

An Early Obesity Prevention Program: HaViSa UC (2009-2019)

Un programa de prevención temprana de la obesidad: “HaViSa UC” (2009-2019)

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What do we know about the subject matter of this study?

The final solution to obesity is prevention, which must be carried out throughout the entire life. However, short- to medium-term preventive programs have not achieved significant improvements in the nutritional status of children and adolescents.

What does this study contribute to what is already known?

This promoting healthy habits Program for infants and preschoolers, carried out in three nurseries and preschool centers, after 10 years of its implementation, has decreased the prevalence of obesity and overweight, however, there is a need for early and permanent preventive programs.

Abstract

Introduction: Prevention is the definitive solution to the serious nutritional epidemiological problem of children in our country and the world, obesity. **Objective:** To describe the results of an obesity prevention program for infants and preschoolers, ten years after its implementation. **Subjects and Methods:** Retrospective, and quasi-experimental study of the overweight and obesity prevalence, in children attending three nursery and preschool centers located at the *Universidad Católica de Chile*, since the implementation of a multidimensional program for early promotion of healthy lifestyle habits (HaViSa-UC) between 2009 and 2019. This study obtained ethical approval. Annual records of anthropometric assessment (WHO 2006) were analyzed using Minitab 17 software. The actions applied by the HaViSa-UC program were the assessment of nutritional status and communication with parents, delivery of healthy food, promotion of an active lifestyle, and education to encourage such healthy habits. **Results** The annual mean was 319 subjects, 14% younger than two years old, and 49.5% were girls. In March 2009 (baseline), 32.6% had overweight and 8.6% obesity; both figures decreased reaching 23.8% and 4.7% respectively, in March 2019. Normal weight increased from 56.9 to 67.4% and malnutrition presented no increase. In the same period, zW/H dropped from 0.84 ± 0.94 to 0.55 ± 0.87 ($p: 0.00$), and zH/A increased from -0.36 ± 0.87 to -0.32 ± 0.90 ($p > 0.05$). **Conclusion:** Since the implementation of the HaViSa-UC Program, the frequency of obesity decreased by 45.4% and overweight by 27.2% in this sample of infants and preschoolers, remaining stable after 10 years.

Keywords:
Obesity;
overweight;
pediatrics;
prevention;
healthy life

Introduction

In the Chilean population, obesity is the most serious epidemiological issue; it has a high and growing prevalence¹⁻³, starts early in life and tends to persist over time^{4,5}. It affects the entire body, with short-term complications such as hypertriglyceridemia, psychological and sleep disorders, as well as medium- and long-term including hypertension, fatty liver, type 2 diabetes, or dyslipidemias, among others⁶. Moreover, its treatment has poor results⁷⁻⁹, and the longer it remains, the worse the quality of life and the higher the morbidity and mortality in adulthood^{10,11}.

Overweight and obesity affect 24% and 11% respectively of children younger than 6 years old, under health control at the public health system². From the first months of life, obesity and overweight prevalence rises and increases after two years of age. In 2018, such prevalence exceeds the eutrophic population of first-grade schoolchildren, with 26.4% of overweight and 24.4% of obesity^{3,12,13}.

Regarding this obesity pandemic and its consequences, there is consensus that the main and definitive solution is prevention with multidimensional strategies implemented early and permanently throughout life. Prevention relies on the universal promotion of lasting lifestyle changes that include a healthy, balanced diet, along with an active lifestyle¹⁴⁻¹⁶. Therefore, increasing protective factors and healthy behaviors from early childhood and maintaining them in later life is a key goal for better cardiovascular health¹⁷.

Chile has made significant progress in public policies against obesity through the implementation of laws No. 20,605 and 20,869, which regulate the food composition and the advertising of unhealthy foods aimed at children¹⁸. However, these efforts must be implemented in all the environment surrounding the child, as suggested by ecological models, which analyze comprehensively and transversally the prevention and treatment of the epidemiological problems in the population^{19,20}.

In obesity prevention programs, the best results are achieved based on changes that involve healthy eating and the promotion of physical activity^{15,21-24}, especially during the first years, when children develop habits that will be progressively more difficult to modify over time.

