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# Effectiveness of a Gamification Strategy to Prevent Childhood Obesity in Schools: A Cluster Controlled Trial

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**Objective:** The aim of this study was to examine the effectiveness of a school-based gamification strategy to prevent childhood obesity.

**Methods:** Schools were randomized in Santiago, Chile, between March and May 2018 to control or to receive a nutrition and physical activity intervention using a gamification strategy (i.e., the use of points, levels, and rewards) to achieve healthy challenges. The intervention was delivered for 7 months and participants were assessed at 4 and 7 months. Primary outcomes were mean difference in BMI z score and waist circumference (WC) between trial arms at 7 months. Secondary outcomes were mean difference in BMI and systolic and diastolic blood pressure between trial arms at 7 months.

**Results:** A total of 24 schools (5 controls) and 2,197 students (653 controls) were analyzed. Mean BMI z score was lower in the intervention arm compared with control (adjusted mean difference  $-0.133$ , 95% CI:  $-0.25$  to  $-0.01$ ), whereas no evidence of reduction in WC was found. Mean BMI and systolic blood pressure were lower in the intervention arm compared with control. No evidence of reduction in diastolic blood pressure was found.

**Conclusions:** The multicomponent intervention was effective in preventing obesity but not in reducing WC. Gamification is a potentially powerful tool to increase the effectiveness of school-based interventions to prevent obesity.

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## Introduction

Childhood obesity has reached epidemic proportions in recent decades (1), producing negative health, economic, and social consequences (2,3). These include an increased risk of type 2 diabetes, cardiovascular diseases, and cancer, a shorter life expectancy, and lower quality of life (2,4).

## Study importance

### What is already known?

- ▶ School-based interventions to reduce obesity and blood pressure have been shown to be effective but with high levels of heterogeneity.
- ▶ Gamification is an innovative approach that employs game design principles (such as a story, points, levels, and rewards) to influence behavioral change. We examined the effectiveness of a nutrition and physical activity intervention using a gamification strategy in schools in Chile. Our study is the first trial to use a gamification strategy to prevent childhood obesity and one of the few studies in Latin America.

### What does this study add?

- ▶ The intervention was codesigned with the students, teachers, and school owners.
- ▶ We found that our multicomponent intervention using gamification was effective to reduce BMI z score by  $-0.133$  BMI standard deviations in Chilean school-children, but we found no evidence of reduction in waist circumference.

### How might these results change the direction of research?

- ▶ A gamification strategy is a promising tool to increase motivation and strengthen the effectiveness of school-based interventions.

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The school environment is a suitable setting for implementing evidence-based interventions to prevent obesity. Several systematic reviews of randomized controlled trials (RCTs) have suggested that school interventions might be effective to decrease adiposity and blood pressure (5-8). Multicomponent interventions addressing both nutrition and physical activity and involving parents and the school community appear to be more effective (6).

However, findings have a high heterogeneity, and recent studies based on randomized controlled trials have reported null findings, casting doubt on the overall effectiveness of school-based interventions to prevent obesity (9,10). Trials to date have relied on classroom-based education or environmental changes without a strong incentive structure to promote motivation and support behavioral change.

Gamification, the use of game design principles to influence socially significant human behavior (11), has gained increasing attention as a tool to influence dietary behaviors and physical activity (12-14). Nonetheless, gamification has, to the best of our knowledge, not been used for preventing childhood obesity.

In the Juntos Santiago trial, we used an innovative, theory-driven gamification strategy to increase motivation and participation in healthy behavioral changes (15). Intervention components address the snacks brought from home and encourage physical activity, with active parent and school community participation. These components are bundled by a community game system that provides internal and external motivators (points, levels, badges, and leaderboards), resulting in structural and fun activity rewards that improve school infrastructure and contribute to sustained intervention effects. The intervention is based on the Behavioral Change Wheel framework (16), in which the gamification strategy incentivizes and motivates students to achieve the Healthy Challenges, increase their knowledge, and win rewards that create an enabling environment.

This study examined the effectiveness of a multicomponent school-based gamification strategy to prevent childhood obesity in fifth- and sixth-grade schoolchildren in Santiago, Chile. We hypothesized that the intervention would result in a reduction in the primary outcomes (BMI, waist circumference) and secondary outcomes (systolic [SBP] and diastolic blood pressure [DBP]).

