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Menu labelling and healthy food choices: a randomised controlled trial

Renata Carvalho Oliveira, Ana Carolina Fernandes and Rossana Pacheco da Costa Proença
Department of Nutrition, Universidade Federal de Santa Catarina, Florianopolis, Brazil
Heather Hartwell
Bournemouth University, Poole, UK
Vanessa Mello Rodrigues
Departamento de Nutrição, Universidade Federa de Santa Catarina, Florianópolis, Brazil
Claudia Flemming Colussi
Department of Collective Health, Universidade Federal de Santa Catarina, Florianopolis, Brazil, and
Giovanna M.R. Fiates
Department of Nutrition, Federal University of Santa Catarina, Florianopolis, Brazil

Abstract

Purpose – The purpose of this paper is to examine the effects of different menu labelling formats on healthy food choices in a real restaurant setting.

Design/methodology/approach – This cross-sectional, randomised and controlled parallel-group trial was conducted in Brazil in 2013. In total, 313 university students were randomly assigned to one of three parallel groups with different menu labelling formats. Of these, data from 233 students were analysed. The others did not attend and were excluded. Intervention Group 1 ($n = 88$) received information in the form of a traffic light plus guideline daily amounts, while Intervention Group 2 ($n = 74$) was presented with ingredients list plus highlighted symbols (IL + S). The control group ($n = 71$) received a menu with no menu labelling. Data were collected on one weekday in a restaurant setting. Trial outcomes were assessed by healthy food choices.

Findings – Healthy food choices of students who received the menu showing IL + S were significantly higher when compared to the other groups. This same menu labelling format positively affected healthy food choices in women, not overweight participants and in participants who often ate out more than twice a week.

Originality/value – Menu labelling format presenting ingredients list and highlighted symbols was positively associated with healthy food choices among the university students in Brazil. This type of labelling could be adopted in future legislation on menu labelling in Brazil and around the world.

Keywords Foodservice, Restaurants, Intervention, Nutrition information, Food choices

Paper type Research paper

Introduction

The term menu labelling can be used in different contexts as a synonym for calorie information (Roberto *et al.*, 2013; Brochu and Dovidio, 2014), for nutritional information (Yoon and George, 2012; Auchincloss *et al.*, 2013), for the coloured traffic light system (Gerlach, 2013; Morley *et al.*, 2013) or for food and nutritional information (Thunstrom and Nordstrom, 2011; Feldman *et al.*, 2013). For the purposes of the present study, menu labelling refers to all calorie information, nutritional information (such as calories and nutrients) and food information (e.g. ingredients list, highlighted symbols to designate "vegetarian" and

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phrases like "contains gluten"), as well as the traffic light system plus guideline daily amounts (TLS + GDA).

Menu labelling is a public health strategy that is debated around the world as a way to help prevent obesity and other chronic diseases by informing consumers' choices (Bleich and Pollack, 2010; Malik *et al.*, 2013). However, only in the USA is it mandatory under the federal law; there, restaurants and similar food service establishments that are part of a chain of 20 or more must provide calorie information on their menus (United States of America Department of Health and Human Services, Food and Drug Administration, 2014). In other countries (e.g. Canada and Australia), menu labelling comes under local laws, but not the federal law.

In Brazil, although there is no national legislation, menu labelling is being discussed by ANVISA (Brazilian Health Surveillance Agency). In some places there are local laws which require nutritional information to be present on menus, but there is no evidence of law enforcement and if this initiative is effective for consumer use (Oliveira *et al.*, 2012).

Consumers report wanting menu labelling to be available to help them make informed choices; this is especially so for those who have dietary restrictions related to health, such as allergies and intolerances, and those with religious or philosophical requirement (Oliveira *et al.*, 2012; Martinez *et al.*, 2013). Unfortunately, they often find it hard to read and understand the information, mostly because of the mathematically complex numeric information on calories and nutrients (Grunert and Wills, 2007; Blumenthal and Volpp, 2010; Tangari *et al.*, 2010).

There is no a standard design to provide menu labelling in restaurants, and the way this information is made available varies substantially. According to the Food Standards Agency in the UK, consumers consider standardisation of menu labelling design important to allow differentiation among dishes, and to facilitate their use and understanding of this information (United Kingdom. Food Standards Agency. Central Office of Information on behalf, 2009).