In Chile, preventive programs have been implemented, such as the one in Casablanca, for two years aimed at school children from 1st to 7th grade and/or teachers, achieving a decrease in obesity from 17 to 12.3% in males²⁵. Another experience, in children from prekindergarten to first grade, after one year, did not achieve any improvement in nutritional status²⁶.

However, there are no reports on younger children, nor are there any programs of longer duration than those described.

In 2009, the HaViSa UC Program (for “Hábitos de Vida Saludable”, in Spanish), aimed at the early promotion of healthy eating habits and physical activity in infants and preschoolers, was implemented in three Early Education centers of the Pontifical Catholic University of de Chile, in order to promote a better health and to prevent obesity.

The objective of this study was to describe the results of this program, ten years after its inception.

Subjects and Method

A retrospective, quasi-experimental, longitudinal design study was conducted to assess changes in the prevalence of obesity and overweight, before and after the implementation of the HaViSa UC program, between 2009 and 2019.

Data from children attending the three UC early education centers were included. Each center is located near or within a university campus (Casa Central, Oriente and San Joaquín), where children of administrative, academic staff, and students of the University and/or UC-Christus Health Network attend. The sample was composed by all the children in attendance during the days of the nutritional assessment in March of each year. Children with incomplete information were excluded.

We recorded age (in months) and gender (F/M) as demographic variables and anthropometric standardized assessments made by two nutritionists (CO, YA).

We included the following variables: weight (grams), height (cm), and z-scores of weight/age index (zW/A), height/age (zH/A), weight/height (zW/H), and body mass index (zBMI). Nutritional status was defined according to WHO reference 2006 (27): obesity (zW/H $\geq +2$), overweight (zW/H +1 to +1.99), eutrophy (zW/H -0.99 to +0.99), risk of undernutrition (-1 to -1.99), and undernutrition (≤ -2). For the last two variables, zW/A was used in children younger than one year and zW/H in children older than one year.

We considered prematurity to correct the chronological age and, in children with Down's syndrome, we used specific curves⁴⁴.

Maternal age and educational level were registered, the second one as a measure of socioeconomic status (SES). The average maternal age in 2009 was 34.6 \pm 5.4 years old, 10.9% completed High school, 45.5% Technik school and 43.6% had a University grade. 99.9% of the children had a full preschool day attendance.

HaViSa UC Program Description

The following actions were gradually implemented in all centers:

1. Assessment of nutritional status and communication with parents

A nutritionist interviewed the parents upon entering the program with a questionnaire on eating habits and physical activity. She then updated the measurement instruments and did an anthropometric assessment in March, July and December, each year. A printed report was also sent to the parents about their child's nutritional status and its evolution, as well as an invitation to interview in the case of detecting malnutrition or weight excess.

2. Healthy eating

We promoted breastfeeding (BF)²⁸⁻³¹, developing a register of breastfed infants, a guide for the extraction and delivery of breast milk, together with guidelines for conservation, handling, and administration at the center. A breastfeeding room was adapted in each center according to the MINSAL 2000 breastfeeding manual, and from 2017, these rooms were equipped based on the MINSAL Implementation Guide of the same year.

To assure food safety, we examined and updated the facilities for the food and milk formula preparation services (SEDILES, RSA. DS977/96), as well as developed a safe practices manual, With periodic monitoring and annual laboratory tests for the staff.

We carried out a baseline assessment of the quality and quantity of complementary foods, which led to the development of food plans in line with the recommendations from: FAO-WHO 2000, MINSAL Child Nutrition Guide 2007 and its 2016 updated version. We placed a special emphasis on including traditional foods³²⁻³⁵, achieving gradual adaptation and good adherence. Monthly reports were published in the notice board and the daily intake record in the child's diary.

Commercial sweetened juices were replaced by cooked fruit water and later by fresh water from water dispensers^{36,37}. The type and concentration of milk formulas were homogenized and adapted to nutritional status. For overweight and obese children from 6 to 12 months old, cereal was not added to milk. Semi-skimmed milk for 12 to 24 months old and skimmed milk for the older³⁸. Snacks sent from home were replaced with fresh fruit provided by the center, and healthy birthday guidelines were sent to parents.

A respectful style of feeding was promoted, with individual and group child participation³². In the case of food rejection, it was not replaced by an alternative food or milk, giving a little earlier the next feed.

