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DOCTORAL DISSERTATION

EARLY PREVENTION OF CHILDHOOD OBESITY: CROSS-CULTURAL VALIDATION OF THE EUROPEAN TOYBOX INTERVENTION IN PRE-SCHOOL SETTINGS

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ABSTRACT

The World Health Organization (WHO) declared obesity a major public health problem in the world and the neologism *globesity* evokes its alarming spread, contributing to a global obesity epidemic, in particular during developmental age.

Children with an excessive ponderal index are more likely to stay obese into adulthood with increased risk of several serious health conditions associated with obesity, which also has a significant social and economic impact. Thus, the development of evidence-based prevention interventions for early childhood (3-5 years of age), deemed a crucial period, is fundamental because the behaviours related to energy balance, the psychological characteristics and the physiological development during this age. Therefore, preschool represents an ideal setting to implement obesity prevention programmes because, on the one hand, a change in behaviour patterns can be encouraged and, on the other hand, a larger population, including children and their families, can be reached.

This research project aims at achieving a cross-cultural validation, in Italy, of the ToyBox intervention designed to prevent early obesity within the preschool settings. An effectiveness trial has already been conducted and the projects has been implemented across Europe thanks to a multi-centre international research funded by the European Commission.

In 2017, following the formal agreement with the steering committee of the ToyBox-Study, for the acquisition of the materials in their English standard version, the trial began and developed over a 3-year period, through different phases: organization and validation of the materials (teachers' guides and assessment tools, in particular the questionnaires targeted to the children's parents and to the teachers); cross-sectional epidemiological analysis of the baseline data related in particular to the dietary pattern; assessment of the feasibility of the intervention. Because of the COVID-19 pandemic, the programme had to be adapted to the health emergency by experimenting a 'distance' implementation of the ToyBox.

Overall, the project involved 10 schools, in 6 provinces in the North, Centre and South of Italy, enrolling a total of 704 children and their parents, and 92 teachers.

Notwithstanding some limitations of the methods and the contents, and the distance implementation, the study has highlighted the relevance, reproducibility and the approval of the intervention and, as an operative result, it has made available an effective prevention tool to the Italian cultural context.

List of abbreviations

ACTH	Adreno Corticotropic Hormon
ALSPAC	The Avon Longitudinal Study of Parents and Children
BMI	Body Mass Index
CDC	Chinese Center for Disease Control and Prevention
CMD	Cardiomiopatia dilatativa
COSI	European Childhood Obesity Surveillance Initiative
COVID-19	Co- Corona - VI virus - D - Disease - 19
CQ	Core Questionnaire
DAD	Didattica A Distanza
DALY	Disability and Death Adjusted Life Years
DQI	Dietary Quality Index
EBRBs	Energy Balance-Related Behaviours
FAO	Food and Agriculture Organization
FFQ	Food Frequency Questionnaire
GDP	GPI: Gross Domestic Product
GF	Growth Factor
HALE	Healthy Adjusted Life Expectancy
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
IM	Intervention Mapping
INHES	talian Nutrition & Health Survey
IOTF	International Obesity Task Force
LE	Life Expectancy

LEPR	Leptin receptor
MC4R	Melanocortina receptor 4
MGRS	Multicentre Growth Reference Study
MSH	Melanocyte Stimulating Hormone
NCHS	National Centre for Health Statistics
OECD	Organisation for Economic Co-operation and Development
PC1	Prohormone convertase 1
POMC	Proopiomelanocortin
PRECEDE-PROCEED	Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation - Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SCT/ SLT	Social Cognitive Theory/Social Learning Theory
SES	Socio-Economic Status
TQ	Teacher's Questionnaire
WAGRO -	Wilms tumour syndrome - Aniridia - Genitourinary Malformation Retardation - Obesity
WHO	World Health Organization
WP	Work Packages
YLL	Years of Life Lost

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INTRODUCTION

According to the World Health Organization (WHO) obesity represents a major public health problem in the world. Since 1975, worldwide obesity has nearly tripled. It has reached epidemic proportions globally; it is widespread in several Countries and it represents one of the most serious public health challenges of the twenty-first century. In 2016, more than 1,9 billion adults, 18 years or older, were overweight; of these over 650 million were obese. The data regarding children are even more alarming: in 2016, over 340 million children and adolescents aged 5 – 19 were overweight or obese and, in 2019, 38 million children, under the age of 5 years, were overweight or obese. Most of the world's populations live in Countries where overweight and obesity kills more people than underweight.

The definition of obesity and overweight has changed over the years; in general, it can be defined as abnormal or excessive fat accumulation that may impair health (WHO, 2004).

It is widely accepted that obesity results from an energy imbalance between energy intake and energy expenditure, and that it depends on the so-called Energy Balance-Related Behaviours (EBRBs), with an increase in a positive energy balance. Thus, treatment and prevention of obesity have to aim to changes in energy balance.

1 OVERWEIGHT AND OBESITY AMONG CHILDREN: DEFINITION AND EPIDEMIOLOGY

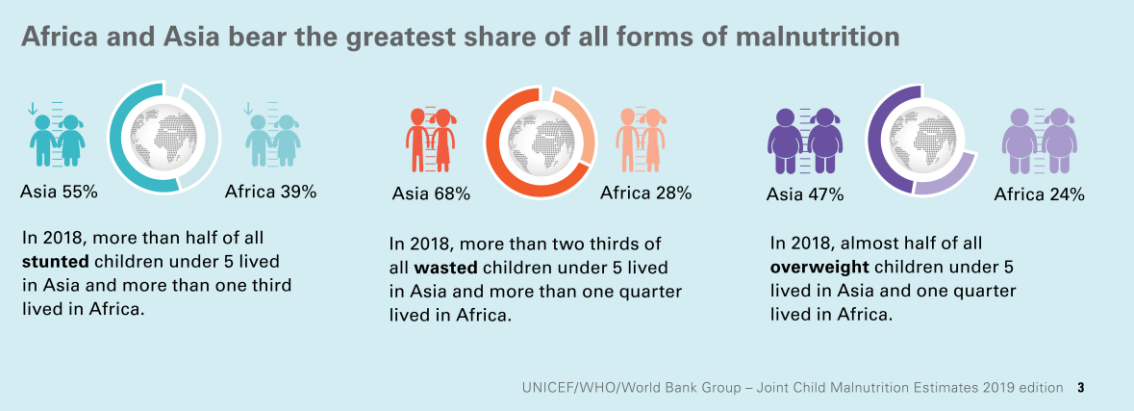
1.1 Impact of overweight and obesity on morbidity and mortality worldwide

Obesity represents one of the most serious public health challenges of the twenty-first century (Lim et al., 2012). In 2016, more than 1,9 billion adults, aged 18 or older, were overweight; of these, more than 650 million were obese. Most of the world's population live in Countries where overweight and obesity kills more people than underweight (WHO a, 2020). According to the WHO, obesity represents a major public health problem in the world, indeed the word *globesity* is often used to describe its rapidly accelerating (Sartorio et al., 2012), it is in fact an escalating global epidemic.

The prevalence of childhood obesity has increased at an alarming rate in several Countries. Children with an excessive ponderal index are more likely to stay obese into adulthood with increased risk of several serious health conditions associated with obesity. Although the relationship between child obesity and health problems is highly complex and there are individual variations influenced by several factors, such as behavioural and socioeconomic factors, it is fundamental to implement earlier preventions and interventions. Moreover, obese children develop chronic diseases, more precociously and more rapidly. The early development of these diseases can profoundly affect the social and economic global impact of obesity.

Obese children, in fact, are at a higher risk of developing diabetes and cardiocirculatory diseases at a younger age, with a higher likelihood of premature death and disability (ISS a, 2014). Obesity and overweight, once considered a condition that affected only high-income Countries, where the risk of childhood obesity is however higher among those groups with a lower socio-economic status, today is an increasing problem also across low- and middle-income Countries, particularly in urban areas. In many of these Countries multiple forms of malnutrition are observed simultaneously (Figure 1) [UNICEF/WHO/World Bank Group - Joint Child Malnutrition Estimates, 2019]. Although they keep tackling undernutrition and infections, these Countries are also experiencing important increases in the prevalence of non-communicable disease such as obesity and overweight. It is not rare to find coexistence of malnutrition and obesity within the same country, the same community and same family.

Figure 1. Coexistence of forms of malnutrition in Africa and Asia [Source: UNICEF/WHO/World Bank Group - Joint Child Malnutrition Estimates,2019].



Children from low- and middle-income Countries are more vulnerable to an inadequate maternal, child and preadolescent undernutrition. These children are exposed to foods rich in fat, sugar, and salt, high in energy and poor of micronutrient, which have a lower cost and nutritional quality. These dietary models, along with reduced physical activity levels, result in a rapid increase in childhood obesity, but still leaving the malnutrition problems unresolved (WHO a, 2020). Moreover, childhood obesity is often underrated as a public health problem in these contexts where, culturally, an overweight child is often considered to be healthy child (WHO b, 2016).

By definition, obesity is excessive body fat accumulation in relation to fat mass, in terms both of absolute quantity, and of specific body fat distribution. Measurements of body fat distribution can be performed with different methods, from skinfold thickness measurements to waist over waist-to-hip ratio, or with more sophisticated techniques such as the ultrasounds, the computerized axial tomography, or the magnetic resonance imaging (Iughetti et al., 2005).

The estimation of body fat in of the population is performed by the Body Mass Index (BMI), which is considered the most representative for predicting excess body fat. Indeed, the BMI is the most efficacious measurement to detect adult obesity and overweight, because it uses standard weight status categories that are the same for men and women of all body types and ages. However, it should be considered as an approximative guide

because one same BMI may not correspond to the same person's percent of body fat (WHO c, 2004).

The BMI is defined as a person's weight in kilograms divided by the square of the person's height in metres (ISS b, 2017):

$$BMI = \frac{weight(kg)}{height^2(m^2)}$$

The BMI is strictly related to the health status. Epidemiological studies have identified that an elevated BMI is associated to multiple chronical diseases. Indeed, people with an increased BMI are more likely to develop chronical diseases such cardiovascular diseases, type-2 diabetes, respiratory diseases, chronic kidney condition, musculoskeletal disorders, many cancers and depression, which have a long-term impact on the quality of life. Moreover, many of these conditions cannot be treated and this increases the risk of premature death and years lived with disability (measured through the epidemiological indicator DALY, Disability and Death Adjusted Life Years) (Ferriero et al., 2015).

In 2015, high BMI accounted for 4 million deaths globally, that is to 7.1% of the deaths occurred for aby cause. Moreover, it was related to 120 million DALYs worldwide, that is to al 4.9% of the DALYs associated to any cause among adults worldwide. Overall, 39% of deaths and 37% of DALYs related to high BMI occurred in those with a BMI <30 kg/m^2 (Figure 2) [Source GBD 2015 Obesity Collaborators, 2017].

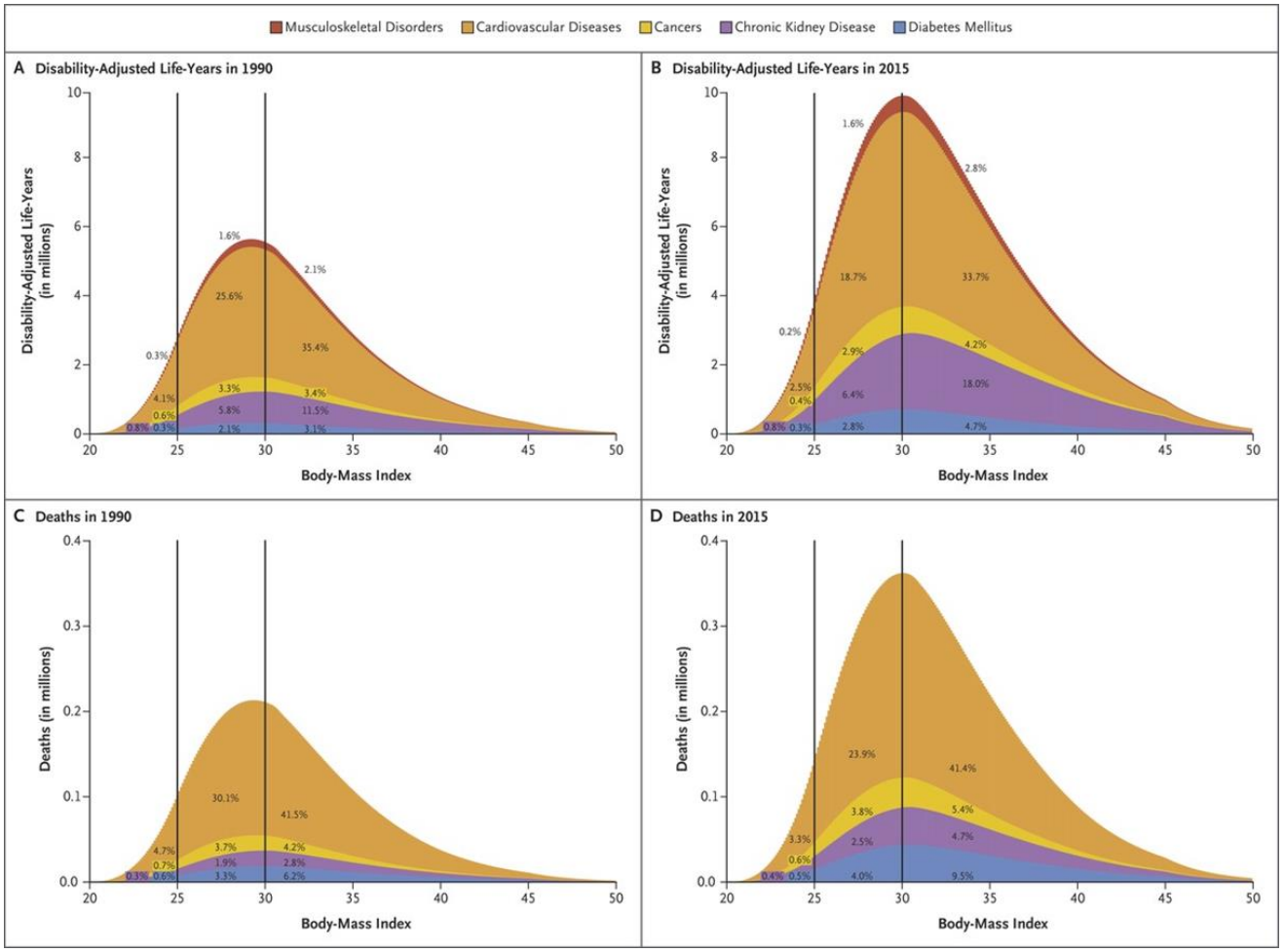


Figure 2. Global Disability-Adjusted Life-Years and Deaths Associated with a High Body-Mass Index (1990–2015). [Source: GBD 2015 Obesity Collaborators, 2017].

Figure 2 reports the disability-adjusted life years (in millions) related to high BMI among adults in 1990 (Panel A) and 2015 (Panel B), and the number of global deaths (in millions) related to high BMI in 1990 (Panel C) and 2015 (Panel D). The two vertical lines mark the BMI thresholds for overweight (25 to 29) and for obesity (≥30 kg/m2). The percentages indicate the proportion of the total number of disability-adjusted life-years or deaths that were contributed by each of the following conditions: cardiovascular disease diabetes mellitus, chronic kidney disease, many cancers and musculoskeletal disorders.

Cardiovascular disease was the leading cause of deaths and DALYs related to high BMI accounting for 2.7 million deaths and 66.3 million DALYs. Globally, 41% of BMI-related deaths and 34% of BMI-related DALYs were due to cardiovascular disease among obese people.

In 2015, diabetes was the second leading cause of BMI-related deaths, contributing to 0.6 million deaths and 30.4 million DALYs; 9.5% and 4.5% of all BMI-related deaths were due to diabetes at BMI >30 kg/m^2 and <30 kg/m^2 respectively.

In 2015, chronic kidney disease was the second leading cause of BMI-related DALYs. Eighteen percent of DALYs occurred at BMI >30 kg/m^2 or higher and 7.2% and 7.3% at BMI <30 kg/m^2.
In 2015, Chronic kidney disease and neoplasms each accounted for less than 10% of all BMI-related deaths, while neoplasms, diabetes, and musculoskeletal disorders each contributed less than 10% of BMI-related DALYs.

High BMI also accounted for 28.6 million years lived with disability, 3.6% of all-cause years lived with disability globally.

Diabetes was the leading cause of DALYs related to BMI (17.1 million years) followed by musculoskeletal disorders (5.7 million) and cardiovascular disease (3.3 million).

In the years between 1990-2015, the global mortality related to high BMI increased by 28.3% from 41.9 per 100,000 in 1990 to 53.7 per 100,000 in 2015. However, in this period, mortality rates did not significantly change: 64.0 deaths per 100,000 in 1990 and 60.2 per 100,000 in 2015.

Similarly, between 1990 and 2015, BMI-related DALYs increased by 35.8%, from 1200 per 100,000 to 1630 per 100,000 while no significant change was observed in age-standardized rates.

Globally, the increased in BMI-related deaths and DALYs due to due to risk exposure and population aging were roughly matched by the decreases in the mortality rate and DALYs (Figure 3) [Source: GBD 2015 Obesity Collaborators, 2017].

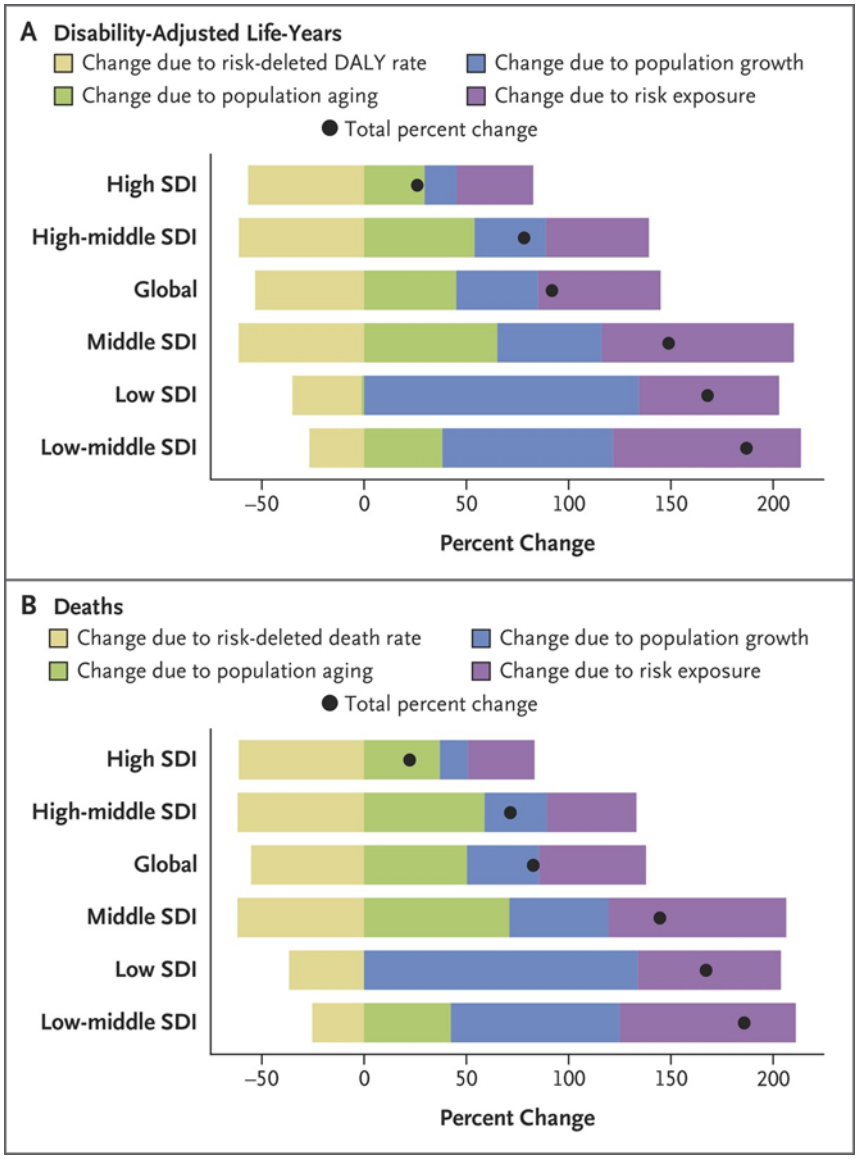


Figure 3. Percent Changes and Drivers of Change in DALY and Deaths at the Global Level, According to SDI (1990-2015) [Source: GBD 2015 Obesity Collaborators, 2017].

Figure 3 reports a detailed analysis of the percent changes from 1990 to 2015 in DALY from any cause (Panel A) and deaths (Panel B) according to whether the changes were attributed to population aging, population growth, exposure to high BMI (risk factor) or risk DALY rates (Panel A) and risk-deleted mortality rate (Panel B) ('risk-deleted rates' are the underlying rates of disease/mortality that would have occurred in the absence of the risk factor). The percent changes were estimated globally and based on the Socio−demographic Index (SDI) divided into 'high, 'high/middle, 'middle', 'low' and 'low/middle.

The study shows that the decrease in the mortality rate due to cardiovascular disease occurs when the risk factor is deleted. Moreover, the changes due to risk exposure to high BMI and to the population aging were roughly equal in terms of their contribution to both percent change of BMI-related deaths and DALYs globally between from 1990 to 2015 (The GBD 2015 Obesity Collaborators, 2017).

Obesity, overweight and the related chronical diseases are not only a major public health problem because of the health budgets spent every year for treating obesity-related diseases; including the indirect costs productivity losses as a consequence of health problems or premature mortality (Ministero della Salute, 2017). Overweight accounts for 9.0% of health expenditure. Likewise, overweight children are more likely to obtain lower scores at school and are less likely to complete higher education, which in the future may constrain the formation of human capital. At a macroeconomic level, all these dimensions negatively affect the GDP of a country and create the conditions for increased fiscal pressure. (OECD Health PolicyStudies, 2019).

According to an estimate by the Organisation for Economic Co-operation and Development (OECD), overweight and obesity will have a significant impact on population health in the next 30 years: nearly 60% of all new diabetes cases will be due to overweight, as well as 18%, 11% and 8% of all cases of cardiovascular disease, dementia and cancers, respectively. In the OECD, there will be about 3 million premature deaths (between the age of 30 and 70) per year due to overweight. On average, 61 people per 100,000 population will die prematurely each year due to overweight (defined as mortality of people aged 30 to under 70.) (Figure 4) [Source: The Heavy Burden of Obesity: The Economics of Prevention, OECD, 2019].

Figure 4. The impact of overweight on premature mortality. Annual number of premature deaths per 100,000 population, average 2020-50 [Source: The Heavy Burden of Obesity: The Economics of Prevention, OECD, 2019].

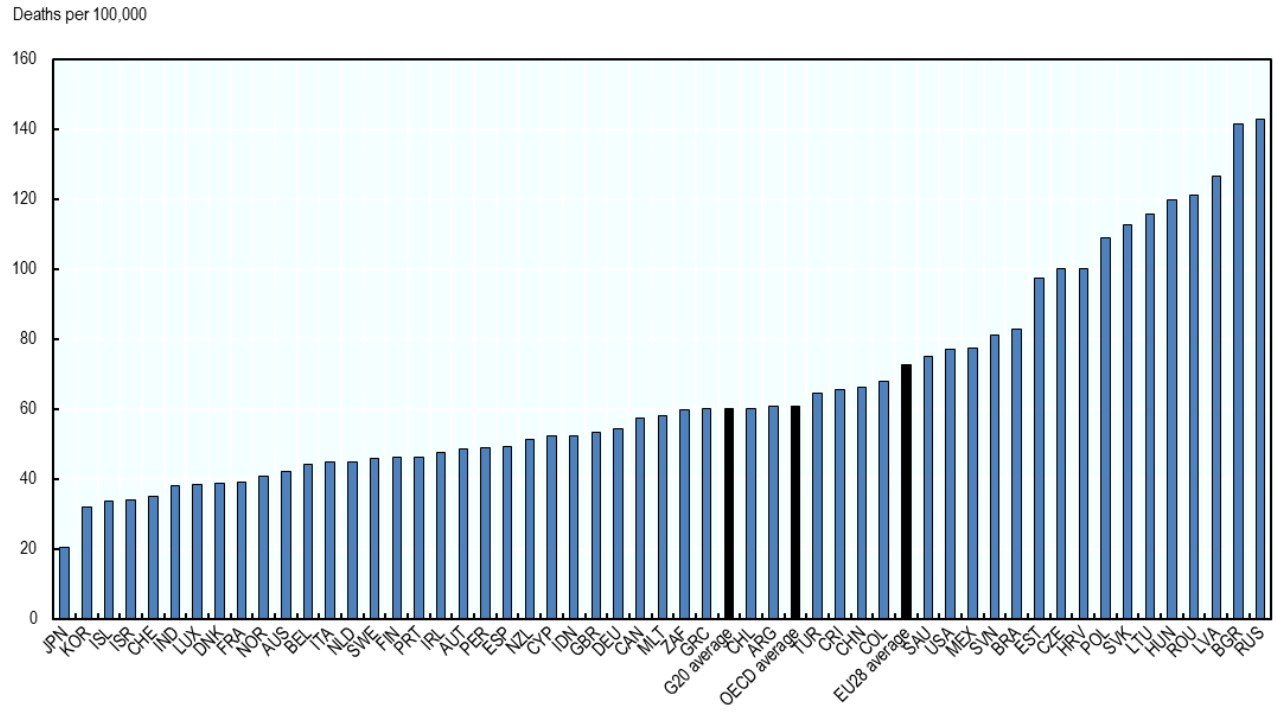


Figure 4 reports the estimated premature mortality rates due to overweight across OECD between 2020 and 2050. The blue bars indicate the average in the analysed Countries, whereas the black vertical bars represent the average in Group of 20 (G20) Countries, the overall average of all the Countries analysed in the OECD survey (OECD average) and the average of the European Union 28 Countries (UE28), respectively. In the EU Countries, this average is higher at 73 per 100,000, driven by high premature mortality rates in Eastern European Countries. Premature mortality is lower in Countries where the overweight prevalence is low and life expectancy is high, such as Japan and Korea. In total, 3 million people will die prematurely every year in the 52 Countries due to overweight in the next 30 years.

The impact of overweight on mortality can also be measured in years of life lost. In the OECD, Countries will lose on average 3,291 life years per 100,000 population every year due to overweight, over the period 2020-50. As mentioned above, in addition to its impact on mortality, obesity also increases the number of disability-adjusted life years. The impact on DALYs is even greater: 3,908 DALYs per 100,000 population every year due

to overweight (Figure 5) [Source: The Heavy Burden of Obesity: The Economics of Prevention, OECD, 2019]. This is nearly 12% of the overall rate of DALYs lost due to disease globally and similar to the cumulative burden caused by stroke and ischemic heart diseases.

Figure 5. The impact of overweight on life-years lost. Life-years (LYs) and disability-adjusted life-years (DALYs) lost per year per 100,000 population due to overweight, average 2020-50 [Source: The Heavy Burden of Obesity: The Economics of Prevention, OECD, 2019].

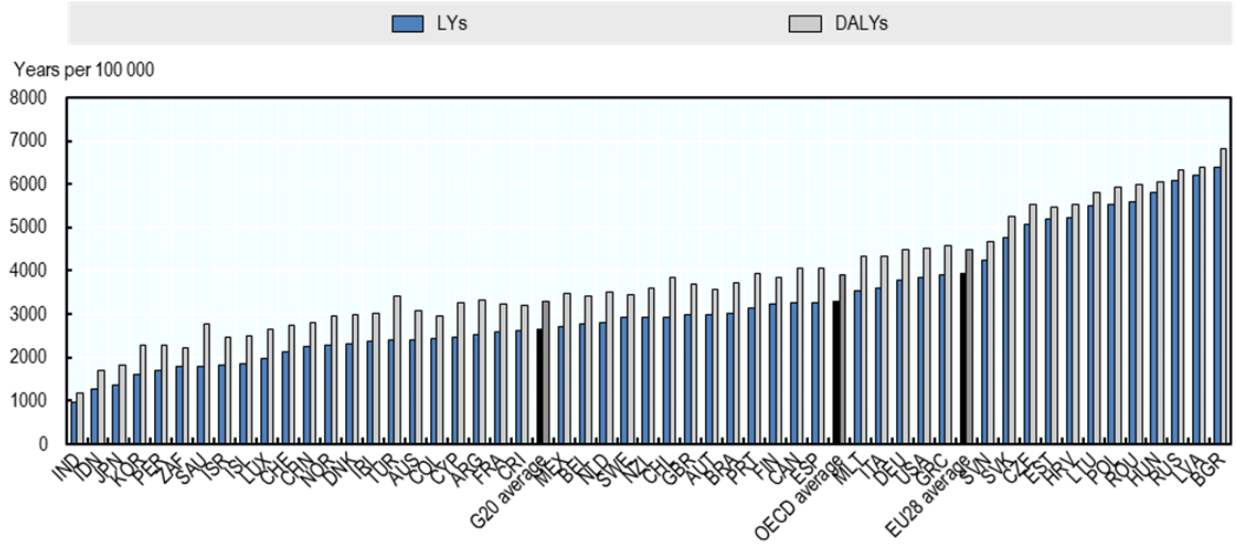


Figure 5 reports the number of years lost (YLL) and DALYs each year from 2020 to 2050 per 100,000 population across the OECD. The blue vertical lines show the average of life-years lost and the light grey lines report the average of the DALYs lost in the analysed Countries; the black and dark grey bars show the average of life-years lost and DALYs in G20 Countries, in the OECD surveyed Countries and in UE 28 Countries, respectively. This is roughly in line with the results reported above, where high BMI was associated with 1,630 DALYs per 100,000 globally (The GBD 2015 Obesity Collaborators, 2017). Looking specifically at the regions considered in this report, the estimated impact of overweight, for 2017, was at 2,587 DALYs per 100,000 for OECD Countries, 2,614 for the EU28 and 2,082 for G20 Countries. The OECD model reports 3.908 DALYs per 100.000 for OECD, 4.495 and 3,289 DALYs for the EU28 and G20 Countries respectively. The impact on DALYs is higher as they look at the average impact over the next 30 years, rather than the current burden. For example, the OECD model takes into account that, in the next 30 years, the population in OECD, EU28 and G20 Countries is

expected to live longer and become older, with the resulting increase in the incidence of non-communicable diseases (OECD Health PolicyStudies, 2019).

This is reflected in life expectancy: overweight and its related conditions will reduce life expectancy (measured with the epidemiological indicator LE, Life Expectancy) by 2.7 years on average in OECD Countries. We should underline that this decrease in life expectancy is the average across the total population – not just for people with overweight. The average for G20 Countries is lower, at 2.5 years, while the EU28 average is higher at 2.9 years. Countries with low overweight prevalence will see a smaller impact on life expectancy, with Japan losing less than a year, compared to Mexico where overweight reduces life expectancy by more than four years. Healthy life expectancy, which uses disease disability weights to calculate the number of years lived in perfect health, (measured with the epidemiological indicator HALE, Healthy Adjusted Life Expectancy), will be reduced even further, by 3.2 years on average in OECD Countries, 3.0 in G20 Countries and 3.3 in EU28 Countries (Figure 6) [Source: The Heavy Burden of Obesity: The Economics of Prevention, OECD, 2019].

Figure 6. The impact on life expectancy (LE) and healthy life expectancy (HALE) in years, average 2020-50. [Source: OECD (2019), The Heavy Burden of Obesity: The Economics of Prevention].

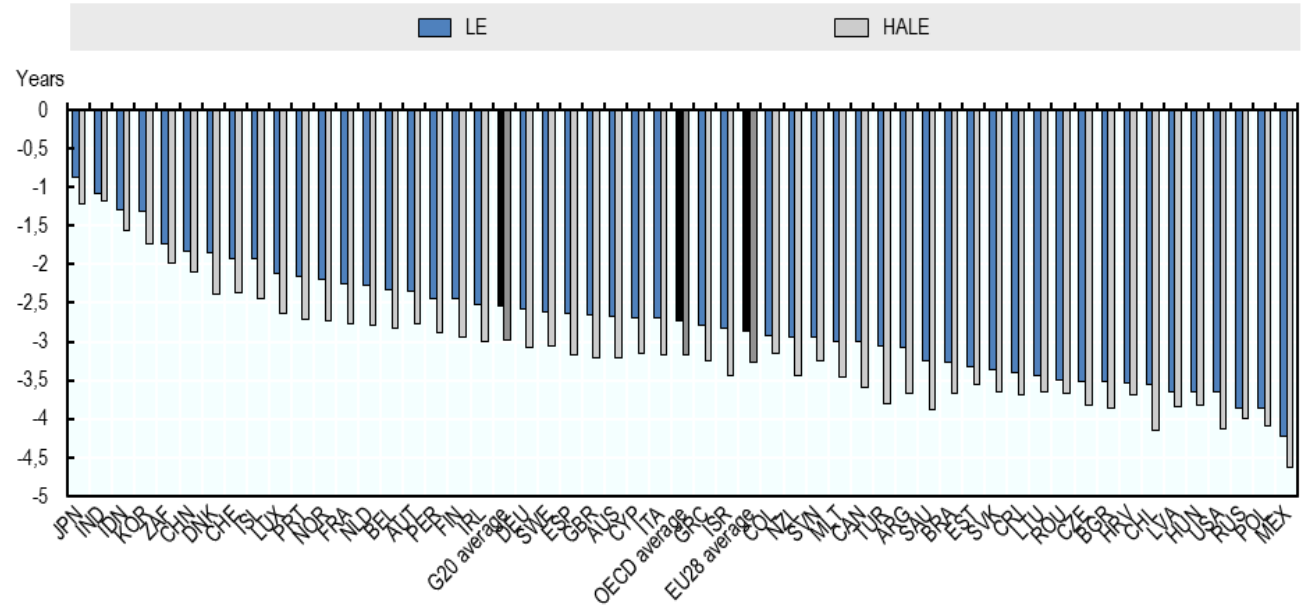


Figure 6 reports life expectancy (LE) and healthy life expectancy (HALE) for the 2020-2050 period. The blue bars describe the impact of overweight on life expectancy, the grey bars represent the impact of overweight on healthy life expectancy across the Countries

in the analysis; while the black and dark grey bars represent the impact of overweight on LE and HALE in the G20 Countries, the average in all the OECD in the analysis and the average of the UE28 Countries, respectively (OECD Health PolicyStudies, 2019).

1.2 When did we start to become obese?

Obesity has officially been recognized only recently as a major public health issue. In 1948, for the first time the WHO included obesity in the sixth revision of the International Classification of Diseases (ICD). At the time, clinical medicine did not yet recognize the issues related to overnutrition, considering it could be treated only with calorie restriction (ISS a, 2014).

Studies document that starting from 1930, world's population started to increasingly gain weight. Until the last decades of the 19th century, developed Countries were still dealing with poverty, malnutrition and communicable diseases, which were considered the main causes of low industrial productivity. In the first decades of the 20th century, studies on poor children reported that the increased intake of energy-dense foods, through added sugars and fats, improved child growth and development. Therefore, the main effort by FAO (Food and Agriculture Organization) was to increase the availability of low-cost calorie sources, mainly edible fats and sugars. This practice became an important approach to reduce malnutrition and to improve industrial productivity. Similar efforts were pursued over the following decades leading to higher dietary energy intake. Although obesity has not represented a concern until the past decades, its prevalence in industrialized Countries started to grow steadily at the beginning of the past century. In the Sixties, national surveys started to provide evidence of the alarming growth of the obesity rates. Data show the steady growth of obesity prevalence over the last decades. The year 2000 marks a turning point for humanity: for the first time in history the number of overweight adults exceeds the number of underweight people. Until few years ago, obesity was considered a condition typical of industrialized Countries, associated with a higher socioeconomic status. Over the last decades, obesity has dramatically increased also across the developing Countries. Initially, the prevalence of overweight and obesity was higher among wealthier individuals, but as Countries developed there was a transition of overweight and obesity to poorer populations. In 1997, the alarming increase in obesity forced WHO to declare obesity as a global epidemic (Caballero B., 2007).

1.3 Definition of overweight and obesity in developmental age

In general, obesity is defined as abnormal or excessive fat accumulation that presents a risk to health (WHO c, 2004). This general definition can be applied also to the developmental age. Since such condition represents a serious health risk at an earlier age, and since obese children are more likely to stay obese into adulthood, it is vital to recognize it and prevent it at its earliest onset.

Ideally, the classification of childhood overweight and obesity should be based on the risk of current and future morbidity and mortality, and on the possibility of comparing different populations. Differently from adulthood, it is difficult to develop a simple index for the measurement of overweight and obesity in children and adolescents because as they grow, children's body composition varies as they age and between boys and girls. The measurement of obesity, in fact, is treated differently for adults and children. In adults, the definition of normal weight is based on the relationship of the BMI with the mortality and morbidity risk: where normal weight status is a BMI 18.5 kg/m^2 – 24.9 kg/m^2 the relative mortality risk is minimum, and it increases progressively with overweight, BMI 25 kg/m^2 -29.9 $kg/m^{2,}$ and obesity BMI>30 kg/m^2 (Ferrera L. A., 2004). There are no data to establish this relationship in children. Since we cannot use the BMI value because it varies by age and sex, the assessment is performed by using percentile growth charts. The normal ranges in the charts are obtained by dividing the collected data set into 100 parts, called percentiles. This division is done so as that a given proportion of the child sample is above and below specific measurements in specific age groups. The 50^{th} percentile represents, for example, the median value of BMI, whereas another curve (corresponding for example to the 30^{th} percentile) reports that a certain percentage of children have lower values (30%) and another percentage (70%) has higher values. We can therefore compare the growth percentiles to normal values (Scotton C., 2010). The BMI percentiles in childhood and adolescence in the literature refer to different populations, because this parameter can influence the normal values range in a not negligible way. Indeed, there are country-specific and international growth charts that provide a set of cut-offs to define the overweight status and/or obesity among children, based on sex and age range.