Because of the lack of standardisation and definition on what is the best menu labelling design, a variety of food and nutritional information formats for packaged food are being adapted for restaurant use, such as the traffic light system and nutrition table formats (Feldman *et al.*, 2013).

However, if the available information is not presented in a simple and easily understandable format, consumers may become confused (Thomas and Mills, 2006). The authors report that consumers have difficulty understanding quantitative information such as calories, fat and sodium counts, but can easily recognise qualitative information about different dishes (Tangari *et al.*, 2010; Ellison *et al.*, 2014).

Studies have shown that providing only calorie information is insufficient to modify the consumer behaviour in restaurants; this suggests that the inclusion of interpretative or descriptive menu labelling formats, besides calories, is required to influence food choices (Kiszko *et al.*, 2014; Schornack and Rozensher, 2014; Sinclair *et al.*, 2014; Fernandes *et al.*, 2016).

Studies have reported that qualitative information, such as healthy symbols and traffic light information, was most effective in promoting healthy food choices in restaurants (Thorndike *et al.*, 2014; Morley *et al.*, 2013; Lassen *et al.*, 2014; Fernandes *et al.*, 2016; Chen *et al.*, 2017). In addition, studies have showed that consumers prefer simple menu labelling formats (such as symbols) and are more likely to use menu labelling when the information is easy to understand and requires minimal effort (Lando and Labiner-Wolfe, 2007; Morley *et al.*, 2013).

A survey conducted in the USA among 487 university students has shown that 96 per cent of participants reported that they wanted menu labelling in canteens and 88 per cent of university students said that menu labelling could affect their food choice at

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least sometimes. Respondents also indicated a preference for less information, focusing more on calories, ingredients and fat (Martinez *et al.*, 2013).

For many students, meals eaten in university restaurants or canteens are their main meals of the day (Hoefkens *et al.*, 2012); and often they describe menu labelling designs in these venues as confusing and difficult to follow (Hoefkens *et al.*, 2011).

The impact of providing menu labelling on food choices may differ depending on different factors, such as age, gender and weight. Young adults (18-24 years) (Dumanovsky *et al.*, 2010; Pulos and Leng, 2010), women (Bezerra and Sichieri, 2009; Bollinger *et al.*, 2011; Heathcote and Baic, 2011) and overweight people (Dowray *et al.*, 2013) tend to see and use menu labelling in their food choices.

In the same way, some studies have reported that consumers who follow special diets or have food-related illnesses would be more nutrient-conscious and would use more menu labelling (Stein, 2010; Girz *et al.*, 2013; Ellison *et al.*, 2014) as well as people who often have lunch away from home (Fernandes *et al.*, 2015).

Therefore, the aim of this study is to examine the effect of different menu labelling formats on healthy food choices in a real restaurant setting. According to the results of a preliminary focus groups study to develop the tested formats (Oliveira *et al.*, 2017), we hypothesised that selected menu labelling formats could influence healthy food choices, especially qualitative information, as ingredients list plus symbols format and traffic light system, because they were the preferred formats reported in the focus groups study.

Method

Study design

A cross-sectional, parallel-group cluster randomised controlled trial was undertaken in Brazil with university students in a restaurant setting in 2013. The participants were randomly assigned to three parallel groups with different menu formats: TLS + GDA; ingredients list plus highlighted symbols (IL + S); or a control group, with no menu labelling (C), to examine the effect on healthy food choices.

Menu labelling formats

The tested menu formats were previously defined in five focus groups conducted with university students in 2013 (Oliveira *et al.*, 2017). Focus groups were conducted with 36 participants. Recruitment was discontinued once the same themes continued to emerge across groups. Themes originating from the content analysis were organised around four menu labelling formats: numerical information of calories; numerical information on calories and nutrients; coloured traffic light system; and food information with list of ingredients and highlighted symbols (contains gluten, lactose, trans fat and/or genetically modified organisms; is suitable for vegetarian and/or organic). University students preferred a list of ingredients plus symbols format, which was considered more understandable and useful to make informed food choices. The traffic light system was considered the second preferred menu labelling format. Numerical information of calories and nutrients as well as only calorie information formats were rejected by most focus group participants (Figure 1).

In this study, the traffic light system was used plus GDA because consumers' feedback in our focus group study suggested that this information is considered more understandable than the traffic light system only. Malam *et al.* (2009) also showed a preference for the traffic light system plus GDA. Traffic light colours designated low (green), medium (amber) or high (red) levels of fat, saturated fat, sugar, salt and calories plus the percentage of the GDA of energy and the same nutrients (United Kingdom Food Standards Agency, 2007; European Food Information Council, 2015).