## Methods

### Trial design

Juntos Santiago is a school-based, longitudinal cluster controlled trial with a 2:1 allocation ratio (intervention:control). We chose this allocation ratio to increase the number of participants exposed to the experimental treatment and improve the acceptability of the trial. The school was the unit of randomization and intervention. We carried out the analysis at the individual level. We registered the study in ClinicalTrials.gov (NCT03459742). There were no changes in the design and methods for the year 2018, but there were some changes in the scope and design for the year 2019 (see online Supporting Information), which did not affect the results reported here. We informed these changes to the Scientific Ethics Committee before the end of 2018. We report the study in accordance with the Consolidated Standards for Reporting Trials (CONSORT) for cluster-randomized trials (17).

### Participants

The student population were children in fifth and sixth grade in schools in the neighboring municipalities of Santiago and Estación Central in Santiago, Chile. All types of schools (i.e., public, private-subsidized, and private schools) in Santiago were eligible for inclusion in the intervention and control arm (71 schools), whereas all types of schools in Estación Central were eligible for inclusion only in the control arm (27 schools). The reason for allocating schools in Estación Central only to the control arm was that it was considered operationally unfeasible to implement the intervention in two municipalities, which would have increased implementation costs substantially. In the present analyses, we compared the trial arm with the control arm including schools in Santiago and Estación Central. In sensitivity analyses, we included only participants from Santiago, where allocation was random. Eligibility criteria were schools with 40 students or more in total (fifth and sixth grade altogether) and acceptance of school participation. All students in fifth and sixth grades were eligible to participate in the study, regardless of weight or health status at baseline.

The Scientific Ethics Committee from the Central Metropolitan Health Service of Santiago approved the trial in accordance with Law 20.120 (2006). We obtained written consent from all parents and caregivers and written approval from all participating students in the intervention arm, except from one school, which provided institutional consent for the school as a whole.

### Intervention development

We designed the trial with the participation of school owners, principals, teachers, students, and public health and gamification experts. We developed the intervention in 2016 as part of the Mayors Challenge application process. We used a Design Thinking approach and designed prototypes of the intervention components to test the assumptions and reduce implementation risks (18). We tested participation interest in three schools with principals, teachers, and 139 parents; we tested the enrollment system in seven schools with 274 students. We consulted experts and practitioners to assess the potential effectiveness and implementation barriers. We carried out a pilot study in three schools for 5 months in 2017 to test the field implementation of the gamification strategy.

### Intervention

The intervention is a gamification strategy consisting of four components: (1) Healthy Challenges of three types: Healthy Snacks Challenge, in which children collect points for bringing healthy snacks for school breaks; Steps Challenge, in which children are given an activity tracker; and Healthy Activity Challenge, in which children and their families collect points by uploading pictures of specific healthy activities defined by the research team; (2) gamification incentives, including the use of points, leaderboards, and badges, to promote behavioral and structural change in the schools; (3) rewards, including a starting kit, activity reward, and structural reward for schools (e.g., climbing walls, improvements in sports infrastructure); and (4) an online platform, where children and parents could monitor the class and individual progress and receive nutritional education. The intervention applies elements to the school, class, and individual level. We consider the Healthy Snacks Challenge, the gamification strategy, and the structural rewards as the main components of the intervention (see Table 1 for details on definitions and implementation). More details on the gamification strategy, intervention delivery, and data collection methods can be found in Table 1 and in the online Supporting Information.

TABLE 1 Summary of the multicomponent intervention in Juntos Santiago trial

|   | Details/description  | Implementation  | Participants                       |
|---|--|---|------------------------------------|
| <b>Component 1: Healthy Challenges</b>  |  |   |                                    |
| <b>Snacks Challenge: Children collect points for bringing healthy snacks from home</b>  | Healthy snacks were defined using the NOVA classification (42). Snacks classified as NOVA 1 (unprocessed or minimally processed) are considered healthy and provided 80 energy points; NOVA 3 provided 40 energy points and NOVA 4 provided 10 energy points. Bringing money or not bringing snacks provides 0 energy points.  | Trained monitors visited classrooms without previous notice before the first morning break, a maximum of three times a month from May to December 2018. We collected data on packaged products using a mobile app, which scanned the SKU in the barcode and linked the SKU to a Food Composition Database built for the intervention. The project team assessed unpackaged foods and coded into 20 predefined categories. | Students and (indirectly) families |
| <b>Activity Challenge: Children collect points for participating in healthy activities together with their families</b>       | Children and their families were suggested healthy activities from a list. Students received 1 crew member point for each family member who participated in the healthy activity. The healthy activities carried out were then converted into crew member points.  | We posted a list of healthy challenges on the Web platform, sent by email to school contacts and mentioned verbally during the Snacks Challenge monitoring visits. From May to August, students verbally described the activities during the game session. We counted crew member points for the class as a whole.  | Students and families              |
| <b>Steps Challenge: Children are given a validated activity tracker and collect points for exceeding 13,000 steps per day</b> | We measured steps using a FitBit Zip activity tracker for 1 week. Students collected miles points for each time they exceeded the threshold of 13,000 steps per day.   | From September onward, students uploaded photos to the Web platform. A trained team member validated the photo and gave them points automatically.  | Students                           |
| <b>Component 2: Gamification strategy</b>   |  |   |                                    |
| <b>Story and characters</b>   | The game was called "Navigator, a healthy adventure." Students traveled in a ship that sailed through seven islands. Each island had dangers (junk food, excess of sugar, plastic, or social media) and they needed energy, crew member and miles points from Healthy Challenges to leave as quickly as possible. <sup>a</sup>   | Students were handed the activity tracker for 7 days once in November 2018. We collected data using an API developed for the intervention.  | Students                           |
| <b>Leaderboard</b>  | Each classroom had a leaderboard. The panel consisted of a ship that sailed through seven islands. To move to the next island, students must have collected enough points and passed an unblocking challenge (e.g., organize a demonstration against sugary foods) before the next game session. The scores of each challenge and the cards used were recorded on the board. | Trained monitors visited each class monthly. The game and its rules were explained in the first session. Students volunteered to take one of eight game roles. <sup>b</sup>   | Students                           |