Due to the necessity of having a commonly accepted standard for international comparisons of overweight, the International Obesity Task Force (IOTF) has provided

the definition of 'international' BMI cut-offs (Cole & Lobestein, 2012). The IOTF has classified the weight status of children and adolescents aged 2-18 years, using specific cut-off points by age and sex, thus providing uniform criteria to assess the weight status and to compare the prevalence data globally.

Table 1 reports the cut-offs for underweight, normal weight, overweight and obesity by sex and chronological age from 2 to 18 years.

Table 1. International Body Mass Index cut-offs for the definition of overweight and obesity. Source (Cole & Lobestein, 2012)

Age	Boys						Girls					
(years)	BMI 16*	BMI 17*	BMI 18.5*	BMI 25*	BMI 30*	BMI 35*	BMI 16*	BMI 17*	BMI 18.5*	BMI 25*	BMI 30*	BMI 35*
2.0	13.60	14.29	15.24	18.36	19.99	21.20	13.40	14.05	14.96	18.09	19.81	21.13
2.5	13.44	14.11	15.02	18.09	19.73	20.95	13.25	13.88	14.77	17.84	19.57	20.90
3.0	13.30	13.94	14.83	17.85	19.50	20.75	13.11	13.73	14.60	17.64	19.38	20.74
3.5	13.16	13.79	14.66	17.66	19.33	20.61	12.98	13.59	14.44	17.48	19.25	20.65
4.0	13.04	13.65	14.51	17.52	19.23	20.56	12.85	13.45	14.30	17.36	19.16	20.62
4.5	12.92	13.53	14.38	17.43	19.20	20.60	12.72	13.31	14.16	17.27	19.14	20.67
5.0	12.80	13.40	14.26	17.39	19.27	20.79	12.59	13.18	14.04	17.23	19.20	20.85
5.5	12.66	13.27	14.15	17.42	19.46	21.15	12.46	13.06	13.93	17.25	19.36	21.16
6.0	12.54	13.16	14.06	17.52	19.76	21.69	12.34	12.96	13.85	17.33	19.62	21.61
6.5	12.44	13.07	14.00	17.67	20.15	22.35	12.26	12.89	13.81	17.48	19.96	22.19
7.0	12.39	13.04	14.00	17.88	20.59	23.08	12.23	12.87	13.83	17.69	20.39	22.88
7.5	12.39	13.06	14.05	18.12	21.06	23.83	12.25	12.91	13.90	17.96	20.89	23.65
8.0	12.43	13.11	14.13	18.41	21.56	24.61	12.30	12.98	14.00	18.28	21.44	24.50
8.5	12.48	13.19	14.24	18.73	22.11	25.45	12.37	13.07	14.13	18.63	22.04	25.42
9.0	12.54	13.27	14.36	19.07	22.71	26.40	12.44	13.16	14.26	18.99	22.66	26.39
9.5	12.61	13.36	14.49	19.43	23.34	27.39	12.52	13.27	14.40	19.38	23.31	27.38
10.0	12.70	13.47	14.63	19.80	23.96	28.35	12.63	13.40	14.58	19.78	23.97	28.36
10.5	12.80	13.59	14.79	20.15	24.54	29.22	12.77	13.57	14.78	20.21	24.62	29.28
11.0	12.91	13.73	14.96	20.51	25.07	29.97	12.94	13.77	15.03	20.66	25.25	30.14
11.5	13.05	13.89	15.15	20.85	25.56	30.63	13.15	14.00	15.30	21.12	25.87	30.93
12.0	13.22	14.07	15.36	21.20	26.02	31.21	13.38	14.26	15.59	21.59	26.47	31.66
12.5	13.40	14.27	15.59	21.54	26.45	31.73	13.64	14.54	15.91	22.05	27.04	32.33
13.0	13.61	14.50	15.84	21.89	26.87	32.19	13.92	14.84	16.23	22.49	27.57	32.91
13.5	13.84	14.74	16.11	22.25	27.26	32.61	14.20	15.13	16.55	22.90	28.03	33.39
14.0	14.09	15.01	16.39	22.60	27.64	32.98	14.47	15.43	16.86	23.27	28.42	33.78
14.5	14.35	15.28	16.69	22.95	28.00	33.29	14.74	15.71	17.16	23.60	28.74	34.07
15.0	14.61	15.55	16.98	23.28	28.32	33.56	15.00	15.97	17.43	23.89	29.01	34.28
15.5	14.87	15.82	17.26	23.59	28.61	33.78	15.24	16.21	17.68	24.13	29.22	34.43
16.0	15.12	16.08	17.53	23.89	28.88	33.98	15.45	16.42	17.90	24.34	29.40	34.55
16.5	15.36	16.33	17.79	24.18	29.15	34.19	15.63	16.61	18.08	24.53	29.55	34.64
17.0	15.59	16.57	18.04	24.46	29.43	34.43	15.78	16.76	18.24	24.70	29.70	34.75
17.5	15.80	16.79	18.28	24.73	29.71	34.71	15.90	16.89	18.38	24.85	29.85	34.87
18.0	16	17	18.5	25	30	35	16	17	18.5	25	30	35

* indicates BMI centile corresponding to BMI at age 18 using pooled LMS-based cut-offs.

Different country-specific growth curves have been developed (GLNBM). In Italy, in 2002, the first national reference charts for weight and height and BMI for children and adolescents aged 6-18 years were produced and the national overweight and obesity cut-offs levels were defined (Table 2) [Fonte: Cacciari et al., European Journal of Clinical Nutrition, 2002].

Table 2. National BMI cut-offs (central-north and south Italy) for overweight and obesity during growth [Source: Cacciari et al., European Journal of Clinical Nutrition, 2002].

	Central-north				South			
	Overweight		Obesity		Overweight		Obesity	
Age (y)	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys
6	19.8	18.1	24.1	23.1	18.6	17.1	22.3	20.6
7	20.2	18.7	24.9	24.3	19.0	17.6	23.0	21.6
8	20.8	19.4	26.0	25.6	19.6	18.2	23.8	22.6
9	21.6	20.2	27.4	26.7	20.3	19.0	24.8	23.7
10	22.5	21.1	28.6	27.6	21.2	19.8	26.0	24.8
11	23.6	22.0	29.3	28.4	22.1	20.6	27.1	25.8
12	24.4	22.9	29.5	29.0	23.0	21.5	28.1	26.8
13	24.8	23.6	29.6	29.3	23.7	22.3	28.8	27.7
14	25.0	24.2	29.7	29.5	24.2	23.1	29.3	28.4
15	25.0	24.5	29.9	29.7	24.6	23.7	29.6	29.0
16	25.0	24.8	29.9	29.8	24.8	24.2	29.8	29.4
17	25.0	24.9	30.0	29.9	24.9	24.7	29.9	29.7
18	25.0	25.0	30.0	30.0	25.0	25.0	30.0	30.0

In 1994, the WHO undertook a comprehensive review of the international anthropometric references for the assessment of children's growth. The review concluded that the references recommended since the end of the seventies, the growth curves of the National Centre for Health Statistics (NCHS) of 1977 based on a sample of formula-fed American infants, were no longer adequate.

Given the need of new international references to describe children's growth properly, the WHO undertook the Multicentre Growth Reference Study (MGRS) between 1997 and 2003 to generate new growth curves for assessing the growth and development of infants and young children around the world. In 2006, the new children's growth charts were published. The MGRS collected growth data and related information from 8440 affluent children from widely differing ethnic backgrounds and cultural settings (Brazil, Ghana, India, Norway, Oman and the USA) (WHO d, 1999).

The new growth curves are expected to provide a single international standard that represents the best description of physiological growth for all children from birth to five years of age (0-5 years) and to establish the breastfed infant as the normative model for growth and development.

In 2007, WHO published a further growth reference standard for school-aged children and adolescents (5-19 years) that provides a proper reference for this age range. To generate the new reference standard, WHO proceeded to reconstruct the 1977 growth

reference from 5 to 19 years, using the original sample supplemented with data from the WHO Child Growth Standards (to facilitate a smooth transition at 5 years), and applying the state-of-the-art statistical methods (de Onis M., 2007).

In the WHO growth curves, the BMI thresholds for overweight and obesity are calculated as median value by age and sex plus a certain number of standard deviations (SD): by age group 0-5 years (Figure 7 and 8) +2 SD, by overweight and + 3 SD by obesity and age group 5-19 years (Figure 9 and 10) +1 SD, respectively (WHO e, 2007).

Figure 7. Girls chart - Growth curve birth to 5 years [Source: Child growth standards, WHO, 2007].

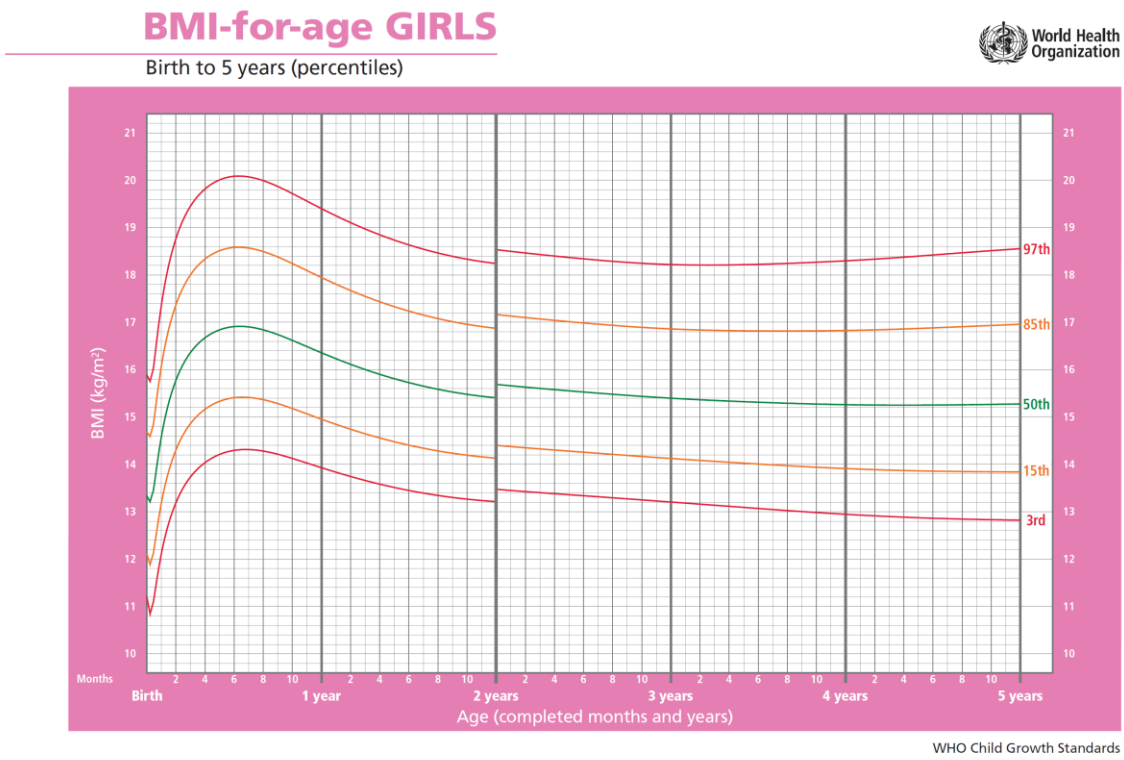


Figure 8. Boys chart - Growth curve 0 to 5 years [Source: Child growth standards, WHO, 2007].

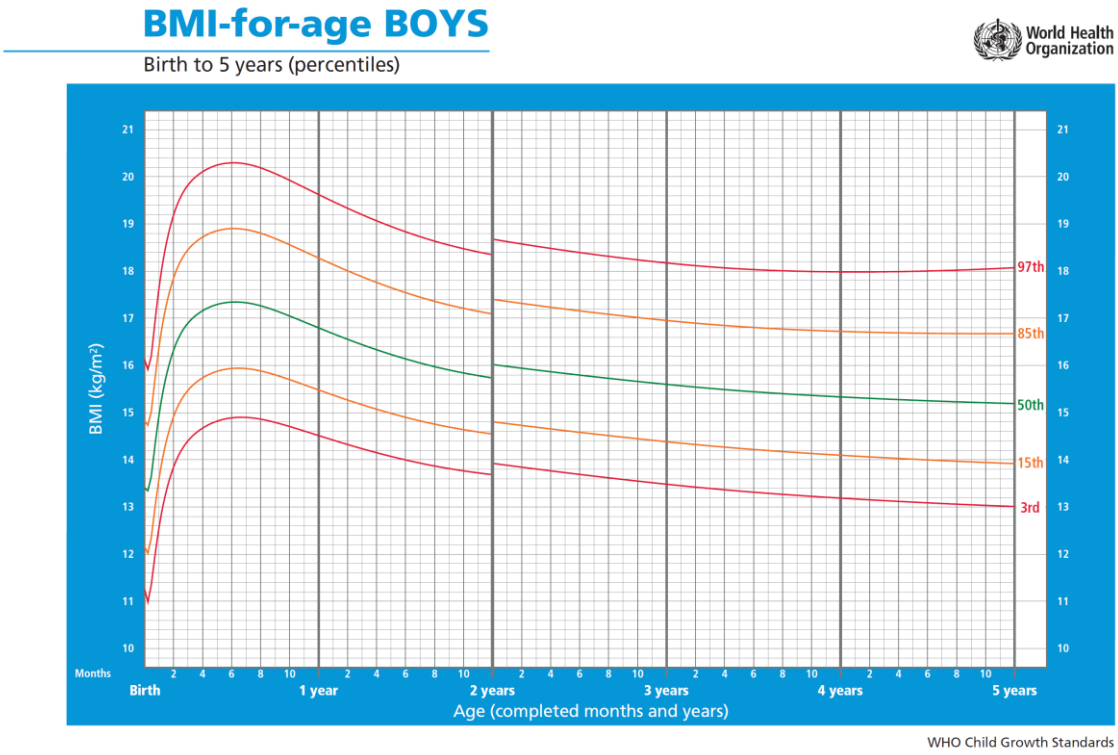


Figure 9. Girls chart – Growth curve 5-19 years [Source: Child growth standards, WHO, 2007].

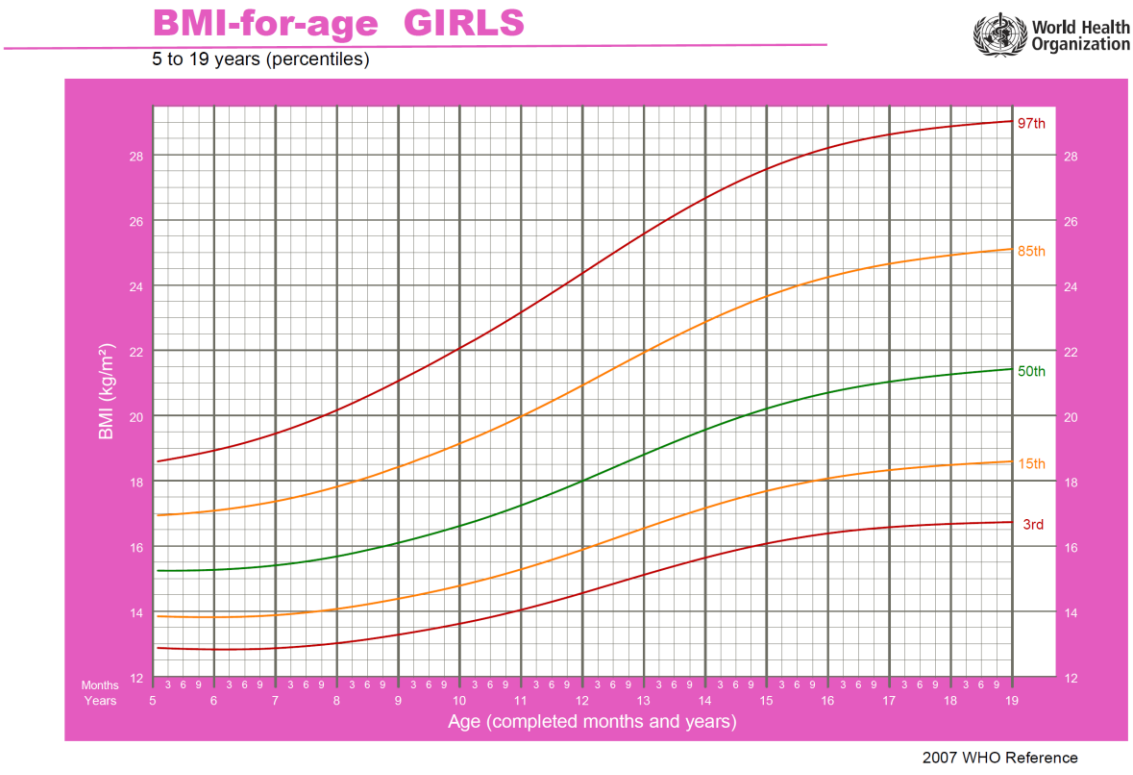
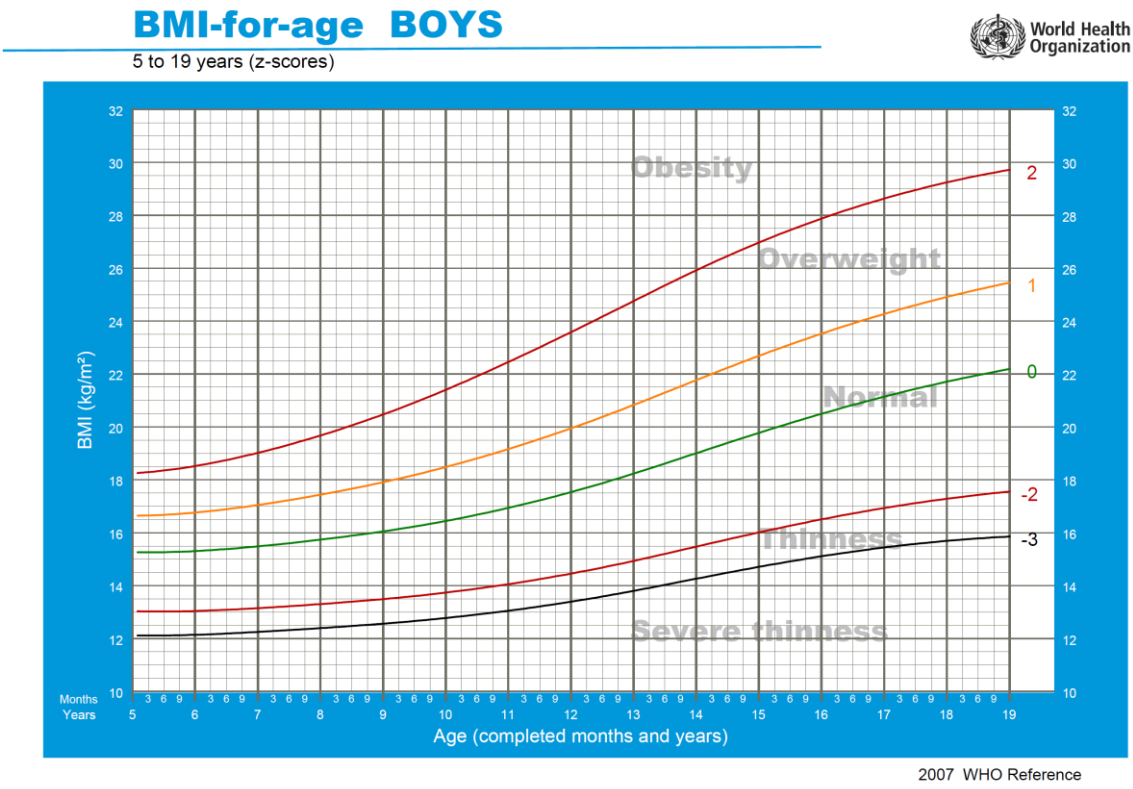


Figure 10. Boys chart – Growth curve 5-19 years [Source: Child growth standards, WHO, 2007].



1.4 Prevalence of overweight and obesity in developmental age

Prevalence rates of neonatal, infant and adolescent obesity is growing worldwide (WHO b, 2016). Recent studies have shown how the tendency towards obesity around 6 months of age. Neonatal obesity is strongly predictive of obesity risk at 24 months (McCormick et al., 2010).

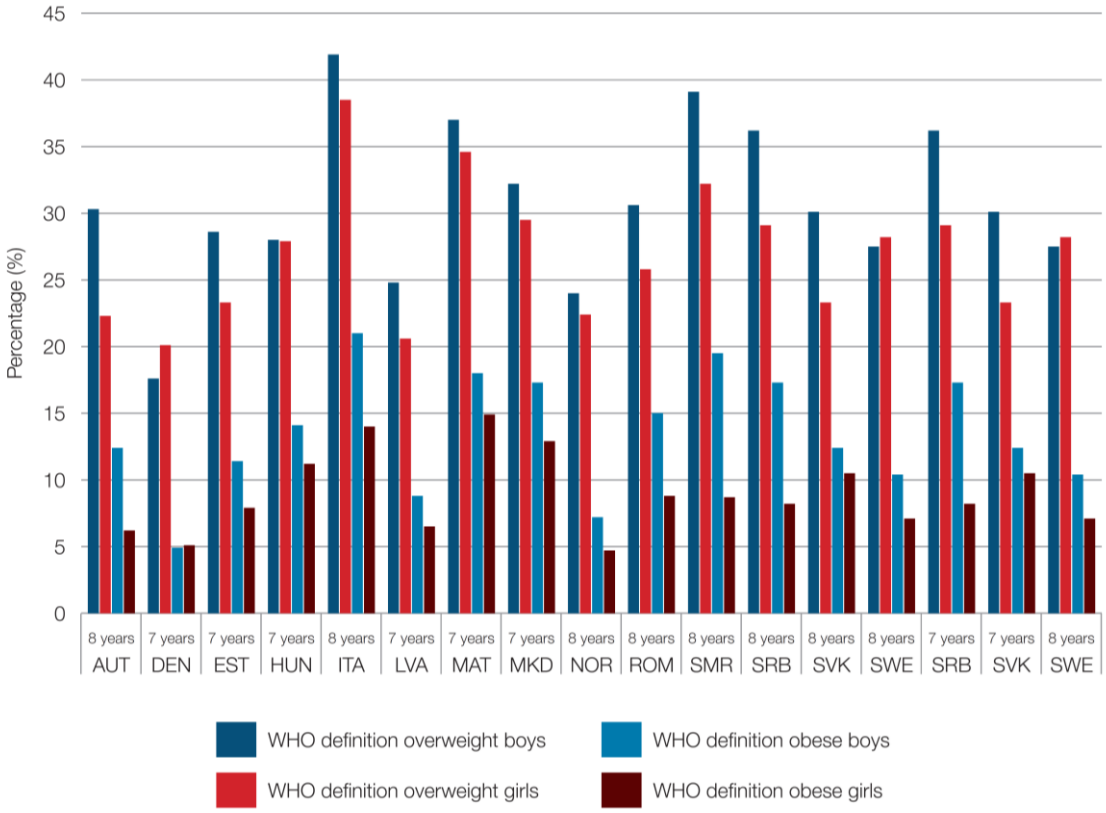
The data regarding obesity during the developmental age are alarming. The number of obese children and adolescents (aged five to 19 years) worldwide has risen tenfold in the last 40 years. In only 15 years, from 2000 to 2015, there was an increase of nearly 11 million. In 2019, an estimated 38 million children under the age of 5 years were overweight or obese (WHO f, 2017). Once considered a high-income country problem, overweight and obesity are now on the rise in low- and middle-income Countries, particularly in urban settings. Almost half of the overweight children under 5 years live in Asia (48%) and a quarter live in Africa (25%). In 2014, a study reported that in Africa the number of overweight or obese children has almost doubled, from 5.4

million in 1990 to 10.6 million in 2014 (ISS b, 2017). If no measure is established, children will be likely to remain obese in adolescence and adulthood.

In Europe, the most accurate data on the prevalence of childhood obesity have been provided by the WHO European Childhood Obesity Surveillance Initiative (COSI). The COSI survey was undertaken in 2007, due to the lack of standardized surveillance data, and for over 10 years it has measured trends in overweight and obesity among primary school aged children. This surveillance system, based on the population, consists in a systematic, standardized and harmonized monitoring of the prevalence of overweight and obesity (based on standardized weight and height measurements) among primary-school children aged 6.0-9.9 years, assessed based on the definition of WHO. Data were collected in subsequent rounds: the first data collection took place during the 2007–2008 school year, the second during the 2009–2010 school year, the third during the 2012–2013 school year and the fourth during the 2015–2016 school year. The fifth round took place during the 2018–2019 school year. The number of participating Countries grew by each round of data collection and in the fourth round 41 Countries participated in the COSI study. The initiative provides nationally representative data along with region-wide data set for analysis of the determinants of childhood overweight and obesity. This vital collaboration between the World Health Organisation and research Institutions from across Europe provides high-quality data that is needed to inform policy and practice in response to the problem of childhood overweight and obesity.

Data from the fourth round highlighted that the prevalence of obesity and overweight in Europe was from 17.6% to 41.9% in boys and from 20.1% to 38.5% in girls, and the prevalence of obesity ranged from 4.9 to 21.0% among boys and from 5.1 to 14.9% among girls (Figure 11) [Source: Mapping the health system response to childhood obesity in the WHO European Region. An overview and country perspectives, WHO, 2019]. The data suggest an increasing north−south gradient, with the highest prevalence of overweight and obesity in southern European Countries (WHO g, 2019). In the Countries that collected data for more than one age group, the prevalence of overweight and obesity tended to increase with age. According to WHO definitions, more boys than girls were overweight and obese in most age groups, particularly at older ages, and in most Countries (WHO h, 2018).

Figure 11. Prevalence of overweight and obesity (WHO definition) in boys and girls aged 6-9 years, in the Countries participating in COSI 2015-2016 [Source: Mapping the health system response to childhood obesity in the WHO European Region. An overview and country perspectives, WHO, 2019].

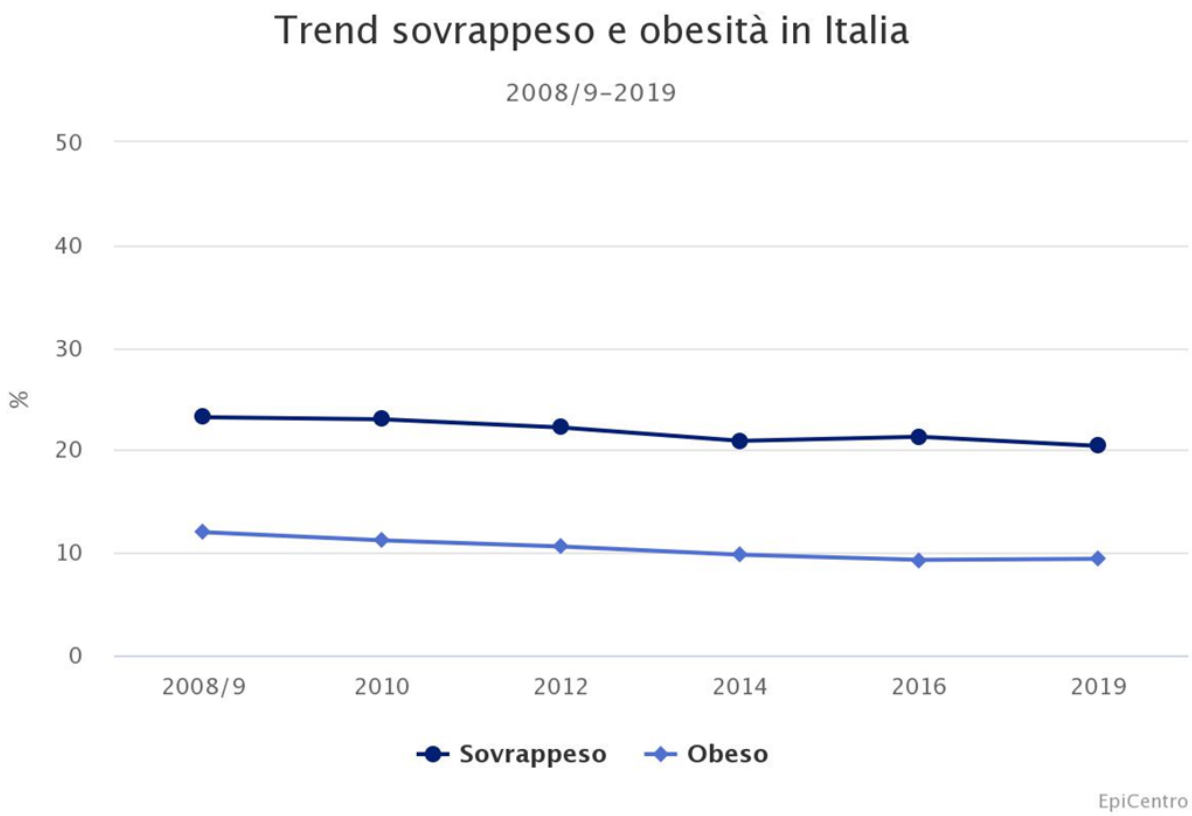


Italy has always taken part in the initiative and with the high number of children (more than 40,000 for each round). Italy, also in the fourth round of data collection COSI (2015-17), was among the European Countries with the highest values of excess weight among children together with other Countries of the Mediterranean area (ISS c, 2020).

The national data are in line with the global trends with a high prevalence of overweight and obesity among pre-school and school-aged children (Maffeis et al., 2006).

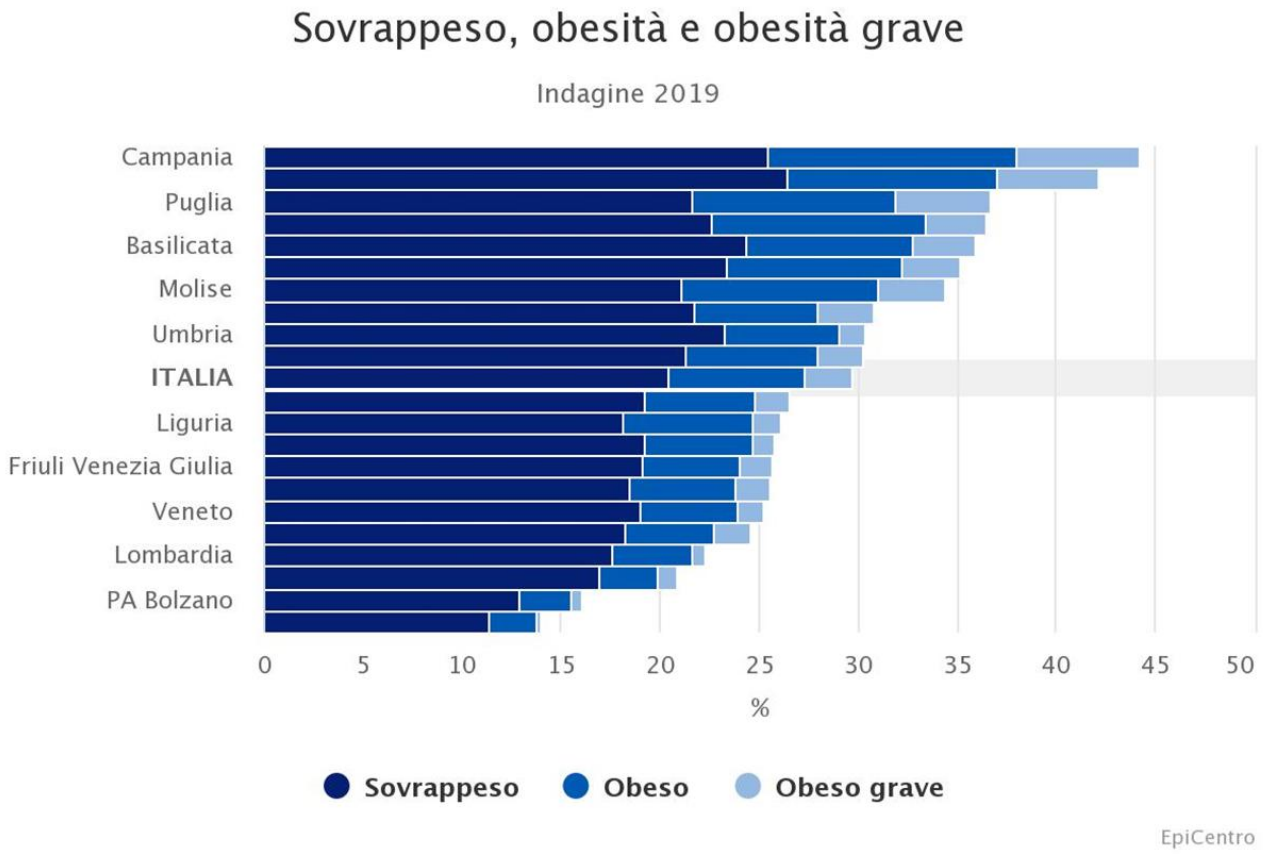
In 2007, the national centre National Centre for Disease Prevention and Control of Noncommunicable Diseases of the Italian National Institute of Health/ financed the "OKkio alla SALUTE" project as part of the COSI survey by WHO. The project is a surveillance system for overweight, obesity and related risk factors in primary schoolchildren, where data are collected every two years. The 2019 survey highlights that 20.4% of participating children are overweight and 9.4% are obese (Figure 12), with higher prevalence in southern and central Italy (Figure 13) (ISS c, 2020).

Figure 12. Trends in overweight and obesity among children aged 8-9 years over time[Source: OKkio alla salute risultati 2019, Epicentro, 2020].



The prevalence of overweight remained relatively stable with a small decline in 2014 and in 2019 compared to the previous rounds; decreasing trends were observed in obesity prevalences.

Figure 13. Prevalence of overweight, obesity, and severe obesity in children aged 8-9 years by region, year 2019 [Source: OKkio alla salute risultati 2019, Epicentro, 2020].



There is a wide regional variation in rates of obesity and overweight where the higher prevalence is in the southern regions.

In Italy, the prevalence of childhood overweight and obesity is still high although, between 2008 and 2016, an improvement in obesity rates was observed. However, there are still relevant regional differences that require targeted interventions (WHO i, 2018).

The increase in childhood obesity exceeded the increase in obesity in adults in many Countries (Weihrauch-Blüher et al., 2018). However, the most recent surveys report that in some developed Countries, the trend of obesity in developed Countries has declined. Even though this trend is confirmed, the prevalence of overweight among school-aged children will still remain high. The understanding and management of the load of obese-related diseases are still a challenge whose resolution is unknown. Moreover, the tendency towards an increase might persist in more disadvantaged social groups and in specific ethnical backgrounds (ISS a, 2014).

Although reports on the prevalence of childhood overweight and obesity in Europe are published regularly, there is a paucity of studies on the prevalence of excess weight among European pre-schoolers (0-5 years). Recent studies showed that the development of obesity may occur in early life, but in many Countries data on obesity surveillance in the first years of life are not yet collected (Garrido-Miguel et al., 2019).

A review published in 2017 gathered together the data of the studies on the prevalence of childhood overweight and obesity (0-5 years) carried out in the WHO/Europe Member States between 1998 and 2015 (Jones et al., 2017). Sixty-one studies analysed the prevalence data of overweight and obesity among different age ranges. For example, 29 studies analysed overweight and obesity outcomes in children who were between 0 and 4 years, while other studies assessed overweight and obesity outcomes in one particular age group, e.g., 3 years. The majority of the studies (38) used the WHO criteria for the definition of overweight and obesity, other studies (20) used the IOTF cut-offs, whereas three studies used nation-specific cut-offs. Table 3 [Source Jones et al., Frontiers in Public Health, 2017] illustrates the variability in the prevalence among regions and Countries, based on all the available data. In the member states, the prevalence of overweight and obesity in children under 5 years ranges from 1 to 28.6%.

These studies provided little consistency in terms of measurements and national representativeness, impacting comparability across Countries and within the same Country. Moreover, only 66% of the member States have data on the prevalence rates for overweight and obesity in children aged 0-5 years.

Table 3. Prevalence of overweight and obesity in children under 5 in the WHO European Region by country from published datasets and literature [Source Jones et al., Frontiers in Public Health, 2017].