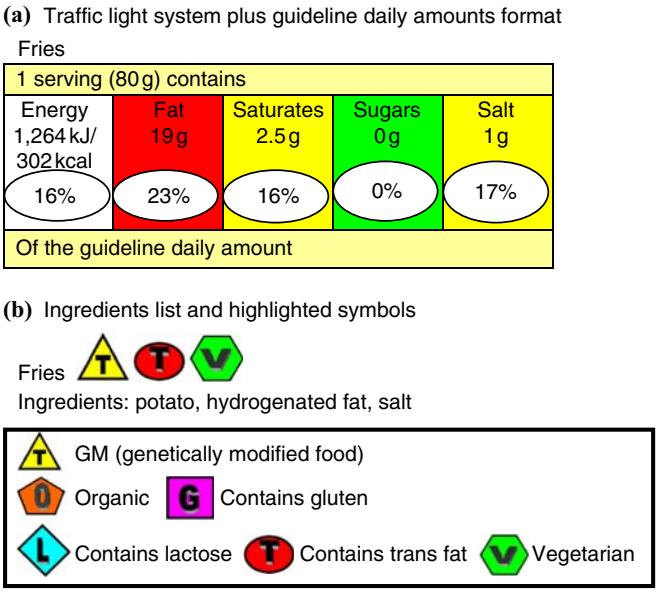

Figure 1.
Menu labelling formats tested by experimental condition

Food information with a list of ingredients and highlighted symbols (contains gluten, lactose, trans fat and/or genetically modified organisms is suitable for vegetarian and/or organic) was adapted from a previous study conducted by Feldman *et al.* (2013).

Selected restaurant

The selection of the location was intentional; we chose a restaurant located near a university campus in Brazil with university students who agreed to participate in the study as consumers.

The restaurant offers a printed menu of the day serving a selection of 18 dishes per day similar a fast buffet setting (five salads, seven side dishes, six meat dishes). Nearly 500 meals are served daily between 11 a.m. and 2 p.m., Monday to Friday. Structure of the menu and recipes are standardised.

Participants and recruitment

To be eligible to participate, students had to be at least 20 years old, in accordance with the World Health Organization adulthood definition (1995) and be undergraduate students. To minimise self-selection bias, the participants were told that the study was a consumer survey in a restaurant. Menu labelling and the word nutrition were not mentioned in any recruitment material.

Subjects were all volunteers, recruited via social media and e-mail messages. Online advertisements contained a link to the registration form, allowing eligible students to be contacted by the research team.

The selected restaurant could support an increase of approximately 250 people per day in addition to their usual 500 customers. Thus, sample calculation was based on 250 people plus 10 per cent due to losses or refusals and 15 per cent due to confounders, giving a total of 313 volunteers.

Some 430 students signed up to participate in the study, from whom 375 volunteers were recruited having met the criteria of eligibility, 313 (83.4 per cent response rate) were blindly

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allocated to the experimental condition. Of these, 233 students attended and participated in the one-day intervention.

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Human Ethics Committee of Federal University of Santa Catarina (Ethics No. 484.782). All students who agreed to participate in the study signed an informed consent form.

Random allocation and blinding

The 313 volunteers recruited were randomly assigned to one of the three parallel groups corresponding to different menu formats: no menu labelling (control group); traffic light system plus GDA (TLS + GDA; IL + S. Randomisation was stratified according to gender, body mass index (BMI) and dietary restrictions. In total, 16 groups were formed to be randomised into one of three menu labelling formats proposed. Block randomisation was carried out with a computer-generated list of random numbers, using codes for the participants by an investigator with no involvement in the trial. A stratified blocked randomisation scheme was used to achieve comparability between the study groups.

Only investigators and staff were kept blind to the allocation.

Study protocol

Data were collected on a weekday during lunch time opening hours (11:00-14:00). All menu labelling formats were tested simultaneously. Upon arrival at the restaurant, each participant met individually with a study staff member and was provided with one of the printed menus having the labelling format corresponding to the group to which they had been randomly assigned. Participants were then asked to look at/ read the menu and order their meal annotating the chosen dishes on a separate tally sheet. Study staff guided this procedure.

Meals chosen by the participants were free. The aim of this stage was to analyse healthy food choices.