3. Promoting an active lifestyle⁴⁰⁻⁴²

The nap or sleep time was reduced from 120 to 90 minutes per day. The use of entertainment movies was suspended, and active play was increased to 15-20 minutes per day, depending on the level. For those over 2 years old, a weekly 30-minute class was set up, conducted by a physical education teacher.

4. Education to encourage healthy living habits

Educational activities for children included play sessions about water, fruit, and vegetable consumption³², family meals³⁹, and feeding structure (timing and quality). As homework, we implemented tokens, a frequency schedule, a placemat for coloring healthy lunch servings, as well as fruit preparation workshops, a workshop with the chef, and a weekly visit to the vegetable garden in one center. In addition, sessions on active play (walking, running, and jumping, children games and circle games [ring a ring o' roses like]), folklore, sports, and less time spent on screens⁴³.

For the first meeting of the year, a video presentation of the HaViSa program was presented to the parents, complementing the information included in the kindergarten regulations. We developed printed material that was attached to each assessment report: anticipation guidelines in March, a guide for meal composition and frequency in July, and recommendations for summer holidays and future school life, in December. A recipe book with the meals that children eat in the centers, was sent to their parents. Also, a recipe book was made with the meals received by children in kindergarten (December 2019).

In addition, we organized educational and training activities on food safety, eating disorders, allergies, and other agreed-upon topics, twice a month for food service personnel and once a month for the preschool teachers and technical staff.

Statistical analysis

The prevalence of the different nutritional statuses was described for each annual assessment between 2009 and 2019. The distribution of z-scores for anthropometric indexes was analyzed using the Ryan-Joiner test and, for each annual assessment, we described averages and SD. Differences according to sex, age, and center were analyzed through the ANOVA for the numerical variables (Fisher's exact test and Tukey's post hoc test) and Chi-squared test for the categorical ones. Prevalence of overweight and obesity in the HaViSa program 2019 were compared with those reported nationally, using the test of one proportion (95% CI). A $p < 0.05$ value was considered significant. We used for the analysis the Minitab17 software.

Ethical aspects

This study was conducted following the ethical standards of the Declaration of Helsinki (1975 and reviewed in 1983) and was approved by the Research Ethics Committee of the Faculty of Medicine, Catholic University of Chile, (#15-007), with exemption from informed consent. Information on the program was provided through the regulations given to parents when their children enter the centers in March of each year. The privacy of sensitive data was respected for the records of the bases and the statistical analyses carried out.

Results

Table 1 describes the main characteristics of the sample, in March during the ten years of the program.

The sample size was similar, with a constant proportion of females, close to 49%. The age was similar across the time, being 14% younger than 12 months, 30% between 12 to 24 months, 28% between 2-3 years and 27.7% over 3.

Figure 1 shows the evolution of the prevalence of nutritional status in March each year, with a rapid decrease from 8.6% (2009) to 3.5% (2013), followed by a slight increase and small fluctuations, up to 4.7% in 2019 ($p = 0.038$). Overweight decreased from 32.7% to 24% and remained stable at 23.8% in 2019 ($p = 0.000$). Therefore, obesity and overweight decreased overall from 41.2% to 28.5% ($p = 0.000$). During these ten years, malnutrition was between 1.1% and 8.8%, corresponding mostly to a group of infants with low weight, and only one case with zW/H lower than -2 . In general, the proportion of eutrophic children increased from 56.9% to 67.4%.

Table 1. Characteristics of infants and preschoolers attending UC nurseries and preschool centers between 2009 and 2019

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
n	267	259	297	320	319	336	319	347	370	357	319
Age (months) ¹	27.7 ±14.8	28.7 ^A ±14.1	29.1 ^A ±14.8	27.9 ±14.7	27.7 ±13.6	27.9 ±13.8	25.4 ^D ±11.7	25.4 ^D ±12.4	25.3 ^D ±11.9	25.9 ±11.1	26.2 ±11.9
Girls (%)	48.7	51.0	50.8	48.7	49.8	50.3	47.3	51.6	48.2	47.9	50.5
Preterm (%)	11 (4.1)	13 (5.0)	8 (2.7)	10 (3.1)	1 (0.3)	4 (1.2)	2 (0.6)	6 (1.7)	10 (2.7)	8 (2.2)	7 (2.2)
Down S. (%)	0 (0)	1 (0.4)	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.9)	1 (0.3)	3 (0.9)	3 (0.8)	1 (0.28)	1 (0.3)
Twins (%)	6 (2.2)	8 (3.1)	4 (1.3)	6 (1.9)	0 (0)	2 (0.6)	2 (0.6)	6 (1.7)	6 (1.6)	6 (1.6)	4 (1.1)

¹Mean ± SD. ^AAge in 2010 and 2011 was higher than the other years ($p < 0.05$). ^DAge in 2015, 2016 and 2017 was lower than the other years ($p < 0.05$).