Reference	Survey year	Country/ region	Source	Age (years)	Sample (*n*)	Cutoffs of BMI (kg/m²)	Prevalence of overweight, including obesity (%)					
							0 year	1 year	2 years	3 years	4 years	Total
Albania Demographic and Health Survey 2008–2009, Institute of Statistics, Institute of Public Health, and I. Macro (28)	2008–2009	Albania	DHS	0–4	1,575	WHO						22.0
Armenia Demographic and Health Survey 2010, National Statistic Service (Armenia), Ministry of Health (Armenia), and I. Macro (29)	2010	Armenia	DHS	0–4	1,491	WHO						15.0
Serbanescu (30)	2001	Azerbaijan	National	0–4	2,426	WHO						4.4
Azerbaijan Demographic and Health Survey 2006. State Statistical Committee (Azerbaijan), Macro International (31)	2006	Azerbaijan	DHS	0–4	2,242	WHO						13.0
UNICEF (32)	2013	Azerbaijan	National	0–4	1,569	WHO						13.0
Greier and Riecheimann (26)	2011–2012	Austria	Subnational	4–5	1,063	German BMI reference						13.0
Belarus Multiple Indicator Cluster Survey 2005, Final Report, Ministry of Statistics and Analysis of the Republic of Belarus (33)	2005	Belarus	MICS	0–4	3,018	WHO						10.0
Bayingana (34)	2004	Belgium	National	1–4	218	IOTF						7.0
Massa (35)	1998–1999	Belgium	Subnational (Limburg)	0–4	970	IOTF						7.0
Verbestel et al. (36)	2008–2009	Belgium	Subnational	0–2	191	WHO		16.9				
Multiple Indicator Cluster Survey (MICS) Bosnia and Herzegovina 2011–2012 Final Report, The Agency for Statistics Bosnia and Herzegovina, et al. (37)	2011–2012	Bosnia and Herzegovina	MICS	0–4	2,078	WHO						17.0
Baykova et al. (38)	2004	Bulgaria	National	1–4	315	WHO		19.1	19.8	5.3	8.8	
Savva et al. (39)	2004	Cyprus	National	2–4	744	WHO			6.4	10.8	18.0	
Savva (40)	2004	Cyprus	National	2–4	647	WHO			5.2	5.4	5.8	10.6
Vignerova et al. (41)	2001	Czech Republic	National	0–4	16,457	WHO	2.1	7.9	5.5	4.8	5.4	
Larsen et al. (42)	2001	Denmark	National	0–4	5,580	IOTF			Girls:12.3 boys: 10.8	Girls: 10.8 boys: 5.2		
Mattheissen et al. (43)	2005–2008	Denmark	National	4–5	-	IOTF					Girls: 21.9 boys: 17.6	
Morgen et al. (44)	1998–2010	Denmark	Subnational	0–1	156,635	WHO	12–13					

(*Continued*)

Table 3 [Continued]

TABLE 1 | Continued

Reference	Survey year	Country/ region	Source	Age (years)	Sample (*n*)	Cutoffs of BMI (kg/m²)	Prevalence of overweight, including obesity (%)					
							0 year	1 year	2 years	3 years	4 years	Total
Schönbeck et al. (61)	2009	Netherlands	National	2–4	4,382	IOTF			Girls: 9.0 boys: 8.7	Girls: 14.4 boys: 8.6	Girls: 18.9 boys: 10.2	
Fronken (10)	2007–2009	Netherlands	National	2	1,878	WHO			9.0			
Juliusson (62)	2003–2006	Norway	Subnational	2–4	2,231	IOTF			16.0	11.0	11.5	
Szponar et al. (63)	2000	Poland	National	1–4	175	WHO		28.6	14.3	12.2	8.7	
Rito (64)	2001	Portugal	Subnational	3–4	1,646	WHO				10.8	10.5	
Bingham (65)	2009	Portugal	Subnational	3–4	3,406	IOTF				17.4	22.9	
National Scientific and Applied Center for Preventive Medicine (NCPM) [Moldova] and ORC Macro (66)	2012	Republic of Moldova	MICS	0–4	1,724	WHO						4.9
Nanu (67)	2004	Romania	National	0–4	3,971	WHO/ UNICEF/ ICCIDD						8.0
Nanu (40)	2004	Romania	National	0–4	3,971	WHO	3.3	8.4	8.3	8.0	5.5	
Nazarova and Kuzmichev (68)	2012–2013	Russia	Subnational	3–4	1,242	WHO						Girls: 18.6 boys: 17.7
MICS (69)	2014	Serbia	MICS	0–4	2,270	WHO						13.9
Encuesta Nacional de Salud 2006 (70)	2006	Spain	National	0–4	2,701	WHO	16.8	12.8	18.4	17.1	17.2	
Serra-Majem et al. (71)	1998–2000	Spain	National	2–4	268	WHO			10.2	15.6	12.9	
Huus et al. (72)	1997–2002	Sweden	Subnational	0.5–4	4,242	IOTF			15.4			
Huss (40)	1997–2002	Sweden	Subnational	0–4	10,438	WHO	4.8	6.6	8.0	7.6	4.7	
Holmbäck et al. (73)	2002	Sweden	Subnational	4	90	IOTF					18.0	
Holmbäck (40)	2002	Sweden	Subnational	4	183	IOTF					21.0	
Enghardt et al. (74)	2003	Sweden	National	4	590	IOTF					18.7	
TLSS (75)	2012	Tajikistan	DHS	0–4	5,478	WHO						6.0
Hacettepe University Institute of Population Studies (76)	2013	Turkey	DHS	0–4	2,519	WHO						10.9
The State Committee of Statistics of Turkmenistan and UNICEF (77)	2015–2016	Turkmenistan	MCIS	0–4	3,785	WHO						5.9

(*Continued*)

Table 3 [Contiued]

TABLE 1 | **Continued**

Reference	Survey year	Country/ region	Source	Age (years)	Sample (*n*)	Cutoffs of BMI (kg/m²)	Prevalence of overweight, including obesity (%)					
							0 year	1 year	2 years	3 years	4 years	Total
Chollet et al. (45)	2007–2009	France	Subnational	3–4	9,558	IOTF				8.4		
Lioret et al. (46)	1998–1999	France	National	3–4	170	IOTF				16.5		
Lioret et al. (47)	2006–2007	France	National	3–4	92	IOTF				10.1		
Unité de surveillance et d'épidémiologie nutritionnelle (18)	2006–2007	France	National	3–4	191	IOTF				11.7	17.9	
Report of the Georgia National Nutrition Survey (GNNS) 2009 (49)	2009	Georgia	National	0–4	–	WHO						20.0
Multiple Indicator Cluster Survey: Georgia Final Report 2005, State Department of Statistics of Georgia (50)	2005	Georgia	MICS	0–4	1,812	WHO						Girls: 16.2 boys: 14.3
Kurth and Schaffrath (51)	2003–2006	Germany	National	0–4	4,667	WHO						3.5
Manios et al. (52)	2003–2004	Greece	Subnational	1–4	2,348	WHO		12.7	13.5	13.8	15.7	
McCarthy et al. (53)	2010–2012	Ireland	Subnational	2	1,189	IOTF						14.0
Whelton et al. (54)	2001–2002	Ireland	National	4–5	2,109	IOTF						Girls: 29.0 boys: 26.0
Whelton (40)	2007	Ireland	National	4–5	1,352	IOTF						27.5
Onyango et al. (55)	2005–2008	Italy	Subnational	0–4	2,977	WHO	2.8	7.3	5.7	10.9	10.2	
The Statistics Committee of the Ministry Economy of the Republic of Kazakhstan (56)	2015	Kazakhstan	MICS	0–4	5,510	WHO						9.3
2012 Kyrgyz Demographic and Health Survey: Key Findings, National Statistical Committee (Kyrgyz Republic) and Macro International (57)	2012	Kyrgystan	DHS	0–4	4,337	WHO						7.0
Zaborskis et al. (58)	1999–2000	Lithuania	Subnational	3–4	451	WHO				5.1	2.0	
Statistical Office of Montenegro (MONSTAT) and Strategic Marketing Research Agency (SMMRI) (59)	2013	Montenegro	MICS	0–4	1,420	WHO						22.3
Van den Hurk et al. (60)	2002–2004	Netherlands	National	4–5	1,781	IOTF					Girls: 16.2 boys: 12.3	
Kuipers et al. (27)	2008	Netherlands	National	2, 5		Dutch reference growth curves			8.4		13.2	

(*Continued*)

Table 3 [Continued]

TABLE 1 | **Continued**

Reference	Survey year	Country/ region	Source	Age (years)	Sample (*n*)	Cutoffs of BMI (kg/m²)	Prevalence of overweight, including obesity (%)					
							0 year	1 year	2 years	3 years	4 years	Total
Multiple Indicator Cluster Survey (MICS) Former Yugoslav Republic of Macedonia Final Report 2011, IPSOS Strategic Puls, et al. (78)	2011	the former Yugoslav of Macedonia	MICS	0–4	3,949	WHO						12.0
Stamatakis (79)	2002–2004	United Kingdom	Subnational	2–4	1,903	WHO			11.7	11.1	10.3	
Whelton et al. (54)	2003	United Kingdom	Subnational	4	104	IOTF					21.0	
Pearce et al. (80)	2000–2002	United Kingdom	National	3–4	12,354	IOTF				23.1		
Hirani and Stamatakis (25)	2003	United Kingdom	Subnational	2–4	4,986	UK BMI						Girls: 26.0 boys: 24.0
UNICEF and State Statistical Committee of the Republic of Uzbekistan (81)	2006	Uzbekistan	MICS	0–4	5,165	WHO						12.8

Reference 39 is work from other authors which was reanalyzed by Cattaneo et al. (40).

A further review published in 2019 analysed the data of thirty-two studies in order to estimate the prevalence of overweight and obesity among European children aged between 2-7 years from 2006 to 2016 (Garrido-Miguel et al., 2019).

Figure 14 [Source: Miguel et al., Nutrients, 2019] shows the prevalence of overweight (including obesity) and obesity among children aged 2-7 years for 27 European Countries from 2006 to 2016. For the definition of overweight and obesity, all the studies used the IOTF definition criteria. Overall, the pooled prevalence estimate of overweight/obesity was 17.9% and the pooled prevalence estimate of obesity was 5.3%. The prevalence of overweight and obesity is distributed heterogeneously across Europe, as indicated by the relevant difference among the different European Countries. Southern European Countries showed the highest prevalence of excess weight and obesity; indeed, the highest estimates have been observed in Italy (32.4%), Greece (29.6%) and Portugal (26.4%). Conversely, lower rates of obesity and overweight were observed in Estonia (8.3%), France (11.0%) and the Netherlands (13.4%) (Figure 15) [Source: Miguel et al., Nutrients, 2019].

Figure 14. Forest plot of the pooled prevalence means of overweight/obesity, and obesity based on the International Obesity Task Force (IOTF) cutoffs, in European children (aged 2–7 years) from 2006 to 2016 [Source: Miguel et al., Nutrients, 2019].

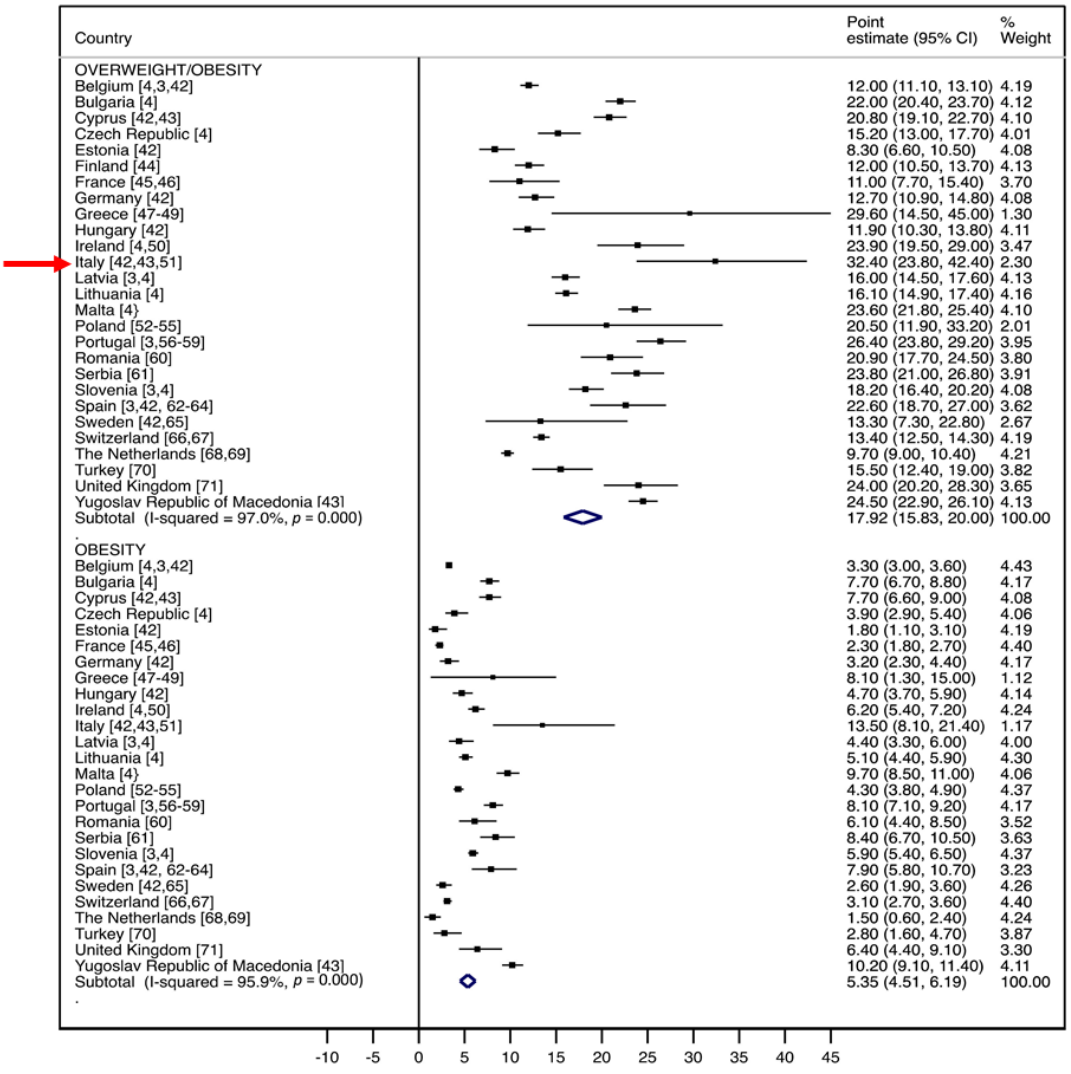
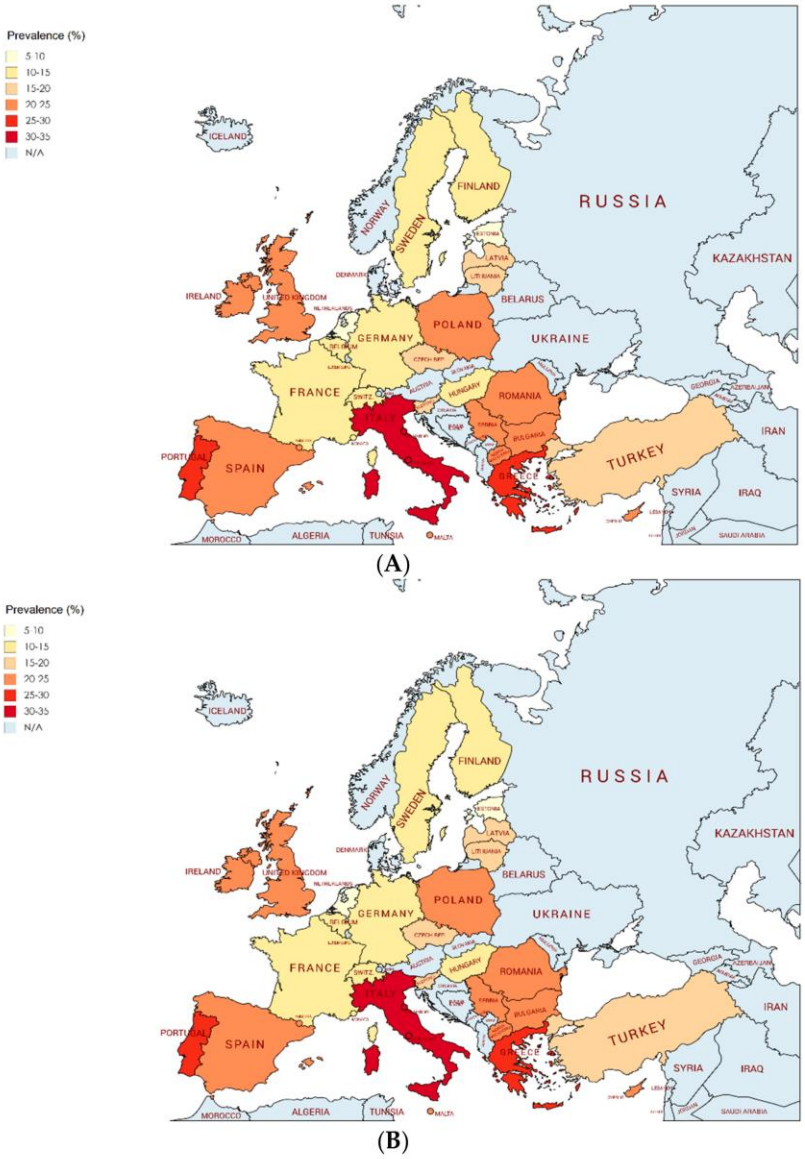


Figure 15. Spatial distribution of the prevalence of overweight/obesity (**A**) and obesity (**B**), based on the IOTF cut-offs, in European children (aged 2–7 years) from 2006 to 2016 [Source: Miguel et al., Nutrients, 2019].



Different limitations, such as the fact that not all the studies guarantee the representative samples of the population, the collected data on weight and height were poorer in some European Countries, differences in the samples, geography, and differences in the quality of the included studies, suggest to pay particular caution in the interpretation of these data.

Early infancy represents a critical period to address the prevention of obesity because the behaviours linked to energy balance, the psychological characteristics and the physiological processes develop at this age (Matusik et al., 2011) (Parsons et al., 1999) (Skouteris et al., 2011). A high prevalence of childhood weight excess, along with wrong eating habits, might be predictive of adult obesity. Therefore, additional measures to address the obesity epidemic in early life should be established for this age range (Garrido-Miguel et al., 2019), starting from the performance of epidemiological surveillance surveys. However, epidemiological surveillance surveys of overweight and obesity for this age range are not yet common in most of the WHO/Europe Member States. It is therefore necessary to strengthen existing surveillance, through timely, regular and quality surveys, to support and inform policy interventions (Jones et al., 2017).

1.5 COVID-19 pandemic emergency and impact on the epidemiological evolution of overweight in developmental age

On December 31 2019, the Health Commission of the Hubei province in China reported a series of patients with pneumonia of unknown etiological cause detected in the city of Wuhan (WHO l, 2020). On January 9, the China CDC (Chinese Centre for Disease Control and Prevention) identified a new coronavirus as etiological cause of this pathology (NewsX, 2020). Since then, the virus has spread globally with a number of growing confirmed cases. The coronavirus was named SARS-CoV-2 and the diseases was called COVID-19 (ICTV, 2020). On March 11 2020, WHO declared that the international cluster of infection caused by the new coronavirus SARS-CoV-2 could be considered a pandemic (WHO m, 2020).

To address the growing number of cases and deaths and in order to avoid the risk of health care system capacity being exceeded, the European Countries and other nations worldwide established social distancing measures, non-pharmacological actions aimed at controlling and slowing the spread of the virus. These large-scale interventions vary across nations but they include measures such as borders closures, closure of schools and of non-essential activities, quarantine and isolation (Flaxman et al., 2020).

As many Countries, including Italy, closed schools, home-based online distance learning has been used in order to ensure continuity of curriculum-based study and learning for all

and to keep students and school community engaged as well as a sense of belonging and connectedness, avoiding the risk of isolation and demotivation (MIUR, 2020).

Although such measure is necessary to mitigate infections and save lives, the prolonged closure of schools may have negative effects on the physical and mental health of children (Brazendale et al., 2017) (Brooks et al., 2020). Stay-At-Home Orders might increase the risk of overweight and obesity. On the one hand, school closure might cause food insecurity, in fact every year millions of children receive free meals at schools, thus increasing the differences in the risk of obesity. Moreover, when children do not go to school, for example on weekends and summer holidays, they are physically less active, they spend more time seated in front of a screen, they have irregular sleep and follow unhealthy diets. Schools have an essential role in the promotion and adoption of healthy behaviours in children (Brazendale et al., 2017). These negative effects on health will probably worsen. During the pandemic, children may have been confined in their homes, probably with energy-dense foods rich in fat and sugar. They may have spent longer hours in sedentary activities and in front of a screen. Data, indeed, show an increased use of online videogames. Screen time is associated to overweight/obesity during childhood, probably due to the association between sedentary activities and consumption of snacks. Although the increase in sedentary activities impacts all children, the highest impact is likely to be on children who live in urban settings and who do not have access to safe external spaces and where to keep social distancing (Rundle et al., 2020).

2 ETIOLOGY OF OVERWEIGHT AND OBESITY IN DEVELOPMENTAL AGE

2.1 Overweight and obesity: determinants of health in developmental age

Excessive fat accumulation, in particular obesity, is recognized as a complex and multifactorial disorder. To understand how overweight and obesity occur in developmental age, different and multiple factors should be investigated along with their relative interplays (Smith et al., 2020).

Different multi-level factors interact in a not completely clear manner, therefore, for the sake of simplicity, we will distinguish them between exogenous and endogenous factors. The former is linked to a chronically unbalanced energy intake relative to its expenditure; the latter depend on genetic, metabolic syndrome and endocrine causes (Aggarwal et al., 2018. Regardless of the causes, the effect is excessive fat accumulation in organism. Therefore, obesity is the result of a complex interplay between the environment and the body's predisposition to obesity (Güngör et al., 2014).

Obesity later in life generally results from the interplay of genetics and lifestyle. In some conditions, the genetic component plays a key role, however in other cases, despite genetics, obesity is largely associated with environmental factors. Indeed, gene–lifestyle interactions are relevant in obesity Moreover, we do not only inherit genes from our family, but also habits, such as eating behaviours and physical activity habits, that children learn to develop at an early age and that will become part of their behaviours (SIdP, 2018). The complexity of this problem, therefore, results from multi-level and interpersonal (family, peers, social networks), community (school, workplace, institutions), government (local, regional, national policies) factors, and the interactions with the same biological processes. In addition, behavioural risk factors, such as unhealthy eating habits and sedentary life, which are often considered the main determinant of overweight and obesity, are strongly linked to complex collective dynamics that involve large sectors: from family to school, from the health institutions to the social organizations and the mass media (Bonciani et al., 2015).

2.2 Endogenous factors

2.2.1 Genetic factors

Obesity is commonly considered to be a heritable trait (Brown C. L., 2015). Relevant evidence exists that suggests the heritability of weight. This evidence has been provided by studies conducted from the end of the eighties and during the nineties which consisted in experimentally-induced positive energy balance in pairs of monozygotic and heterozygotic twins (Bouchard & Tremblay, 1990) (Bouchard et al., 1990) (Bouchard et al., 1996), and by studies conducted on adopted children (Stunkard et al., 1986). To date, these studies, based on overfeeding, are no longer conducted. The current guidelines for good clinical practice, regarding trials carried out on human individuals, ensure the protection of the safety and well-being of trial subjects (article 3 of Law Decree n. 200 dated November 6, 2007). The data obtained from the studies on monozygotic and heterozygotic twins and on adoptees indicated a genetic contribution to the BMI ranging from 40 to 70%. Different pairs of twins show significant differences in the percentages these caloric surplus are deposited as body tissue, but the tendency towards a higher adiposity within each twin pair is highly similar, which indicates that genetic factors contribute to individual weight gain susceptibility, in a given family environment (Bouchard & Tremblay, 1990) (Bouchard et al., 1990) (Bouchard et al., 1996). The study conducted on adopted children showed a strong relationship between the BMI of the biological parents and the weight categories (‘thin’, ‘median weight’, ‘overweight’, and ‘obese’) of the adoptee; no relationship was found between the BMI of foster parents and the weight category of the adoptee. Furthermore, the relation between biologic parents and adoptees was not confined to the obesity weight class, but was present across the whole range of body fatness, from ‘very thin’ to ‘very fat’ (Stunkard et al., 1986). Therefore, different individuals have a different genetic propensity to deposit caloric surplus as body tissue in a specific family environment, which is defined ‘obesogenic’ environment. Although the role of the genes in determining overweight and obesity has now been established, it is reasonable to think that the increasing prevalence of obesity is not due to a recent change in the genetics of humanity. The current obesity epidemic has been driven by environmental factors, including in particular the limitless availability and composition of food and physical inactivity. The ability to accumulate fat during times of abundance would be an evolutionary advantage (Farooqi I., 2005).

More than 600 genes related to the development of childhood obesity have been described through the regulation of processes such as appetite, satiety, and energy expenditure (Morales Camacho et al., 2019). However, understanding the actual contribution of the single genes to obesity is complicated. Indeed, obesity is a very complex condition resulting from gene–environment interactions. However, as mentioned above, usually families do not inherit only the genetic material but also the environments and the habits and therefore correlations between specific genes and obesity are difficult to be established. However, there are forms of genetic obesity, where a specific genetic alteration determines the development of complex disease phenotypes, including obesity phenotype. These conditions are very rare and represent only a small part of all the obesity cases across the populations. Obesity in developmental age accounts for genetic or endocrine causes in no more than 3% of the cases (Ospedale Pediatrico Bambino Gesù, 2020). Nonetheless, they represent a useful study for the understaffing of molecular mechanisms that govern energy homeostasis.

2.2.2 Comorbidity

Genetic disorders linked to obesity are of monogenic and syndromic origin.

Monogenic obesity. Forms of monogenic obesity known to date are the result of germline mutations that disrupt the genes responsible for the protein synthesis that regulate systemic energy homeostasis. The physiological regulation of energy balance occurs through a complex network of hormonal signals that cooperate via cross-talk between peripheral (gastrointestinal tract, adipose tissue) and central (hypothalamus) tissues (Buonsanti G., 2019).

Melanocortin 4 receptor (MC4R) deficiency is the commonest monogenic form of severe childhood obesity, which causes hyperphagia and hyperinsulinemia. Further less frequent alterations involve the genes that regulate leptin, the leptin receptor gene (LEPR), pro-opiomelanocortin (POMC) and prohormone convertase1 (PC1).

The transcription of the leptin gene occurs in adipose tissue and produces highly conserved mRNA expressed in the uterus and it regulates weight on birth and pubertal development. Leptin has an immunostimulating action in ovulation, but its main activity consists in exerting its medium- and long-term anorexigenic functions. Patients

with congenital leptin deficiency have hyperphagia and obesity from early infancy. The administration of recombinant leptin is a valid treatment.

Mutations in the leptin receptor gene cause deficiency of the leptin-receptor; this brings about a phenotype similar to the leptin deficiency. Moreover, subjects with LEPR deficiency show a rapid increase in weight in their first months of life, with severe hyperphagia, severe obesity and hyperinsulinemia.

The proteolytic cleavage of proopiomelanocortin (POMC) produces both the Melanocyte Stimulating Hormone (MSH) and the Adrenocorticotropic Hormone (ACTH): MSH has a double role in controlling appetite and in the development of pigmentation of skin and hair, whereas ACTH stimulates the adrenal glands. Germline mutations in the POMC genes determine red pigmentation of hair and ACTH deficiency and marked hyperphagia from 4-5 months resulting in severe obesity.

Prohormone convertase 1 deficiency is one of the rarest forms of monogenic obesity. PC1 enzymes cleaves POMC and it is involved in the processing of many prohormones within the enteric cells and in the nerves that express PC1 in the gastrointestinal system, including insulin. This has been described in only two patients: a woman and a new-born. The disease is characterized by early-onset severe obesity (childhood), hypercortisolemia, hypoglycaemia (due to the altered processing of POMC and proinsulin) and increased circulating levels of some pro-hormones. Both patients had disorders of intestinal absorption of the small intestine (Farooqi I. S., 2005).

Syndromic obesity. Forms of syndromic obesity are disorders where obesity is a clinical characteristic, often associated with mental retardation, dysmorphic features and organ-specific developmental abnormalities. Among them is Trisomy 21, a syndrome where obesity is associated with intellectual disability, physical anomalies, structural disorders, autoimmune diseases, hearing and respiratory problems.

Prader-Willi syndrome is a disease characterized by a disfunction in the hypothalamus and pituitary gland associated with severe hypotonia during infancy and in the first two years of life and to hyperphagia, which increases the risk of pathological obesity during childhood and adulthood, along with learning disabilities, behavioural and psychiatric problems.

The majority of patients affected by Albright hereditary osteodystrophy have a wide range of clinical manifestations, including short stature, rounded face, subcutaneous ossifications and characteristic shortening and widening of long bones in the hands and feet, and obesity; intellectual deficiency is less frequently described.

Cohen syndrome is characterized by microcephaly, characteristic facial features, hypotonia, non-progressive intellectual disability, myopia retinal dystrophy, neutropenia and truncal obesity.

Bardet-Biedl syndrome can affect multiple organ systems, it is mainly by obesity, polydactyly, pigmentary retinopathy, hypogonadism, and renal abnormalities.

Alström syndrome is a multisystemic disorder characterized by vision alterations, hearing loss, obesity insulin resistance and hyperinsulinemia, diabetes mellitus, heart disease (dilated cardiomyopathy), renal and hepatic abnormalities.

We also mention WAGR syndrome, whose acronym stands for its main features, Wilms's tumour, Aniridia, Genitourinary abnormalities, and mental Retardation (Brown et al., 2015) (Orphanet, 2020).

Endocrine disorders: among the causes of endogenous obesity are the most common endocrine disorders, whose treatment generally resolves obesity. Children with endocrine disorders account for only a very small percentage (Crocker et., 2011).

Hypothyroidism is associated with modest weight gain (BMI increase in children of only 1–2 kg/m^2). Hypothyroidism leads to increased permeability of capillary walls, which creates extravascular leakage and retention of water, decreases in resting energy expenditure and diminution of linear growth.

Growth hormone deficiency (Growth Factor, GF) is also associated with childhood obesity. In addition to its ability to stimulate protein synthesis and increase fat free mass, GF also stimulates adipocyte lipolysis. GF deficiency thus leads to increased fat mass, especially in a central distribution, along with decreased lean mass. It is also characterized by short stature with height generally lower than -3 standard deviations.

Cushing syndrome or hypercortisolism in children is associated with growth deficiency, visceral obesity, hirsutism, increased appetite and hypertension. The excess

glucocorticoid production leads to increased gluconeogenesis, insulin resistance, inhibition of lipolysis and stimulation of lipogenesis.

Childhood obesity is also associated with persistent hyperinsulinemia caused by a series of mutations in different genes resulting in elevated insulin production by the Pancreatic β-cells or by insulinoma, a tumour in the pancreas of β-cells that produce an excess amount of insulin. The excessive production of insulin results in increased food consumption to keep blood sugar level balanced leading to obesity.

Finally, among the endocrine disorders associated with childhood obesity there are also structural disorders of the hypothalamus. Hypothalamic obesity may arise after injury to, or congenital malformation of, the hypothalamus. The hypothalamus is involved in appetite regulation and energy expenditure. Specifically, the ventromedial hypothalamic nucleus (VMH), arcuate nucleus (ARC), paraventricular nucleus dorsomedial nucleus (DMH), and the lateral hypothalamic area (LHA) are all involved in control of appetite and energy expenditure, through the production of several neuropeptides involved in appetite regulation and energy expenditure. Disorders or malformations may impact the transmission of the signals related to food intake and appetite regulation. Patients affected by hypothalamic obesity are generally lethargic with a reduced energy expenditure. They can also have endocrinopathies, including the GH deficiency, hyperthyroidism, early or delayed puberty and diabetes insipidus (Crocker et., 2011) (Aggarwal et al., 2018).

2.2.3 Epigenetics of childhood obesity

As already mentioned, over the last decades there has been an increase in chronic and degenerative conditions worldwide, including obesity, particularly among children. Such scenario requires the urgent definition of the complex interplays between the new data regarding the environment along with the genomic elements preserved across million years of evolution, and the effects that these interplays seem to have on the human phenotype transformations. Neither the traditional medical genetics nor the considerations regarding the changed dietary and lifestyle behaviours, nor the most authoritative theories which have been implemented to explain the increase in specific conditions suffice to account for these complex interplays. The phase of embryofoetal ontogenesis appears to be particularly susceptible to environmental information and particularly to maternal stress signals, to eating habits and polluting

agents, because cells are very plastic in their differentiation potential: indeed, the different epigenetic marks define individual variations and phenotypic outcomes. Foetal embryonic cells have the capability and necessity to define their epigenetic asset in response to the information deriving from the mother and, through her, from the external world. Epigenetics is defined as the study of heritable changes of gene expression, not involving changes in a DNA sequence (Fanos V., 2017). One of the main mechanisms responsible for epigenetics is DNA methylation, consisting in the inhibition/activation of certain genes, thus activating or repressing their functions and the histone acetylation. DNA methylation is a chemical DNA modification characterized by the biochemical addition of a methyl group (-CH3) to nucleobases. The intrauterine environment plays a key role in foetal development and in the long-term foetal epigenetic programming that can be transmitted after birth until adults. Epigenetic changes usually occur during prenatal development or in first postnatal period. Diets can highly influence DNA methylation. Research evidence suggests that maternal nutrition is a determinant factor in epigenetic changes. Some foods that are rich in folate, methionine, choline, vitamin B-12 and pyridoxal phosphate are donors (or cofactors) of the biological factors that produce methyl. Since these are micronutrients, the diet has an evident key role in the expression of some genes, in particular those associated with the main metabolic regulations, such as those of energy balance or body composition.

Moreover, even the presence of obesity or of metabolic alterations may result in childhood obesity. An example of the correlation diet-epigenetics is the glycaemic status of the mother during pregnancy and the weight status of the child. Exposure to prolonged hyperglycaemia during the intrauterine life (mothers with insulin obesity or diabetes) may impact the weight status of offspring at birth or in adult life. Hyperglycaemia impacts on the birth weight, leading to an excessive growth and weight, but, in addition to the effects on body weight, it can increase the likelihood of insulin-resistance and obesity later in adulthood. In fact, the nutritional signals that reach the developing hypothalamic systems during pregnancy might influence the susceptibility of these neurons in the response to similar signals also after birth. Not only maternal nutrition during gestation but also early nutrition in infancy may influence later child health outcomes including obesity (Di Vico et al., 2014) (Crocker et al., 2011) (Thaker V., 2018).

2.3 Exogeneous factors

Obesity that results from chronic positive energy balance, influenced by multiple factors, is only in part due to genetics, and it is mainly the result of social, behavioural and environmental factors. Today, children live in increasingly obesogenic environments, where gaining overweight is extremely easy, whereas keeping fit requires constant and consistent efforts (Fisberg et al., 2016), and environment plays a key role. The term obesogenic refers to the social, cultural, economic and infrastructural influences, opportunities or life conditions that influence the possibility of an individual to have a healthy lifestyle and that favour weight gain instead of weight reduction, thus leading to obesity. An obesogenic environment consists of all those factors that have been shown to be correlated to the possible causes of obesity, through intricate and complex interplays. Individual unhealthy or obesogenic behaviours are associated with the surrounding macro-environments, including family, school and neighbourhood; which, in turn, are influenced by macrosystems such food industry and government policies (Bonciani et al., 2015).

2.3.1 Individual behaviours

Individual behavioural risk factors, including unhealthy eating habits (consumption of food with high energy density, processed food, sugar-sweetened beverage, snacks, skipped meals, large portion sizes and consumption of fruit and vegetables) as well as physical inactivity and sedentariness, which are often considered the main determinants of overweight and obesity, are strictly related to complex collective dynamics that involve large sectors of society: from family to school, from health institutions to social organizations and the mass media (Aggarwal et al., 2018) (Bonciani et al., 2015).

Studies show that a healthy child nutrition, among other factors, is fundamental for an optimal growth and development. To establish and maintain healthy eating habits in this life phase is important because the habits learned during childhood are likely to last also in adulthood. The Avon Study (The Avon Longitudinal Study of Parents and Children, ALSPAC) (Emmett et al., 2015), a longitudinal study conducted on children and their parents that investigated diet, growth and development of obesity during childhood, highlighted that during pre-school years the most important change in nutrition occurs

and the nutrition-related behaviours learned at this age appeared as influencing diet and development of lifelong eating patterns. Behavioural changes were noticed with an increase in the intake of free sugars, 12% rising to 16% of energy, percentages that are higher than the maximum 10% of energy recommended. The increased consumption of sugar is probably associated with the increased consumption of foods high in energy density, such as sweets, sugar-frosted breakfast cereal, puddings and ice-cream. Sugary drinks also have an impact; although milk is the most consumed drink among pre-school children, sweetened beverages come second, which include both soft drinks and fruit juice with added sugar. The consumption of fruit and vegetables is very low: more than 10% of children had not eaten any vegetables, and more than 15% had not eaten any fruit during the recording period at each age. Although a diminution in the consumption of saturated fat was reported, its intake was still above the recommendation of 10% of energy. These results suggest that preschool could be a key time to provide a healthy eating environment for children and to educate parents about a healthy lifestyle (Emmett et al., 2015).

Physical inactivity and sedentary behaviour are strictly related to childhood obesity resulting in a dramatic reduction in energy expenditure. Pre-school children should be physically active for at least 180 minutes per day. In a European child sample, only 10.1% of pre-school children reached the levels of daily physical activity on weekdays and a lower percentage (4.3%) on the weekends (De Craemer et al., 2018). Preschool children spend most of their time in sedentary activities, which seems to increase as they grow older. The factor that mostly contributes to sedentary behaviours is the screen time, that is the time spent with screen media. Although TV still seems to be the most common device among children until six years of age, computer/videogames, tablets and smartphones have become largely available (Miguel-Berges et al., 2019). Some prospective studies have reported that the longer time spent in sedentary activities, in particular watching TV or playing videogames, contributes to a higher risk of developing obesity. To prevent the development of obesity, efforts should be implemented to reduce sedentary behaviour and increase physical activity (Aggarwal et al., 2018).