Measures

Sample characteristics. During recruitment, volunteers completed a brief online questionnaire about their age, gender, frequency of eating out, weight, height and dietary restrictions. Gender was categorised as male/female, age was categorised as 20-30; 31-40; $>$ 40 years old, frequency of eating out was categorised as $\leqslant$ twice a week; $>$ twice a week, dietary restrictions was categorised as do not have; vegetarian/vegan; disease, allergy or intolerance.

Body weight and height. Body weight and height were self-reported by participants during recruitment of volunteers. BMI was categorised as not overweight (< 25 kg/m^2) and overweight ($\geqslant 25$ kg/m^2), according to the World Health Organization (1995).

Healthy dishes. Healthy foods were classified according to a public policy document, the Dietary Guidelines for the Brazilian Population (Ministério da Saúde, Brasil, 2008; Ministry of Health, Brazil, 2015), and also according to the Food Diversity Index for Assessment of Diets (Bernardo *et al.*, 2015). Criteria to classify dishes as healthy were:

(1) salads: raw and cooked vegetables (low-fat; boiled/steamed/roasted/grilled/braised) – without dressing;

(2) side dishes: raw and cooked vegetables (low-fat; boiled/steamed/roasted/grilled/braised) – without sauce; cooked beans; cooked cereals, potatoes, roots (low-fat; boiled/steamed/roasted/grilled/braised); and

(3) main courses: beef, pork, chicken, turkey, fish and seafood (low-fat; boiled/steamed/roasted/grilled/braised).

According to the proposed classification method, ten of the 18 dishes offered at the restaurant on the day of the study were classified as healthy (55, 6 per cent):

(1) salads: (three from five) lettuce and rocket, raw carrot and beet salad, boiled onion/aubergine/courgette mix;

(2) side dishes (four from seven): boiled rice, boiled brown rice, boiled black beans, pasta without sauce;

(3) main courses (three from six): roasted beef, roasted chicken, beef in tomato saucel;

(4) eight of the offered dishes (44.4 per cent) were classified as less healthy;

(5) salad: pasta salad with mayo; boiled cauliflower with mayo (because of having mayonnaise sauce);

(6) side dishes: potato chips, fried cassava flour (*farofa*), stewed cabbage with bacon (high fat dishes); and

(7) main courses: beef lasagne, fried chicken steak and fried breaded fish (high fat dishes).

A typical Brazilian meal is composed of three or four types of salads (with vegetable oil, vinegar or lemon juice and salt as dressing), rice, beans, meat dishes, potatoes or other side dishes.

Healthy menu items are prepared based on fresh food, minimally processed food and cooking ingredients (such as salt) (Ministry of Health, Brazil, 2015). It was not considered the amount of salt, but the use of processed and ultra-processed food with high salt contents.

Statistical analyses

All analyses were conducted using STATA 11 statistical software (Statacorp, College Station, TX, USA) in 2014. A p-value of < 0.05 was accepted as statistically significant. No participant was excluded from the analyses.

Sample characteristics reported as frequencies (per cent) were compared between groups using χ^2 test (Hammond *et al.*, 2013; Morley *et al.*, 2013). ANOVA reported as mean and a 95 per cent confidence interval was used to examine cross-sectional associations between healthy food choices and each experimental condition and to examine associations by gender, BMI, dietary restrictions and frequency of eating out. When a significant difference was found, Bonferroni *post hoc* test was performed to determine the differences between each pair of groups.

Results

Recruitment and retention

The flow of participants through the study is shown in Figure 2. From the 375 volunteers assessed for eligibility, 313 (83.4 per cent response rate) were included and randomised as follows and 62 students were excluded in enrolment. In total, 104 students were allocated to the control group, 103 to TLS + GDA and 106 IL + S. Of these, data from 233 students were analysed. The others did not attend and were excluded.

In the one-day intervention, there were 71 participants in the control group, 88 in the TLS + GDA group and 74 in the IL + S group.

Overall characteristics of participants

There were no significant differences in sample characteristics across experimental conditions (Table I).