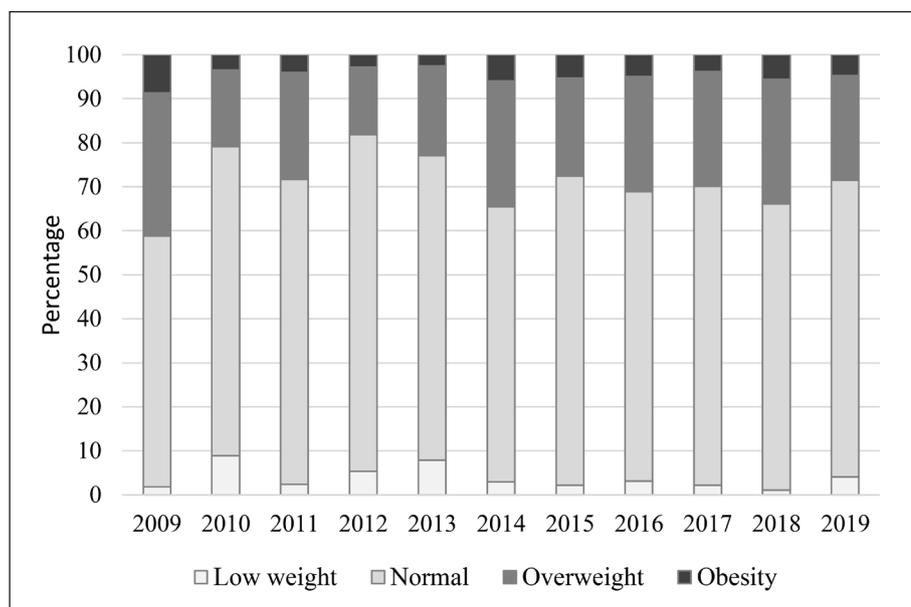


Figure 1. Prevalence of nutritional status in infants and preschoolers attending UC nurseries and preschool centers from 2009 to 2019*. Obesity: zW/H score $\geq +2$. Overweight: zW/H score $+1$ to $+1.99$. Low weight: $zW/H \leq -1$ (WHO reference 2006).

*The prevalence of obesity (Chi2 test, $p = 0.038$); in 2009 was higher than in 2010, 2012, 2013, 2017 ($p < 0.05$) and 2019 ($p = 0.05$). ** The prevalence of overweight + obesity (Chi2 test, $p = 0.000$); in 2009 was higher than the other years except 2014 y 2018.

Table 2. Anthropometric indicators in infants and preschoolers attending UC nurseries and preschool centers, from 2009 to 2019

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
N	267	259	297	320	319	336	319	347	370	357	319
z W/H	0.84 ^A ±0.94	0.32 ^C ±0.91	0.59 ^B ±0.87	0.36 ^C ±0.88	0.36 ^C ±0.88	0.65 ^B ±0.88	0.55 ^B ±0.84	0.60 ^B ±0.87	0.59 ^B ±0.79	0.67 ^B ±0.80	0.55 ^B ±0.87
z H/A	-0.36 0.96±	0.03 ^B ±1.08	-0.25 ±0.98	-0.11 ^B ±0.98	-0.11 ±0.96	-0.26 ±0.90	-0.36 ±0.91	-0.41 ±0.94	-0.47 ±0.91	-0.30 ±0.90	-0.32 ±0.9

zW/H: z-score for Weight/Height index. zH/A: z-score for Height/Age index (OMS 2006 Growth curves), as Mean ± SD. ^AzW/H in 2009 was higher than all the other years ($p < 0.001$). ^BzH/A in 2010 and 2012 were higher than the other years except for 2013 ($p < 0.005$), ANOVA and Fisher tests.