2.3.2 Environmental influences: micro-environments

From the micro-environmental viewpoint, family, school and neighbourhoods play an important role (Aggarwal et al., 2018). We have already highlighted that we don't only inherit the genetics from our family but also habits that have an impact on the onset/prevalence of obesity. Indeed, family is one of the most important social setting where children learn and adopt behaviours associated with food consumption, sedentariness and physical activity. Parents are important agents of socialization who play the role of health promoters, role models and educators in the life of their children. In general, food consumption may be considered an experience of socialization through which, within the family environment, children learn skills, role models values and the necessary motivation for a responsible functioning. This process involves the parents who, through their behaviours, transmit rules, knowledge, attitudes and behaviours. Studies reported a series of parental behaviours which are strictly related to the eating habits of children. For instance, the availability (in quantitative and qualitative terms) of food at home and the control over the accessibility of the food might increase its consumption. Furthermore, using food as a reward is associated with unhealthy eating habits in children, probably because the foods used as a reward are often unhealthy foods. In addition, parents are role models for children, who mimic the food parenting practices. Role modelling might be used as a parental strategy to promote the consumption of specific foods (Yee et al., 2017). The same principle applies to sedentary behaviours and physical activity. In the early years of life, parents play a critical role in developing and shaping their children's physical activity and sedentary behaviours through role modelling and creating a healthy home environment that increases physical activity and reduces sedentariness.

Parental behaviours are associated with levels of physical activity and sedentariness in children. Research evidence suggests a strong association with parents' encouragement and support of children's physical activity and with the level of parents' physical activity, and a moderate association with parental self-efficacy and with the reduced parents' own screen time (Xu et al., 2015).

School environment is an important setting where behavioural changes associated with obesity may occur. Children spend most of their time at school where the generally consume 1/2 meals; schools offer physical activity programmes, such as Pedibus

(Pedibus-Italia.it, 2011), exposing children to physical activity and, in some cases, also to opportunities of movement before and after school, like cycling or walking to school; many schools provide programmes of health education; school allows to reach a high number of children in relatively short time; schools are also a powerful social network made of schoolmates, teachers and moreover, through children, parents and families can also be reached. Therefore, schools are the ideal setting where to implement prevention strategies and, once the programme has been accepted by a school, it is likely to be maintained for a longer time (Verrotti et al., 2014). Conversely, school might become obesogenic if no emphasis is put on nutrition and physical activity. The lack of playing fields and sports structures, unhealthy school lunches and the availability of snacks and unhealthy beverages in schools increase the risk of obesity (Aggarwal et al., 2018).

2.3.3 Environmental influences: macro-environments

From the macro-environmental point of view, the food industry and government policies should be taken into considerations. The production of foods high in fats, sugar and/or salt and the use of complex marketing practices introduce a wide choice of highly-processed products on the market, which are convenient and affordable (Aggarwal et al., 2018). Childhood obesity is the clearest demonstration of the strength of environmental influences: children are far more receptive to commercial messages than recommendations form their teachers or health care providers (Branca et al., 2007).

Governments are responsible for promoting safe environments and physical activity with playing fields, bike lanes and pedestrian areas. Strong government's childhood obesity strategies are also necessary to limit the availability of unhealthy foods, such as the introduction of a sugar tax on sugary beverages (Food Navigator-latam, 2019), a clear food labelling and price control for fruit and vegetables (Aggarwal et al., 2018). Moreover, policy makers should take into consideration that obesity is also the results of social difference and, at the same time, it is the cause of obesity. Socially vulnerable groups are more affected by obesity because they live in neighbourhoods that do not facilitate active transport and leisure, they have less access to education and information about lifestyles and health, and cheaper food options are nutrient poor and energy dense providers (Branca et al., 2007).

3. PREVENTION IN DEVELOPMENTAL AGE

Prevention of childhood obesity is a public health priority at global level. Moreover, since obesity in early childhood is likely to persist in adulthood, overweight and obesity should be acknowledged as soon as possible to treat excess weight and the related complications and to implement prevention strategies on the general population and on high-risk subjects (SIO & ADI, 2017). Furthermore, we should underline that obesity is more difficult to treat in adulthood than in developmental age as it requires changes in lifestyle (Verrotti et al., 2014).

The monitoring of the interventions aimed at preventing childhood obesity, performed by the WHO European region (Europe WHO, 2007), has reported that in Europe programmes to fight obesity have finally been implemented. Although the majority of the Countries acknowledge the priority of preventing childhood obesity and although some programs have already been implemented, none has yet been proved to be efficacious (ISS d, 2020). Indeed, only few intervention programmes demonstrated long-term effects or have been implemented on a large scale so as to have a significant impact on public health. To formulate theories that allow to explain the development of childhood overweight and obesity, and therefore to understand where and how to intervene for the implementation of a long-term prevention, it is necessary to consider the interaction of the different genetic, biological, psychological, behavioural, interpersonal and environmental factors (Smith et al., 2020). Indeed, childhood obesity is an incredibly complex condition. The adoption and implementation of actions that involve the different fields remains a challenge and to date no Country has been able to control the obesity epidemic. The majority of the strategies adopted should take into consideration the need to involve different stakeholders (ISS d, 2020). Indeed, the strategies for the prevention and management of overweight and obesity in children should be implemented at multiple levels, at individual, community and political level, also working through target groups (such as children, adolescents, pregnant women and high-risk social groups, like ethnic minority groups or low-income groups), working on the environments (family, school and health and commercial sectors) and on the approaches (education, community development, the use of media and the environmental, political and infrastructural change) (Branca et al., 2007).

Genetic factors may have a significant impact on the individual predisposition to overweight/obesity; however, the increased prevalence of overweight and obesity, occurred in prenatal and post-natal age, play an important role in the alteration between energy intake and consumption (Agenzia di Sanità Pubblica Regione Lazio, 2007).

For the sake of simplicity, the interventions aimed at preventing childhood obesity have been classified by age and by the target setting of the intervention.

3.1 Interventions before and after pregnancy

Many of the known risk factors, such as those related to diet, physical activity, sedentariness, etc, can occur in distinct developmental stages, offering specific opportunities of intervention. Age-specific risk factors have been identified already in the pre-natal period. While obesity in both parents may increase the risk in the child, the pre-gestational BMI of the mother and weight gain during pregnancy have been directly associated with obesity in early childhood and childhood (Brown et al., 2015). Analyses of data dating back to the end of the 20th century showed that maternal obesity in early pregnancy more than doubles the risk of obesity in pre-schoolers (Whitaker R., 2004). A recent metanalysis (Voerman et al., 2019) demonstrated that maternal overweight and obesity are positively and consistently associated with the BMI of their offspring. A higher maternal pre-pregnancy BMI is associated with a higher risk of overweight/obesity and with a higher BMI across childhood. Moreover, not only are maternal overweight and obesity associated with a higher risk of developing childhood overweight/obesity, but the risk is progressively higher among children with mothers having grade I, II and III obesity, respectively. In addition to pre-pregnancy BMI, higher maternal pre-pregnancy BMI and gestational weight gain were associated with an increased risk of childhood obesity. Findings showed that an excessive gestational weight gain was related to a 39%–72% higher risk of overweight throughout childhood. On a population level, 11% to 19% of childhood overweight/obesity could be attributed to excessive gestational weight gain. Maternal obesity does not only affect pregnancy outcomes, but may also have persistent long-term effects on offspring (Voerman et al., 2019).

Women health status around the conception period, once a neglected topic, is now a focus of increasing interest. Indeed, preconception health is a key determinant of pregnancy success and next generation health. Unhealthy eating habits and obesity are rife among

women in reproductive age. Heightened awareness of preconception health, particularly regarding diet and nutrition, is necessary. To date, only few dietary intervention actions have been taken before conception. To make a significant impact on preconception health, we need a dual strategy that improves nutritional status across the lifecourse and particularly during reproductive ages, ideally during the sensitive period of adolescence when most women will not be planning pregnancy, while targeting all women who are thinking of conceiving, providing the opportunity of acting earlier to mitigate potential negative effects for the mother and the offspring (Stephenson et al., 2018).

Maintaining gestational weight gain within the guidelines is especially important for women who are overweight or obese at the time of conception and should be an important component of prenatal counselling (Brown et al., 2015). Moreover, both over- and under-nutrition at this stage are thought to affect foetal programming and predispose to future obesity and metabolic disorders (Savona-Ventura& Savona-Ventura 2015). This suggests that starting a pregnancy with a BMI in the normal range and avoiding an excessive weight gain might help reduce the risk of obesity in new-borns. Therefore, pregnancy can be an optimum moment to inform women and, where necessary, to try to change their eating and physical activity habits to avoid an excessive weight gain. Indeed, the interventions aimed at weight control in pregnancy focus mainly on physical activity and eating behaviours. A Cochrane review evaluated the effectiveness of diet or exercise, or both, interventions for preventing excessive weight gain during pregnancy (Muktabhant et al., 2015). Research evidence shows that interventions focused on diet or physical exercise, or both, can preventing excessive weight gain during pregnancy (on average by 20% overall). Dietary interventions included different types of diets such as hypocaloric diets specific for subjects with diabetes, healthy or low-carbohydrate dietary patterns. Regular physical activity is a fundamental part of healthy lifestyle and most guidelines support moderate-intensity physical activity during pregnancy. Moreover, there are further advantages for the health of women and new-borns health, which are applicable to the majority of healthy pregnant woman, regardless of their gestational weight. For example, the women in the intervention groups had a significantly higher likelihood of experiencing a low weight gain compared to the control group, of introducing higher amount of dietary fibre and a lower energy intake, and of reaching and maintaining higher levels pf physical exercise. With regard to excessive weight in children at birth

(macrosomia: birth weight>4 Kg), we found no statically significant difference between intervention and control groups, although the effect estimate suggested a small difference in favour of the intervention group. For example, the supervised exercise-only intervention group approached statistical significance (P = 0.07). The review also included Italian interventions aimed at reducing gestational weigh gain. Their findings support customized dietary interventions during pregnancy (Di Carlo et al., 2014) and dietary interventions combined with physical activity (Petrella et al., 2014). However, most included studies were carried out in developed Countries and it is not clear whether these results are widely applicable to lower income settings (Muktabhant et al., 2015).

The aim of these interventions should be not only the reduction of pre-conception weight, but also the introduction of healthy lifestyle patterns, suitable for gestational weight control, which should become part of everyday life. Parents, in particular the mothers, of high-risk children should be encouraged to adopt healthy dietary patterns for the entire family, starting from pregnancy and after the birth of offspring. Indeed, the parental control of dietary habits is the best solution to influence children's behaviours (Savona-Ventura& Savona-Ventura 2015).

3.2 Interventions in early childhood

Research shows that the ages between 0 and 5 years is a critical period in the development of overweight and obesity and that childhood overweight and obesity is highly predictive of adult obesity. Therefore, early prevention efforts are a clear priority (Hemmingsson E., 2018). There are additional risk factors that might correlate with future childhood overweight/obesity, in addition to those detected before and after pregnancy, such as gestational BMI and excessive weight gain, which become evident in infancy, such high birth weight and rapid infant weight gain (Brown et al., 2015).

Effective interventions aimed at these modifiable risk factors are fundamental to address childhood obesity.

3.2.1 Interventions on children from 0 to 24 months

The first 1,000 days of a child's life, from conception to 24 months, represent a crucial period for the development and prevention of childhood obesity. During pregnancy and

the first 2 years, metabolic, immunologic, sensorial, behavioural, developmental and growth parameters are shaped and which will persist for the rest of a person's life (National Academies of Sciences, 2016). This is considered the most critical period for the induction of those pathophysiological derangements eventually leading up to obesity. Any intervention whose aim is to reduce the risk of such imprinting to occur should therefore be focused on this specific early-life period (Mameli et al., 2016). A review of the modifiable childhood obesity risks that occur in the first 1,000 days supports the strong existing evidence for the aforementioned modifiable obesity risk factors during gestation and early infancy, such as the association between high birth weight and higher weight-for-length (Woo Baidal et al., 2016). Many studies have attempted to determine optimal dietary intake during infancy, but the results are conflicting (Brown et al., 2015). Amongst the perinatal factors, particular attention has been given to breastfeeding that represents the most protective form of nutrition against the development of obesity and it is strongly recommended by WHO (WHO n, 2019). Breastfed infants are less likely to become overweight or obese. However, findings were inconsistent, with other studies finding null results (Marseglia et al., 2015). A review carried out in 2016 reported that targeted interventions to promote breastfeeding, included in the survey, resulted in significantly improved breastfeeding rates, however there were no differences in child BMI compared with the control group (Blake-Lamb et al., 2016).

A Cochrane review of 2019 evaluated the effectiveness of interventions based on diet and physical activity, or both, to prevent childhood obesity (Brown et al., 2019). The review analysed the included interventions with subgroup analysis by three different groups: 0-5, 6-12, 13-18 years. Given the heterogeneity across all three age groups, children could not be considered as one sample only. Effective interventions on children of 3-4 years are less likely to be effective on adolescents and *vice versa*. Although childhood obesity trends are increasing in low- and middle-income Countries, most trials were conducted in high-income Countries (91%), a small percentage in upper-middle-income Countries (8%) and only one in lower-middle income Countries (1%) (Figure 16) [Source: Brown et al. Cochrane Database of Systematic Reviews, 2019], underlining the necessity of further interventions across these Countries.

This systematic review also included interventions that promote breastfeeding and also in this case the interventions, although breastfeeding rates increased, did not have

significant effects on the children's BMI compared with the controls. The only exception is an Australian study, based on early home visits from a specially trained research nurse to provide guidance on supporting breastfeeding but also on the later introduction of solid foods, tummy time and active play, family physical activity and nutrition on the basis of the national guidelines. This intervention proved to be effective in reducing BMI in the first 2 years (Wen et al., 2012). It has been suggested that it is the infant's degree of self-regulation while breastfeeding rather than the composition of breastmilk which may be protective (Brown et al., 2015). Formula feeding might increase the risk of overnutrition among infants because they have an increased control over the feeding of the infant compared with breastfed infants who display a greater influence over their intake (National Academies of Sciences, 2016).

Complementary feeding and premature complementary feeding, which usually occur between 6 and 24months, represents another important change in the child's life and both the introduction time and the selection of foods might increase the likelihood for obesity (Brown et al., 2015). The review of 2016 reported, among the effective interventions, only a small number of interventions focused on parental dietary and physical activity behaviours. They have a multi-level approach, based on dietary theories or on the communication of behavioural pattern changes that can continue across the life course (Blake-Lamb et al., 2016).

The interventions to reduce obesity risks in these early years are focused on the behavioural aspect strictly related to the family environment. Indeed, family plays an important part at this stage. Children learn dietary behaviours from their experiences, but external influences have a relevant effect. Parents influence the dietary behaviours of their children as they represent role models through their dietary practices, their approaches to and opinions on food and the dietary practices that they implement with their children. The interventions aimed at a so-called 'responsive feeding' that encourages the infant to eat autonomously based on their hunger and satiation clues, had the best results (Heller & Mobley, 2019). As children grow and become more independent, familial influences on eating behaviours may diminish, and other factors such as those of peers and other role models (e.g., teachers) may become more influential (De Cosmi et al., 2017).

The systematic Cochrane review of 2019 (Brown et al., 2019) has found moderate-certainty evidence that diet combined with physical activity interventions reduced BMI. Neither diet (moderate-certainty evidence) nor physical activity interventions alone (high-certainty evidence) compared with control reduced in children aged 0-5 years. However, dietary and physical activity behaviours adopted during childhood are likely to be life-long. The potential cumulative effect of small, though sustainable, changes for a heathier diet and a more physically active lifestyle might bring about long-term effects to reach and maintain normal weight in individuals, communities and populations (Brown et al., 2019). We hope that the early involvement of children in sports activity can be translated into a regular physical activity pattern to prevent adiposity. This intervention on lifestyle modification should be constantly promoted by health promoters, starting from health care services, who should adopt a pro-active policy for the early identification of adiposity (Savona-Ventura & Savona-Ventura, 2015). We should also highlight that these interventions do not seem to cause any disorder or adverse event, including eating disorders or excessive concern for weight, and there is no evidence that childhood obesity interventions increase inequalities (Brown et al., 2019).

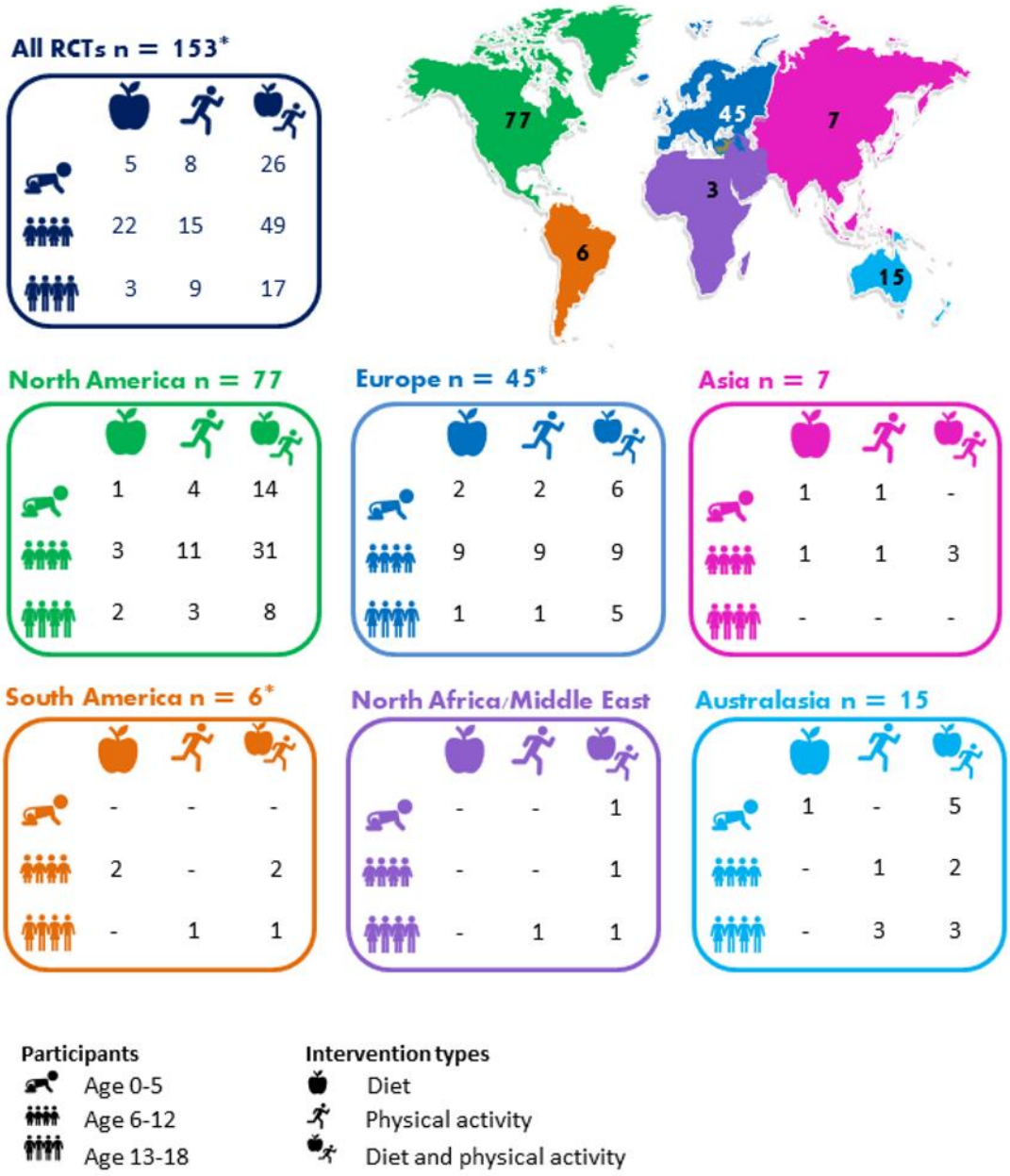


Figure 16. Distribution of studies (RCTs, Randomized Controlled Trials) by location, age of children and type of intervention. [Source: Brown et al. Cochrane Database of Systematic Reviews, 2019].

3.2.2 Interventions in pre-school age

Most of the interventions included in the Cochrane review are targeted to school age children (from 6 years), highlighting the current scenario where interventions for early infancy, which is the most critical time for obesity prevention, are lacking (Figure 16) [Source: Brown et al. Cochrane Database of Systematic Reviews, 2019]. However, over the past years, an increasing number of interventions focused on preschool children have

been promoted (3-5 years). Pre-school age represent a critical time to address obesity, first because the dietary and physical activity patterns are shaped during this age, second because, during this phase, parents have a higher control over the child's environment compared with school age and adolescence. Indeed, the existing childhood obesity interventions in pre-school children are generally multi-component, family-based, behavioural interventions with a focus on diet and physical activity (Kuhl et al., 2012).

3.3 Settings for the intervention strategies

Intervention strategies for the prevention and management of overweight/obesity in children occur in various service contexts and within and in collaboration with several services provider systems. This is due in large part to the risk factors inherent to familial, school, and community/societal levels. There is some correspondence between the sample being targeted and the context. Community and school-based interventions are far more likely to be universal, where the sample does not consider weight status, or selective, where the target sample is overweight or at-risk for obesity; e.g., ethnic minority, low income, compared to the indicated (majority of target sample is in the obese range) models more commonly found in primary and specialty healthcare systems. Therefore, also the specific objectives and the intervention strategies are related to the context, to the sample and to the approach. The intervention strategies for the prevention and management of childhood overweight/obesity can be distinguished into community, family and school-based interventions (Smith et al., 2020). This distinction is often only theoretical because there are multi-component interventions which are delivered and implemented in multiple settings.

3.3.1 Community-based interventions

Community interventions are defined as incorporating policies and strategies aimed at reducing the population risk of obesity through legislation, modifications to the built environment, provision of accessible resources, and changes in economic/pricing/food subsidies. Community interventions can involve the use of media, businesses (e.g., restaurants offering healthy menus), community health services, community gardens, community or recreational centres, city planning, and the local governments. Interventions delivered in community settings have the ability to provide high degrees of access and exposure to strategies and programs to racially diverse, low-income children,

who are at the highest risk of overweight/obesity. Interventions delivered in community settings can be effective, but the impact could be diminished through the lower likelihood of intervention completion due to living in lower socioeconomic circumstances (Smith et al., 2020).

A recent review conducted in 2018 reported that, compared to school- or family-based interventions, there is a paucity of community-based studies (Bleich et al., 2018). Among the reviewed studies, only seven community-based interventions were reported. Only a randomized clinical trial was found where a public leisure centre was established as the seat for the intervention that was focused on policies, programmes and the leisure facilities, including also group workshops and home visits. Such intervention resulted to be ineffective in the reduction of child's BMI. The remaining six interventions, with a quasi-experimental design, had inconsistent, positive, negative or null results. The effective interventions were multi-setting (community, family, school) and brought about improvements in the school lunches (e.g., fresh fruit served every day), school and after school health and nutrition education programmes and physical activity, involvement of parents (e.g., newsletters), and safe walking and biking routes to school. The effective interventions were based on the combination of diet and physical activities, they were also multi-sector interventions that involved local government institutions, capacity building, school and family. An intervention, designed to improve the levels of physical activity and to incorporate stress reduction strategies through the collaboration between school, local governments and stakeholders, yielded a negative effect (higher waist circumference) (Bleich et al., 2018). The paucity of community-based interventions may be due to their multiple challenges and implications, as they require the active contribution of the local governments and of other institutions, private companies, associations, and the community itself. The combination of a community and clinical intervention could hold hope, especially for at-risk groups (ethnic minorities living in a low-income community). These interventions using a community-based participatory approach and a strong experimental design could achieve the long-term goal of reducing both child BMI, the prevalence of overweight/obesity in childhood (Smith et al., 2020).

3.3.2 School-based interventions

School-based interventions take place during school hours or after-school hours for children in kindergarten through high school, and being focused exclusively in the school or delivered primarily in the school setting with secondary settings of family/home, primary care, or community. Considering that the majority of children spend a significant amount of their day in school, many preventive interventions have leveraged schools as a setting to improve the obesogenic environment by promoting more physical activity in physical education classes and recess, improving school playgrounds and nutritional options in school cafeterias, and providing healthy lifestyle education in classes or other school policies. Multi-component interventions targeting two or more health behaviours (i.e., physical activity, dietary outcomes, sedentary behaviour) are more effective when compared to single-component interventions (Smith et al., 2020). In the above-mentioned review of 2018, the majority of the interventions included were school-based interventions. Effective interventions (BMI reduction) included secondary settings of family/home, not only involving the family but also making a complementary environment for the implementation of the interventions (e.g., through home physical activity sessions), and combined diet and physical activity, including elements aimed at reinforcing or increasing the duration of physical exercises, to implement nutrition education programmes and to improve self-regulation and self-efficacy of the participants. Moreover, the interventions that had inconsistent results were based on the combination of diet and physical activity with common characteristics of other interventions (e.g., increased physical activity duration) and, despite the family engagement, the interventions took place exclusively in the school setting (Bleich et al., 2018). Although increasing consumption of fruit, vegetable and water is important, health behaviour modifications are not sufficient for significant long-term obesity management. Partnerships between schools and community-based interventions which also engage parents are fundamental (Smith et al., 2020). A small number of school-based interventions included in the 2018 review were conducted within pre-school settings. These interventions yielded different, both positive and null, results All interventions included the household as a complementary setting; some interventions focused on physical activity alone, others combined diet and physical activity. Only one intervention, which yielded positive results, included a multi-component approach with changes in

policies, environmental changes and educational programmes for children, teachers and parents (Bleich et al., 2018). In sum, the preschool and school contexts hold promise for improving weight-related behaviours and adiposity outcomes; however, parents should be engaged in the process of supporting and reinforcing their children's health behaviours for these programs to be maximally effective (Smith et al., 2020).

3.3.3 Family-based interventions

The home environment has long been considered one of the most powerful influences on children's healthy behaviours. Playing an integral role in physical activity, diet, screen time and sleep, parents can exhibit positive parenting practices (e.g., role modelling) and provide a healthy, supportive environment (e.g., provisions of fresh fruits and vegetables), thereby shaping their children's lifelong habits and preventing the onset of childhood obesity. Family-based interventions are defined as involving either passive or active parental involvement, often with parents viewed as the primary or sole agents of change. Active parental involvement entails repeated engagement, such as participation in workshops, counselling, or educational sessions; passive involvement does not integrally involve the parent or guardian (e.g., brochures, newsletters). Most studies on infants (e.g., 0-5 years), tend to use the home environment as a setting aimed at supporting the caregiver while working with the child. Specifically, family-based interventions targeting positive behaviour support have been use. Positive behaviour support has been identified as a way to reduce weight gain through improving the family's ability to support and work with the child (healthier diet and improved physical activity). Long-term prevention trials using family-based intervention to target positive behaviour support found that children randomized to the intervention had lower BMI in the years following participation. This finding was particularly promising given that these trials did not explicitly focus on child weight (Smith et al., 2020). In the review of 2018, only family-based interventions were included; these interventions were implemented through associations working at community level, but they aimed at changing family dietary patterns and the screen time and none of them yielded positive results (Bleich et al., 2018).

Synergies between those who have a potential or actual role in improving the lifestyle of a local community are much needed. Projects should engage different stakeholders within the community to encourage children, family and citizens to participate (figure 17)

[Source: National Academies of Sciences, Engineering, and Medicine, The National Academies Press, 2016], promoting healthy behaviours through the creation of a virtuous school-family-community partnership (Tripodi et al., 2012).

Figure 17. A spectrum of opportunities (a) and levels of influence and contexts (b) to promote healthy practices to promote healthy practices in early care and education settings [Source: National Academies of Sciences, Engineering, and Medicine, The National Academies Press, 2016].

3.4. ToyBox-study

The European Commission financed a controlled randomized study for obesity prevention in early years, within the Seventh Framework Programme, the ToyBox-study

(http://www.toybox-study.eu/). It is a multicomponent intervention, implemented in Preschools that involves the family, aimed at preventing premature obesity and that ensures optimal growth and development. The project has been implemented in six European Countries: Belgium, Bulgaria, Germany, Greece, Poland and Spain.

The ToyBox project has been developed by a research group coordinated by Professor Y. Manios from the Harokopio University in Athens (Greece).

3.4.1 Systematic approach for the development of the preschool Toy-Box-intervention in the preschool setting to prevent obesity in early childhood

The first step in the development of such intervention was the identification, through a systematic literature review and the evaluation of the interventions already implemented at international level, of the main EBRBs and their determinants for pre-schoolers, the evaluation of the existing behavioural patterns and the educational strategies that best support the behavioural change in this age group, and the evaluation of the environments that influence the implementation of preschool-based health promotion activities (Special Issue: The ToyBox-Study, 2012).

Focusing on pre-schoolers is fundamental to prevent obesity because this is a critical period to change obesity risk factors and to influence the adoption of healthier and long-lasting habits. Although with some differences, the majority of pre-schoolers (95-100%) attend pre-school across European Countries (https://www.eurydice.org/). Therefore, it seems to be the ideal setting to implement actions aimed at promoting health.

3.4.1.1 Evidence from literature reviews

The reviews carried out by the ToyBox research group and which led to the development and implantation of the intervention are examined below.

Model for the development of the programme. As the research group developed the ToyBox-intervention, they pointed out large-scale socioecological frameworks providing a holistic multifactorial and cost-effective approach necessary to support obesity prevention initiatives in preschool age was missing. The ToyBox-study has been developed to fill this gap.

The results of several systematic reviews have revealed that most of the studies addressing obesity prevention are of low methodological rigor. Their ineffectiveness can be partly

attributed to the fact that they were not guided by a careful enough systematic evidence-based development process (too general, not well informed by evidence from earlier research and not rooted in behaviour change theory) and they have failed to include intervention strategies tailored to the most important and modifiable determinants of the key health behaviours. In addition, school and family environmental factors have not been addressed properly, and the stakeholders' views, the contextual factors and policy framework were not taken into account.

Initially, the ToyBox team of researchers conducted a systematic review of the prospective studies and secondary data analyses, to identify the key behaviours associated with obesity among pre-schoolers. Moreover, systematic reviews and focus group research to identify the determinants of the behaviours correlated to energy balance, that is understanding why young children choose to eat the foods they eat or why they do (or do not do) physical activity and have sedentary behaviours.

Based on insights gained at local level, using the results of reviewing and critically appraising existing behavioural and the educational strategies on what works best with young children, but also examining the contextual framework at schools the ToyBox-study was conceived and developed. The multidisciplinary team of researchers developed the intervention according to a systematic stepwise approach that combines the use of the PRECEDE-PROCEED model (Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation- Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development) and the intervention mapping protocol (Intervention Mapping, IM), incorporated as an intermediary step between the PRECEDE and PROCEED components of the P-P (IM) model, as exemplified in the scheme in Figure 18 [Source: Manios et al., Obesity Reviews, 2012]. The IM, along with the work packages (WPs) constituting it, was used as the planning framework for the development, implementation and evaluation of the obesity prevention program. The tasks derived from this systematic approach were operationalized in 10 WPs.

Two WPs (WP5 and WP9) were devoted to the assessment of policy and contextual factors and cost effectiveness. ToyBox-study addressed different policy or sociocultural factors in most WPs; namely in WP3 the sociocultural determinants of behaviours were assessed; in WP6 intervention material was culturally adapted; in WP7 process evaluation

was performed including assessment of socio-cultural and contextual factors. Finally, WP10 will support public health policy decision-making and inform relevant stakeholders.

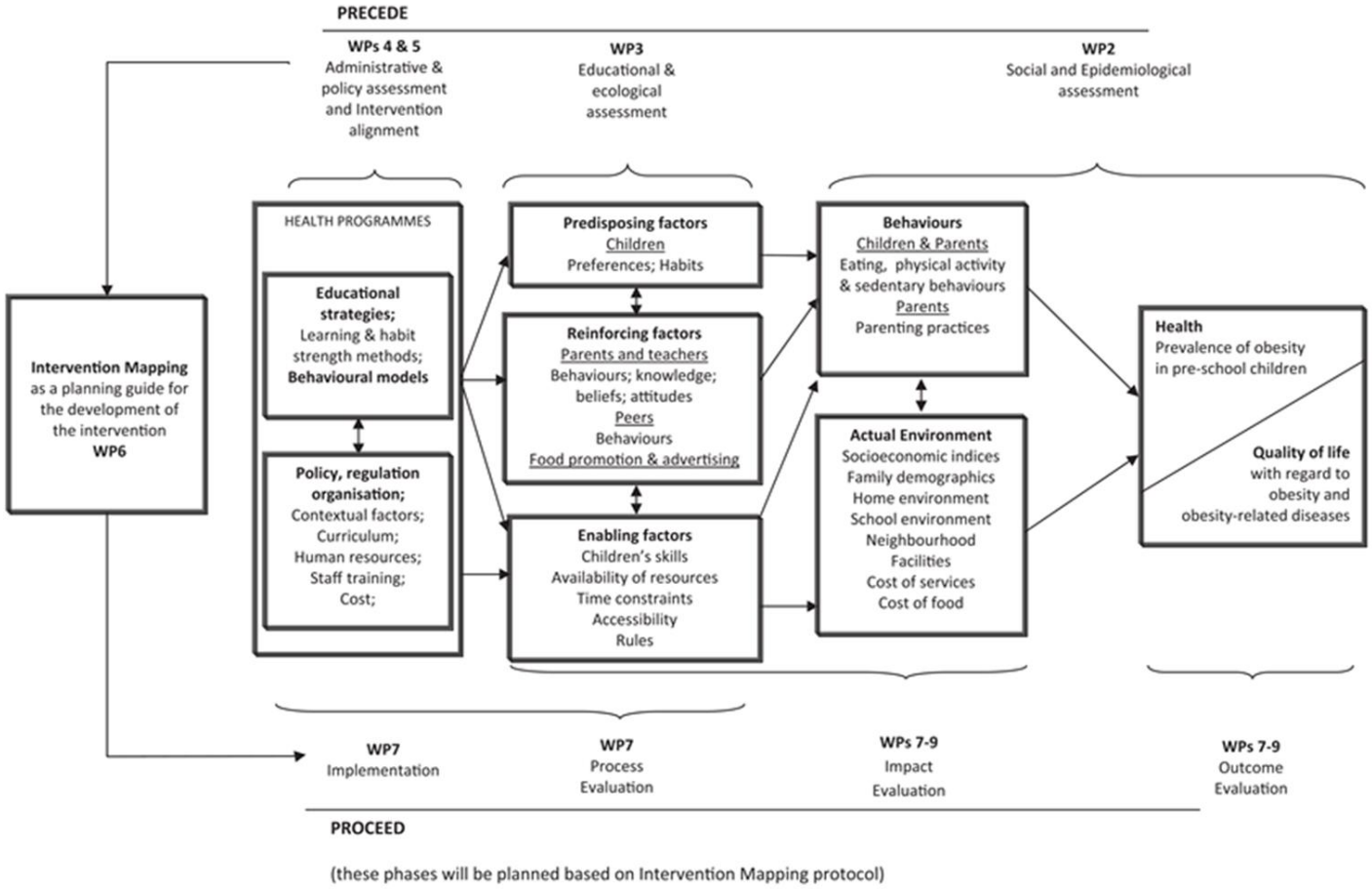


Figure 18. The systematic approach used in the ToyBox project: PRECEDE-PROCEED model for use in pre-school children [Source: Manios et al., Obesity Reviews, 2012].

Identification of the determinants for the behaviours correlated to energy balance. The main key behaviours associated with obesity in pre-schoolers, the so-called EBRBs, and their determinants were identified through the systematic review of the literature and evaluation of the interventions already implemented at international level. The interaction of behaviours such as physical activity, sedentary behaviour and eating behaviour determines whether or not a positive energy balance or weight gain is experienced. The best way to influence these EBRBs is to use a multidisciplinary approach, based on a simultaneous focus on target behaviours and their determinants. Due to a paucity of reviews in the literature that combined the different determinants for the above-mentioned ERBS in pre-school children, researchers investigated the determinants correlated to each single behaviour, seeking to integrate the results for all the three behaviours. The analysis of the data showed that attending preschool in a rural area is positively associated with physical activity. Sex, age and socioeconomic status (SES) are not associated with physical activity, whereas for ethnicity an indeterminate result was found. Sex and ethnicity were not associated with sedentary behaviour and indeterminate results were found for age and socioeconomic status. Consequently, prevention strategies focused on the three behaviours should target pre-schoolers of all age ranges, both boys and girls, regardless of SES and ethnicity. With regard to environmental variables, findings highlighted that weekdays are significant determinants for physical activities and sedentary behaviour. Children are more physically active and more sedentary on weekdays than at weekends. Therefore, physical activity should be increased at weekends and sedentary behaviours should be reduced on weekdays. With regard to behavioural variables, when children watch TV they are more likely to consume more sugary drinks and savoury snacks and less fruit and vegetables. Consequently, the reduction of screen time might lead to a reduction in the consumption of sugary drinks and snacks. The analysis of the literature highlighted that several determinants were studied only in one or two of these behaviours, thus it is difficult to draw overall conclusions on the determinants of the three behaviours. Moreover, for each behaviour, studies were conducted on wide range of different determinants, thus making their comparison difficult (De Craemer et al., 2012).

Epidemiological evidence on excess weight status among pre-schoolers and its determinants in Europe. In order to evaluate the epidemiological data related to excessive weight among pre-schoolers and the association with the determinants among European intervention children, before developing the intervention, secondary analyses of the data sets of six European Countries participating in the ToyBox-study were conducted. Prevalence of overweight and obesity across the Countries ranged from 8% to 30% and 1% to 13%, respectively, with highest rates in Southern European Countries (e.g., Spain and Greece). In general, a higher prevalence of overweight and obesity was detected among girls compared with boys. Positive associations between sedentary behaviours and overweight indices were found, mainly screen time. The majority of the reviewed studies did not report a significant association between physical activity and overweight. This does not align with the results of the review carried out by the research team which found strong evidence of an inverse association between physical activity and overweight among pre-schoolers (te Velde et al., 2012). These differences in the outcomes may be the result of methodological limitations. With regard to dietary behaviour, the review yielded insufficient and inconsistent results for the association with overweight indices. However, this did not imply that there was no association between dietary behaviours and overweight. Children of parents with high body mass index or low SES were at increased risk of overweight/obesity (van Stralen et al., 2012).

