorie Only* (mean = 850.9, SD = 389.9), *Calorie Traffic Light* (mean = 857.4, SD = 366.0), and *Multi-Traffic Light* conditions (mean = 855.5, SD = 344.5). For calorie consumption, participants in the *Calorie Only* condition consumed significantly fewer calories (mean = 744.2, SD = 368.1) compared to participants in the *No Information* condition (mean = 839.6, SD = 318.8; $\beta = -68.1, p = .048$). No significant contrasts were observed for the *Calorie Traffic Light* (mean = 776.8, SD = 350.9; $\beta = -47.7, p = .17$) or *Multi-Traffic Light* conditions (mean = 764.9, SD = 326.2; $\beta = -59.0, p = .09$). In addition,

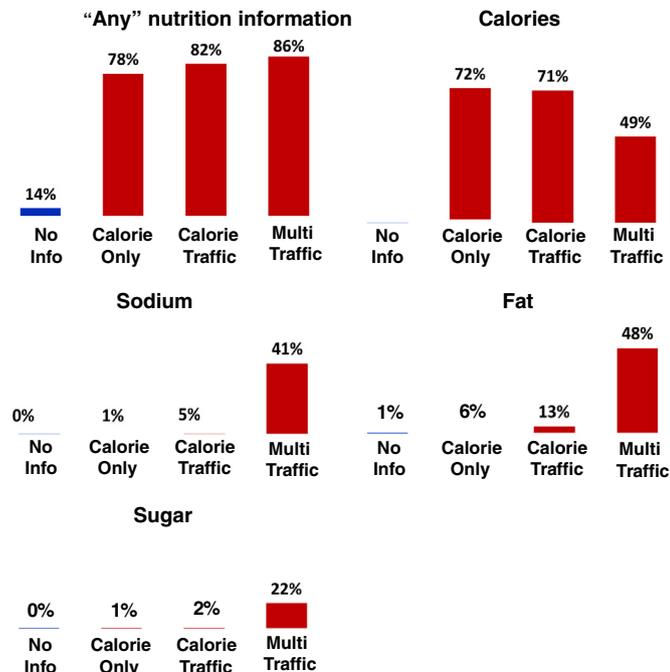


Fig. 2. Recall of nutritional information on menus by experimental condition.

Table 3
Perceived influence of nutritional information by experimental condition.

	No info n = 162	Cal only n = 165	Cal traffic n = 156	Multi-traffic light n = 152	Total n = 635
Not at all*	85.2%	50.9%	37.2%	38.4%	53.3%
A little	6.2%	25.5%	40.4%	30.5%	25.4%
A lot	8.6%	23.6%	22.4%	31.1%	21.3%

* Includes "Did not notice nutrition information" and "Don't know" responses.

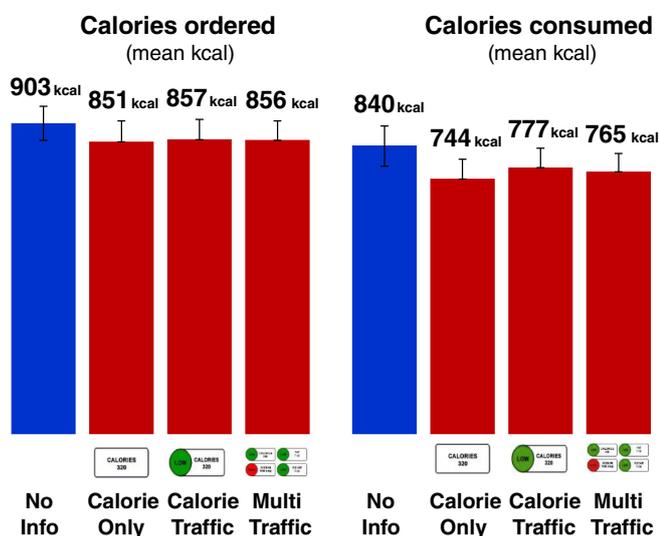


Fig. 3. Mean calories ordered and consumed by experimental condition ($n = 63$).

no significant differences were observed for ordering or consumption of sodium, fat, or sugar across conditions.

Discussion

The current study is among the first empirical studies of menu labeling conducted in Canada. The findings indicate that providing nutrition information on menus increases recall and use of nutrition information, as well as knowledge of calorie amounts, similar to previous studies (Roberto et al., 2010).