The proportion of low stature ranged from 1.56 to 5.05% and of tall stature from 0 to 3.44%.

zW/H had a greater decrease in the first 4 years of the program, with a slight increase and stabilization afterward, globally, between 2009 and 2019, it fell from 0.84 ± 0.94 to 0.55 ± 0.87 ($p = 0.0004$), with a difference of -0.29 ± 0.07 (-0.43; -0.15), $p = 0.000$. zH/A increased from -0.36 ± 0.87 to -0.32 ± 0.90 , with a difference of 0.036 ± 0.08 (-0.12; 0.19) $p > 0.05$. Table 2 shows the averages of both anthropometric indexes for each year and Figure 2 graphs their evolution.

When comparing the different centers according to zW/H, we observed a similar trend towards improvement, although with heterogeneity in the first years. There was a higher zW/H in one center where 68% of parents have administrative responsibilities, and a lower zW/H in another center where 80% perform professional or academic work, however, the difference was only significant in 2016 and, the last three years, the three centers presented similar results (Figure 3).

There was no difference in the frequencies of overweight or obesity or zW/H regarding sex. In relation to age, there was a trend towards a higher proportion of malnutrition due to excess (obesity + overweight) in children older than two years of age, but the difference was significant ... only in 2009 and 2014. Also, the zW/H was higher in those children older than two two years during the first period, although without difference in the last three years (Figure 4).

Figure 5 shows the frequency of nutritional status in the UC centers in March 2019, as well as the latest national prevalence figures available from the centers of the National Nursery Schools Board (JUNJI) in 61,000 children, year 2019¹², Fundación Integra in 92,000 children, 2018¹³, and the report of the Ministry of Health, MINSAL, in 922,000 children younger than 6 years, under well-child care in the Public Health System in 2017². In the HaViSa UC centers, there was a lower and significant prevalence of malnutrition due to excess.

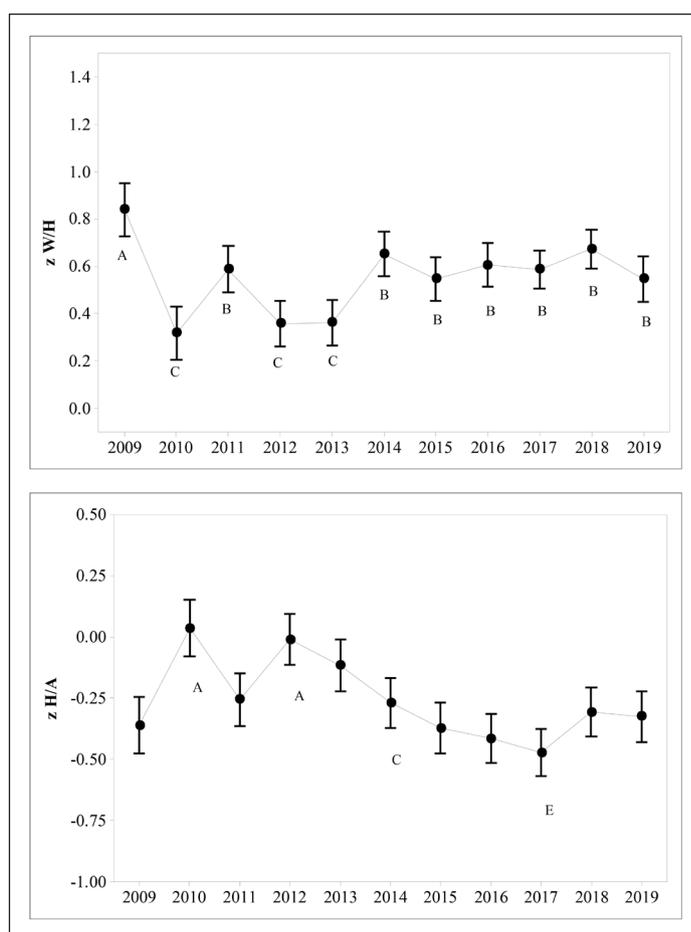


Figure 2. Average of zW/H and zH/A scores in infants and preschoolers attending UC nurseries and preschool centers from 2009 to 2019*.

zW/H: z-Score for Weight/Height. zH/A: z-score for Height/Age (WHO reference, 2006). ^AzW/H in 2009 was higher than zW/H of each of the other years ($p < 0.001$). ^AzH/A in 2010 and 2012 were higher than the other years, except 2013 ($p < 0.005$), ANOVA & Fisher tests.