Evidence of tools used across Europe for the evaluation of the target behaviors of the ToyBox intervention. Valid and reliable measures of energy balance-related behaviours are required when evaluating the effectiveness of public health interventions aiming at prevention of childhood obesity. This descriptive review was performed to collect data on the assessment tools of the behaviours targeted by the ToyBox intervention (food intake, physical activity and sedentary behaviour) across the used in obesity intervention strategies across pre-schoolers. Parentally reported food records and 24-h recalls were commonly used to assess food intake. Subjective levels of physical activity and sedentary behaviour were commonly accessed via parentally reported questionnaires. Accelerometry was used to obtain objective measures of physical activity. Insufficient evidence of tool evaluation was provided. However, insufficient data on this tool assessment were provided. The survey highlighted the existence of relevant difference in

the study planning, in the population samples, in the tool assessment methodologies; moreover, a certain variability was found also across the studies that used the same tool. Since results are inconsistent and there is no gold standard for the assessment of energy balance-related behaviours, there are only more appropriate assessments, a series of recommendations have been provided. When possible, the use of food records is recommended to appraise nutrient intake and the consumption of food across preschool children, whose validity and reliability should be tested before the intervention. Moreover, the use of accelerometry is recommended to obtain more appropriate measures of physical activity levels. Sedentary behaviour could be assessed via questionnaires that include key indicators of sedentarism and are able to differentiate individual practices. The choice of methodology for the assessment of specific intervention effects should be equally balanced between required accuracy levels and feasibility, and be guided by the intervention targets (Mouratidou et al., 2012).

Evidence from prospective studies on the association between EBRBs and excess weight status in preschool children. Upon the development of the ToyBox-intervention, evidence supporting the association between physical activity, sedentary behaviours and dietary intake during early childhood and the development of overweight and or obesity later in life had not yet been systematically and simultaneously reviewed. Therefore, the current review aimed to identify the association between energy-balance behaviours in pre-schoolers that are prospectively related to overweight/obesity later in childhood. Studies examining the prospective association between at least one relevant behaviour measured during preschool period (children aged 4-6 years at baseline) in relation to at least one anthropometric measurement at follow-up (age <18 years) were included. Strong evidence was found for an inverse association between total physical activity and overweight. Moderate evidence was observed for a positive association between television viewing and overweight. Insufficient evidence was found for an association between dietary intake or specific dietary behaviours and overweight. However, insufficient evidence for this association does not imply that there is evidence that support the lack of this association. Because of the heterogeneity in the assessed dietary behaviours, we could not draw reliable conclusions. These results suggest that interventions aiming to prevent overweight among preschool children should focus on promotion of total physical activity and limitation of screen time and that further research

is needed to establish whether and which dietary behaviours are important for obesity prevention in this age group. However, despite the lack of evidence for dietary behaviours from the present review, future interventions may already target specific dietary behaviours that are highly prevalent and for which there is a clear rationale as well as preliminary evidence that these behaviours are associated with overweight, or evidence from studies conducted on groups of different age ranges that support the association with overweight, e.g., the intake of sugary beverages (te Velde et al., 2012).

Factors that influence screen time in pre-school children. Pre-schoolers spend significant proportions of their waking hours being sedentary. Screen time (i.e., television/DVD viewing and computer use) has been negatively associated with several health outcomes. However, when the ToyBox-project was being developed, interventions aiming to reduce pre-schoolers' sedentary behaviour were scarce and the majority of the results obtained were of quantitative type. Since parents play a key role in the health-related behaviours of pre-schoolers, identifying parents' perceptions of their preschool children's screen time might represent an important source of information. This study aimed to explore the perceptions of parents from different cultures and geographical areas, of their preschool children's screen time through participating in different focus groups. Overall, one hundred twenty-two parents of low and medium-high socioeconomic status from six European Countries with children between 4 and 6 years old were involved in 24 focus groups. Results showed that children in preschool age already tend to watch TV and most parents do not express worries about their children's TV viewing time. Education is considered to be the main benefit of watching TV. Moreover, TV was often used for babysitting and calming down. In general, parents had only informal rules about TV viewing (e.g., 'permission needs to be asked to turn on the TV'), formal rules were not yet perceived as necessary. Remarkably, in most Countries, parents of a low SES had almost no rules regarding watching TV. Children can watch TV all day long or whenever they want. In the literature, an inverse association was reported between the rules regarding screen time and TV, DVD/video, videogames and computer use among preschool children. Therefore, setting rules in screen time might be an effective strategy to reduce the hours of TV viewing. Computer and active games use are less frequent compared with TV viewing. Some parents were worried that computer use could make children nervous, it could have a negative influence on children's psychological and

physical development, Thus, parents considered playing outside to be better than playing active games inside. Although, parents in the focus groups reported computer use not to be excessive at preschool age, already at this age it might be appropriate to counsel parents on setting rules about how long the computer should be used to generate adequate habits of computer use in preschool children. Inconclusive results were found for the influence that siblings or friends have on the children's screen time across all focus groups. In general, parents had no limitations and no specific rules for their children in watching TV with siblings or friends. To decrease sedentary behaviour, attention could be paid on how pre-school children and their siblings or friends can decrease their sedentary behaviours together. Parental habits at home and the weather conditions were the two most frequently mentioned factors that influence children's screen time. Therefore, alternative non-sedentary activities could be suggested to the parents as a replacement for TV watching along with information on how to set rules for screen time (De Decker et al., 2012).

Psychological and educational strategies applied to young children's eating behaviours

Childhood is a critical age both for development of lifelong eating habits and behavioural risk factors for obesity. However, the reviews available before the development of the ToyBox reported that the majority of the childhood obesity prevention interventions took place within the so-called school contexts and that had a limited success, particularly those focused on dietary intake. Schools are obviously convenient and practical settings to carry out such interventions; however, there are two major weaknesses to this approach that may explain the lack of success: first, engagement of parents and consideration of the family environment is often too limited; second, it has been argued that by school age (e.g., older than 6), quite strong eating habits may already have formed. By contrast, younger pre-school children are in the early stages of learning about eating habits, and just developing their own likes and dislikes. Thus, it is this transitional preschool period that may be a more effective stage for obesity prevention. Eating is an outcome that can be influenced by a complex array of sensory, physiological, genetic, temperamental, social (family, parental, peer), cultural, environmental and learned inputs. Thus, the research team of the ToyBox conducted a review of the extant literature examined in the context of current understanding of the psychological and behavioural processes (including likes/dislikes) and of the behavioural traits, such as innate taste preferences,

food neophobia and picky eating, enjoyment of food, impulsivity, eating rate and satiety responsiveness that underlie the development of eating behaviour in young children. These are important influences of children's responsiveness to dietary practices, as well as predictors of obesity risk. However, family food environment and experience are particularly important among small children to establish dietary habits and preferences. Thus, giving information on a healthy diet to parent or children may not be sufficient, effective strategies should indeed be provided. Acceptance of healthy foods can be encouraged, within a favourable social environment, by the repeated exposure to brief tastes of new, healthy foods, by five to ten repeated tastes. Recent evidence suggests rewarding healthy eating can be successful, even for verbal praise alone, but that palatable foods should not be used as rewards for eating. Intake of healthier foods can be promoted by increasing portion sizes of vegetable (or fruits), especially in the beginning of the meal. Parental strategies of pressuring to eat and restriction do not appear to be effective causally linked to obesity, but are instead primarily responses to children's eating tendencies and weight. Indeed, it might result in a reduced intake (of the less palatable foods) and in food selection. Moreover, introducing strict restrictions on palatable foods, often considered unhealthy, increases children's tendency to eat these foods. Moderate rather than frequent restriction may improve healthy eating in children. With regard to portion size and satiety responsiveness, children should learn to regulate their eating, avoiding external control and distractions so that the quantity eaten corresponds to the actual needs. Portion sizes should respond to the child's needs. Actively positive social modelling by adults (parents/teachers) can be effective in encouraging healthier eating (Gibson et al., 2012).

Strategies promoting physical activity in preschool. To evaluate educational strategies promoting physical activity that are used in the preschool setting in the context of obesity prevention program, the ToyBox research carried out a systematic review of a total of 19 studies based on different determinants: the amount of physical activity, the importance of the environmental changes, teachers training, the opportunities for physical activity. Outcomes considered were: time and intensity of physical activity, motor skills or measures of body composition. Ten studies added physical activity lessons into their curriculum, one study provided more time for free play, eight studies focused on the social and play environment. Most interventions implemented physical activity sessions that

lasted 30-45 minute; however, also 10-minute sessions repeated more times per day proved to yield positive results. In fact, physical activity patterns of small children correspond to brief intense physical activity sessions followed by moderate exercises. The existence or installation of playground markings or fixed play equipment had no effect, whereas the presence or addition of portable play equipment was positively correlated with moderate-to-vigorous physical activity. Portable play equipment, such as balls and other objects, encourage more children, as they can be used more and generally is used for moderate-to-vigorous physical activity. Teacher training may be a key element for successful interventions. The reviewed studies showed that the levels of physical activity in children are correlated to behaviours and skills of the teachers. The outcomes of this review support the importance of the teachers' awareness on physical activity and their capability to support children's learning and moto development. Teacher's enthusiasm and their strategies to promote physical activity are further relevant factors. To overcome time constraints, a suggested solution is to integrate physical activity into daily routines and other areas of the preschool curriculum (Kreichauf et al., 2012).

Behavioural models and behaviour change strategies for preschool children. During the development of childhood obesity prevention interventions, behavioural models and the most appropriate theories of the behavioural change should be considered. Examples of behavioural models and theories that have been used in the research on childhood obesity prevention include the trans-theorical model, the theory of planned behaviour, and the socio-ecological models. However, the immature development of small children (4-6 years) diminishes the predictive power of the socio-cognitive theories in explaining their behaviours. Therefore, a careful selection of the theorical background and the definition of the most suitable models and strategies are remarkable to address non-structured behaviour among children, as well as their social and physical environment. The models based on individual decisional processes are not suitable for influencing a behavioural change in small children. Family and school influence is critical for the development of behaviours associated with nutrition and physical activity. Thus, in order to identify behavioural models and the most effective strategies to build the theorical framework of the ToyBox intervention, a systematic review was conducted childhood obesity prevention interventions among 4, 5 and 6 years who had 6 month or more follow-ups. Outcomes included markers of weight gain, markers of body composition, physical

activity behaviour changes and dietary behaviour changes. The review included studies that used a reference behavioural model. The most commonly used model was social cognitive theory (SCT/social learning theory (SLT) either as a single model or in combination with other behavioural models. Studies that used SCT/SLT in the development of the intervention had significant favourable changes in one, or more, outcome measures. The key strategies of SCT/SLT that were used in the development of these interventions were modelling (observational learning) and the techniques to support the development of the skills and a higher self-efficacy. Moreover, the interventions that appeared most effective combined high levels of parental involvement and interactive school-based learning, targeted physical activity and dietary change, and long-term follow-ups. Interventions should also be focused on developing children's (and parents') perceived competence at making dietary and physical changes (Nixon et al., 2012).

Organization and regulation. Although upon the project development, obesity prevention efforts for school-aged children and adolescents were increasing in number, little has been done to address the problem in the preschool age. To develop and implement a successful health promotion programme for this age group and that contributed to obesity reduction, the focus was on the programme characteristics (predisposing, enabling and reinforcing factors or effectiveness of the programme/innovation) and on the environmental factors where the programme was later implemented (implementation effectiveness). Portion of the environment includes existing policies, legislation and regulation at national, regional or local level that might support or reduce the effectiveness of the programme development and implementation. Thus, the ToyBox research team described an overview of existing policies, legislation and/or regulations and health promotion activities in the preschool setting. Across the six participating European Countries data were gathered on policies and activities aiming to improve healthy eating and PA of young children (age group 4-6 years) in Belgium, Bulgaria, Germany, Greece, Poland and Spain. Based on evidence from previous studies, fours sectors were considered relevant for health promotion: urban planning and transports, education, public health care and marketing. The survey identified a limited number of influencing policies, regulations and/or legislation exists for improving diet and physical activity in small children, and specifically, none regarding urban planning and active transport to pre-school. Overall, in the six participating Countries, 30 relevant documents were identified

fulfilling the selection criteria, most of which were implemented at national level and a small number at regional level. With regard to the focus, the majority of documents dealt with general health promotion or health eating and physical activity; others were focused on improving diet and others on physical activity. The majority of policies, regulation and/or legislation involved pre-schools and schools in general (including preschools) and only a limited number of these policies focused also on the general population. With regard to health promotion activities, 45 activities in the pre-school setting were found. High-quality health promotion interventions were identified only in three of the six ToyBox participating Countries: Belgium, Germany and Spain. On the other hand, no health promotion settings focused on diet and physical activity were found in preschools in Greece, Bulgaria and Poland. Results showed that the majority of documents found in the six Countries would have promoted the implementation of the ToyBox intervention or of other health promotion activities in preschool settings. No consistent information was found on the effective implementation and/or evaluation and on the potential impact of existing policies, regulation and legislation on childhood dietary and physical activity habits, across all the relevant policy sectors. Therefore, it was not possible to demonstrate that the policies, regulation and legislation would have promoted the intervention implementation (Nethe et al., 2012).

3.4.1.2 Summary of recommendations for the development of the ToyBox intervention

General considerations.

- Since most successful interventions include parents, their involvement through role modelling should be a fundamental part of any intervention aimed at this age group. Giving only notions or information, even only through newsletter, is not satisfactory. For example, evidence suggests that the increased levels of physical activity of fathers/male guardian increases the levels of physical activity in small children. Where the parents' efforts to increase their own levels of physical activity are limited by the lack of local infrastructures, the authorities should provide adequate support, for example, by providing playing areas, areas dedicated to physical activity and free-access activity programmes. If the intervention occurs only within the school setting and the efforts to involve parents fails, teachers could be considered role models. Clear and simple

messages should be provided to teachers and parents, supported by theories, not excessive in number, and aimed at bringing a positive behavioural change in children.

- With regard to the intervention materials, the level of parents' literacy should be taken into account along with the acceptance of the material by the parents, teachers and children. The risk is that if the materials are not accessible to everyone, only those with a higher education would feel encouraged to use them. Therefore, tests could be performed to assess the usability of new or existing materials in the target population before the intervention implementation. Not testing the materials might increase health inequalities across target population.
- Parents/tutors should be the main target of the intervention, but the outcomes (change in the BMI, in the levels of physical activity and in diet behaviour) should be evaluated on children.

Intervention approaches.

- There should be a simultaneous focus on physical activity and dietary behaviours through a combined and simple intervention.
- The intervention should include rewards for children (praise, but not food) so that they adopt the desired behaviours.
- The key elements for successful interventions are role modelling (through older friends/peers, teachers and parents) and the techniques to facilitate the development of competencies. These approaches increase the success of an intervention because the levels of self-efficacy in parents, teachers and children increase.
- The intervention should have a common framework and sufficiently flexible so that it can be adapted to the target population. In school-based interventions, teachers should be enabled to adapt the different modules to their classes and they should be encouraged to include activities typical of their country and culture.

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Physical activity and sedentary behaviour.

- Interventions regarding physical activity should consider that, across the target population, there may be children who could have problems or feel uncomfortable in following specific physical activities regimens.
- In the school-based interventions, the physical activity component should be integrated in the everyday school activities, where possible, without requiring a pre- or post-school implementation.
- The intervention should promote at least 120–180-minute physical activity sessions al both on weekdays and at weekends. Participation in physical education classes and active play time are important, as well as all those moderate-to-intense physical activities, in reaching this goal. It is also important to suggest the modalities by which children can reach the levels of physical activity recommend on the weekends, for example participating in physical activities organized in local sports club or gong to playing areas.
- The intervention should include a limit to screen time equal to at least 1 hour per day (or the amount of time recommended by the national guidelines, if lower than 1 hour per day).
- The activities that aim at increasing the levels of physical activity should be based on games/plays, and should be performed in different environment and accessible to every child. Forced participation to competitive sports or activities which children are incapable to do (or feel they are incapable) not only does not bring about any benefits but it can even be discouraging.

Healthy diet.

- The component concerning a healthy diet should increase the awareness of parents, guardians and teachers on how to change children's reluctance to taste new foods and on the importance to become familiar with new and healthy foods at a young age.
- Healthy foods and drinks, including fruits and vegetables, should always be available and accessible to children, both at school and at tome. In contrast,

children should be less exposed to unhealthy foods and drinks such as sugary drinks and snacks.

- Teachers should discuss with children about the hindrances in choosing healthy foods and having a well-balanced diet, and how these limits can be overcome (for example, by seasoning vegetables with a sauce they like). Tasting new and healthy foods is particularly useful. Another effective strategy is allowing children to participate in the choice of the menu and in the preparation of the food they eat, both at school and at home.

Simple messages.

Physical activity and sedentary behaviour.

- Encouraging active transport (walking or biking) for short distances.
- Encouraging the visit of places where children can be physically active.
- Discouraging the installation of any screen in the bedroom (television, computer or PlayStation).
- Encouraging non-competitive physical activity.
- Encouraging parents to dress their children with proper sports outfits for indoor and outdoor physical activities.
- Encouraging the development of a large and active game increasing the playing areas in schools where it is possible to play in all seasons.
- Providing play equipment during breaks and encouraging children to be physically active.
- Reducing the total time spent in sedentary activities in class and at home, transforming activities from passive into active.

Healthy diet.

- Encouraging the consumption of lunches together at school and together with the family at home.
- Encouraging the provision of a wide variety of healthy foods, in particular fruits and vegetables, and discouraging unhealthy food intake such as sugary drinks and savoury snacks.
- Discouraging food intake in front of TV, game consoles, etc.

Strong evidence suggests that the current practices by the marketing sector undermine the efforts of creating a healthy food environment for children. The approach to prevent childhood obesity described in this paper should, therefore, be integrated by polities that reduce the negative influence of the marketing sector on children's diet. For the research group, the marketing sector has an important role in helping children and their families to have a healthy and cost-effective diet. The policy makers and the service providers should trust the effectiveness of the aforementioned childhood obesity prevention strategies. However, in order for the intervention to be effective, it is important to reflect on how these strategies (focused on improving diet and physical activity levels) integrate with other critical aspects of the programme. The WHO declared that the hardest challenge in addressing childhood obesity is the need to raise awareness and mobilize community-wide efforts and involvement at all levels of government. Childhood obesity is not a problem of the education sector only, it should be addressed at a multi-sector level, recognizing the important role of the local governments, of the non-government organizations and of the media. Indeed, any effective intervention programme should include components such as leadership support, coordination, development of the workforce, development of the network, monitoring feedback, proper cultural adaptation and implementation of adequate policies, which, however, still lack in effectiveness. Future studies should focus on translational research and evaluate the best practices to implement interventions that can be embedded in the practices and in the existing operative systems, that can be effectively widened, supported over time and guarantee fair outcomes (Summerbell et al., 2012).

3.4.2 Implementation of the European Toy-Box intervention

The recruitment of the children and of their parents was performed mainly in the pre-school setting, but also at day-care centres or in crèches, according to the organization specific to each participating country.

Based on the preliminary results, the study design was fine-tuned and the implementation was conducted in six participating European Countries. The intervention was launched in 2012 with the collection of the baseline data and was implemented within the 2012-2013 school year, at the end of which the follow-up data were collected for verification of results (Manios et al., 2014). More than 7,000 European children were recruited.

The ToyBox interventions focuses on the following four EBRBs: 1) drinks consumption; 2) snack consumption; 3) physical activity; 4) sedentary behaviour.

It is based on the use of standardized material which is equal across the participating European Countries, and which was translated and adapted to the local culture.

The interventions involve four levels of action; the first three levels were implemented in the school setting and the fourth level focused on changing the home environment through parents/caregivers.

- Baseline data assessment.
- Teacher training. The ToyBox intervention involved teacher training sessions where intervention material was presented and information on its implementation in the specific school setting was given. These training sessions were performed on the basis of standardized protocol and by using structured educational units.
- The specific activities can be classified into the following levels:
    - Level 1. Teachers have to introduce permanent environmental changes in the classroom and in school, in order to create an environment that supports the implementation of the four target behaviours (e.g., by installing water stations and magic snack plates, to favour water and healthy snacks consumption; creating safe spaces to favour children's movements).
    - Level 2. Teachers promote the four behaviours regularly in class, based on the daily active participation of the whole class (e.g., by reminding children to drink water regularly, having small active breaks twice in the morning and twice in the afternoon, and by arranging a daily break for the whole class to eat healthy snacks, having two 45-minute physical education sessions per week).
    - Level 3. Teachers implement fun classroom activities with the active participation of the whole class, for a minimum of one hour per week (e.g., experiments, stories having the kangaroo hand-puppet as their protagonist, where children can repeat the same movements as the characters in the stories, etc.). Teachers will be trained to use the kangaroo hand-puppet and also to follow the four target behaviours in order to increase the effects of the intervention through *role modelling*.

- Level 4. Parents/caregivers are encouraged and given advice through simple and enjoyable materials (described above) to implement relevant environmental changes in the household to become themselves role models and implement the desirable behaviours together with their children.

3.4.3 Design and assessment tools of the ToyBox intervention

The ToyBox-study is a multicomponent intervention, implemented in preschool settings, involving family and aiming to prevent obesity and guarantee optimal growth and development in pre-schoolers. It has a randomized controlled design that has been implemented in six European Countries: Belgium, Bulgaria, Germany, Greece, Poland and Spain (Manios et al., 2014). The baseline measurements of the ToyBox-intervention were conducted on children born between January 2007 and December 2008 (i.e., the age range was from 3.5 to 5.5). These children and their families were recruited mainly at preschools, but also at day care centres or crèches, depending on the country regulations and legislation. A geographical standardized randomized approach by socio-economic level was applied for the recruitment of schools, teachers, families and children in all Countries. Finally, 1,003 schools (from now onwards, the word will be used for example purposes only, including all the aforementioned school settings across the Countries where the intervention was implemented) were selected from the municipalities randomly selected. The recruited municipalities were then randomly allocated to the intervention or control group (2: 1).

The timeplan of the ToyBox-intervention was designed so as to account for country-specific differences with regard to the opening and closing dates of the kindergartens and the duration and timing of national holidays. Recruitment of participants started in February 2012 and baseline data was collected between May and June 2012. The intervention was implemented within the academic year 2012–2013 from September 2012 to June 2013. Follow-up evaluation was performed between May and June 2013. In order to have comparable data, authors had to ensure that baseline and follow-up measurements for all children were executed 12-months apart. For this reason, a limit of deviation of maximum 2 weeks between baseline and follow-up measurements dates per preschool was allowed. The process evaluation and assessment of cost-effectiveness were conducted during the teachers' training sessions and the implementation phase of the

intervention. A detailed description of the ToyBox-intervention timeline is presented in Figure 19 [Source: Manios et al., Obesity Reviews, 2014].

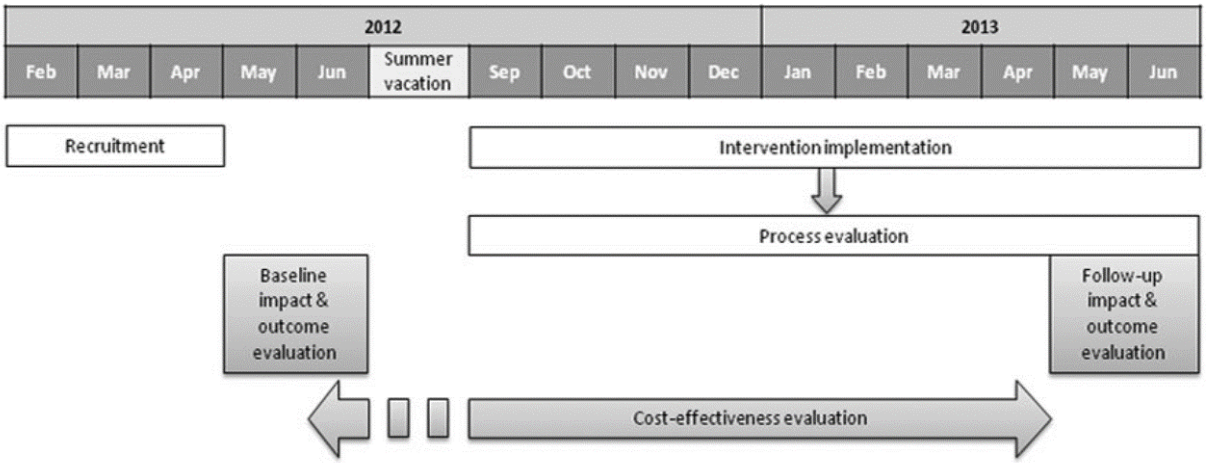


Figure 19. Timeplan of the ToyBox-intervention [Source: Manios et al., Obesity Reviews, 2014].

To guarantee the accuracy of the assessment process, to obtain valid and reliable measures and reduce data heterogeneity, which may result from potential measurement errors and from the differences across the Countries, multiple actions were implemented. Using standardized assessment procedures was fundamental to obtain consistent, comparable and uniform findings. On the one hand, this has allowed to increase the validity and reliability of the measures necessary to evaluate the association between diet and physical activity and overweight/obesity; on the other hand, it has allowed to examine also the effectiveness of the intervention in childhood obesity prevention. The study followed standardized procedures, such as common manuals of operation across all Countries, describing step-by-step to be followed by the researchers for impact and outcome evaluation and common tools for assessment. Similarly, standardized procedures for data entry/cleaning and quality control were in place. The timeframe of the preparatory studies (anthropometry training, reliability and validity of the impact assessment tools) and the baseline and follow-up data collection evaluation conducted within the ToyBox-study is presented in Figure 20 (Manios et al., 2014). The choice of standardized assessment tools across centres was based on previous European surveys and on the review of the assessment tools used in the obesity prevention strategies at European level (Mouratidou et al., 2014).

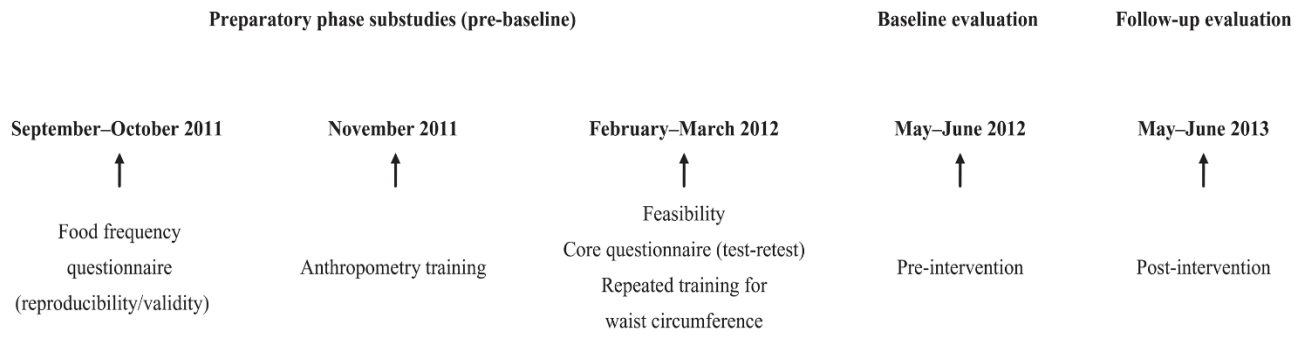


Figure 20. Timeframe followed during the preparatory phases and baseline/follow-up measurements [Source: Mouratidou et al., Obesity Review, 2014].

3.4.4 Assessment results of the ToyBox-study

The impact results of the ToyBox intervention were reported in several publications that examined its multiple aspects (change in behaviours, cost-benefit assessment, role of the different stakeholders).

A study examined the effect of the ToyBox intervention on plain water and beverages intake (one of the four EBRBs of the intervention). The ToyBox action had limited effects on water intake and beverages consumption among the recruited pre-schoolers. However, the intervention led to a reduction in prepacked juices consumption in the intervention group compared with the controls. Since excessive prepacked fruit juice consumption is a relevant problem among pre-school children, a decrease in their consumption following the intervention was a positive result. Consumption of sugar-sweetened and high-calorie beverages, such as soft drinks, among pre-schoolers seems to be more limited than prepacked juices. They are also high in sugar and are not recommended as water source. Moreover, more favourable effects on beverage choices were found in pre-schoolers whose parents/caregivers and preschool teachers had higher implementation scores (given based on the level of household change implementation, questionnaire filling, etc.) compared to those with lower implementation scores, highlighting the role of the parents/caregivers and teachers (Pinket et al. a, 2016).

A further work investigated the mediating role of parenting practices on the association between SES and beverage intake (plain water, soft drink and prepacked fruit juice) in ToyBox-intervention pre-schoolers (Pinket et al. c, 2016). The excessive intake of added

sugars through these sweetened beverages can lead to an energy imbalance and thus to overweight.

The development of healthy habits should already start in the first years of life. Given the young age of preschool children, parents play a fundamental role in developing a home environment that stimulates healthy eating habits. Pre-schoolers of lower SES drink more sugared beverages and less plain water than their high SES peers. Moreover, significant SES-differences were found for all parenting practices. Higher SES was associated with less availability of soft drinks/prepacked fruit juice, higher availability of plain water, less permissiveness towards sugared beverages, more awareness of the negative advice on daily soft drink/prepacked fruit juice consumption, more encouragement to drink plain water, less rewarding with sugared beverages compared to the lower SES pre-schoolers (Pinket et al. c, 2016).

A study investigated the effect of the intervention on the overall dietary quality (Dietary Quality Index, DQI) and of its four sub-components (variety, adequacy, moderation and overall balance). Moreover, the study tried to assess whether the potential effects of the intervention differed based on the SES. The intervention had no effect on the DQI. However, effects were reported in two sub-components. In the intervention group, the adequacy and balance components reported a higher increase in the scores. Children from the intervention group improved their food choices compared to the control group. This resulted to be a positive outcome compared to the low scores obtained on these sub-components at baseline. The specific messages on the quality of the food choices might have made parents more aware on their choices and therefore on the dietary quality of their children. Regarding the balance component, children from the intervention group reported a higher improvement in the compliance to the guidelines. This is a positive outcome, as children from the intervention group followed the recommendations on the intake of fruit and vegetables and broke rules less frequently as regard the consumption of unhealthy snacks. The focus by the ToyBox intervention on the recommendation of the guidelines regarding the consumption of drinks and healthy snacks might have led parents to consider and apply the recommendations to other foods.

With regard to the SES, contrary to expectations, no different results were reported on the grounds of the SES. A possible explanation can lie in the fact that the ToyBox intervention was not specifically targeted to parents/caregivers with lower SES. They

might have had difficulties in understanding the educational component of the intervention (Pinket et al., 2017).

Moreover, the role of the ToyBox intervention on sedentary behaviours of pre-schoolers was investigated. The data analysis of the ToyBox intervention performed in Belgium reported some effects in specific subgroups (girls in preschool age, boys in preschool age in schools with both high and low SES, pre-schoolers with higher levels of baseline sedentariness) (De Craemer et al., 2016). The Toy-Box intervention appeared to have small though significantly positive effects against sedentary behaviours in European pre-schoolers. In particular, positive intervention effects were found for computer/videogames use on weekdays and on weekend days; in the total sample, the intervention group showed a decrease in computer/videogames use compared to the controls group (Latomme et al., 2017).

The effectiveness of the ToyBox intervention on the improvement of the physical activity levels, was investigated, in particular the number of steps (objectively measured) taken every day by the children in the total sample and in the Country-specific samples. Moreover, studies investigated whether the higher score for the evaluation of the teachers or of parents/caregivers was associated with more positive effects on the levels of physical activity in children. With regard to the total sample, the intervention did not result in significant effects, which implies that the intervention did not have any effect on children's physical activity in terms of steps taken each day. Country-specific analysis did not report any effect. The lack of effects on children's physical activity is in line with other studies in the literature.

We could have expected higher effects in children from Bulgaria and Greece, because these were Countries with the lowest number of steps/day taken based on the baseline assessment. However, the analysis of the data showed that the intervention had no effects in these Countries. This may be due to the decrease in physical activity in association with the children's age. Moreover, the ToyBox intervention was focused on four different behaviours (beverages intake, snack intake, sedentary behaviours and physical activity) during an entire school year, which means that the physical activity module was implemented only for a limited time (i.e., 6 weeks). However, teachers were encouraged to continue the implementation of the components of the physical activity intervention

during the entire school year. The implementation of the interventions for a longer period (more than 6 months) might increase the effects (De Craemer et al., 2017).

A further study examined the role of the family determinants on the ToyBox intervention effects on healthy and unhealthy snacks consumption by pre-school children. No significant effect of the intervention was found, neither on the consumption of unhealthy snacks nor on the consumption of fruit and vegetables. However, the intervention was effective in improving parenting rules on unhealthy snack consumption by children (i.e., the restriction not to consume them during their screen time and the permission to consume them on specific occasions) and on unhealthy snack consumption by parents, while it increased parents' awareness on the recommendations regarding snack intake. With regard to healthy snacking, the ToyBox intervention has improved children's attitude towards fruit and vegetables (Lambrinou et al., 2018).

The evaluation of the effects of the snack consumption intervention on the total sample and on those specific to each Country, revealed that the intervention did not have any effect on the everyday snack consumption by children. The lack of effects aligns with the data reported for other surveys regarding physical activity (De Craemer et al., 2017), beverages consumption (Pinket et al., 2016) and sedentary behaviour (Latomme et al., 2017). Although no effects on snack intake behaviours were found, the aforementioned study by Lambrinou et al. (2018) showed that the ToyBox intervention induced some improvements in the determinants for the target behaviour, which represents the first step for the behavioural change. With regard to the possible causes, it is likely that, in the PRECEED phase, all the determinants for the snack consumption behaviour were not identified. Or, as hypothesized by De Craemer et al. (2017), the implementation of the unit targeted to snack consumption might have a shorter duration. As mentioned above, the ToyBox-study was implemented during a school year, i.e., for 24 weeks and, as for physical activity, the unit relative to snack consumption lasted 6 weeks, suggesting, once more, that the implementation for a longer period of time might increase its effects. Although teachers were encouraged to continue the implementation of the different components of the snack consumption unit during the entire school year, they might have done it only for a shorter period. Moreover, the process evaluation score by teachers or

parents/caregivers was not correlated to more positive effects on snack consumption (De Craemer et al., 2020).

Strong evidence from an analysis on the influences of the parents' nutritional attitudes, of the behaviours and of the knowledge on healthy and unhealthy snack consumption in small children indicated that parents' snack consumption behaviours were associated with their children's snack consumption. Parents' healthy and unhealthy snack consumption was correlated with healthy and unhealthy snack intake in their children, but not *vice versa*. Moreover, children who consumed snacks almost every day had parents who reported to have snacks more frequently compared with parents of children who did not have snacks regular snacks every day. These associations might respect the fact that the child learns snack consumption behaviours through the parenting model, although other mechanisms may be involved, including exposure and opportunity related to the availability of snacks at home. The available data did not allow to discriminate among these likelihoods; however, in this case, the parent/caregiver is the main person to take care of the child's diet and the snack consumption by the parent/caregiver was predictive of the child's snack consumption, regardless of the number of snacks available, taking into account the fact that the role modelling promotes the consumption of both snacks and fruit and vegetables (Gibson et al., 2020).

The analysis of the factors correlated to the compliance with the recommendations reported in the guidelines on physical activity, on sedentary behaviour and on sleep in preschool children, both on weekdays and on weekends, found an association with few factors. This study used the data from the Belgian sample of the ToyBox-study. Results indicated that older pre-schoolers satisfied the guidelines on physical activity, on sedentary behaviours and sleep compared to younger children. A possible explanation is that older children have more benefits from a structured school day than younger children. Children with a normal weight status fulfilled the guidelines compared with underweight children. Moreover, children whose parents do not spend much time watching TV at the weakened satisfied the guidelines; in fact, preschool children whose parents watch much TV during the weekend were less likely to satisfy the recommendations. This confirms that parents are important role models in the life of their children and their behaviours influence their children's habits. Finally, among the few predictors associated with the

fulfilment of the recommendations, was father's education level. Children whose fathers had a higher education were more likely to fulfil the recommendations. Thus, when considering the compliance with the combined recommendations on physical activity, sedentary behaviour and sleep, it is important to focus on preschool children with a lower SES. On weekends, only the attendance at sports clubs seemed to be significantly associated compared to the three guidelines, showing that being a member of a sports centre club was probably mistaken for complying with the guidelines in younger children (De Craemer et al. b, 2020).

A study was also conducted with the aim of assessing parental perceptions, attitudes and awareness on their children's sedentary behaviours and the association with TV/video/DVDs watching and the total screen time of their children. A strong association was found between the total screen time of children and parental practices for setting rules. Limits and rules set by parents on TV viewing and total screen time resulted in a reduction in the TV/video/DVDs watching in the sample. Stricter rules or attention to screen time recommendations were therefore associated with a reduced screen time in the ToyBox intervention sample (Miguel-Berges et al., 2019).

Furthermore, studies were conducted to examine the cost-effectiveness of the ToyBox-intervention (Pil et al., 2014). In obesity prevention, the benefits for health can slowly increase over time. An analysis on the cost-effectiveness of the intervention estimates the long-term impact of the ToyBox-intervention on the prevalence of obesity-related complications compared with actual practices. Early intervention efforts are needed to prevent the onset of obesity and its long-term effects. Estimates of the cost-effectiveness of long-term health benefits of the ToyBox-intervention in six European Countries were performed in order to inform decision-makers on the value for money of this intervention in the prevention of obesity (Pil et al., 2014).