(Continues)

TABLE 1 (continued).

|   | Details/description   | Implementation  | Participants                             |
|---|---|---|--|
| <b>Game sessions</b>  | In game sessions we counted all the points. The class needed to have enough energy and crew member points to move to receive the unblocking challenge and move to the next island. If it did not, the class was able to convert the points into fruit coins and buy cards to exceed a predefined threshold. | Game sessions were carried out monthly for approximately 30 minutes in the classroom. Monitors counted the energy and crew member points and asked certain roles to buy cards in case points were not enough. Cards were allowed to increase the number of points. If this was insufficient, we gave classes the possibility to do a feat challenge (a simple fun activity done in the classroom). In practice, monitors adjusted the points so that all classes would do the feat challenge. | Students and teachers                    |
| <b>Component 3: Rewards</b>   |   |   |  |
| <b>Starting kit</b>   | Initial reward was given at the beginning of the project to motivate students. The box contained a bottle for water and educational materials.  | We delivered a starting kit during the first game session, which was done after the anthropometric measurements.  | Students and teachers                    |
| <b>Structural rewards: Children win improvements in school infrastructure for physical activity and nutrition</b> | Students chose the structural rewards (one reward per school) from a closed list. An architect and the project team defined the list. Schools received the structural rewards after leaving the fourth island. Examples include climbing walls, tennis tables, and refurbishment of sport courts.           | All 15 schools won the structural rewards, which we delivered during November and December 2018. In some cases, providers were not able to deliver on time and we provided structural rewards after the end of the school year.   | Students, teachers, and school community |
| <b>Activity rewards</b>   | Classes received the activity rewards after reaching the seventh island and winning the unblocking challenges.  | Out of 61 classes, 21 won the activity rewards. The activity reward was a full day at the Educational Farm in Lonquén.  | Students, teachers, and parents          |
| <b>Component 4: Online platform</b>   |   |   |  |
| <b>Online platform</b>  | An online platform featured different profiles for children, teachers, and parents where they could see their advance on the Healthy Challenges. Children or parents had to upload pictures of healthy activities at least once a month.  | Profiles were ready in June. The option on the platform to upload photos of healthy activities was ready on October 1.  | Students, teachers, and parents          |

API, application program interface; SKU, stock keeping unit.

<sup>a</sup>Because of the uncertainty of the use of activity trackers, miles points were planned to be extra. In practice, the activity trackers were handed out in December 2018, and the miles points collected were not incorporated in the game.

<sup>b</sup>The roles were captain, cook, artist, scientist, navigator, explorer, defender, and sentry.



## Control arm

Schools in the control arm received standard education provision included in the school curricula. Additionally, students and parents received access to the online platform, where parents and students could find educational leaflets and videos (see online Supporting Information for details).

## Outcomes

We followed up participants at 4 and 7 months. The prespecified primary outcome was the mean difference in BMI  $z$  score and waist circumference between trial arms at 7 months. Prespecified secondary outcomes were the mean difference in BMI, SBP, and DBP between trial arms at 7 months. Registered dietitians collected the data using a measurement protocol; we trained them before each round of data collection to standardize procedures.