As expected, the analysis of the new cases entering each year were younger than those already attending the centers, with an age of 19.1 ± 12.7 months for new cases vs. 30.6 ± 11.7 months for the old ones ($p = 0.000$).

Figure 3. Average in zW/H score in infants and preschoolers attending three different UC nurseries and preschool centers from 2009 to 2019*.

zW/H: z-Score for Weight/Height (WHO reference, 2006). 1,2,3: PUC Centers. *Difference between at least two of the centers in each year, (ANOVA, $p < 0.005$).

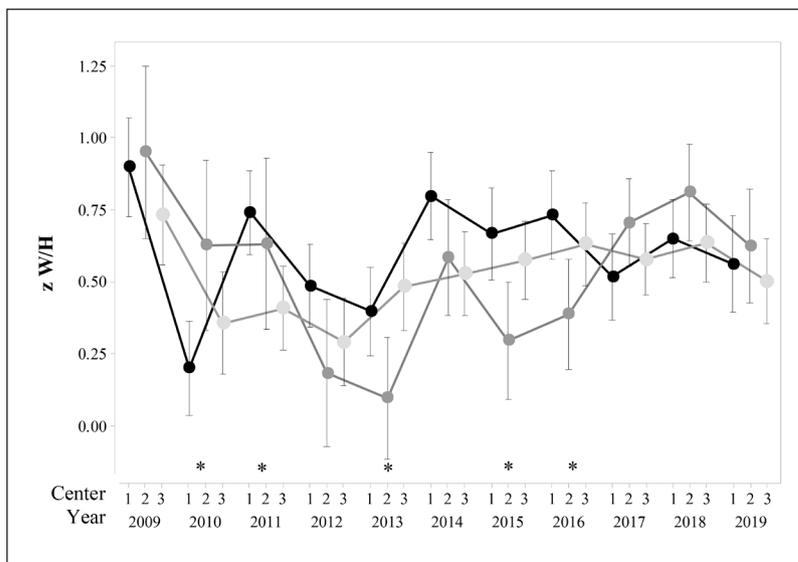
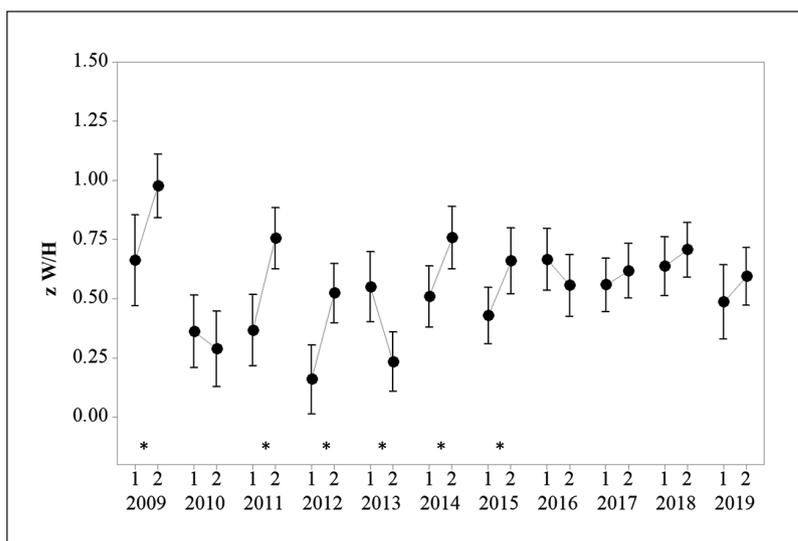


Figure 4. Average in zW/H score by age, in infants and preschoolers attending UC nurseries and preschool centers from 2009 to 2019*.

zW/H: z-Score for Weight/Height (WHO reference, 2006). 1: Children younger than two years old, 2: Children 2 or more years old. The lines join the averages of both age groups for each year. *Significant differences (T-test, $p < 0.05$).