The ToyBox-study was included in the Cochrane review of 2019. In particular, the reviews by Birnbaum et al. (Birnbaum et al., 2017) and by Pinket et al. (Pinket et al. a, 2016) were included among the studies awaiting classification H (Brown et al., 2019).

The above-mentioned studies report some results of the ToyBox interventions. Findings show that the intervention, by introducing some changes not only in the school setting but also in households, for both children and parents, is a valid obesity prevention

intervention. The intervention targets a group age (pre-schoolers) critical for prevention interventions. The adoption of a lifestyle based on healthy behaviours in the early years can lay the foundations for an optimal growth and development and for long-term health. Moreover, at this age, it is easier to change behaviours that have not yet been deeply ingrained.

4 RESEARCH PART
TRANS-CULTURAL VALIDATION OF THE EUROPEAN TOYBOX INTERVENTION IN THE ITALIAN PRE-SCHOOL SETTING

4.1 *Outline* of the research

The research scope of this Doctoral dissertation is the transcultural validation of the European ToyBox intervention, whose contents, operational and scientific aspects have been described under section 3.4.
Its development, with no dedicated funding, involved a propaedeutic phase and five research phases over three years, from 2018 throughout 2020 as described below and also represented in Figure 21:

1) Phase 1 – Propaedeutic:
   - Formal agreements with the coordinator of the steering committee of the ToyBox-Study, Professor Yannis Manios of the Harokopio University of Athens (Greece), according to the policies of the European project (ToyBox consortium) aimed at the acquisition and the permission to use the materials and implementation method of the activities. All the materials were provided in their standard version, in English (May 2015);
   - drafting of the research protocol and ethical approval by the Internal Ethical Review Board of the University of L'Aquila, Italy, (ethics committee approval n.35/2018 dated 15/05/2018).

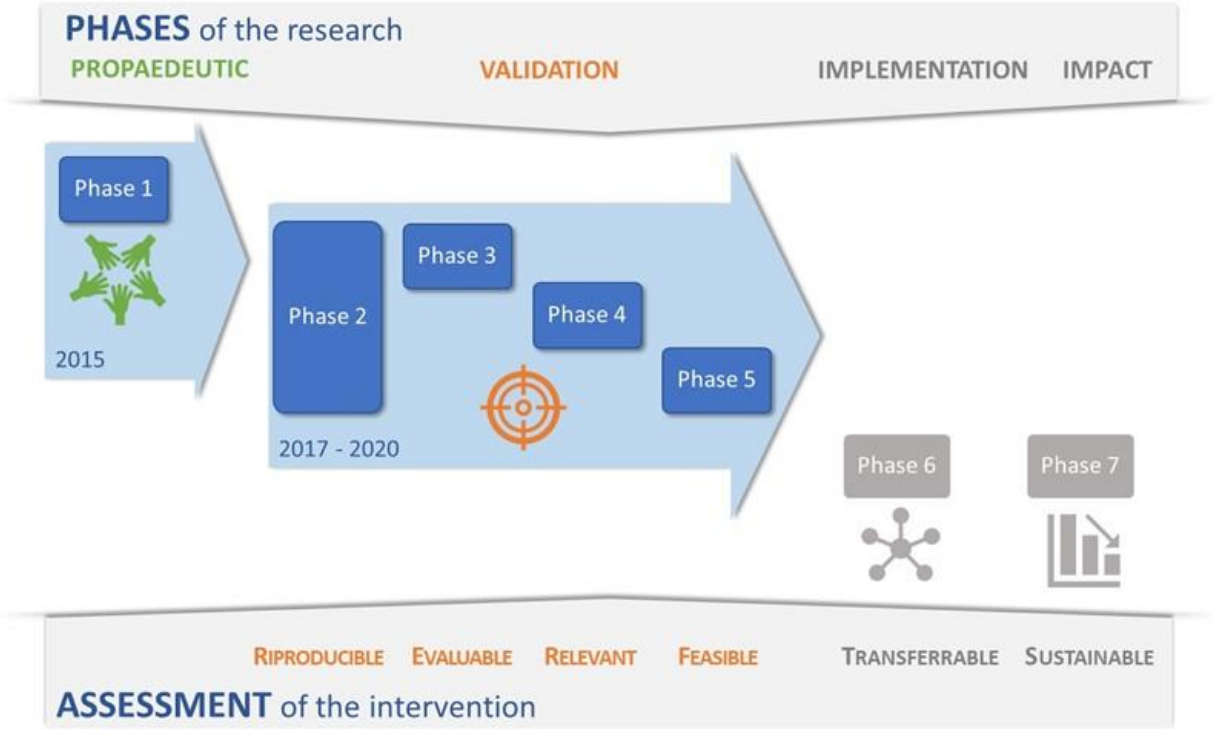
2) Phase 2 – Organization of the Guides and Assessment tools (2017-2018):
   - Translation, localization, editing and face validity (judged by experts) of the Teachers' Guides (a teacher's general manual and four classroom activities guides);
   - Translation, localization, editing and face validity (judged by experts) of the questionnaires for the effectiveness and process evaluation.

3) Phase 3 – Tools validation for the effectiveness evaluation (2017-2018):
   - Test-retest study on the 'Core' and 'Food Frequency' questionnaires for the caregivers.

4) Phase 4 – Cross-sectional epidemiological analysis of the baseline data (2018-2019):
   - Prevalence of Overweight and Obesity;
   - Consumption of food and beverages (description, appropriateness of the overall dietary behaviour to the Mediterranean model, consumption of sugary drinks).
5) Phase 5 – Intervention feasibility assessment (anno 2020):
   - Adjustment of the intervention to the COVID-19 emergency;
   - Experimental distance implementation of the ToyBox;
   - Process evaluation.

As shown in the figure, these are the preliminary phases of a broader process of dissemination of the ToyBox across Italy, which should provide for further phases of implementation and assessment of the impact of a project that may be defined as 'Intervention of Transferrable and Sustainable Prevention' (Faggiano F., 2017).

Figure 21: Outline of the research



Phase 1 – Propaedeutic (formal agreements with the ToyBox Study Steering Committee and ethical aspects)
Phase 2 – Organization of the Guides and Assessment tools
Phase 3 – Tool validation for effectiveness evaluation
Phase 4 – Cross-sectional epidemiological analysis of the baseline data
Phase 5 – Intervention feasibility evaluation
Phase 6 – Intervention implementation
Phase 7 – Impact and sustainability assessment

Overall, to date the research involved 10 Schools, in 6 provinces of Northern, Central and Southern Italy, enrolling a total of 704 children and their parents and 92 teachers (Table 4).

Table 4. Size of the research.

	PHASE 3	PHASE 4	PHASE 5	TOTAL
Objective	Measures validation	Epidemiological analysis	Intervention feasibility	
Design	Test-retest (stability)	Cross-sectional	Experimental (pre-post)	
School year	2017-2018	2017-2018 2018-2019	2019-2020	
Geographic area (province)	L'Aquila	Ascoli Piceno, L'Aquila	Asti, Frosinone, L'Aquila, Rieti, Torino	6 Provinces
Schools	2	5	5	10*
Children (teachers)	108	332	372	704
Teachers	19	49	43	92

*During phase 5 schools other than those of Phase 3 and 4 were recruited.

4.2 General scope of the research

This research aimed at carrying out field experiments in Italy using an intervention validated at European level for the health promotion and obesity prevention in preschool children and their families. The three following general goals were defined:

1) Assessing the feasibility of the ToyBox intervention in the Italian setting, under each aspect (management, implementation, evaluation) providing the community (e.g., families and municipalities) with an intervention easy to be implemented because of its high level of standardization;
2) Validating a study patterns of the outcome variables and of the determinants of the behaviours related to obesity on a sample of Italian children and their families
3) Experimenting activities of scientific communication on healthy diet and lifestyle at an early age.

For each of the Phase, from 2 to 5, the specific goals and the methods will be illustrated along with the main findings. In this dissertation, they will be referred to the nutritional component of the intervention only (Drinking and Snacking Behaviour).

4.3 Phase 2-Creation of General Guide and Assessment tools

4.3.1 Specific goal

The goal of Phase 2 of the intervention was to create the educational resources (teachers' guides and information and practical material for the families) and arranging the assessment tools.

This phase was fundamental, as it laid the foundations for the launch of the project that was then implemented: the materials and the assessment tools, delivered in their standard version in English, were translated into and arranged in Italian.

The creation of the educational resources activities was not a mere translation into Italian, but it also included the editing of the materials and of the tools, which was propaedeutic to their use, though still in line with their original format and face validity.

A careful analysis of the materials was then carried out in order to reach a high level of quality, not only from the point of view of accuracy of the text (spelling, grammar and syntax), but also from the point of view of the suitability and conformity with the Italian cultural context, as in the multicentric ToyBox-Study. Moreover, a graphical arrangement of the materials was performed (e.g., layout, layout of pictures, etc.) delivering a both digital and paper format, conforming to the original.

Finally, a face validity was developed through the unstructured collection of experts' opinions from the nutrition and motor sciences areas, before the educational material was used and before the statistical assessment of the reliability of the questionnaires (test-retest reliability).

All the intervention materials and tools are listed and described briefly below.

4.3.2 Educational materials

- *Materials for Teachers*. Each teacher was given: a Teachers' General Guide and four classroom activities guides, one for each of the target behaviour (Figure 22).
    - Teachers' General Guide. This guide is designed for teachers only and includes general information on the reasons that led to the intervention development, information use to guide teachers in the ToyBox implementation, as well as a timeplan as example/guide to follow for the implementation of the provided activities.

· Classroom Activities Guides. They include: The classroom activities guide on Drinking Behaviour; the classroom activities guide on Snacking Behaviour, the classroom activities guide on Sedentary Behaviour, and the classroom activities guide on Physical Activity. Each Guide, focused on one of the target behaviours, includes all the information and the instructions on their implementation in the school setting (and household setting involving parents), the activities provided for each target behaviour.

Figure 22. Covers of the Teachers' General Guide and of the Classroom Activities Guides.

• *Materials for Parents*. To engage parents, ad hoc materials were created for the activities to do at home. The material was provided concurrently with the activities performed in the school setting through newsletters, tip cards and display posters (Figure 23). These materials aim to transfer the key messages of the intervention to the parents and to focus on behavioural objectives alongside school activities.

· Newsletters. Nine newsletters were developed: an introductory newsletter and two for each target behaviour: Newsletter 1 and 2 on Drinking Behaviour; Newsletter

1 and 2 on Snacking Behaviour; Newsletter 1 and 2 on Sedentary Behaviour and Newsletter 1 and 2 on Physical Activity.

- Tip Cards. Eight tip cards were created, two for each target behaviour: Tip Cards 1 and 2 on Drinking Behaviour; Tip Cards 1 and 2 on Snacking Behaviour; Tip Cards 1 and 2 on Sedentary Behaviour, and Tip Cards 1 and 2 on Physical Activity.
- Display posters. Four posters were created, one for each target behaviour, to colour and hang at home: Poster on Drinking Behaviour; Poster on Snacking Behaviour; Poster on Sedentary Behaviour, and Poster on Physical Activity.

Figure 23. Covers of the Introductory Newsletter and of the Tip Card 1 for Drinking Behaviour and Poster for Snacking Behaviour.

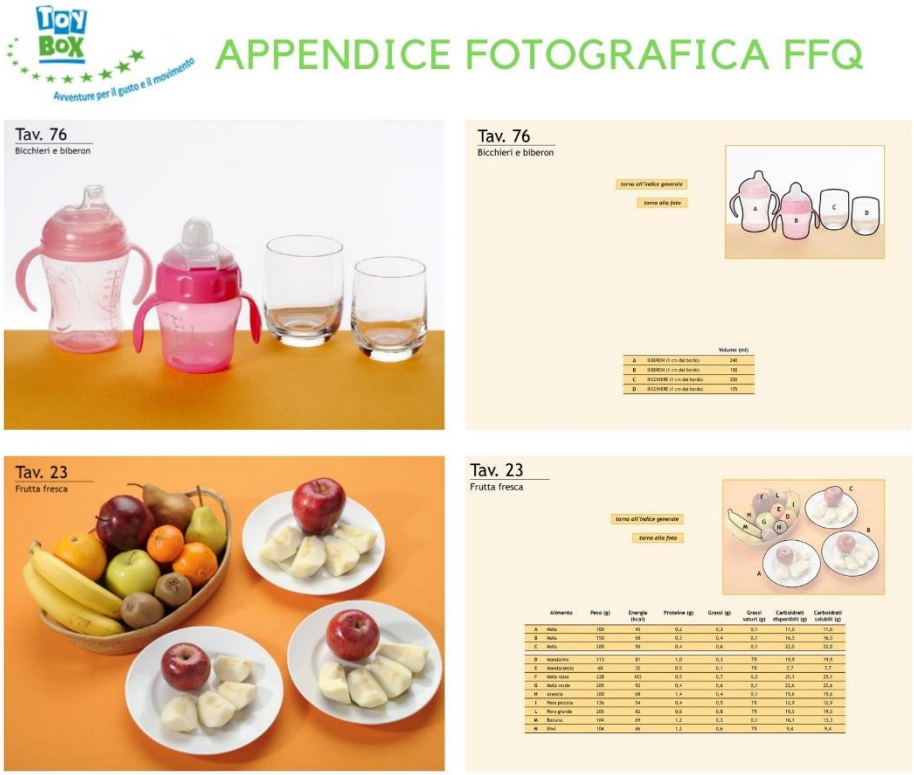
4.3.3 Questionnaires

- *Teacher's Questionnaire*.
  - Teacher's Questionnaire (TQ). The TQ includes 72 items, and it is designed to assess self-efficacy, habits, awareness, attitudes and social influence of the teachers in relation to the target behaviours (Annex 1).
  - Process Questionnaire – Logbook of intervention. The logbook on intervention is a structured log to be filled in, throughout the duration of the intervention, at the end of each month. Therefore, at the end of the intervention, we had six Logs for each classroom. Intensity (activities delivered/completeness) and the compliant and effective implementation of the ToyBox intervention, the exposure of children/parents/teachers to the intervention and the satisfaction regarding the intervention and the materials were assessed through this tool (Annex 2).
  - Process Questionnaire – intervention feasibility. This questionnaire was designed for the post-intervention assessment of the teachers. It is target only to teachers of the intervention participating schools and includes a set of questions aimed at assessing the general opinion on the ToyBox programme and the satisfaction of the experience once implemented (Annex 3).
- *Parents' questionnaire.*
  - Core Questionnaire (CQ). The CQ is aimed at assessing the socio-demographical and perinatal risk factors, and the information related to the four EBRBs. The CQ includes three different components: 1) the family setting and the factors correlated to the lifestyle, e.g., parents' education level and occupation of parents/caregivers; child's sleep pattern; 2) behaviour of parents/caregivers and the behaviour of children with reference to the four target behaviours (drinking behaviour, snacking behaviour, physical activity and sedentary behaviour) and 3) perinatal factors, e.g., weight at birth or breastfeeding duration. Overall, the questionnaire consists of several items (229) related to both the habits of the children and of the parents/caregivers. A clinical record of the child was included at the end of questionnaire, including information on a series of diseases (Annex 4).
  - Food Frequency Questionnaire (FFQ). The FFQ aims at assessing the children's dietary habits (main meals, snacks consumed at home and outside, for example at

school), which are relevant for the goals of the ToyBox interventions in the last 12 months, both in terms of consumption frequency and consumption quantity. Thus, a photographic atlas was built and provided to parents to facilitate the identification of the consumption quantities (Cardon et al, 2016) of which an example is given in Figure 24. The FFQ includes 44 items relative to the food and beverage consumption patterns; the intake of supplements was also investigated (Annex 5).

- Questionnaire for the post-intervention assessment of parents. The questionnaire was developed for the post-intervention assessment of parents. It is exclusively targeted to parents and it consists of a series of questions aims at assessing the general opinion on the ToyBox programme and the satisfaction about the experience of each parent once during its implementation (Annex 6).

Figure 24. Illustrative tables included in the photo appendix page created for the drafting of the FFQ.



4.4 Phase 3-Validation of the tools for the effectiveness evaluation

4.4.1 Specific objectives

During Phase 3, the validation of the Italian version of the two questionnaires for families or, more in general, to the so-called 'caregivers', (i.e., a person who provides care to children, who not always are their parents) was carried out, aimed at the effectiveness assessment: the CQ and FFQ.

4.4.2 Design of the study

The study is structured according to an observational test-retest design.

The recruitment of the sample and the data collection occurred between September 2017 and February 2018. A formal application of scientific collaboration was sent via email to the local Boards of Education along with the study protocol, the questionnaire for the parents/caregivers, the information material and the consent form for the participation in the study and the personal data processing. Before the questionnaires were handed out, two meetings were held with the teachers of each preschool aimed at illustrating how to complete questionnaires. In compliance with other participating European Countries, the questionnaires were handed after obtaining the consent to participate in the study and the authorisation to process personal data by the questionnaire responders (parents/caregivers). The same group of caregivers was asked to compile the questionnaire twice, the second administration after two weeks. The timespan of two weeks is long enough to prevent a memory effect: that is, on the retest, the questionnaire responder cannot remember the sequence of the responses already given on the first completion of the questionnaire. At the same time, it is short enough so that, possibly, the required information does not change.

4.4.3 Sample

The selection for the schools and of the classes was based on a criterion of convenience and not of statical representativeness of the local population. The study was performed in two schools of the province of L'Aquila (Italy) for a total of 3 schools: the High School "Argoli" in Tagliacozzo (Preschool "M. Montessori") and the Comprehensive School "A. B. Sabin" in Capistrello: 1- School of Capistrello 2- School of Castellaffiume. During

school year 2017/2018, a total of 10 classes were enrolled, of which 6 in the High School in Tagliacozzo, 4 in the Comprehensive School in Capistrello (3 in the school of Capistrello and 1 in the school of Castellafiume), involving 19 teachers. Preschool children only (3-6 anni) whose parents/caregivers granted their consent were included in the study.

4.4.4 Measurement methods and tools

CORE QUESTIONNAIRE. The questionnaire is aimed at the assessment of the demographical and risk factors of the perinatal period, and of the information on four EBRBs, specifically the consumption of plain water and beverages, physical activity, consumption of snacks and sedentary behaviour.

Overall, the questionnaire includes 229 items regarding both the habits of children and of parents/caregivers divided into six sections: 1. Socio-demographic variables (32 items); 2. consumption of plain water and beverages (24 items); 3. consumption of snacks (71 items); 4. physical activity (27 items); 5. sedentary behaviour (38 items); 6. Information on perinatal health (37 items) (Annex 4).

FOOD FREQUENCY QUESTIONNAIRE. After compiling the CQ, parents/caregivers were asked to describe the habits of their children in the FFQ over the last 12 months. The FFQ includes questions regarding main meal, snacks consumed both at home and outside, e.g., preschool, sports facilities, and the following food groups:

- Juices and other drinks
- Milk, yogurt and cheese
- Fruit and vegetables
- Bread
- Potato, rice and pasta
- Meat, poultry, fish products
- Legumes dishes
- Breakfast cereals
- Biscuits, cakes and pastries
- Sugar, jam and other spreads
- Chocolate

- Desserts
- Savory snacks.

For each food group, the frequency of consumption was asked on a six-point scale, ranging from "never o less than once a month" to "every day". Parents were then asked to write the category of size portion more adapted to the average daily consumption. The reply categories varied according to the dietary product and a list of common standard measures was given (e.g., a cup = 225 ml). Moreover, parents/caregivers could refer to a photographic appendix designed to facilitate the selection of the portion sizes (see paragraph 4.3.3, Figure 24). No distinction is made between the consumption on weekdays and on weekend in the food frequency questionnaire. The consumption of the main meals was assessed by asking on a six-point scale how many days per week (from "never or less than once a month " to "every day") children had breakfast, lunch, dinner and snacks (Annex 5).

4.4.5 Data storage and statistical analysis

Data were stored in Google Drive modules and the database was retrieved and analysed using the statistical software STATA 14 IC. In particular, the variables regarding food consumption frequency and the attitude measurements on the ordinal scales were converted in numerical numbers. The statistical analysis was targeted to the description of the sample and to the assessment of the stability of the test-retest through correlation analyses through the Spearman's rank correlation coefficient, applied to the scores of the single items. The acceptability criteria used are the following: rho<0.30, ‘Low’; 0.30≤rho<0.60, ‘acceptable; rho≥0.60, ‘High’. Descriptive measures of central tendency were calculated (mean, median) and of variability and of variability (standard deviation and interquartile range). In the comparison of the questionnaire scores, tests for the assessment of the association among the categorical variables (Chi-Squared test with Fisher's correction) and for the assessments of the variance among the mean values and the quantitative variables between groups (ANOVA test) were applied.

4.4.6 Results relative to the Core Questionnaire.

Overall, we collected 108 questionnaires, of which only 48 in the retest phase, with an overall proportions of questionnaire retrieved of 44.4%, maximum in the School of Capistrello (57.9%) and minimum in the School of Castellafiume (only 25%) as displayed in Table 5.

Table 5. Absolute number of questionnaires (CQ) collected in the schools and proportions of questionnaire retrieved at retest in the retest phase.

School	TEST	RETEST	Proportions of questionnaire retrieved at retest
01 - Tagliacozzo	73	33	45.2%
02 - Capistrello	19	11	57.9%
03 - Castellafiume	16	4	25.0%
Total	108	48	44.4%

The questionnaire in the test phase (taken as a reference for the description of the overall sample of monitored children) in 90.7% of the cases was completed by the mothers (98 out of 100), and in the remaining 8.3% by the father (9 out of 108, such proportion is higher in the subset of children with a biological mother who was not born in Italy, $p<0.05$ with the Fisher test), except in one case where the questionnaire was compiled by other child's caregiver.

The 96.3% of the sample consists of children born in Italy (104/108), whereas 3 were born in Albania, and for 1 child no information was given on the country of origin.

Overall, 20.4% of the mothers and 13.9% of the fathers were not born in Italy, chiefly in European countries (prevalently Albania, Romania). The 13.0% of children have both parents not born in Italy and this association results statistically significant ($p<0.001$), with the Fisher's exact test). In 4.6% of the sample, adults speak mainly a language other than Italian in their households. In 86.1% of the cases, the family consists of mother and father, in 5.6% only of the mother, in 4.6% of mother, father and grandparents or other adults, in 1.9% of the mother and a new partner, and in the remaining 1.9% of other adults without biological parents (grandparents, friends). In 41.7% of the children, the education level of the questionnaire responder is 'average' (from 13 to 16 years of schooling, which corresponds to secondary high school diploma), is 'high' in 31.5% (more than 16 years if schooling, degree or post-graduation studies), and the level is 'low' in 21.3% (up to 12

years, elementary and lower secondary school). The level of education of the spouse/partner, if present, is ‘average’ in 34.3% of children (from 13 to 16 years of schooling, which corresponds to the upper secondary school diploma), is ‘high’ in 24.1% (more than 16 years if schooling, degree or post-graduation studies) and ‘low’ in 30.6% (up to 12 years, elementary and lower secondary school) and it results statistically associated with the level of the questionnaire respondent ($p<0.001$ Fisher's exact test). The main occupation of the questionnaire respondent (almost exclusively the mothers) in the last six months was of working type (23.2% have a full-time job and 23.2% have a part-time job), followed by full time homemaker (30.6%), whereas 9.3% results ‘unemployed’ or they are engaged in ‘other’ activities (6.5%). Even for the spouse/partner, the main occupation was of working type with a higher percentage (72.8% has a full-time job and 2.9% part-time), followed by ‘other’ occupations (6.8%), whereas 7.8% results to be ‘unemployed’ or ‘unable to work’. The average age of the questionnaire respondent is 35.8 years ± 6.0 years (range 23 – 50 years), whereas that of the spouse/partner, where present, is 39.7 ± 6.7 years (range 25 – 58 years).

The distribution of children by gender is homogenous: 54 females and 52 males (gender was not indicated for two children) with percentage values corresponding to 50.9% and 49.1%, respectively. The average age is 4.6 ± 0.9 years (range 1.9 – 6.0 years). The most represented age range is 5 years and older (39.1%), followed by 4 years up to less than 5 years (34.3%) and by the less prevalent age range of younger than 4 years (26.7%), and this distribution does not show any significant association with the gender of the children. In the everyday activities, the questionnaire respondent is also the person who does more frequently the most important tasks, like preparing the child for school (77.6%), taking the child to school (61.1%), collecting the child from school (53.7%), cooking for the child (74.5%), helping them to eat (62.9%), and finally, supervising their outdoor activities (54.7%), compared with the spouse/partner, grandparents, or other people. However, this may be considered important data to assess the accountability of the responses to the proxy questionnaire, by the questionnaire respondent who, therefore, has more time and more occasions to observe the child compared with other persons in the household.

Table 6 reports the data for the single items relative to the assessment of the test-retest stability in the section of the questionnaire regarding the consumption of beverages by the caregivers: for all the items an ‘acceptable’ level of stability is reported (Spearman's rank correlation coefficient between 0.30 and 0.60) in a statistically significant way, also at less high levels of the consumption of drinks (both sugared and light).

Table 6. Spearman correlation between test and retest scores for the single items relative to the caregivers’ beverage consumption frequency (rho values are reported in red<0.30, low).

Beverage	**rho**	**sign.**	
B1. Plain water	0.405	0.004	**
B2. Homemade fruit juices and fresh homemade juice	0.506	0.000	***
B3**.** Prepacked juices	0.549	0.000	***
B4. Light beverages	0.335	0.020	*
B5. Sugar-sweetened beverages	0.308	0.034	*

Instead, in the case of the attitudinal variables on the child’s beverage consumption (behaviours, experiences, perceived adequacy, beliefs, Table 7) ‘poor’ levels (rho di Spearman<0.30) of stability are reported for some single items, in particular B.10, rho=0.280; B.10, rho=0.274; B.15, rho=0.227 and B.18, rho=.0215). However, in all four cases, the level of significance is poor, p>0.05).

Table 7. Spearman correlation between test and retest scores for the single items relative to the caregivers' beverage consumption frequency (rho values are in red <0.30, low).

	rho	sign.	
Behaviours and experience			
B6. My child can drink prepacked beverages or prepacked fruit juices whenever he/she asks for.	0.468	0.001	***
B7. I have always plain water ready for my child	0.456	0.001	**
B10. I encourage my child to drink plain water	**0.280**	0.054	n.s.
B11 If I would like to drink soft drinks or prepacked juices, I would try to restrain myself because of the presence of my child.	0.334	0.022	*
B14. There is always water on the table at mealtimes	0.434	0.002	**
B17. I make prepacked beverages and fruit juices always available for my child.	0.563	0.000	***
B19. My child is allowed to drink prepacked beverages and fruit juices as much as he/she likes.	0.581	0.000	***
B20. I give beverages or fruit juices to my child as a reward or to comfort him/her	0.480	0.001	***
B21. During meals there are always prepacked beverages and fruit juices on the table	0.359	0.012	*
B22. My child drinks prepacked beverages and fruit juices only on certain occasions, e.g., during birthday parties.	**0.274**	0.060	n.s.
B13. My child prefers drinking prepacked beverages and fruit juices to drinking water	0.525	0.000	***
B15. I find it difficult to give my child water if he/she wants soft drinks or prepacked juices.	**0.227**	0.122	n.s.
B16. My child does not like drinking plain water	0.386	0.007	**
Perceived adequacy			
B12. I am happy with the plain water consumption of my child	0.416	0.003	**
B18. The amount of water drunk by my child is within the recommended values	**0.215**	0.143	n.s.
Beliefs			
B8. It is bad for my child to drink soft drinks every day	0.349	0.015	*
B9. It is bad for my child to drink prepacked fruit juices every day.	0.468	0.001	***
B23. How often do you think your child should drink prepacked beverages and juices?	0.662	0.000	***
B24. How many glasses of plain water do you think your child should drink every day?	0.4236	0.01	*

Table 8 and Table 9 show the levels of stability relative to the items on the caregivers' snack consumption: the test-retest correlation results to be 'acceptable' for all the items relative to the snacking frequency both on weekdays and on weekend days.

Table 8. Spearman correlation between test and retest scores for the single items relative to the caregiver's frequency of consumption of snacks between main meals on weekdays and weekends.

	rho	Sign	
Weekdays			
C1. Breakfast	0.481	0.0005	***
C2. Morning snack (between breakfast and lunch)	0.384	0.0078	**
C3. Afternoon snack (between lunch and dinner)	0.560	0.0000	***
C4. Evening snack (after dinner)	0.454	0.0013	***
Weekend days			
C1. Breakfast	0.376	0.0085	***
C2. Morning snack (between breakfast and lunch)	0.506	0.0002	***
C3. Afternoon snack (between lunch and dinner)	0.312	0.0309	*
C4. Evening snack (after dinner)	0.347	0.0170	*

With regard to the type of food consumed (Table 9), the value of the correlation coefficient is low for the following categories: C.10 Cakes, muffins, etc. (rho=0.263, n.s.), C.21 Fresh fruit (rho=0.299, $p<0.05$) and C.22 Vegetables (rho=0.154, n.s.).

Table 9. Spearman correlation between test and retest scores for the single items relative to the caregiver's frequency of consumption of specific foods between main meals on weekdays and (rho values are in red<0.30, low).

	rho	Sign	
C9. Nuts, peanuts, oleaginous fruits or dried fruit	0.637	0.0000	***
C10.Cakes/muffins	**0.263**	0.0709	n.s.
C11.Wholewehat bread	0.514	0.0002	***
C12.Biscuits	0.405	0.0043	**
C13.Salatini, crisps and other savoury snacks	0.521	0.0001	***
C14.Crackers, breadsticks	0.617	0.0000	***
C15.Chocolates	0.320	0.0264	*
C16.Sweets	0.678	0.0000	***
C17.Cheese	0.538	0.0001	***
C18.Savory pies/savoury tarts	0.423	0.0027	**
C19.Yogurt/fresh cheese	0.443	0.0016	**
C20.Pizza	0.416	0.0032	**
C21.Fresh fruit	**0.299**	0.0410	*
C22.Vegetables	**0.145**	0.3263	n.s.

Table 10 shows the levels of stability relative to the attitudinal variables of the children's snack consumption. An acceptable level is reported for all the single items, with the exception of C.34 ('I think that eating sweet/savoury snacks is not harmful to my child, rho=0.285, $p<0.05$).

Table 10. Spearman correlation between test and retest scores for the single items relative to the variables relative to the context and attitudes, behaviours and opinions of the caregivers on the snacks consumed by their child (rho values are in red<0.30, low).

	Rho	**Sign**	
Beliefs on the child's preferences			
C23. My child prefers eating fruit or vegetables as a snack	0.370	0.0104	*
C24. My child likes drinking milk and or eating dairies as a snack	0.652	0.0000	**
C25. My child likes eating cereal/bread as a snack	0.664	0.0000	**
Frequent food proposals			
C26. I often give fruit and/or vegetables as a snack to my child	0.467	0.0008	***
C27. I often give milk and/or dairies as a snack to my child	0.569	0.0000	***
C28. I often give cereal/bread as a snack to my child	0.546	0.0001	***
Regular food proposals			
C29. I regularly prepare snacks with fruit or vegtables for my child	0.454	0.0012	**
C30. I regularly prepare snacks with milk and/or dairies for my child	0.629	0.0000	***
C31. I regularly prepare snacks with cereal/bread for my child	0.618	0.0000	***
C35. I regularly prepare sweet or savoury snacks for my child	0.485	0.0006	***
Rules			
C36. My child is not allowed to have snacks while watching TV	0.479	0.0006	***
C37. My child is allowed to eat fruits or vegetables as snacks without asking	0.574	0.0000	***
C38. My child does not have to ask for permission to drink milk and/or eating dairies, cereal/bread as snacks	0.498	0.0003	***
C39. My child is allowed to eat sweet or savoury snacks only on specific occasions, e.g., during birthday parties	0.429	0.0023	**
C40. I give my child sweet or savoury snacks as a reward or to comfort him/her.	0.517	0.0002	***

Table 10 [Continued]

Barriers			
C41. I find difficult to prohibit my child from eating sweet or savoury snacks if he/she starts to throw a tantrum	0.558	0.0000	***
C42. I find difficult to stop myself from eating sweet or savoury snacks if my child is with me	0.494	0.0004	***
C32. My child chooses to eat sweet or savoury snacks even when he7she has the opportunity of eating fruit or vegetables	0.609	0.0000	***
C33. My child chooses to eat sweet or savoury snacks even when other children eat fruit or vegetables	0.454	0.0012	**
Opinions			
C34. I think that eating sweet or savoury snacks does not harm my child	**0.285**	0.0495	*
C43. I am happy with the food habits of my child with regard to the consumption of snacks	0.583	0.0000	***

4.4.7 Results of the Food Frequency Questionnaire

The FFQ was completed by a subset of caregivers, corresponding to 90 children, of which 40 only in the retest phase, with an overall proportions of questionnaire retrieved at retest of 44.4%, highest in the School of Capistrello (55.5 %) and minimum in the School di Castellafiume (only 16.7 %) as reported in Table 11.

Table 11. Absolute number of questionnaires (*FFQ*) collected in the schools and proportions of questionnaire retrieved at retest in the retest phase.

School	TEST	RETEST	Proportions of questionnaire retrieved at retest
01 - Tagliacozzo	52	26	50.0%
02 - Capistrello	20	11	55.0%
03 - Castellafiume	18	3	16.7%
Total	90	40	44.4%

Table 12 summarizes the data by single item relative to the assessment of the test-retest stability in the section of the FFQ on children's consumption of 'Juices and other drinks.'

The item relative to the plain water consumption has a very low value of the Spearman's rho (-0.026, n.s.). However, this is due to the fact that the caregivers who completed the questionnaire gave homogeneous responses and nearly all of them coincided in the highest consumption frequency rates, hence in statistics a 'ceiling effect' occurs; this is

substantiated by the high correlation in the variable measuring the daily amount of water (rho=0.638, p<0.001). Conversely, poor correlation levels, are reported for the consumption frequencies of light beverages (rho=0.298, n.s.) and for the daily amount of fruit juices, both homemade (rho=0.283, n.s.) and prepacked (rho=0.296, n.s.).

Table 12. Spearman correlation between test and retest scores for the single items relative to the frequency of consumption of 'Juice and other drinks' and to the daily quantity (rho values are in red<0.30, low).

	Frequency of consumption			Quantity		
Juice and other drinks	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
Plain water	**-0.026**	0.8752	n.s.	0.638	0.0000	***
Sugared drinks	0.800	0.0000	***	0.632	0.0000	***
Light drinks	**0.298**	0.0616	n.s.	0.584	0.0001	***
Homemade fruit juice	0.861	0.0000	***	**0.283**	0.0772	n.s.
Prepacked fruit juice	0.494	0.0012	**	**0.296**	0.0641	n.s.
Herbal tea	0.521	0.0006	***	0.541	0.0003	***
Smoothies	0.439	0.0046	**	0.358	0.0234	*

Instead, with regard to the items relative to 'Milk, yogurt and cheese' (Table 13) and to 'Fruit and vegetables' (Table 14), an acceptable correlation is reported, except for the measure of the daily quantity of raw vegetables (rho=0.167, n.s.).

Table 13. Spearman correlation between the test and retest scores for the single items relative to the consumption frequencies of 'Milk, yogurt and cheese' and daily quantities.

	Frequency of consumption			Quantity		
Milk, yogurt and cheese	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
Plain milk	0.414	0.0080	**	0.564	0.0002	***
Sugared or Flavoured milk	0.567	0.0001	***	0.418	0.0073	**
White Yogurt	0.644	0.0000	***	0.606	0.0000	***
Sugared or Flavoured Yogurt	0.584	0.0001	***	0.540	0.0003	***
Cheese (cheese spread, cheese slices, ricotta cheese)	0.537	0.0004	***	0.425	0.0063	**

Table 14. Spearman correlation between test and retest scores for the single items relative to the frequency of consumption of 'Fruit and vegetables' and daily quantities (rho values are in red <0.30, low).

	Frequency of consumption			Quantity		
Fruit and vegetables	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
Dried fruit	0.556	0.0002	***	0.453	0.0033	**
Canned fruit	0.635	0.0000	***	0.643	0.0000	***
Fresh fruit	0.666	0.0000	***	0.608	0.0000	***
Raw vegetables	0.585	0.0001	***	**0.167**	0.3036	n.s.
Cooked vegetables	0.334	0.0353	*	0.332	0.0363	*

Even for the 'Bread, pasta, rice, potatoes' category (Table 15) the stability of the items resulted to be acceptable, except for the measure of the consumption frequency of the whole wheat bread (rho=0.289, n.s.).

Table 15. Spearman correlation between test and retest scores for the single items relative to the frequency of consumption of 'Bread, pasta, rice, potatoes' and daily quantities (rho values are in red<0.30, low).

	Frequency of consumption			Quantity		
Bread (including buns and toasts)	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
White bread and other bakery products	0.412	0.0083	**	0.532	0.0004	***
Brown bread and other whole wheat bakery products	**0.298**	0.0617	n.s.	0.508	0.0008	***
Pasta, rice, potatoes						
Pasta	0.572	0.0001	***	0.878	0.0014	**
Rice	0.680	0.0000	***	0.463	0.0026	**
Fried potato products	0.450	0.0035	**	0.522	0.0006	***
Potatoes (steamed, boiled, etc.)	0.627	0.0000	***	0.629	0.0000	***

The results from the items relative to the consumption of meat and poultry and of meat-based products showed some issues (Table 16): in the first case, the levels of correlation of both frequencies (rho=0.225, n.s.) and of the quantity (rho=0.208, n.s.) were low; in the second case, only the levels related to quantities were poor (rho=0.295, n.s.).