We measured weight using a digital scale (Seca 813). We discounted weight of clothing following an equivalence table in grams. We measured height using a Seca 213 stadiometer. We assessed waist circumference using a Lufkin W606PM tape measure. We calculated BMI as the weight (in kilograms) divided by height (in meters) squared. We used WHO growth reference to calculate BMI  $z$  score. We performed all measurements twice; we entered the average of both measurements in a mobile app data collection form.

We measured blood pressure after 5 minutes of rest using an Omron HEM-7120 sphygmomanometer and followed standardized methods defined in the measurement protocol. We measured blood pressure once and did a second and third measurement when the blood pressure was higher than normal values for gender, age, and height (according to international pediatric guidelines) (19). We report the average of the three measurements. An external evaluator carried out audits in 25% of students measured at 4 and 7 months. No changes to trial outcomes occurred after the trial began.

## Sample size

We calculated the sample size based on the primary outcome, BMI  $z$  score. We designed the study to detect a 0.072 mean difference in BMI  $z$  score, using the pooled standardized mean difference from a large meta-analysis as a reference and the standard deviation (SD) of the mean difference from similar studies (5,20,21). This effect size (which roughly translates into a reduction of 0.22 kg/m<sup>2</sup> in BMI) has been estimated to translate into relevant reductions in the prevalence of obesity and diabetes (22). We considered a power of 80% and a two-sided  $\alpha$  of 0.05. We used G\*Power 3.0 for sample size calculations (23). This sample size was multiplied by a design effect calculated assuming an intra-class correlation coefficient at the school level of 0.02 for 15 schools (design effect 1.28), to obtain the final sample size. The final sample size should be at least 5,000 participants in total, which was expected for the final scale-up during the year 2019. The current sample size was underpowered to detect such small differences in BMI  $z$  score, but it is comparably larger than previous studies set to detect mean differences in BMI  $z$  score close to 0.25 (9,10).

## Randomization, implementation, and blinding

We used a computer-generated sequence for the randomization. Given the socioeconomic differences between Chilean school types, we stratified by school type (public, private-subsidized, and private). Within

each stratum, all schools in Santiago were randomly allocated to each trial arm, whereas all schools in Estación Central were randomly selected but allocated only to the control arm. Within each arm, we invited schools sequentially to participate using a random sequence proportional to the total number of students, resulting in schools with more students being more likely to be invited.

An epidemiologist located at a remote site from trial location (PZ) generated the random sequence and assigned schools to treatment arm. The implementation team from the Municipality of Santiago (MC, PE, VM) was responsible for the enrollment of schools, classes, and students. We considered concealment from randomization unfeasible, and schools were informed of their assignment status before enrollment. We did not observe differences in the proportion of schools who accepted to participate between trial arms (Supporting Information Table S1). Blinding of participants and research counselors was not possible because of the nature of the intervention.

## Statistical analysis

SP, PZ, CC, and JK analyzed the data. We analyzed all participants according to the group they were originally assigned. Students who received partial or no intervention remained in the original intervention arm. We report the analyses at 4 and 7 months. We used descriptive statistics to assess the balance between trial arms at baseline.

We did the primary analyses using linear mixed-effects models to account for the dependency between repeated measurements and clustering at class and school levels (24). The analysis used all participants with baseline data and at least one measurement point at 4 or 7 months. We did not include in the analyses schools that refused to participate or individuals without baseline data or with no follow-up data. Mixed models allow to vary the number of observations within each participant, handling missing data more efficiently than other analytical approaches (25).

We fitted a four-level strict hierarchy multilevel model with measurement occasion (level 1) nested within students (level 2) nested within classes (level 3) and nested within schools (level 4). We used the likelihood ratio test to compare the multilevel model with a single-level regression and to examine the need to account for clustering at the class and school levels. The results of the LR showed the need for a hierarchical model adjusting for all four levels of clustering. We adjusted for baseline values by fitting the model without the treatment variable but with the time variable and the interaction between time and treatment in the model (26).

The primary analysis included adjustment for confounding for individual- and school-level covariates. Individual covariates were sex, age, nationality (Chilean or other), and type of school schedule (full time, morning, or afternoon). School covariates were school type (public, private-subsidized, and private), vulnerability of the school, and the total number of students. We obtained information on individual covariates from the students using a self-administered computer questionnaire. We obtained school-level information from the Chilean Ministry of Education (27). We defined vulnerability as the percentage of students classified as “priority” or “preferential” by the Ministry of Education under Law 20248/2008 (see online Supporting Information for definitions). The primary analysis includes schools in Santiago (with random allocation) and Estación Central (non-random allocation) to adhere to

our preregistered analysis plan. We report estimates only for schools in Santiago, which might provide more robust causal effects, as sensitivity analyses.