The calorie amounts of ordered meals were not significantly different across menu labeling conditions; across all three experimental conditions in which nutrition information was displayed, participants ordered meals with approximately 50 fewer calories compared to participants in the *No Information* control group; however, this finding was not statistically significant. Nevertheless, calorie consumption was significantly lower among participants who ordered from menus that displayed calorie amounts. The magnitude of this reduction—96 cal, or 11% of calories consumed—were substantial. In the two previous calorie labeling studies that reported the number of calories ordered and consumed, neither found a discrepancy in the proportion of meals that were consumed (Harnack et al., 2008; Roberto et al., 2010). However, at least one previous study found evidence that participants altered their consumption behavior in response to menu labeling by consuming fewer calories following the meal later in the day. The current findings suggest that measuring consumption—and not just food ordering—may be important when assessing the impact of menu labeling policies.

The current study was among the first to compare different formats and nutritional content within the context of menu labeling. The results indicate that displaying calories numerically performed equally well, or even better, than calories presented in “traffic lights”. Although traffic lights have been consistently found to increase understanding of nutrient amounts, most of this research has been conducted with respect to pre-packaged food (Campos et al., 2011). Unlike pre-packaged foods, which are typically viewed one product at a time and require comparisons across packages, menu labeling displays calorie amounts for different options immediately adjacent to one another. Therefore, in

contrast to pre-packaged foods, comparing calorie amounts across menu items may actually be easier in the absence of traffic lights.

Policies that mandate calorie labeling on menus have been criticized on the grounds that they exclude a range of other important nutrients. The current study found that adding nutrients to menu labeling had little effect. When fat, sugar, and sodium were displayed on menus in addition to calorie amounts, participants showed significantly higher levels of recall for these nutrients. However, when presented with this longer list of nutrients, participants were less likely to recall the calorie content of their meal compared to when menus displayed calories only. Adding nutrients to menus may have increased the cognitive demand associated with processing this information and findings of the current study suggest there may be a limit to the amount of nutrition information that consumers are able or willing to process. In addition, there were no significant differences in consumption of fat, sodium or sugar across conditions: indeed, those in the *Calorie Only* condition appeared to consume slightly less sodium, fat and sugar than those in the *Multi-Traffic Light* condition, in which these amounts were displayed on menus. These differences were not statistically significant, but suggest that displaying sodium, fat, and sugar was no more effective in altering consumption of these nutrients than displaying calories alone. Further research is required to examine both the feasibility and potential impact of displaying more than one nutrient on menus, as well as the extent to which calorie labeling may prompt consumers to request information on other nutrients, which is available upon request in many restaurants.

Study limitations

This study has several limitations. First, the study was conducted in an experimental setting. Although the design allowed for more precise estimates of food intake, the setting was not a naturalistic environment in which restaurant ordering and consumption typically occur. Second, participants were presented with menus typically associated with a full-service or “sit-down” restaurant, whereas *Subway* is a quick-service establishment that uses menu boards. Collectively, these factors may have affected food ordering or consumption; however, it is unlikely that these limitations would account for the differences observed between experimental conditions.

Implications

The US is set to become the first country in the world to require mandatory disclosure of calorie amounts on menus among restaurant chains with 20 or more locations (US Food Drug Administration, 2011). In Canada, no jurisdictions mandate nutritional labeling on menus to date. The current research suggests that calorie information on menus may reduce caloric intake as a function of both meal selection and the amount of food and beverages that are consumed. As the first Canadian study, the findings provide preliminary evidence for the efficacy of displaying calorie information on menus and menu boards in Canada.

Conflict of interest statement

This study was funded by a research grant from the Canadian Cancer Society Research Institute. Scholarship funding was provided by an Ontario Graduate Scholarship (S.G.), a Canadian Institutes for Health Research (CIHR) Master's Award (S.G.) and a Population Interventions for Chronic Disease Prevention (PICDP) Training Grant funded by CIHR, the Heart and Stroke Foundation of Canada and the Propel Centre for Population Health Impact at the University of Waterloo (S.G.). Funding was also provided by a CIHR New Investigator Award (D.H.) and a Canadian Cancer Society Research Institute Junior Investigator Award (D.H.). The authors have no conflicts of interest or financial disclosures to report.

Appendix A. CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	pages 3–5
	2b	Specific objectives or hypotheses	Page 6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	Page 7
	4b	Settings and locations where the data were collected	Page 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Pages 9–10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	Page 7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 6
	11b	If relevant, description of the similarity of interventions	Page 7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 9
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 6
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Given for each table.
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Pages 9–11.
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Tables & pages 9–11.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Pages 9–11.
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pages 12–13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 12.
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 11–13
Other information			
Registration	23	Registration number and name of trial registry	In progress
Protocol	24	Where the full trial protocol can be accessed, if available	In progress.
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 14.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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