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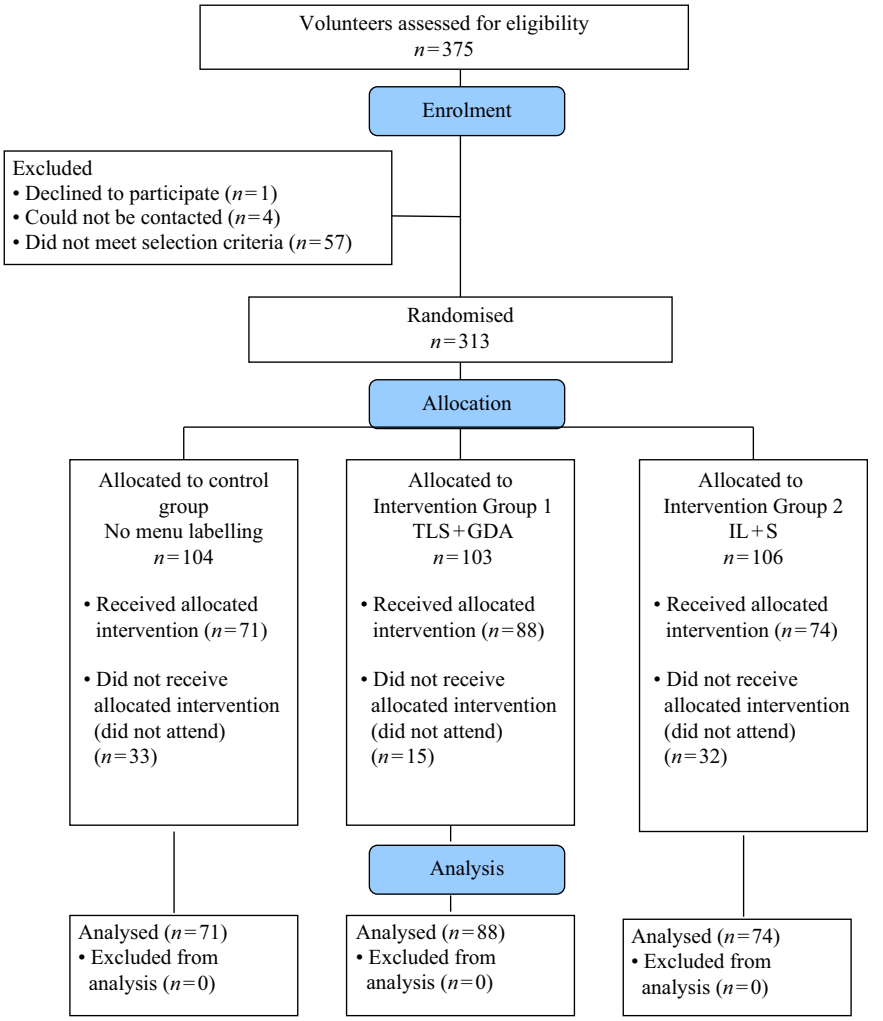

Figure 2.
Participants flow diagram

Healthy food choices by experimental condition

The total of 18 items on the restaurant menu, the mean of items chosen by participants in control group was 8.3 items, in TLS+GDA was 8.0 items and in the IL + S was 8.9 items.

Considering the 12 healthy items on the restaurant menu, the mean of healthy items chosen by participants in control group was 5.6 items (67.6 per cent of the chosen items), in TLS + GDA was 5.4 items (67.5 per cent of the chosen items) and in the IL + S was 6.2 items (69.8 per cent of the chosen items). The number of healthy food choices was significantly higher among students who received the IL + S menu ($p < 0.05$) across experimental conditions (Table II).

The presence of IL + S information positively affected women's healthy food choices, not overweight participants and also the healthy food choices of those participants who ate out more than twice a week.

Variable	Control ($n = 71$)	TLS + GDA ($n = 88$)	IL + S ($n = 74$)
Gender			$p = 0.786$[a]
Male	36 (50.7%)	49 (55.7%)	38 (51.4%)
Female	35 (49.3%)	39 (44.3%)	36 (48.6%)
Age			$p = 0.738$[a]
20-30	68 (95.8%)	85 (96.6%)	73 (98.6%)
31-40	2 (2.8%)	2 (2.3%)	0 (0%)
> 40	1 (1.4%)	1 (1.1%)	1 (1.4%)
BMI			$p = 0.706$[a]
Not overweight (< 25 kg/m^2)	55 (77.5%)	72 (81.8%)	57 (77.0%)
Overweight (⩾ 25 kg/m^2)	16 (22.5%)	16 (18.2%)	17 (23.0%)
Dietary restrictions			$p = 0.885$[a]
No dietary restriction	60 (84.5%)	70 (79.5%)	58 (78.4%)
Vegetarian/vegan	3 (4.2%)	6 (6.8%)	5 (6.8%)
Disease, allergy or intolerance	2 (2.8%)	6 (6.8%)	5 (6.8%)
Dieting	6 (8.5%)	6 (6.8%)	6 (8.1%)
Frequency of eating out			$p = 0.653$[a]
⩽Twice a week	18 (25.4%)	17 (19.3%)	17 (23.0%)
> Twice a week	53 (74.6%)	17 (19.3%)	17 (23.0%)