We carried out three sensitivity analyses: (1) analyses restricted to the Municipality of Santiago where schools were randomly allocated; (2) analyses using complete cases; and (3) analyses using multilevel multiple imputation (see online Supporting Information for details). Intraclass correlations for each outcome are reported in Supporting Information Table S2. We used package *lme4* for the linear mixed effects models. We used R version 3.5.3 for all analyses. The

Statistical Analysis Plan and R script can be found in online Supporting Information.

## Results

A total of 24 schools (5 controls in Santiago and 4 in Estación Central) participated in the study (Figure 1). Among 3,872 eligible students at baseline, we obtained written consent and approval from 2,466 students (63.7%). We assessed 2,320 students (709 controls) at baseline and analyzed 2,197 students (653 controls), 89.1% of those who provided

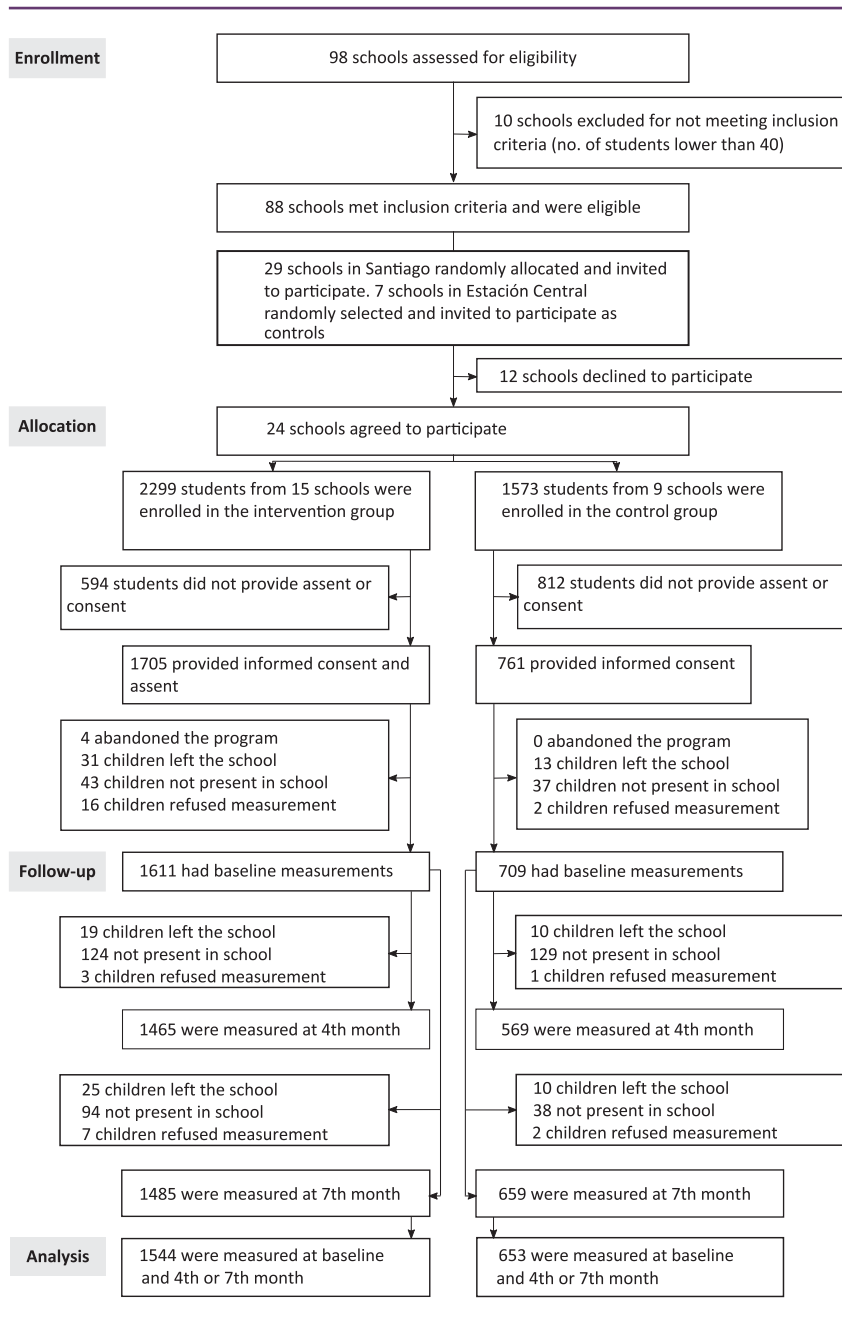


Figure 1 Juntos Santiago trial profile.

informed consent. Recruitment took place between March and early May 2018.