Table 16. Spearman correlation between test and retest scores for the single items relative to the frequency of consumption of 'Meat and poultry and meat-based products' and daily quantities (rho values are in red<0.30, low).

	Frequency of consumption			Quantity		
Meat, poultry and meat-based products	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
Meat and poultry	**0.225**	0.1635	n.s.	**0.208**	0.1968	n.s.
Fish e prodotti della pesca	0.312	0.0502	n.s.	0.498	0.0011	**
Meat-based products	0.324	0.0417	*	**0.295**	0.0647	n.s.
Legumes						
Legumes	0.376	0.0168	*	0.481	0.0017	**

Finally, all the items relative to confectionaries resulted to be stable at an 'acceptable' level (Table 17), with the exception of the daily quantities of biscuits (rho=0.147, n.s.) and of sugar products (sweets, rho=0.165, n.s.).

Table 17. Spearman correlation between test and retest scores for the single items relative to the frequency of consumption of cakes (e.g., cookies, cakes, cereal, chocolate, etc) and to the daily quantities (rho values are un red <0.30, poor).

	Frequency of consumption			Quantity		
Breakfast cereal	**Rho**	**Sign (p)**		**Rho**	**Sign (p)**	
Sugar-free breakfast cereal	0.594	0.0001	***	0.333	0.0356	*
Sugar-coated breakfast cereal	0.451	0.0035	**	0.463	0.0026	**
Biscuits, cakes, pastries and sweets						
Cakes, sweet snacks, brioches	0.352	0.0258	*	0.612	0.0220	*
Biscuits	0.646	0.0000	***	**0.147**	0.3663	n.s.
Cream puffs and dry biscuits	0.659	0.0000	***	0.519	0.0006	***
Sugar products	0.599	0.0000	***	**0.165**	0.3088	n.s.
Jam and other spreads						
Chocolate cream spread and jam	0.330	0.0404	*	0.4945	0.0012	**
Chocolate and desserts						
Chocolate	0.588	0.0001	***	0.310	0.0520	n.s.
Milk cakes and ice-creams	0.539	0.0003	***	0.448	0.0037	**
Savoury snacks						
Savoury snacks	0.466	0.0024	**	0.369	0.0192	*

4.5 Phase 4-Cross-sectional epidemiological analysis

During Phase 4, an observation study with a cross-sectional design was conducted for the preliminary assessment of the eating behaviour of a sample of pre-schoolers eligible to be enrolled in the target territory, accounting for the following aspects:

1) healthfullness of children's dietary habits
2) presence of excess body weight.

4.5.1 Objectives of the study

The study during Phase 4 had the following specific objectives:

- assessing the compliance of the consumption frequencies of food groups with the Guidelines for the preschool age, as delivered by the medical-scientific community;
- describing the children's activities with respect to the consumption of beverages and foods between main meals;
- estimating the weekly consumption frequency and the daily average amount of beverages and foods rich in free sugars;
- estimating the prevalence of the overweight/obesity status based on the international standards defined by the BMI scores and waist circumference.

4.5.2 Design of the study and recruitment of the sample

The study consists of an observational survey with a cross-sectional design. The recruitment of the sample and data collection took place in the provinces of L'Aquila and of Ascoli Piceno in the school year 2017-2018, based on the protocol of scientific research collaboration with the Educational Boards, in compliance with the law on the ethical protocols regulating the participation in the study and handling of personal data.

Overall, five Schools were enrolled:

- two schools in the province of L'Aquila for a total of 3 schools: The High School "Argoli" in Tagliacozzo ("M. Montessori" preschool) and the Comprehensive school "A. B. Sabin" in Capistrello: 1) School of Capistrello; 2) School of Castellafiume, involving 6 classrooms and 19 teachers.
- three institutes in San Benedetto del Tronto (AP): The Comprehensive School 'San Benedetto del Tronto – CENTRO' – seat of the Preschool 'Marchegiani' preschool; the Comprehensive School 'San Benedetto del Tronto – CENTRO' – seat of the 'Togliatti' preschool; the "Teresa e Pietro Merlini" private preschool, involving 15 classrooms and 30 teachers.

The participation in the study was voluntary, therefore the selection of the schools and of the classes was not performed through a randomized method, therefore it is not statistically representative of the local population.

Overall, the sample includes 107 children recruited in the province of L'Aquila (hereafter referred to as 'Sample – AQ) and 225 children recruited in San Benedetto del Tronto (hereafter referred to as 'Sample – SB'). Children were all in their preschool age (3-6 years) and their parents/caregivers granted their consent to participate in the study. However, the different types of data, due to the different availability of the School Institutes and to completeness of data by the recruited families, does not result to be homogenous, as reported in Table 18.

Table 18. Stratification of the sample of pre-schoolers by subject of the epidemiological analysis and geographic area.

PROVINCE	No. Schools	Compliance with Dietary Guidelines (no. children)	Consumption of snacks and beverages (no. children)	Anthropometry (no. children)
L'Aquila	2	107	82	-
Ascoli Piceno	3	225	209	202
TOTAL	5	332	291	202

4.5.3 Tools for the collection, examination and processing of the data

The data collection was performed only after obtaining the consent to participate in the study and the authorization and the personal data and consent disclosure of the respondents (parents/caregivers) by signing a written document (personal data and consent disclosure).

QUESTIONNAIRES. Between February and May 2018, the two questionnaires (CQ e FFQ) described in paragraph 4.4.4, were administered to the participating families of the five School Institutes.

ANTHROPOMETRIC MEASUREMENTS. In the 'Sample – SB' (three School Institutes), in the same period, the anthropometric data collections in the classroom were carried out by trained personnel with the collaboration of the teacher.

Data collection was followed by the electronic storage of the data through Google Drive modules and database retrieved and processed with the statistical software STATA/SE 14.2 ® from June to December 2018.

4.5.4 Statistical analysis

In the statistical analysis, measures of frequency, of central tendency (arithmetic mean and percentiles) and of variance (standard deviation, range) were used. To compare the scores of the questionnaire, we used association tests for categorical variables (Chi Square statistic with Fisher's correction) and, for quantitative variables, tests for difference between groups (parametric, such as Student's t-test and non-parametric, such as Wilcoxon's test and Kruskall-Wallis test) and test for trend across groups (non-parametric Cuzick's test).

4.5.5 Results – Healthfulness of children's dietary habits

4.5.5.1 Adherence of the consumption frequency of diet groups to the Guidelines by pre-school age

To assess the healthfulness of the dietary habits of the pre-schoolers enrolled in the study, we compared the data through the FFQ on the frequency and quantity of consumption of food groups and the Guidelines released by the Italian Society of Paediatric Gastroenterology, Hepatology, and Nutrition (SINGEP) in collaboration with the Bambino Gesù Children's Hospital in Rome (Scaglioni & Bettocchi, 2016).

Data refer to 332 children of the same chronological age, on average 4.6 ± 0.9 years (range 2.6 – 6.4 years), distributed in 183 females (55.4%) and 147 males (44.6%).

Table 19 reports the percentage of children who consume specific foods with the recommended frequency and quantity.

Table 19. Compliance with to the SINGEP Guidelines – Bambino Gesù Children's Hospital [Source: Scaglioni & Bettocchi, 2016] by Food Group: percentage % of children who consume each food with the recommended frequency.

Food groups and recommended consumption frequency		**Territory**[(a)]		**Age groups**			**Total**
		AQ	**SB**	**< 4 years**	**4-5 years**	**>5 years**	
Milk - Yogurt							
1-2 servings per day		64.0	52.0	64.7	56.4	48.6	55.9
After 3 years of age semi-skimmed milk		31.4	25.1	27.1	26.6	27.8	27.2
Pasta, Rice, Spelt, Barley							
Every day, at lunch and dinner		82.9	69.5	75.0	73.4	71.4	73.1
Whole wheat pasta or parboiled rice recommended		0.0	0.0	0.0	0.0	0.0	0.0
*Bread*1/2 sandwich per meal		39.5	33.8	35.3	35.1	35.8	35.4
Whole wheat bread recommended		10.0	8.0	9.5	12.0	4.9	8.6
Meat	3-4 times per week	65.1	79.9	74.1	73.4	78.0	75.4
Fish	3-4 times per week	34.9	45.1	48.2	34.0	45.0	42.4
Legumes	3-4 times per week	36.1	37.3	37.7	36.2	36.7	36.8
Eggs	Once a week	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Cheese	Once a week	16.3	27.0	24.7	21.3	24.8	23.6
Oil seeds	3-4 times per week	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Cold cuts	once a week	29.1	36.3	29.4	26.6	45.0	34.4
Fruit	3 servings per day	35.5	28.9	28.8	32.6	31.6	31.0
Vegetables	2 servings per day	3.6	3.0	2.4	2.2	4.7	3.2

Table 19. [Continued]

Seasonings Every day, extra virgin olive oil to be preferred	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
Herbs/Spices Every day, limiting salt	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.

[(a)]AQ=Province of L'Aquila; SB= San Benedetto del Tronto (AP)

In particular:

- MILK – YOGURT. 55.9% of the total sample consumed milk/yogurt 'every day', 1 – 2 servings. This proportion was higher in the sample-AQ compared with sample-SB (n.s. but the value of p=0.06) and it was also higher among younger children (age < 4 years) compared with the older (age > 5 years) with significant difference in the test for the difference in proportions ($p<0.05$).

  Less than 1/3 of the total sample respected the recommendation of eating 'semi-skimmed' milked after 3 years of age and this percentage resulted to be quite homogeneous across the territory and the age group;
- PASTA, RICE, SPELT, BARLEY. 73.1% of the total sample respected the recommendation of eating these carbohydrate foods at lunch and dinner ('every day') with a statistically significant difference between the two territories (higher in the sample-AQ - 82.9% - *vs* sample-SB –69.5%, $p<0.05$);

  With regard to the recommendation of 'preferring durum wheat pasta', or 'whole wheat' pasta or parboiled rice, none of the respondents referred this preference to their child;
- BREAD. The intake of bread, from the analysis of the data of the FFQ was reported with an 'every day' frequency (which corresponds to the recommendation of eating at least '½ bread roll per day'). Overall, 35.4% complied with these recommendations, with a moderate primacy of the sample-AQ (39.5%) over the sample-SB (33.8%), though not statistically significant;

  Lower percentages of compliance are reported for the recommendation of using 'whole wheat' pasta or bread or 'with little refined flour', respected only by 8.6% of the overall sample, without any significant difference between the samples, not even by age group, although a lower percentage was reported among the older children compared with other age groups (4.9% *vs* 9.5% and 12.0%);

- MEAT. Overall, 75.4% ate meat 3-4 times per week as recommended in the Guidelines, equally across the different age groups but significantly different between the sample-AQ where the rate of compliance was lower (65.1%) *vs* the sample-SB (79.9%, $p<0.01$). However, the review of the responses given to the FFQ highlights that the difference is ascribable to a level of excessive meat consumption in the sample-AQ, because 17.4% of the parents reported that their children eat meat 5-6 times per week (proportion corresponding to 9.3% in the sample-SB);
- FISH. 42.4% of the total sample ate fish '3-4 times per week' as recommended, less frequently in the sample-AQ (34.9%) *vs* sample-SB (45.1%) possibly for the geographic position of the territory near the sea, even if the difference was not statistically significant (n.s.);
- LEGUMES. 36.8% of the overall sample ate legumes based on the recommended frequencies ('3-4 times per week') and this percentage was particularly homogenous with respect to the stratification by territory and by age. The remaining proportions can be attributed to lower consumptions;
- CHEESE. The recommendation of consuming cheese in limited portions or 'once a week' was respected by a low percentage of the overall sample (23.6%) lower – at the margin of statistical significance – in the sample-AQ (16.3%) than sample-SB (27.0%, $p=0.0506$). A greater percentage (accounting for 58.1% in the sample-AQ and 39.7% in the sample-SB) consume it in excessive quantities, that is 2-4 times per week;
- COLD CUTS. 34.4% of the overall sample consumed cold cuts 'once a week', as recommended, and with a higher proportion in older children (>5 years of age). The low compliance is ascribable to the higher proportion of children who consumed these foods 2-4 times per week (45.4% of the sample-AQ and 44.6% of the sample-SB);
- FRUIT. Less than one third of the overall sample (31.0%) ate 3 serving of fruit per day with homogeneous stratification by territory and age;
- VEGETABLES. This is a food group whose consumption was less adherent to the recommendations: only 3.2% of the children ate '2 portions per day' of vegetables and this percentage was quite homogeneous in the two samples by age group.

We could not calculate the consumption frequencies rates from the FFQ– and therefore also the levels of compliance with the recommendations by pre-school age – referred to ‘Eggs’, ‘Oily seeds – Dried fruit’, ‘Seasonings’, ‘Herbs – Spices’ - because not present among the reviewed items.

4.5.5.2 Daily food habits: snacks and beverages

Data refer to 291 children, 156 females (54.9%) and 128 males (45.1%), of the same chronological age, on average 4.6 ± 0.9 years (range 2.6 – 6.4 years), to our knowledge (for 7 children, sex was not reported by the parents).

Table 20 reports the daily meal patterns: approximately 16% of children did not have breakfast every day (in particular, 3.8% never or less than once a week). Dinner was the main meal most frequently consumed (92.1% of children have it every day). Every day, 61.4% of children had in-between meals and 76.6% drank between meals: therefore, nearly two thirds of children ‘are exposed’ to the food choice of *snacking* and three quarters are exposed to the choice of beverages.

Overall, 88.0% of children had a regular school meal intake, 4.8% only occasionally and 4.1% never. The percentage of children who take vitamin-mineral or other supplements was 17.8% (12.3% with an almost weekly frequency), among the most frequent multi-component supplements (data not reported in the table).

Table 20. Frequency rates of consumption of main meals by children.

	Never or hardly ever	1-3 times/month	1 day/week	2-4 days/week	5-6 days/week	Every day	NR	
Breakfast	3.8%	1.0%	1.7%	3.8%	3.4%	84.2%	2.1%	100.0%
Lunch	1.7%	0.0%	1.0%	1.7%	4.1%	89.0%	2.5%	100.0%
Dinner	1.7%	0.3%	0.7%	0.3%	2.4%	92.1%	2.5%	100.0%
Eats between the main meals	4.5%	2.8%	2.4%	16.2%	10.3	61.4%	2.4%	100.0%
Drinks between the main meals	1.0%	0.0%	1.4%	6.2%	9.6%	76.6%	5.2%	100.0%

Frquency of consumtpion of some foods and beverages

Table 21 reports the frequency rates of the intake and the daily quantities of 'Juice and other drinks' as median levels (the value separating the higher half from the lower half of a data sample) and third quartile (the value reached and surpassed by 25% of the sample). An optimal frequency of consumption of plain water (i.e., every day) is reported in 96.9% of the sample, however, compared to quantities, the third quartile ranges between '700 and 800 ml/day', lower than the recommended quantity, i.e., 1.600 ml/day, therefore less than 25% of the sample reach the recommended values of consumption, whereas the median is 'between 500 and 600 ml', which means that half of the sample do not drink more than this quantity. The frequency of the intake of drinks (both sugared and light) is '1-3 days/months' and the quantity is '100-200 ml/day' in 75% of the sample.

The frequency of the intake of homemade fruit juices is 1 day/week, and the quantity is 100-200 ml/day in 75% of the sample, and it is lower than the frequency consumption of prepacked juices that, instead, is 2-4 days/week, but the quantity is still 100-200 ml/day. On the other hand, the frequency of the intake of herbal teas and smoothies results to be 'never or less than once a month' in 75%.

Table 22 reports the consumption of 'Milk, yogurt and cheese'. The intake of white milk was higher than other dairy products, although only 25% of the sample drank it 'every day' (value corresponding to third quartile), whereas half of the sample drank it no more

than ‘2-4 days/week.’ This intake was higher than the consumption of flavoured milk, which had a lower median level (‘never or less than once a month’) and a lower third quartile (‘1 day/week’); the relative daily quantities resulted to be also higher for white milk (third quartile corresponding to ‘between 200 and 300 ml/day’) compared to flavoured milk (third quartile ‘between 100 and 200 ml’).

White yogurt (not sugared) was consumed less frequently: the third quartile corresponds to ‘1 day/week’, and the median is low (‘never or less than once a month’), the quantities were moderate compared to the value of the third quartile (‘between 65 and 195 gr’) but low in the median level (‘65 g or less’). Conversely. flavoured yogurt (sugared) was consumed more frequently: the third quartile corresponded to ‘5-6 days/week’, and the median to ‘2-4 days/week’; the quantities resulted to be moderate both in the median value and in the third quartile (‘between 65 and 195 g’ in both cases).

Twenty-five percent of the children ate cheese (cheese spread, melted cheese, cheese slices, ricotta cheese, cottage cheese) at least ‘2-4 times/week’ and the daily intake was not higher than 30-40 g, whereas half of the sample did not eat cheese more than ‘1 day/week’ and quantity was not higher than ‘between 20 and 30 g’.

The median consumption of fruit and vegetables is given in Table 23. A very low frequency of intake was reported for dried and canned fruit (the third quartile corresponds, to ‘1-3 days/month’ and to ‘never or less than once a month’, respectively). Conversely, frequency of fresh fruit was higher, whose median level corresponded however to ‘5-6 days/week, i.e., 50% of children did not eat fresh fruit every day and, where consumed, the level of intake was only120-150 g/day the (third quartile) in 75% of the sample.

The consumption of vegetables was lower: in 75% of the sample, the frequency of intake of ‘raw vegetables’ was ‘5-6 days/week’ and the quantity was in the range of ‘60-90 g/day’, whereas the consumption of cooked vegetables was lower (in 75% of the sample, the frequency of intake was ‘2-4 days/week’ and the quantity was in the range of ‘60-90 g/day’).

Table 24 reports the consumption of Bread (including bread rolls and toasts). Overall, a limited consumption of white bread was reported, whose median value was ‘2-4 times/week’, whereas the third quartile corresponds to a daily consumption (‘every day’), whereas, in the third quartile, the quantity was not higher than ‘30-60 g/day’. The median

frequency of intake of whole wheat bread is low, in fact, 50% of the children in the sample eats this food ‘never or less than once a month’ and only 25% of the sample eat it once a week and the quantity is in the median value of ‘30 g or less’ in the third quantile, corresponding to ‘between 30 and 60 g’.

Table 21. Children's consumption of 'Juice and other drinks: categories of frequency and average daily quantity of consumption corresponding to the median and third quartile.

	Frequency of consumption		Average Daily Quantity	
JUICES AND OTHE DRINKS	**Median**	**3° quartile**	**Median**	**Third quartile**
Water	Every day	Every day	Between 500 and 600 ml	Between 700 and 800 ml
Sugar-sweetened beverages	Never or less than once/month	1-3 days/month	100 ml or less	Between 100 and 200 ml
Light beverages	Never or less than once/month	Never or less than once/month	100 ml or less	100 ml or less
Homemade fresh fruit juice	1-3 days/month	1 day/week	Between 100 and 200 ml	Between 100 and 200 ml
Pre-packed fruit juices	1 day/week	2-4 days/week	Between 100 and 200 ml	Between 100 and 200 ml
Herbal teas (herbal tea, black tea, green tea, chamomile, etc.)	Never or less than once/month	Never or less than once/month	100 ml or less	Between 100 and 200 ml
Smoothies (of any type, also prepacked)	Never or less than once/month	Never or less than once/month	100 ml or less	Between 100 and 200 ml

Data referred to the responses given; missing data were excluded from the total.

Table 22. Children's consumption of 'Milk, yogurt and cheese': categories of frequency and average daily quantity of consumption corresponding to the median and third quartile.

	Frequency of consumption		Average Daily Quantity	
MILK, YOGURT AND CHEESE	**Median**	**3° quartile**	**Median**	**Third quartile**
White milk	2-4 days/week	Every day	Between 100 and 200 ml	Between 200 and 300 ml
Sugared or flavoured milk	Never or less than once/month	1 day/week	100 ml or less	Between 100 and 200 ml
White yogurt	Never or less than once/month	1 day/week	65 g or less	Between 65 and 195 g
Yogurt with different flavours or sugared before consumption	2-4 days/week	5-6 days/week	Between 65 and 195	Between 65 and 195 g
Cheese (cheese spread, melted cheese, ricotta cheese, cottage cheese	1 day/week	2-4 days/week	Between 20 and 30 g	Between 30 and 40 g

Data referred to the responses given; missing data were excluded from the total.

Table 23. Children's consumption of 'Fruit and vegetables': categories of frequency and average daily quantity of consumption corresponding to the median and third quartile.

	Frequency of consumption		Average Daily Quantity	
FRUIT AND VEGETABLES	**Median**	**3° quartile**	**Median**	**Third quartile**
Dried fruit (raisins, plums, apricots and dried figs, etc.)	Never or less than once/month	1-3 days/week	20 g	20 g
Canned fruit (cherries in syrup, canned pineapple, etc)	Never or less than once/month	Never or less than once/month	35 g or less	35 g or less
Dried fruit	5-6 days/week	Every day	Between 90 g and 120 g	Between 120 g and 150 g
Raw vegetables	2-4 days/week	5-6 days/week	Between 30 g and 60 g	Between 60 g and 90 g
Cooked vegetables (steamed, boiled, grilled, stewed)	2-4 days/week	2-4 days/week	Between 30 g and 60 g	between 60 g and 90 g

Data referred to the responses given; missing data were excluded from the total.

Table 24. Children's consumption of 'Bread, pasta, rice and potatoes: categories of frequency and daily median quantity of consumption corresponding to the median and third quartile.

	Frequency of consumption		Average Daily Quantity	
BREAD (including bread rolls and toasts)	**Median**	**3° quartile**	**Median**	**Third quartile**
White bread and other bakery products	2-4 days/week	Every day	Between 30 g and 60 g	Between 30 g and 60 g
Brown or whole wheat bread or other whole wheat bakery products	Never or less than once/month	1 day/week	30 g or less	Between 30 g and 60 g

* cooked

Data referred to the responses given; missing data were excluded from the total.

Table 25. Children's consumption of sweet foods (e.g., biscuits, cakes, cereal, chocolate, etc.): categories of frequency rates and average daily quantity of consumption corresponding to median values and third quartile.

	Frequency of consumption		Average Daily Quantity	
BREAKFAST CEREAL	**Third quartile**	**Median**	**Third quartile**	**Median**
Sugar-free breakfast cereal	Never or less than once/month	1-3 days/month	15 g or less	Between 15 g and 45 g
Sugar-coated breakfast cereal	Never or less than once/month	1-3 days/month	15 g or less	Between 15 g and 40 g
BISCUITS, CAKES, PASTRIES AND SWEETS				
Cakes, sweet snacks, brioches	1 day/week	2-4 days/week	Between 35 g and 70 g	Between 35 g and 70 g
Biscuits	2-4 days/week	5-6 days/week	Between 15 g and 30 g	Between 15 g and 30 g
Cream puffs and dry biscuits	Never or less than once/month	1-3 days/month	35 g or less	35 g or less
Sugar products	1 day/week	2-4 days/week	Between 5 g and 10 g	Between 10 g and 15 g
SUGAR, JAM AND OTHER CREAM				
Chocolate cream spread and jam	1 day/week	1 day/week	10 g or less	between 10 g and 20 g
CHOCOLATE AND DESSERTS				
Chocolate	1 day/week	2-4 days/week	25 g or less	Between 25 g and 50 g
Milk cakes and ice-creams	1-3 days/month	1 day/week	50 g or less	Between 50 g and 100 g
SAVOURY SNACKS				
Savoury snacks (cream crackers, taralli, crisps, bread sticks)	1 day/week	2-4 days/week	Between 25 g and 75 g	between 25 g and 75 g

Data referred to the responses given; missing data are excluded from the total

Table 25 reports the frequency of consumption of simple carbohydrates and sugared foods, such as cereal, biscuits, cakes, brioches, chocolate spread creams and jams.

The most frequently consumed products in this food group were biscuits for which the median value of the frequency corresponded to '5-6 days / week' while the average daily quantity, was 'between 15 and 30 g'. 'Cakes, sweet snacks, brioches' and 'sugar-based products' (confectioneries, lollipops, etc.) were consumed by 25% of the sample at least '2-4 times/week' in a quantity equal to 'between 35 and 70 g' (third quartile) for cakes, corresponding to at least 'between 10 and 15 g' (third quartile) for sugar-based products (e.g., confectioneries, lollipops, etc.).

Chocolate, chocolate spread creams and jams were consumed less frequently (median value corresponding to 1 day/week) and, with the same frequency rates, also savoury snacks. However, the value of the third quartile for chocolate and savoury snacks highlighted that 25% of the sample consumed these products more than 2-4 times per week.

Drinking and snacking in between meals

Table 26 reports the frequency of consumption of snacks between regular main meals in children, as reported in the questionnaire completed by their parents. The group 'Yogurt cheese spread, etc.' represented the most frequently consumed food across all '*snacking foods',* by 52.9% of the sample, followed by 'Fruit (fresh, dried or canned)', consumed by 49.5%. the food group. 'Bread, toasted bread and similar, e.g., focaccia bread' was consumed by approximately 40% of the children and, in an almost identical proportion, also the group 'Cakes and sweet cookies'. Less than a third of the sample consumed starchy snacks among 'Grilled bread, cream crackers, bread sticks, rice cakes etc.' (29.2%). The consumption of 'Sweets or chocolate' was reported for a proportion of children lower than a fifth of the sample (17.9%) whereas only 12.0% of the sample consumed savoury snacks reach in energy density, e.g. crisps. For all the other food groups reported in the questionnaire, the proportions of consumption were lower than 10%, particularly for the 'Vegetables (cooked or raw)' consumed only by 5.8% of the sample.

The reported proportions were homogenous across boys and girls and age groups, with no significant difference, except for the consumption of 'Cakes and biscuits' that increased steadily from the youngest (29.9% among children less than 4 years) to the oldest age groups (64.3% among children older than 6 years, $p< 0.05$ in the Chi Squared test).

Table 26. Proportions of children who habitually have in-between meals (*snacking*).

Food	**No.**	**%**
Yogurt, cheese spread, etc.	154	52.9%
Fruit (fresh, dried or canned)	144	49.5%
Cakes and sweet cookies	118	40.5%
Bread, toasted bread and similar, e.g., focaccia bread	116	39.9%
Grilled bread, cream crackers, bread sticks, rice cakes etc.	85	29.2%
Sweets or chocolate	52	17.9%
Crisps and other savoury snacks	35	12.0%
Breakfast cereal	25	8.6%
Other dairy products, e.g., cheese	19	6.5%
Vegetables (cooked or raw)	17	5.8%
Other (specified)*	8	2.7%
Does not eat between main meals	7	2.4%

*cold cuts, oleaginous fruit

Compared to the characteristics of the parents (education level, foreign country of origin, weight status) uneven proportions at a statistically significant level were detected only in the following comparison by specific 'snack foods':

- The consumption of 'Fruit (fresh, dried. canned)' was higher among the children of mother with a 'high' level of education *vs* the children of mothers with a 'lower' education (56.2% *vs* 37.5, $p<0.05$ in the Chi Squared test);
- The consumption of 'Cakes and biscuits' was higher among the children of mothers born in Italy *vs* those born in foreign countries (41.9% *vs* 27.0%, respectively $p=0.083$), was higher among the children of mothers with a higher level of education *vs* the children of mothers with a lower education (50.8% *vs* 25.0%, respectively $p<0.01$) and higher among the mother with a normal weight status *vs* overweight or obese mothers (44.6% *vs* 19.4% *vs* 33.3%, respectively);
- The consumption of 'Bread, toasted bread and similar, e.g. focaccia bread' was higher among the children of mothers born in Italy *vs* those born in another country (43.2% *vs* 24.3, respectively $p<0.05$);
- The consumption of 'Sweets and chocolate' was higher among the children of overweight/obese mothers *vs* underweight or normal weight mothers (27.0% *vs* 15.1%, respectively $p<0.01$).

Table 27 reports the frequency of intake of beverages by children in between meals, as reported in the questionnaire completed by the parents. Water represented the most frequently consumed drink by 89.7% of the total sample, followed by 'Prepacked fruit juices' (44.7% of the sample), 'Homemade fruit juice, homemade fresh fruit juice' consumed by 29.2%, and 'White milk' by '16.5% of the children. The other beverages reported in the questionnaire have proportions of consumption lower than 10%. The reported proportions are evenly distributed between boys and girls and by age group, with no significant difference.

Table 27. Proportion of children who habitually consume the different beverages between regular main meals (*drinking*).

Beverage	**No.**	**%**
Plain water (excluding water contained in other beverages)	261	89.7%
Pre-packed fruit juices	130	44.7%
Fresh fruit juices, homemade fresh fruit juices	85	29.2%
White milk	48	16.5%
Smoothies (any type, also prepacked)	21	7.2%
Herbal teas (herbal teas, black tea, green tea, chamomile, etc.)	17	5.8%
Sweetened milk or chocolate-flavoured milk (e.g., Nesquik Chocolate Milk)	17	5.8%
Sugared beverages (fizzy drinks such as cola, lemonade, cold tea, etc.)	16	5.5%
Other (please specify)*	5	1.7%
Light drinks (e.g., Cola *light*, etc.)	3	1.0%
Does not drink between main meals	1	0.3%

*plant-based milk (rice milk), sweetened tea

The only beverage that did not account for any different in the consumption proportions with respect to the characteristics of the household was water: its consumption between main meals is more frequent among the children of mothers with a medium/high education level *vs* the children of mothers with a lower education level (92.6% *vs* 68.8%, respectively $p<0.001$) and more frequent in the children of mother and fathers born in Italy (91.1% and 91.4% respectively) *vs* mothers and fathers born in other countries (78.4% e 68.8) in a statistically significant way ($p<0.01$).

Attitudinal variables of the parents referred to the consumption of sugar-sweetened beverages

In the Core-Questionnaire, attitudinal determinants were detected referred to the parents regarding the intake of beverages by their child.

Table 28 reports the structure of the variables, arranged on 5-point Likert-type scales with interval scales ranging from 1 (minimum value) to 5 (maximum value). The relative items are reported for each determinant:

1. 'Normative behaviour on the intake of beverages' includes 6 items (B17, B19, B20, B21, B22);
2. 'Support to the consumption of water' includes 3 items (B7, B10, B14);
3. 'Perceived barriers for the consumption of water *vs* beverages or sugared juice' includes 3 items (B13, B15, B16);
4. 'Beliefs on sugar-sweetened beverages and health', includes 2 items (B8 and B9);

The respondents gave their opinion for each of the single items, using anchors such as 'strongly disagree' (=1) a 'strongly agree' (=5). The arithmetic mean of the scores relative to the items was then calculated to obtain only a numerical value for the four determinants.

Table 28. Structure of the attitudinal variables and scoring system: Likert scales and single items in the Core Questionnaire (Annex 4).

Normative behaviour on the intake of beverages (score 1 -5)
B6. I allow my child to drink prepacked beverages and fruit juices any time he/she wants
B17. I have always prepacked beverages and fruit juices available for my child
B19. My child is allowed to drink prepacked beverages and fruit juices in the quantity he/she prefers
B20. I give beverages or fruit juices to my child as a reward or to comfort him/her
B21. There are always prepacked beverages and fruit juices at mealtimes
B22. My child drinks prepacked beverages and fruit juices only on certain occasions, e.g., during birthday parties.
Support to the consumption of water (score 1 -5)
B7. I have always plain water ready for my child
B10. I encourage my child to drink plain water
B14. There is always water on the table at mealtimes
Barriers perceived for the consumption of water *vs* sugar-sweetened beverages and fruit juice (score 1 -5)
B13. My child prefers drinking prepacked beverages and fruit juices to drinking water
B15. I struggle to make my child drink water when he/she wants prepacked beverages and fruit juices
B16. My child does not like drinking plain water
Beliefs on the health risks related to the intake of sugar-sweetened beverages (score 1 -5)
B8. Drinking beverages every day harms my child's health
B9. Drinking prepacked fruit juices every day harms my child's health

The information on the correct weekly amount of 'beverages and pre-packed juices' and on the correct daily amount of 'water' are detected only by one question for each of the two aspects, always measured by a score from 1 (minimum correctness) to 5 (maximum correctness) as reported in Table 29.

Table 29. Structure of the questions on the correct information on the recommended consumption of beverages and prepacked fruit juice and water (score 1-5).

B23. How often should your child drink beverages and pre-packed fruit juice? The weekly portions correspond to the number of times/week	
Never	5
On specific occasions, e.g., during birthdays	5
1 glass or less per week	4
2-4 glasses per week	3
5-6 glasses per week	2
1-2 glasses per day	2
3-4 glasses per day	1
5 or more glasses per day	1
I don't know	1
B24. How many glasses of water should your child drink every day?	
None or almost none	1
1 glass or less per day	1
2 glasses per day	2
3 glasses per day	3
4 glasses per day	3
5 glasses per day	4
6 glasses per day	5
7 more glasses per day	
8 or more glasses per day	5
I don't know	1

We verified whether the values of the scores relative to the attitudinal variables detected in the parents presented any difference with regard to the children's habits, i.e., the children's intake of beverages between main meals, as reported in Table 30.

Table 30. Attitudinal variables referred to the parents stratified by beverage intake by their children. Arithmetic means of the scores on a 5 point interval scale and statistical significance of the difference in the non-parametric test of the rank sum test.

Beverages		Permissiveness	Water encouragment	Water barriers	Health beliefs	Info beverages/juice	Info water
water	yes	1.86	4.69	1.79	3.93	3.82	4.07
	no	2.08	4.53	1.76	3.91	3.48	4.00
		n.s.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
sugar-sweetened beverages	yes	2.48	4.68	2.28	3.57	3.21	3.86
	no	1.85	4.67	1.76	3.94	3.82	4.07
		p<0.001	*n.s.*	*p<0.05*	*n.s.*	*p=0.052*	*n.s.*
pre-packed juice	yes	2.06	4.65	1.90	3.70	3.22	4.14
	no	1.73	4.69	1.70	4.11	4.24	3.99
		p<0.001	*n.s.*	*p<0.05*	*p<0.001*	*p<0.001*	*n.s.*
fresh juice	yes	1.94	4.62	1.88	3.79	3.68	4.15
	no	1.85	4.69	1.75	3.98	3.83	4.03
		n.s.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*
sweetened milk	yes	2.33	4.67	2.18	3.34	3.00	3.81
	no	1.85	4.67	1.77	3.96	3.83	4.08
		p<0.01	*n.s.*	*p<0.05*	*p<0.01*	*p<0.05*	*n.s.*
white milk	yes	1.96	4.58	1.78	3.68	3.62	4.18
	no	1.86	4.69	1.79	3.97	3.82	4.04
		n.s.	*n.s.*	*n.s.*	*n.s.*	*n.s.*	*n.s.*

Caption:
Permissiveness= loose normative behaviour with regard to the beverage intake
Water encouragement=Encouragement to the consumption of water
Water barrier=Perceived barriers for the consumption of water *vs* sugar-sweetened beverages and juice
Health beliefs=Beliefs on the health risks associates with the intake of sugar-sweetened beverages
Info juice and beverages=Correct information on the recommended quantity of prepacked juice and beverages
Info water=Correct information on the recommended daily quantity of water

The variables 'Permissiveness' and 'Water barriers' reported the lowest values (the mean of the 1 to 5 scale point was in both cases always lower than 2.5) characterizing, therefore, an attitude and behavioural rules limiting the consumption of beverage and prepacked juices by the parents. Moreover, parents perceived few barriers to the consumption of water, therefore they believed that their children had a favourable attitude towards healthier beverages. Finally, the scale values for the 'Permissiveness' were statistically higher among parents whose children consumed sugar-sweetened beverages *vs* parents whose children did not consume them:

- sugar-sweetened beverages, respectively 2.48 *vs* 1.85 ($p<0.001$)
- pre-packed juices, respectively 2.06 *vs* 1.73 ($p<0.001$)
- sweetened milk, respectively 2.33 *vs* 1.85 ($p<0.01$).

Likewise, the scale values for the 'Water barriers' were higher in terms of statistical significance among those parents whose children consumes sugar-sweetened beverages *vs* parents whose children did not consume them:

- sugar-sweetened beverages, respectively 2.28 *vs* 1.76 ($p<0.05$)
- pre-packed juice, respectively 1.90 *vs* 1.70 ($p<0.05$)
- sweetened milk, respectively 2.18 *vs* 1.77 ($p<0.05$).

The mean value of parents' attitude 'Water encouragement' resulted to be higher compared to all the other variables and always higher than 4.5, however no statistically significant difference was observed with regard to the consumption of soft drinks by children.
The mean values of the variable 'Health beliefs', which measures the perceived risks for their children's health associated with the intake of soft drinks and pre-packed juices, were always higher than the central value of the scale (3.0) and in two comparisons, they were statistically lower among the parents of the children who consume them:

- pre-packed juices, respectively 3.70 *vs* 4.11 ($p<0.001$)
- sweetened milk, respectively 3.34 *vs* 3.96 ($p<0.01$).

Finally, the mean values of the scores referred to the correct information of the parents on the recommended consumption of water and pre-packed beverages by their children reported a good level of awareness, higher in the consumption of water (always higher than 3.5) *vs* the consumption of beverages (always higher than 3.0). The latter, moreover, has significant difference compared with the children's consumption of some sugar-sweetened beverages, in particular, information results to be less correct among the parents of children who consume them:

- sugar-sweetened beverages, respectively 3.21 *vs* 3.82 ($p=0.052$)
- pre-packed juice, respectively 3.22 *vs* 4.24 ($p<0.001$)
- sweetened milk, respectively 3.00 *vs* 3.83 ($p<0.05$).