New children had a higher frequency of malnutrition and a lower frequency of obesity or overweight, difference that was significant only in 2010 and 2011 (χ^2 , $p = 0.001$ and $p = 0.000$). However, the zW/H of new children increased between 2010 and 2019, from 0.39 ± 0.85 to 0.59 ± 0.82 , with a difference of 0.20 ± 0.08 (CI: 0.0415; 0.3578 and $p = 0.013$).

Discussion

This study shows the results of an obesity prevention program implemented in three early education centers for over ten years, which was associated with a

decrease in overweight by 27% and in obesity by 45%. This drop in the prevalence of -8.76% and -3.91% respectively, has been significant and stable, which is considered a success, considering that in Chile the prevalence of overweight has increased in children under 6 during this period by +0.74, and obesity by +2.28%².

The program implemented actions aimed at improving both eating and physical activity habits together, which, with moderate evidence, works better in children under 6 years of age¹⁵. It is also in line with recent studies on obesity prevention from the first year of life²¹, which favors the continuity and better outcome of strategies applied afterward. It is a multidimensional intervention, involving different measures.

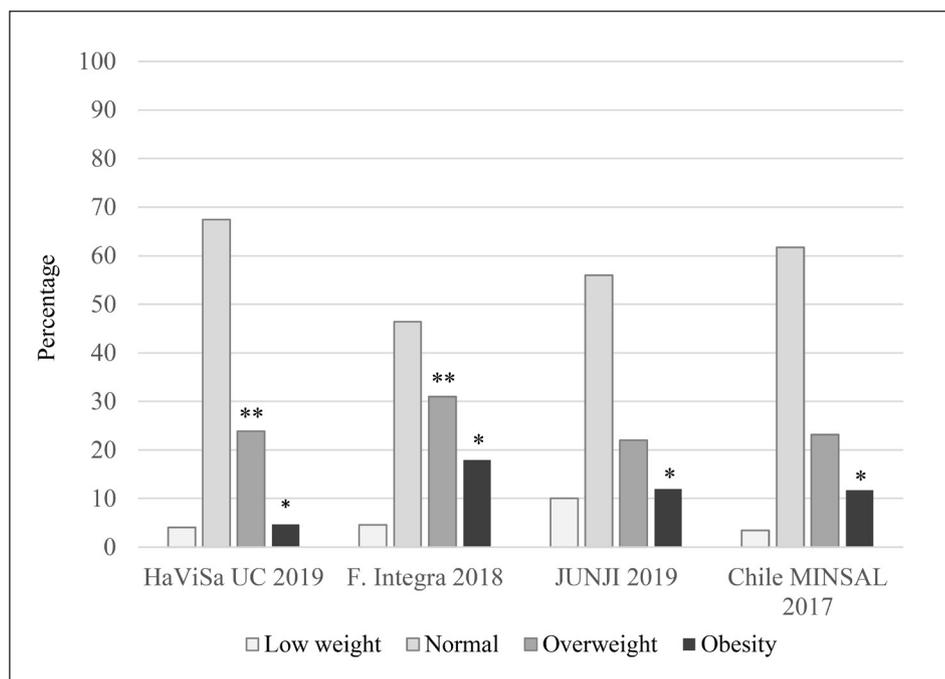


Figure 5. Comparison of nutritional status prevalence in infants and preschoolers attending UC nurseries and preschool centers in 2019, with those available nationally.

Obesity: zW/H score $\geq +2$. Overweight: zW/H score $+1$ to $+1.99$. Low weight: zW/H ≤ -1 (WHO reference 2006). *The prevalence of obesity in HaViSa PUC centers was lower than the other three reports (p. 0.000). **The prevalence of overweight in HaViSa PUC centers was lower than F. Integra (p. 0.005).

Most of the changes implemented were structural, in other words, whose mechanism of action is independent of the actions or wishes of the individual or her/his family. Some examples include changing commercial juices to water dispensers or the snack previously sent from home to a fruit provided by the center, as well as decreasing the food servings or changing to skim milk in those over two years of age with obesity.

There were also activities dependent on the will or action of the individual or family (agentic), corresponding to educational activities, such as guides and recommendations sent to the home, sending placemats with the size food serving or educational workshops. Others were mixed actions, which involve environmental changes, but the subject still has decision-making power (e.g., exercise devices at the kindergarten, or the incorporation of physical education class). Since children stay for a significant proportion of their daily lives in the centers, structural measures are probably the most effective in the short term and educational actions, most of the mixed type, in the medium and long term.