Table 2 summarizes the baseline characteristics of participants. Intervention and control schools had similar levels of vulnerability (46.6% and 54.1%) and mean number of students (989.1 [433.4] and 1,052.3 [564.5]). Students in the control arm were more often male (64.5% vs. 58.4% in the intervention arm), of foreign nationality (24.3% vs. 21.9% in the intervention arm) and attended school full time compared with the intervention arm (67.7% and 59.1%). Anthropometric measurements were similar in the control and intervention arms at baseline. We observed similar baseline characteristics when the analysis was restricted to randomly allocated schools in the Municipality of Santiago (Supporting Information Table S3).

### Primary outcomes

Table 3 shows the results of the primary and secondary outcomes at baseline, follow-up, and the adjusted differences at 4 and 7 months. We did not observe differences in BMI *z* score and waist circumference at 4 months. At 7 months, the intervention arm had lower BMI *z* score than the control arm after adjusting for school and individual covariates

**TABLE 2** Baseline characteristics of 2,320 fifth- and sixth-grade students participating in the Juntos Santiago trial by trial arm

|  | Intervention    | Control       |
|--|-----------------|---------------|
| <b>Individual level</b>                |                 |               |
| <b>No. of students</b>                 | 1,611           | 709           |
| <b>Age (y)</b>                         | 11.08 (0.75)    | 11.15 (0.79)  |
| <b>Male sex</b>                        | 941 (58.4%)     | 457 (64.5%)   |
| <b>Other nationality</b>               | 347 (21.9%)     | 163 (24.3%)   |
| <b>Student schedule</b>                |                 |               |
| Full time                              | 952 (59.1%)     | 480 (67.7%)   |
| Morning                                | 518 (32.2%)     | 139 (19.6%)   |
| Afternoon                              | 111 (6.9%)      | 51 (7.2%)     |
| <b>School level</b>                    |                 |               |
| <b>Type of school</b>                  |                 |               |
| Public                                 | 776 (48.2%)     | 428 (60.4%)   |
| Private-subsidized                     | 595 (36.9%)     | 252 (35.5%)   |
| Private                                | 240 (14.9%)     | 29 (4.1%)     |
| <b>Vulnerability %</b>                 | 46.6 (20.9)     | 54.1 (13.6)   |
| <b>Mean number of students</b>         | 1,052.3 (564.5) | 989.1 (433.4) |
| <b>Anthropometric measurements</b>     |                 |               |
| <b>Weight (kg)</b>                     | 42.9 (10.0)     | 44.0 (11.0)   |
| <b>Height (cm)</b>                     | 144.8 (7.7)     | 145.3 (7.7)   |
| <b>BMI (kg/m<sup>2</sup>)</b>          | 20.3 (3.6)      | 20.7 (3.9)    |
| <b>BMI <i>z</i> score</b>              | 1.01 (1.16)     | 1.06 (1.21)   |
| <b>Waist circumference (cm)</b>        | 70.1 (9.7)      | 71.1 (10.2)   |
| <b>Systolic blood pressure (mmHg)</b>  | 102.7 (10.8)    | 100.8 (10.1)  |
| <b>Diastolic blood pressure (mmHg)</b> | 66.2 (8.4)      | 66.2 (7.6)    |

Data are means (SD) or counts (%).

and baseline values (adjusted mean difference at 7 months:  $-0.13$ , 95% CI:  $-0.25$  to  $-0.01$ ). At 7 months, the waist circumference was similar between the intervention and control arms (adjusted mean difference at 7 months:  $-0.43$  cm, 95% CI:  $-1.56$  to  $0.71$ ).

### Secondary outcomes

We did not observe differences between trial arms in BMI, SBP and DBP at 4 months. At 7 months, students in the intervention arms experienced a reduction in their BMI compared with controls (adjusted mean difference  $-0.42$  kg/m<sup>2</sup>, 95% CI:  $-0.78$  to  $-0.05$ ) and SBP (adjusted mean difference  $-1.41$  mmHg, 95% CI:  $-2.44$  to  $-0.38$ ). DBP was similar between intervention and control arms at 7 months (adjusted mean difference  $-0.64$  mmHg, 95% CI:  $-1.46$  to  $0.18$ ).

Analyses restricted to the Municipality of Santiago (where schools were randomly allocated) showed similar results (Supporting Information Table S4). The adjusted mean difference in BMI *z* score was  $-0.22$  (95% CI:  $-0.36$  to  $-0.08$ ) and the adjusted mean difference for waist circumference was  $-0.35$  cm (95% CI:  $-1.86$  to  $1.16$ ). Other sensitivity analyses were consistent with the main analyses and did not change our conclusions (Supporting Information Tables S5 and S6).