Notes: $n = 233$. [a]χ^2 test. There were no significant differences in demographic and behavioural factors across experimental conditions

Table I. Sample characteristics by experimental condition

Variable	Control ($n = 71$) Mean	CI 95%	TLS + GDA ($n = 88$) Mean	CI 95%	IL + S ($n = 74$) Mean	CI 95%
Total	5.6	5.2-6.0	5.4	5.0-5.8	6.2*	5.9-6.6
Healthy salads	2.3	2.0-2.6	2.1	1.8-2.4	2.6	2.3-2.9
Healthy side dishes	2.1	1.9-2.3	2.2	2.0-2.4	2.3	2.1-2.5
Healthy main courses	1.2	1.0-1.4	1.1	0.9-1.3	1.3	1.1-1.5
Gender						
Male	6.0	5.5-6.6	5.9	5.3-6.4	6.3	5.8-6.9
Female	5.2	4.7-5.7	4.8	4.2-5.5	6.1*	5.6-6.6
BMI						
Not overweight (< 25 kg/m^2)	5.8	5.3-6.2	5.2	4.8-5.7	6.4*	6.0-6.7
Overweight (⩾ 25 kg/m^2)	5.1	4.3-5.8	6.1	5.1-7.1	5.8	4.9-6.6
Dietary restrictions						
No	5.6	5.1-6.0	5.3	4.8-5.8	6.1	5.7-6.5
Yes	5.9	5.0-6.9	5.7	4.9-6.5	6.6	6.0-7.2
Frequency of eating out						
⩽ Twice a week	6.1	5.2-6.9	5.6	4.3-6.8	5.8	5.0-6.6
> Twice a week	5.5	5.0-5.9	5.4	4.9-5.8	6.3*	5.9-6.7

Note: *Significant p-values ($p < 0.05$) – ANOVA *post hoc* Bonferroni

Table II. Mean number of healthier food items chosen by experimental condition

As shown in Table II, there were no significant differences in number of healthy food choices items chosen across individual dishes (salads, side dishes, main courses) and dietary restrictions in the different intervention groups.

TLS + GDA format had no significant effect on healthy food choices.

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Discussion

The more qualitative menu labelling format (IL + S) was positively associated with healthy food choices. These results indicate that visual information on ingredients and components of dishes can quickly and effectively help consumers compare different options and select the healthier ones when deciding what to eat in a restaurant setting. A possible explanation for the effectiveness of this menu labelling format is the fact that it is a simple, easy to understand informative format which demands little time to be evaluated.

According to a systematic review (Fernandes *et al.*, 2016), qualitative information may prove more effective in promoting healthy eating. In the UK, Alexander *et al.* (2010) investigated consumer attitudes towards menu labelling and found that they preferred qualitative menu labelling, without the presence of numbers to avoid confusion when using this information. Similarly, in the USA, other researchers also reported that simple menu labelling formats including the use of symbols are preferred by consumers, who are more likely to use menu labelling that requires minimal effort when compared to quantitative information (Lando and Labiner-Wolfe, 2007; Morley *et al.*, 2013).

Traffic light labelling is also considered a simple menu labelling format and studies have shown a positive relationship between the traffic light system and healthier food choices (Heathcote and Baic, 2011; Morley *et al.*, 2013; Thorndike *et al.*, 2014; Yepes, 2014). In the present study however, this was not the case, as the TLS + GDA format was not as effective as IL + S on influencing the choice of healthier foods. A possible explanation for this result is the fact that the menu of selected restaurant contains much more items than those of other studies, which may demand more time for reading and understanding when compared to the ingredients list plus symbols information besides being able to confuse the consumers when there are different colours' combinations in the many items of the menu, for example, are three yellow alerts better or worse than one green, one yellow and one red?