It is important to consider that prevention programs should not increase disparities, that is, they should not only favor groups with a lower risk of obesity⁴⁵. The homogeneous response in the last three years of the three centers in our sample, with different socioeconomic levels, is an indirect indicator of the absence of this effect. Another undesirable conse-

quence may be an increase in underweight children, but although in these 10 years there was a slight increase in malnutrition from 1.87 to 4.08% (+2.21%), this was comparable to the increase from 2.7% to 4.4% (+1.7%) reported in children under 6 years of age in the care of the Chilean public system². This subgroup was especially monitored, and almost all had zW/H between -1 and -1.7. They were premature babies, twins, or children with chronic pathologies, as well as a number of children with constitutional thinness, a physiological condition in which overfeeding is not recommended.

The main strength of this program is its permanent nature, an essential characteristic for maintaining favorable results, since facing the highly obesogenic environment, which presents slow improvement, it requires the constant encouragement of healthy living habits. Another important advantage is its implementation during the initial period of life when the change of habits and family adherence are favored⁴⁶. The fact that the program is multidimensional also represents a strength, since it includes changes in diet and physical activity, and covers all participants from an educational point of view: children, kindergarten staff and the family. Constant training of professionals and staff at the centers is essential, as well as raising their awareness of the need for good self-care.

A limitation of this study is the lack of a control group as well as the analysis of annual cut-off in diffe-

rent groups of children. However, the good results in terms of the stability and long duration of this program contrast with what has happened nationally with this pandemic. In order to evaluate the results longitudinally, we are developing an analysis of the growth trajectories of the children who completed a stay of at least two years in the centers.

Another limitation is the lower representativeness of this sample since it is made up of children of administrative and academic staff and students, therefore, the proportion of families with a lower socioeconomic level is lower than that of the general population, which represents a risk factor for obesity⁴⁷. Despite this, at the beginning the frequencies of obesity and overweight were similar to the national prevalence, achieving an important initial decrease that, with minor fluctuations, has remained stable, while they have increased in the general population.

This good initial response was probably due to the fast and effective implementation of dietary changes, the entry of infants who were less overweight or obese in 2010 and 2011, who were immediately incorporated into the program, as well as the leave of children with prolonged overweight ... and possibly, a lower reversibility.

The increase in overweight after 2013 (although at a lower level than initially) may be due to the annual entry of children with higher zW/H from that year onwards, who, although not more frequently diagnosed as overweight or obese when entering to the program, easily fell into these categories. The need for ongoing education of the environment and the updating of the strategies implemented also plays a role, in the face of an external environment that holds many obesogenic risk factors.

One aspect to consider is the variety of interventions that we added and adapted over time to the HaViSa program, which does not allow attributing the favorable effect achieved to specific measures. However, on the one hand, we applied the best available evidence to the changes implemented^{15,48} and, on the other hand, it was necessary to face the new needs of a project that became a permanent program.

Regarding the aspects to improve, we must increase physical activity, which poses the next challenge of studying the level of physical activity at home, and take action according to the results, stimulating a decrease in sedentary lifestyles and especially the time spent on screens⁴⁰⁻⁴³. There is also a need for ensuring that the advances made are not lost upon entering school, which is a critical time of increasing independence and influence of peers and the environment.

During this period, we think that the favorable effect of close and regular information to parents has been useful to timely report the acceleration of

weight gain and to provide tools for improving when the child is younger and/or has less overweight. One factor that influences the nutritional worsening is the decrease or absence of regular health check-ups at school age, which affects the perception of the problem⁴⁹.

Although this program is a targeted intervention, it has been successful in reducing obesity in this sample of infants and preschoolers. We recognize that there is a need for coordinated population health policies that favor healthy environments in terms of food and physical activity and that these are more cost-effective, however, there must be a permanent commitment from the whole of society. Through this report, we hope to provide preventive tools that are useful to public institutions that take care of children of this age, in order to develop joint efforts and become educational establishments that truly promote health.

In conclusion, this study shows that 10 years after the implementation of the HaViSa prevention program, there has been a significant and permanent decrease in obesity and overweight in these three centers.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: This study has been approved by the corresponding Research Ethics Committee, which according to the characteristics of the study has exempted the use of informed consent.

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