### Intervention delivery

All schools and classes participated actively in the intervention. All classes (61/61) received a monthly activation visit to follow the count of points, levels, and badges. The Healthy Snacks Challenge started in April, and all classes received at least 16 visits to monitor the healthy snacks, and 79.5% of students were effectively monitored. The Steps Challenge was significantly delayed because of the bankruptcy of Jawbone, the original activity tracker chosen for the study. A total of 47 classes (77%) and 1,229 participants (71%) received the activity trackers, out of which 45% synchronized the tracker with the FitBit mobile app. We invited all classes to participate in the Healthy Activity Challenge, but participation was overall low: from September to December, 177 students (10.2%) uploaded pictures of healthy activities.

### Discussion

This cluster controlled trial aimed to examine the effectiveness of an innovative, multicomponent, school-based gamification strategy in Santiago, Chile. The intervention consisted of a game system of internal and external motivators, healthy challenges, and structural and fun activity rewards. We found promising evidence of a reduction of BMI *z* score, BMI, and SBP but no evidence of improvement in waist circumference and DBP.

Comparison with previous studies is limited because of the innovative nature of the intervention. We observed a reduction in BMI *z* score and BMI, which is consistent with previous findings of school-based interventions from systematic reviews and meta-analyses. The effect size appears to be larger than the pooled effects sizes for BMI *z* score (5,6) and BMI in meta-analyses, even though our confidence intervals are compatible with a large range of effect sizes (7,8,28). Our findings reinforce the idea that multicomponent interventions are more effective to prevent childhood obesity than single-component interventions (7,29).

We did not observe a reduction in waist circumference. Earlier evidence is inconsistent, from some studies showing reductions in waist



**TABLE 3** Adjusted differences for primary and secondary outcomes at 4 and 7 months in 2,197 students participating in the Juntos Santiago trial by trial arm

|                                 | Intervention arm, mean (SD) |             | Control arm, mean (SD) |               | Mean difference, adjusted for clustering only (95% CI) |                        |                        | Mean difference, fully adjusted (95% CI) |      |      |
|---------------------------------|-----------------------------|-------------|------------------------|---------------|--|------------------------|------------------------|--|------|------|
|                                 | 4 mo                        | 7 mo        | 4 mo                   | 7 mo          | 4 mo   | 7 mo                   | 4 mo                   | 7 mo                                     | 4 mo | 7 mo |
|                                 |                             |             |                        |               |  |                        |                        |  |      |      |
| <b>Primary outcomes</b>         |                             |             |                        |               |  |                        |                        |  |      |      |
| <b>BMI z score</b>              | 0.98 (1.13)                 | 0.92 (1.15) | 1.10 (1.19)            | 1.07 (1.19)   | -0.096 (-0.26 to 0.07)                                 | -0.147 (-0.31 to 0.01) | -0.080 (-0.20 to 0.04) | -0.133 (-0.25 to -0.01)                  |      |      |
| <b>Waist circumference</b>      | 70.9 (9.5)                  | 71.1 (10.2) | 72.1 (10.4)            | 72.10 (10.43) | -0.89 (-2.32 to 0.54)                                  | -0.96 (-2.39 to 0.47)  | -0.12 (-1.17 to 0.92)  | -0.43 (-1.56 to 0.71)                    |      |      |
| <b>Secondary outcomes</b>       |                             |             |                        |               |  |                        |                        |  |      |      |
| <b>BMI</b>                      | 20.4 (3.6)                  | 20.5 (3.7)  | 21.1 (4.0)             | 21.09 (4.03)  | -0.40 (-0.89 to 0.10)                                  | -0.53 (-1.02 to -0.04) | -0.24 (-0.60 to 0.12)  | -0.42 (-0.78 to -0.05)                   |      |      |
| <b>Systolic blood pressure</b>  | 101.8 (11.3)                | 99.4 (9.1)  | 102.0 (9.8)            | 101.2 (9.3)   | -0.21 (-1.64 to 1.23)                                  | -1.73 (-3.14 to -0.33) | 0.23 (-0.87 to 1.34)   | -1.41 (-2.44 to -0.38)                   |      |      |
| <b>Diastolic blood pressure</b> | 66.0 (8.2)                  | 64.4 (6.4)  | 65.4 (7.6)             | 65.1 (7.5)    | 0.55 (-0.43 to 1.52)                                   | -0.68 (-1.63 to 0.26)  | 0.81 (-0.02 to 1.62)   | -0.64 (-1.46 to 0.18)                    |      |      |