In our study, the IL + S labelling format positively affected healthy food choices by women. This is in accordance with other studies on the subject. Brazilian researchers suggested that Brazilian women indeed make healthier choices when eating out (Bezerra and Sichieri, 2009). Additionally, it has been reported that women are more likely to use menu labelling, and are more motivated to try to understanding it (Lando and Labiner-Wolfe, 2007; Driskell *et al.*, 2008; Bates *et al.*, 2009; Heathcote and Baic, 2011).

Although studies showed inconsistent association between menu labelling formats and weight status, the presence of IL + S information positively affected healthy food choices in not overweight participants (Harnack *et al.*, 2008; Lee-Kwan *et al.*, 2016).

The presence of IL + S information also positively affected healthy food choices in participants who ate out more than twice a week. In this study, the restaurant selected is an everyday restaurant offering a menu with simple dishes. A possible explanation is that people who often have lunch away from home at everyday restaurants look for a healthy diet and simple dishes, making healthier food choices than people who almost never eat out or eat out at leisure restaurants looking for special and different dishes including unhealthy food (Fernandes *et al.*, 2015).

Healthy food choices were not significantly different across dishes group and dietary restrictions for all menu labelling conditions. The significantly difference of healthy items was a result of the combination of different items selected, not across dishes group. Although associations between menu labelling conditions and dietary restrictions were not found, the provision of information on ingredients complemented by symbols does enable people who have health, religious or other related dietary restrictions to choose foods while respecting their habit, without having to ask the attendants the ingredients of each dish, which could be considered embarrassing or restricting the act of eating away from home because they did not have their food choices hampered.

Mandatory description of ingredients on restaurant menus could potentially lead to the revision of recipes by owners, in order to make them healthier and thus more attractive to consumers. The action could also result in a positive marketing campaign for the venue.

Conclusions

Results of this study indicated a menu labelling format presenting food information with ingredients list and highlighted symbols on the presence of gluten, lactose, trans fat, GMO, as well as on being organic and/or suitable for vegetarians was positively associated with healthy food choices in a real setting.

By positively influencing healthy food choices, the provision of food information with a list of ingredients and highlighted symbols in restaurants menus could become part of a public policy designed as a strategy to empower consumers, promote health and address the escalation of obesity and other chronic diseases. Food information with ingredients list and highlighted symbols could be adopted in future legislation on menu labelling in Brazil and around the world.

Strengths and limitations

The main strength of this study is the use of rigorous methods to conduct a randomised controlled trial in a real setting with concurrent control and intervention groups at the same place. The setting was a real place (a restaurant) in which ordering food and consumption naturally occurs. According to literature reviews (Kiszko *et al.*, 2014; Sinclair *et al.*, 2014; Long *et al.*, 2015), most menu labelling studies have been conducted in artificial or laboratory settings, which is a limitation in itself to offer recommendations for practice or policy.

To the best of our knowledge, this is also the first randomised controlled trial to test menu labelling formats in a real setting presenting influence on healthier food choices as outcome.

However, this study has some limitations. The study involved a rather uniform group of university students, homogeneous in terms of age, educational and behavioural aspects. University students are nevertheless important public health actors, and acquired behaviours during this period that can persist for all their lives (Nelson *et al.*, 2008; Blichfeldt and Gram, 2013).

Another limitation concerns the fact that the intervention occurred during only one day at only one restaurant and it was not collected data on the amount of food that people consumed. Participants did not necessarily consume the food that was selected.

Generalisability of the findings to other restaurants and populations requires further research. Future studies should seek to confirm the trial findings with adults in the general population and in different types of restaurants.

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(The Appendix follows overleaf.)

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Appendix

Table AI. 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 2-3
	2b	Specific objectives or hypotheses	Page 4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Pages 4-5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	Pages 5-6
	4b	Settings and locations where the data were collected	Page 5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pages 6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Pages 6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	Page 6
	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 enroled participants, and who assigned participants to interventions	Page 6
Blinding	11a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	Page 6
	11b	If relevant, description of the similarity of interventions	na
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	

(*continued*)

Section/topic	Item No.	Checklist item	Reported on page no.
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 8
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 8
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 7-8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page7-8
	14b	Why the trial ended or was stopped	na
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 18
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page 9
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)	Page 20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page 20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	na
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	Page 10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 9-10
Other information			
Registration	23	Registration number and name of trial registry	na
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 12

Table AI.

Corresponding author
Rossana Pacheco da Costa Proença can be contacted at: rossanacosta50@gmail.com

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