Mean difference between intervention and control arm, adjusted for baseline values and individual-level (age, sex, nationality, student schedule) and school-level covariates (type of school, % vulnerability, and total number of students). Means and SDs in intervention and control arm are unadjusted. Waist circumference is in cm. BMI is in kg/m<sup>2</sup>. Systolic blood pressure and diastolic blood pressure are in mmHg. The sample size was 2,260 for models adjusted for clustering only and 2,197 for fully adjusted models.

circumference closer to 1.6 to 1.7 cm (30,31) to others showing no change (9,32,33). A recent meta-analysis of school-based physical activity interventions showed a very small pooled effect on waist circumference of  $-0.14$  (34). Another meta-analysis of physical activity interventions observed a reduction in BMI  $z$  score but did not find evidence of a reduction in waist circumference (35). This indicates that the intervention might be more effective in reducing body weight than abdominal fat accumulation.

This study showed a small reduction in SBP and no change in DBP. Our results in SBP are in line with findings of meta-analyses, which found a pooled reduction in SBP of 1.9-1.6 mmHg (5,36). The lack of effect on DBP contrasts with reductions in DBP close to 1.4-1.2 mmHg described in previous meta-analyses (5,36). A discrepancy between the effects on SBP and DBP has also been observed in modest salt-reduction trials (37) but could also be the result of a mediating effect of BMI on changes in SBP and not DBP (5).

We observed some imbalance in the baseline characteristics of participants. Covariate imbalance is a common challenge in cluster-randomized trials, because of the difficulties in recruiting clusters and the correlated nature of the individual-level data at the cluster level (38). This translates in a greater risk of selection bias than individual-level randomized trials (39). In our study, covariate imbalance could be explained by a relatively low number of clusters (40), lack of allocation concealment (i.e., schools allocated to the intervention group are more likely to participate), and the fact that schools in Estación Central were eligible only to control schools and, hence, were not randomly allocated. In addition, nonparticipation at the individual level could have also resulted in selection bias. The impact of the lack of allocation concealment is probably small, given we did not observe differences between trial arms in the proportion of schools who accepted to participate. Likewise, our sensitivity analysis including only randomly allocated schools in Santiago was consistent with the main analyses. Selection bias due to individual nonparticipation is possible, although the consent rates in our study are higher than previous trials (10,41). All in all, our results remained robust under several sensitivity analyses, suggesting that the risk of selection bias is likely to be small.

The Juntos Santiago trial has several strengths. We developed the intervention using Design Thinking principles with active participation of experts and school communities over the span of 2 years. The Juntos Santiago trial has an adequate sample size and high rates of follow-up, with 91.5% of students measured and no loss of schools or classes. We used objective outcomes and a standardized protocol with a robust quality control procedure, which reduces the likelihood of measurement error. Potential residual confounding due to randomization at the cluster level is reduced by adjusting for several individual- and school-level covariates. The trial was carried out by a local government using existing administrative infrastructure. This type of implementation increases the external validity of the study and demonstrates the feasibility of the implementation in real-world settings of developing countries like Chile.

However, some limitations are noted. In addition to the risk of selection bias discussed here previously, we carried out the intervention during a short period of time, and we were not able to fully implement the Healthy Challenges. Healthy Activity challenges started with delay, and the Steps Challenge was implemented toward the end of the intervention and for a small number of participants. Nonetheless, we believe the

components of the intervention that were delivered (Healthy Snacks, the gamification per se, and the infrastructure rewards) are the core components of the intervention and can explain the observed effect. If anything, the partial delivery could have led to an attenuation of the trial effects. Finally, we assessed participants at the end of the intervention, and we do not know whether the effect is sustained over time.

## Conclusion

A gamification strategy was an effective intervention to prevent obesity and reduce SBP in schoolchildren in Santiago, Chile. Further research should explore the perceptions of students, teachers, parents, and school staff about the intervention and the cost-effectiveness of the trial. Gamification is a potentially powerful tool to increase the effectiveness of school-based interventions to prevent obesity. Transferability to other settings, however, requires an understanding of the students' motivations and behavioral challenges and the implementation of participatory mechanisms to tailor the intervention to diverse behavioral, social, and institutional cultures. **O**

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We welcome data access requests for the Juntos Santiago trial data. Requests should be addressed to the corresponding author. Anonymized data from all participants will be freely available, immediately after publication. We included the translated trial protocol and statistical analysis plan, as well as the R code, as online Supporting Information. The data will be shared on requests describing the planned use of the data, after the approval of the trial guarantors and corresponding authorities at the Municipality of Santiago.

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