4.5.6 Results – Anthropometry

Anthropometric data were collected in 202 children (116 females and 86 males), from only 'Sample-B', attending the Schools of San Benedetto del Tronto (Province of Ascoli Piceno).

The calculation of the BMI allows the evaluation of the overweight/obesity status based on the international classification of the cut-off values used in prevalence studies (Cole & Lobstein, 2012).

Since waist circumference is deemed a good indicator of central fatness, more sensitive than BMI, both in children and in adults, it is also a predictor of cardio-vascular diseases and of dysmetabolic syndromes (e.g., noninsulin-dependent diabetes, dyslipidaemia), a second evaluation of the overweight was performed through the collocation of the waist circumference percentile values compared to the waist circumference percentiles of European American youths (Fernández et al., 2004), the only percentiles to provide reference values also for early childhood (from 2 to 6 years).

Table 31 reports the values of the 50th, 85th and 97th percentiles of the weight, height and BMI measurements, and the values of the 50th, 75th and 90th waist circumference percentile detected in the sample of children, stratified by age and sex. To perform the comparison with the international standards of the MGRS (WHO d, 1999) for the values of weight-for-age, height-for-age and BMI-for-age and with the waist circumference percentile values provided by Fernandez et al, 2004, these standards are reported in Table 32.

The percentile values measured in the study sample were nearly always higher than the standards, in some cases higher than 10%, in particular:

- For the weight, values were always higher in males (in 12 comparisons out of 15 higher than 10 %) and for females they were higher in 12 comparisons out of 15 (for 11 it was more than 10 %) and lower in 3 comparisons out of 15;
- For the height, values were always higher in males except for 3 comparisons out of 15 where they resulted to be lower that the standards; the same was reported for the females;
- For the BMI, values were always higher in males (in 5 comparisons out of 15, it was more than 10%) the same values were reported for the females (in 9 comparisons out of 15, it was more than 10%);

- For the waist circumference, values were always higher in males (in 5 comparisons out of 15, it was more than 10%) and they were always higher in the females (in 2 comparisons out of 15, more than 10%) except for 2 comparisons.

Table 31. Percentile values of the anthopometric values estimated in the sample of preschoolers, stratified by sex and age.

	Weight (kg)			Height (cm)			BMI (kg/m^2)			Waist circumference (cm)		
Years of age	**50°**	**85°**	**97°**	**50°**	**85°**	**97°**	**50°**	**85°**	**97°**	**50°**	**85°**	**97°**
Males												
2 years	14.9	15.7	15.7	92	92	92	17.8	19.0	19.0	52	52	52
3 years	16.1	18.6	20.5	100	104	107	16.1	17.7	18.8	54	57	58
4 years	18.1	20.5	24.0	104	112	116	16.7	18.4	19.7	55	58	58
5 years	19.5	24.0	51.6	107	117	119	16.4	20.0	43.4	56	59	61
6 years	22.6	30.0	36.2	114	123	129	16.4	21.8	22.9	60	61	66
Females												
2 years	14.2	17.5	17.5	94	96	96	17.5	19.4	19.4	53	53	59
3 years	15.2	18.4	21.4	98	103	107	16.2	17.9	20.1	53	55	58
4 years	18.3	20.7	24.0	104	107	110	16.9	19.6	18.4	55	57	61
5 years	20.5	24.5	31.8	112	117	124	17.0	19.4	22.8	56	58	62
6 years	20.1	23.0	24.5	106	112	123	18.0	19.7	21.8	56	57	59

Table 32. Percentile values for the anthropometric measurements indicated by the international standards of the WHO Multicentre Growth Reference Study [MGRS] and by Fernandez et al, 2004.

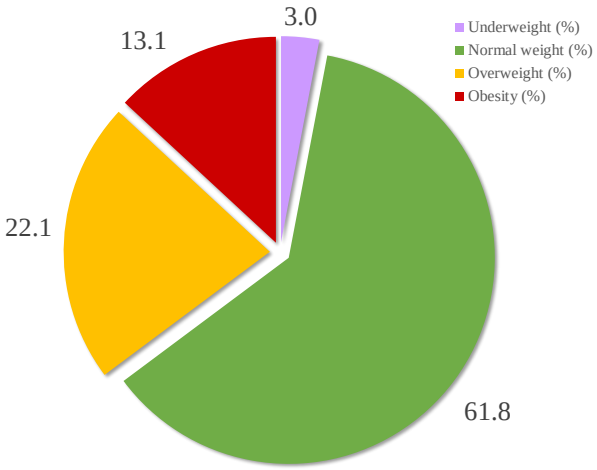
Years of age	**Weight (kg) (WHO-IOTF)**			**Height (cm) (WHO-IOTF)**			**BMI (kg/m2) (WHO-IOTF)**			**Waist Circ. (cm) (Fernandez, 2004)**		
	50°	**85°**	**97°**	**50°**	**85°**	**97°**	**50°**	**85°**	**97°**	**50°**	**75°**	**90°**
Males												
2 years	12.2	13.7	15.1	87.1	90.3	92.9	16.0	17.4	18.7	47.1	48.6	50.6
3 years	14.3	16.3	18.0	96.1	99.9	103.1	15.6	17.0	18.2	49.2	51.2	54.0
4 years	16.3	18.7	20.9	103.3	107.7	111.2	15.3	16.7	18.0	51.3	53.8	57.4
5 years	18.3	21.1	23.8	110	114.8	118.7	15.2	16.7	18.1	53.3	56.5	60.8
6 years	20.5	23.6	26.7	116	121.1	125.2	15.3	16.8	18.3	55.4	59.1	64.2
Females												
2 years	11.5	13.1	14.6	85.7	89.1	91.8	15.7	17.2	18.5	47.4	49.6	52.5
3 years	13.9	15.9	17.8	95.1	99	102.2	15.4	16.9	18.2	49.3	51.9	55.4
4 years	16.1	18.6	21.1	102.7	107.2	110.8	16.3	16.8	18.3	51.2	54.2	58.2
5 years	15.7	18.2	21.3	109.4	114.4	118.4	16.3	17.0	18.6	53.1	56.5	61.1
6 years	20.2	23.7	27.3	115.1	120.4	124.8	15.3	17.1	18.9	55.0	58.8	64.0

Table 33 and Figure 25 show the prevalence of underweight, normal weight, overweight and obese children calculated using the international cut-off values (Cole & Lobstein, 2012).

Table 33. Prevalence rates of overweight and obesity across gender.

	Females (113)	**Males (86)**	**Total (199)**
Underweight n. (%)	4 (3.5)	2 (2.3)	6 (3.0)
Normal weight n. (%)	69 (61.1)	54 (62.8)	123 (61.8)
Overweight n. (%)	24 (21.2)	20 (23.3)	44 (22.1)
Obesity n. (%)	16 (14.2)	10 (11.6)	26 (13.1)

Figure 25: Prevalence rates of overweight and obesity across gender.



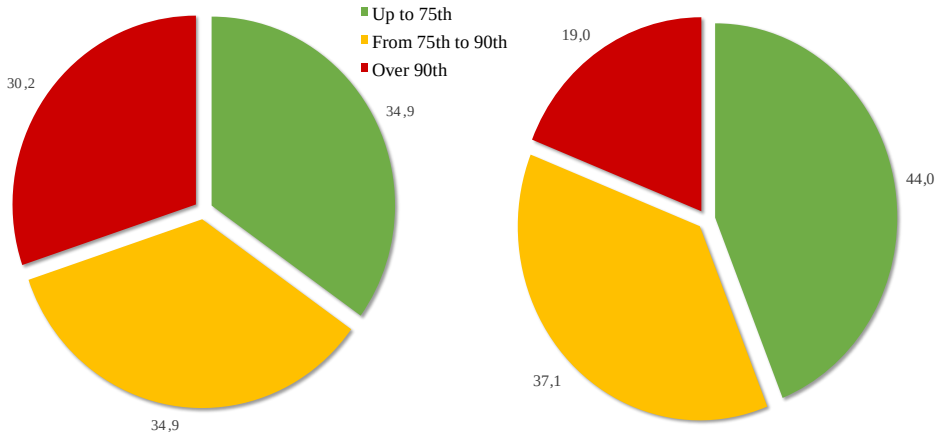
Overall, the overweight prevalence is at 22.1% and the obesity prevalence is at 13.1% in the whole sample, whereas the underweight prevalence rates is at 3.0%, with no statistically significant difference between males and females (n.s. Chi Squared test with Fisher's correction).

Table 34 and Figure 26 show the distribution of the children relative to the length of the waist circumference based on international percentile standard values specified in the materials and methods section: in this classification, 23.8% of children resulted to have a waist circumference higher than 90th percentile, mostly in males vs. females (30.2% *vs* 19.0 %), but this difference did not result to be significant in the Chi Squared test with Fisher's correction.

Table 34. Distribution of the sample in three percentile groups relative to the waist circumference according to the percentile values of Fernandez, 2004 by gender.

	Females (116)	**Males (86)**	**Total (202)**
	n. (%)	n. (%)	n. (%)
Up to 75th	51 (44.0)	30 (34.9)	81 (40.1)
From 75th to 90th	43 (37.1)	30 (34.9)	73 (36.1)
Over 90th	22 (19.0)	23 (30.2)	48 (23.8)

Figure 26. Distribution of the sample in three percentile groups relative to the waist circumference according to the percentile values of Fernandez, 2004 by gender.



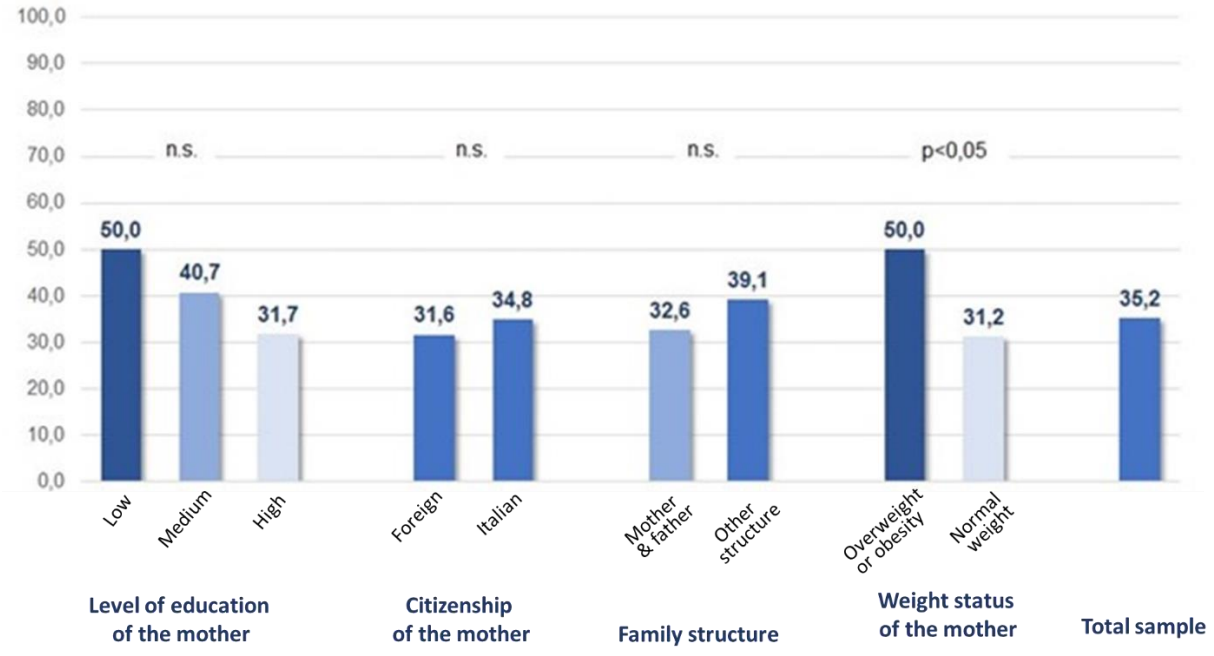
The prevalence of overweight+obesity was estimated in relation to specific sociodemographic variables of the family unit, as reported in Figure 27. Some differences were detected:

- With regard to the educational level of the mother, the proportion was higher among the children born to less-educated mothers (50.0%) and decreased in the children born to mothers with a medium (40.7%) and high (31.7%) level of education, however no statistical significance was reported in the Chi squared test with Fisher's correction;
- With regard to foreign citizenship, the difference appeared less high, accounting for 31.6% among the children born to foreign mothers and 34.8 % among those born to Italian mothers; however, the difference appeared higher if we considered only the extreme status of obesity (not distinctively represented in the graph), whose proportions accounted for 5.3% (foreign mothers) and 13.4%

(Italian mothers), also in this case, the differences were not statistically significant;

- With regard to the family structure, the level of overweight resulted to be lower in the 'regular' family units composed of mother and father as compared to other family structures (e.g., single-parent family, presence of grandparents): 32.6 *vs* 39.1%, respectively; however, no statistically significant difference was detected;
- With regard to the weight status of the mother, a statistically significant association was observed: among the children of overweight-obese mothers, the prevalence of overweight resulted to be 50.0% *vs* 31.2 % among the children of normal-weight mothers ($p<0.05$ in the Chi Squared test with Fisher's correction).

Figure 27. Prevalence of overweight+obesity of the children stratified by certain socio-demographic variables.



Parents were asked report if their child watched TV during main meals, as a sedentary behaviour that could be associated to a poor physical activity level but also to unhealthy dietary habits. Findings showed that 39.4 % of the children watched TV 'often or always' while they had breakfast, 3.5% while they have their morning snack, 20.0% during lunch, 36.1% while they consume their afternoon snack and 52.9% during dinner. However, no

significant association or interesting tendencies in the overweight– obesity levels were observed and behaviours in meals and TV.

4.6 Phase 5- Experimental implementation of the European ToyBox intervention in the COVID-19 emergency

On occasion of the COVID-19 emergency, during April 2020 the *ToyBox in Quarantine* project was developed, therefore, the ToyBox-intervention was adapted during the global emergency. On 31 January 2020, the day after the statement by the WHO, the Italian Government declares the emergency status. In February, taking into account the increasing spread of the epidemic and the increase in the cases across the nation, after a meeting of the Operative Committed in the seat of the Department of the Civil Protection, the Council of Ministries, approved the Law Decree (n.6 dated 23 February 2020) that introduced urgent measures for COVID-19 prevention and control. The Decree was then followed by further Prime Ministerial decrees that introduced further restrictions, in particular the school closure (Prime Ministerial Decree 4 March 2020) and border/travel restrictions to some areas (Prime Ministerial Decree 8 March 2020) which were soon extended at national level (Prime Ministerial Decree 9 March 2020) until 18 May 2020 along with some provisions regarding production, commercial, recreational activities, and prohibitions of crowd-gathering in public places (Italian Government, 2020). Thus, the Italian Government imposed restrictive measured (known as 'lockdown') with the closure of all schools, of sports centres, of shops and announced a stay-at-home order, except for health, work and essential needs.

The ToyBox project could be easily adapted to the quarantine, as it is based on an educational approach focused on the change of the environmental determinants, in such context adaptable to the household environment. Moreover, it involved a role-modelling approach by meaningful adults, that is parents and other caregivers and teachers, and it offers tools suitable to the requirement of interpersonal distance that children had to respect under the Government regulations.

Since the programme could not be carried out in the school setting, it focused the attention on the household environment, but without excluding school activities. Indeed, it provided an effective support to the distance teaching and learning adopted also by preschools. The school, through the help of the parents, remained the protagonist of the ToyBox intervention, assisting parents and encouraging them to implement relevant environmental changes to become role models. The parental educational style, that is the ways and functions by which parents approach their children, promotes the development of the process of maturation in infancy to

make children more autonomous (Confalonieri & Olivari 2013), a fundamental aspect for the adoption of the behaviours learned with the ToyBox.

ToyBox in Quarantine used distance teaching to reach children. In the age group 0 – 6 years, this type of education consists mainly of a set of proposals that were sent to parents daily or weekly, involving activities, games (64.5%), videos including readings of stories or songs (66.7%) to do at home with the help of the parents. Live interactions among small groups including parents and children (Bosoni et al., 2020) could also be organized. In such context, the ToyBox was not a further burden as it supported the teachers in their everyday work with the children and their parents, helping the teacher in the implementation of the preschool educational goals.

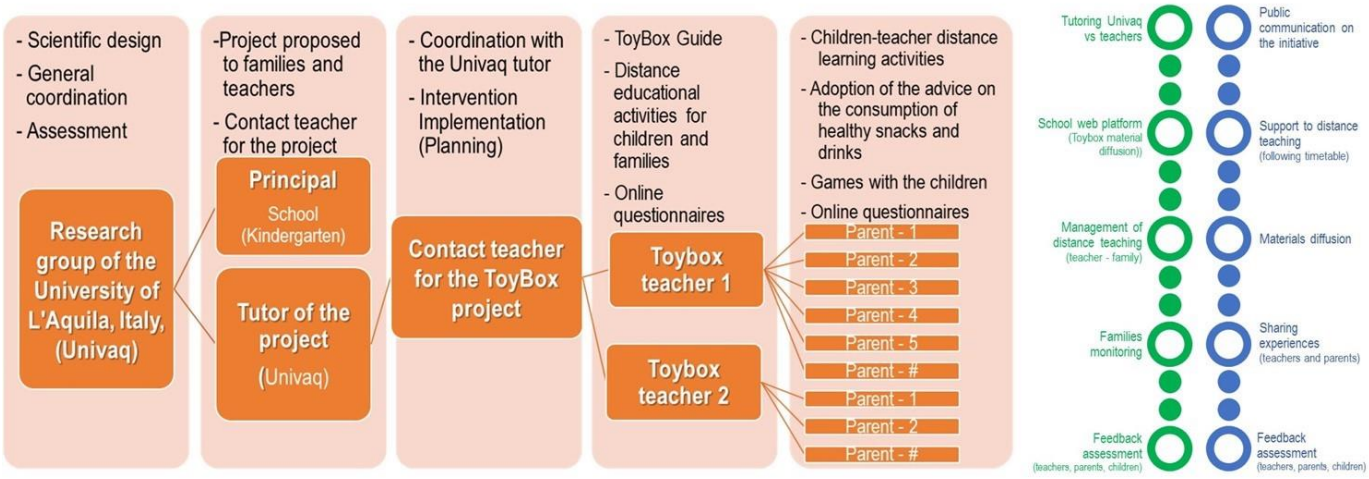
The enrolment of the schools was carried out expeditiously. It started in mid-May, by sending the proposal that included:

1. The Scientific Protocol, reporting the goals, the trial methods and the research group;
2. The Planning (in two versions, one having specific dates and the other having unspecified dates);
3. The Acceptance form to be completed.

4.6.1 Planning of the educational activities included in the intervention

The structure of the programme is summarized in Figure 28.

Figure 28: Flow-chart of the ToyBox-intervention in quarantine.



The educational material of the ToyBox-intervention described in paragraph 4.2 was adapted. In particular, the following materials were developed and used:

- Teacher's guide: *ToyBox in quarantine* guide to guide the teacher in the programme implementation.
- A set of materials such as newsletters, tip cards, display posters and a drawing to send to parents.
- Units including story-telling, stories to narrate to children based on the 'drinking behaviour' and on the 'snacking behaviour'.
- Units on household activities, entertaining activities to suggest to parents and to do at home together with the family.

Specifically, we sent:

- 2 recipes on the Snacking Behaviour;
- 1 manipulative skill activity on the Drinking Behaviour (creation of a cup for water);
- 4 games of sensory perception (2 on the Drinking Behaviour and 2 on the Snacking Behaviour);
- 3 experiments (2 on the Drinking Behaviour and 1 on the Snacking Behaviour).

Furthermore, questionnaires were given to both parents and teachers.

In detail, the obesity prevention intervention focuses on two behaviours: drinking behaviour and snacking behaviour, and it assists teachers and parents in the creation of a physical and

social environment that supports their promotion. To reach these goals, the programme focuses on two behavioural goals:

1) Children drink water to quench their thirst;
2) Children consume healthy snacks.

We used multiple platforms for public outreach: the IT platforms used by each school, each school could use their platform for the distance teaching; when the school did not use IT platforms, instant messaging systems (e.g., WhatsApp) could be used. Finally, an ad hoc Facebook page was created (https://www.facebook.com/ToyBox-study-Italy-107423064315505), for the public outreach of the initiative and the feedback of its users.

The planning of the activities is reported in a time plan (Table 35), as a guide for the teacher for the correct sequence and performance of the activities, as follows:

1) Before the beginning of the programme: distance training

All the materials were sent to the teachers in the week prior the beginning of the programme so that the teacher could contact the research group for any clarification. In fact, we asked the teachers to view the materials and to understand how to implement the intervention, before the beginning of the programme.

2) During the implementation of the programme: distance working with the children on stories, entertaining activities and experiments

The temporal order of the implementation of the two target behaviours could be organized in a flexible manner and adapted to the topics and the projects of the school year. An example can be the following (reported in the time plan):

"the implementation for the first 2 weeks and ½ of the behaviour pattern related to the drinking behaviour and for the following 2 weeks and ½ of the behaviour pattern related to the snacking behaviour. We ask you to read, record and send the stories so that children can maintain a contact with their teachers, and they are better encouraged to carry out the programme. We ask you to be as more present as possible also in other activities; it would be appreciated if you could record yourself while you are doing these activities or record the instructions for their performance to encourage children and their families to do them".

Table 35. Planning of the activities included in the ToyBox in quarantine programme.

	Tipo di attività		Formazione e avvio		Programma																
					Consumo di bevande									Consumo di snack							
	Unità	Newsletters, Posters e Tip cards	0°	0°	Settimana 1		Settimana 2				Settimana 3			Settimana 4			Settimana 5			Settimana 6	
			dal 11-mag al 18-mag 2020		18-mag	20-mag	22-mag	25-mag	27-mag	31-mag	01-giu	03-giu	05-giu	08-giu	10-giu	11-giu	15-giu	17-giu	19-giu	22-giu	24-giu	26-giu
Formazione		**Materiale formativo**	F	F																	
Introduzione		Newsletter introduttiva		✓																	
Consumo di bevande	Attività didattica a distanza			▶	▶	▶	▶	▶	▶	▶	▶										
	1. Storie aventi come protagonista il canguro	1			✓																
		2				✓															
		3					✓														
	2. Giochi di percezione sensoriale	1						✓													
		2							✓												
	3. Esperimenti	1								✓											
		2									✓										
	Lavorare con i genitori	Poster					✓														
		Newsletters			1°			2°													
		Tip cards				1°			2°												
Consumo di snacks	Attività didattica a distanza			▶										▶	▶	▶	▶	▶	▶	▶	▶
	1. Ricette	1												✓							
		2													✓						
	2. Storie aventi come protagonista il canguro	1												✓							
		2													✓						
		3														✓					
		4															✓				
		5																✓			
	Treno del cibo																		✓		
	3. Giochi di percezione sensoriale	1																		✓	
		2																			✓
		3																			
	4. Esperimenti	1																			
	Lavorare con i genitori	Poster														✓					
		Newsletters												1°		2°					
		Tip cards													1°			2°			
Questionari insegnanti	Questionario conoscenze e attitudini TEST			Q																	
	Questionario conoscenze e attitudini RETEST																				
	Questionario di processo - Log programma											Q									
	Questionario di processo-fattibilità dell'intervento																				
Questionari genitori	Core Questionnaire TEST		Q																		
	Core Questionnaire RETEST																				
	Gradimento dell'intervento																				

4.6.2 Educational approach

- *Engagement of the parents*. Teachers were asked to involve the parents, sending the material (newsletters, tip cards, posters and a drawing to colour in for the children) at the opportune moment (see the time plan).
- *Continuity*. A fundamental component of the programme was to remind children to carry out the recommended behaviours correctly, not only when the activities of the ToyBox programme had been sent, but any time that the teacher had the opportunity. Integrating the promotion of the target behaviours in the curriculum statement was important.
- *Giving children the opportunity of practicing and being active*. Pre-schoolers need practical experience where they can be active. The teacher can support them by stimulating as many senses, feelings, early cognitive abilities as possible, through these experiences. We included these types of activities in the ToyBox, such as experimenting sensory games. The more a child participates and is involved, the more he/she will learn and grow.
- *Creating a supporting environment.* Children at this age do not choose the beverages and snacks they consume based on their healthfulness. Therefore, the choice of the food depends mainly on what is more inviting and attractive for them in that moment. If they are given the opportunity to choose, children will follow their natural crave for sweet, fat and rich in energy foods and soft drinks, as they are guided by their instinct and by the rapid awareness of what better satisfies their hunger. However, we have to make sure to develop a physical and social environment that provides them with a variety of healthy food choices, such as fruit and vegetables, although we are aware of their preference for foods that are energy dense. Therefore, we should eliminate foods rich in fat and sugars from their environment, otherwise children would choose these, and instead we should provide healthy snacks that they can eat when they are hungry. The teacher can encourage the household environment, if water is always available, children will drink it more often. The same applies to healthy snacks.
- *Encouraging*. Children develop and learn more when they can act and speak together with other children and adults. By speaking they become aware of what they are doing or feeling in specific situations and they learn to behave differently the following time. Therefore, the teacher should stimulate the children in the classroom to express their

ideas and thoughts (this principle is underlined as a suggestion in the stories with the kangaroo). Encouraging children to follow the recommend behaviour, to drink water, and to appreciate it, will spark their enthusiasm.

- *Being role models*. Teachers too should be role models and encourage parents to be role models and to participate in these activities. In general, children learn many things by observing role models. These role models can be real people such as the parents at home and the teacher at preschool: children, in fact, watch adults' behaviours and if they satisfy the expectations that they have for the children.
- *Characters as role models: the Kangaroo: the role model and friend.* Even the personified characters of films, TV, books and songs can be role models. The little Kangaroo of the ToyBox programme is destined to become such role model. The wish is that children become friends with the Kangaroo so that this will become a friend that encourages children to consume healthy snacks. Children can learn specific behavioural strategies from the Kangaroo, for example how to behave when they are 'tempted' to eat unhealthy snacks. In particular, children in preschool age love characters such as that of the kangaroo and they enjoy stories and fairy tales because these become part of their 'magical thinking', which is typical of this developmental stage. Therefore, we included many stories on the kangaroo and his friends in the classroom activities; some stories are related to the situations that children experiment in their everyday life, while others have a more fabulous character.

4.6.3 Design, enrolled sample and tools of the process assessment

An in-progress process and post-intervention assessment was developed.

The following five School institutes participated in the trial, involving more schools, for a total of 8 schools:

1) The Comprehensive School Mazzini-Fermi di Avezzano (L'Aquila, Abruzzo Region, Italy)
    a. 'Montessori' School
    b. 'Nennolina' School
2) The High School of Borgorose (Rieti, Lazio Region, Italy)
    a. School in Borgorose
    b. School in Corvaro

c. School in Torano

3) The State-recognized private school ‘San Benedetto’ in Cassino (Frosinone, Lazio, Italy)
4) The Comprehensive School Castell'Alfero di Montechiaro D'Asti (Asti, Piemonte Region, Italy)
5) The Comprehensive School of Brusasco di Verrua Savoia (Turin, Piemonte Region, Italy)

At the beginning of the project, 43 teachers and 372 children were enrolled, as reported in Table 36.

Table 36. Sample of schools in the Project ‘ToyBox in quarantine’ in the School Year 2019-2020.

School	**Number of teachers**	**Number of children**
High School of Borgorose	13	86
Comprehensive School Mazzini-Fermi	20	181
Comprehensive School of Castell'Alfero	3	27
Comprehensive School of Brusasco	4	28
State-recognized private school San Benedetto	3	50
Total	*43*	*372*

Through the same channels used for the training and the development of the intervention (IT school platforms for distance learning or other IT systems such as instant messaging, e.g., WhatsApp), the school staff and the families were invited to participate in the assessment by completing the questionnaires online for the evaluation of the process and of the satisfaction.

Three questionnaires compiled online (Google Modules) where used for the teachers and the parents, following the timing reported in the timeplan.

1. Programme logbook (1 per teacher, during the programme) (Annex2)
2. Feasibility of the intervention (1 per teacher, post-intervention) (Annex 3)
3. Questionnaire for the parents to evaluate their satisfaction of the intervention (1 per parent, post-intervention (Annex 6)

The proportion of participation was good for the sample of teachers (39/43, equal to 90.7%) but very poor for the parents (25/372, only 6.7%).

4.6.4 Results

4.6.4.1 Compliance with the programme of activities

The compliance with the programme was assessed through the 'Weekly log book' compiled by the teachers, regarding three aspects:

- The teaching of educational units included in the programme through synchronous learning, through the production of videos by the teachers that the families would have shown to their children in an asynchronous remote learning;
- Frequency of the 'reminders' including specific support/encouragement for the families to adopt healthy habits into the household routine;
- Sending information material to the families (Newsletters, Tip Cards, Posters).

Tables 37 and 38 and Figure 29 report the proportion of teachers who carried out the different activities included in the programme about the drinking behaviour and the snacking behaviour. This proportion is then referred also to the way of delivery of the activities, synchronous or asynchronous, that is with video recordings sent by the teachers to the families.

The activities that had higher proportions of implementation were:

- 'The water cup' (97.4% of the teachers in synchronous, and 56.4% in video);
- The Kangaroo stories focussed on drinking (82.1% in synchronous and 53.8% in video) and on snacking (85.3% in synchronous and 58.8% in video);
- The experiments referred to the soft drinks (71.8% in synchronous and 30.8% in video).

Apart from the 'Stories with the Kangaroo #1 #2 #3' the compliance was higher in the first phase of the programme regarding the snacking behaviour and both for the synchronous and asynchronous modality.

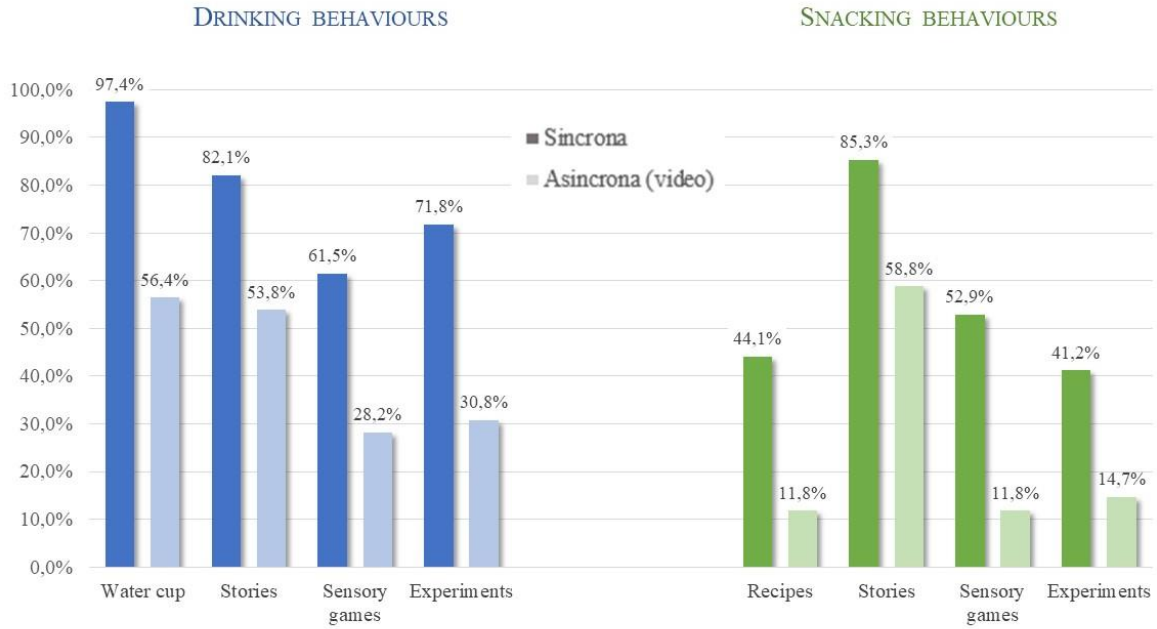
Table 37. Proportion of teachers who carried out the activities about the drinking behaviour (39 respondents).

	synchronous	asynchronous (video)
The water cup	97.4%	56.4%
Stories with the Kangaroo: #1 #2 #3	82.1%	53.8%
Sensory games on the drinking behaviour: #1 #2	61.5%	28.2%
Experiments: #1 #2	71.8%	30.8%

Table 38. Proportion of teachers who carried out the activities about the snacking behaviour (34 respondents).

	synchronous	asynchronous (video)
Recipes: #1 #2	44.1%	11.8%
Stories with the Kangaroo: #1 #2 #3 #4 #5	85.3%	58.8%
Sensory games on the consumption of snacks: #1 #2 #3	52.9%	11.8%
Experiments#1	41.2%	14.7%

Figure 29. Proportion of teachers who carried out the activities about the drinking behaviour and the snacking behaviour (34 respondents).



With regard to the regularity of the teachers in reminding parents and children the healthy daily behaviours (e.g., drinking water regularly, consuming healthy snacks regularly by programming the moments dedicated to their consumption during the day), better results were observed also in the first phase of the programme (drinking behaviour) as compared to the second phase (snacking behaviour) as reported in Table 39 and Figure 30.

Table 39. Regularity of the reminders referred to specific behaviours measured on an interval scale from 0 ('never') to 4 ('always').

Have you regularly reminded parents and children to	No. of answers	Media	Stand. Dev.
drink water?	39	3.72	0.51
drink water after they were physically active?	39	3.62	0.54
have healthy snacks at home?	34	3.50	0.83
have a break every day for the morning snack at a set time?	34	3.21	0.96
have a break every day for the afternoon snack at a set time?	34	3.12	1.01

On an interval scale from 0 ('never') to 4 ('always'), in fact, the arithmetic mean of the scores relative to regularity were always above the 3rd quartile (score> 3.00) but they were higher for the actions regarding water ('drinking water', 3.72 and 'drinking water after we have been physically active', 3.62) as compared to all the actions about snacking ('having healthy snacks at home', 3.50; 'morning snacks', 3.21; 'afternoon snacks', 3.12).

Figure 30. Regularity of the reminders referred to specific healthy behaviours measured on an interval scale from 0 ('never') to 4 ('always').

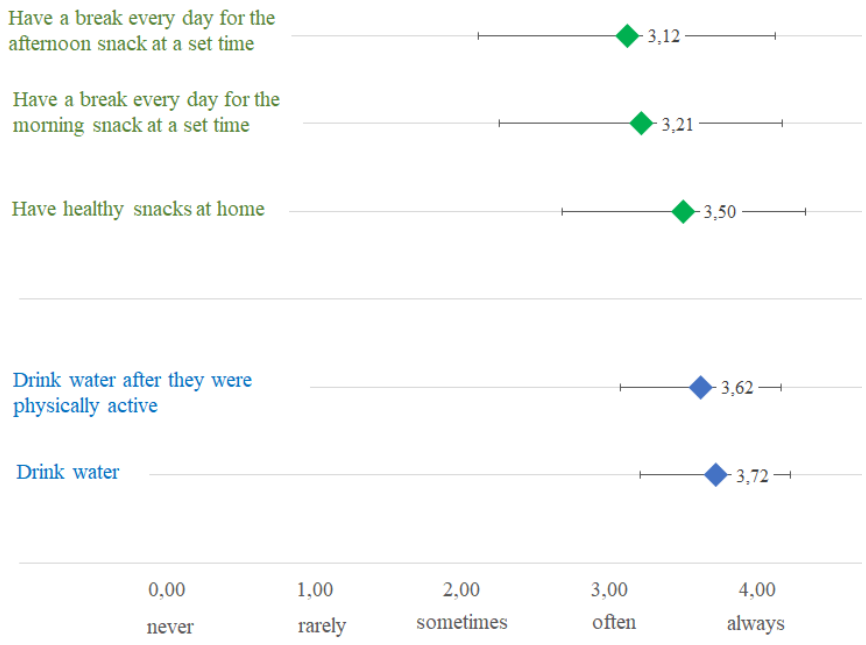


Table 40 reports the information relative to the educational materials sent to the families. None of the materials reported a full compliance by the teachers, even if the lack of

compliance was moderate (from 1 to 4) and we cannot exclude that some teachers worked with classrooms followed by other colleagues engaged in the implementation of the ToyBox.

The time span for the distribution of the material is quite long (for 8 items/11 corresponding to three weeks), that is within the interval the group of teachers showed a lack of homogeneity in sending the material to the family, and little coordination was reported in the participating schools as compared to the planning proposed. The delays can be ascribed to the distance and to the difficulties associated with the performance of the school activities.

Table 40. Compliance with the distribution of the educational materials to the families: frequency of teachers who conformed and time span of distribution referred to each product.

	Frequency	Time span (weeks)
Introductory Newsletter	37/39	2
1° Newsletter Drinks	38/39	3
2° Newsletter Drinks	36/39	2
1° Newsletter Snacks	33/36	3
2° Newsletter Snacks	33/36	3
1° Tip card Drinks	38/39	3
2° Tip card Drinks	38/39	3
1° Tip card Snacks	33/36	2
2° Tip card Snacks	33/36	3
Poster Drinks	38/39	3
Poster Snacks	31/36	3

4.6.4.2 Feasibility of the project and satisfaction of the teachers

The general judgement on the ToyBox Programme was estimated using a Likert scale on the different dimensions of feasibility, with a score from 1 to 5, as reported in Table 41 and in Figure 31.

Among the negative aspects, the worst was ‘It produced a lot of extra work’ (2.97), followed, in a decreasing order: ‘It has too many components to implement’ (2.90), ‘It

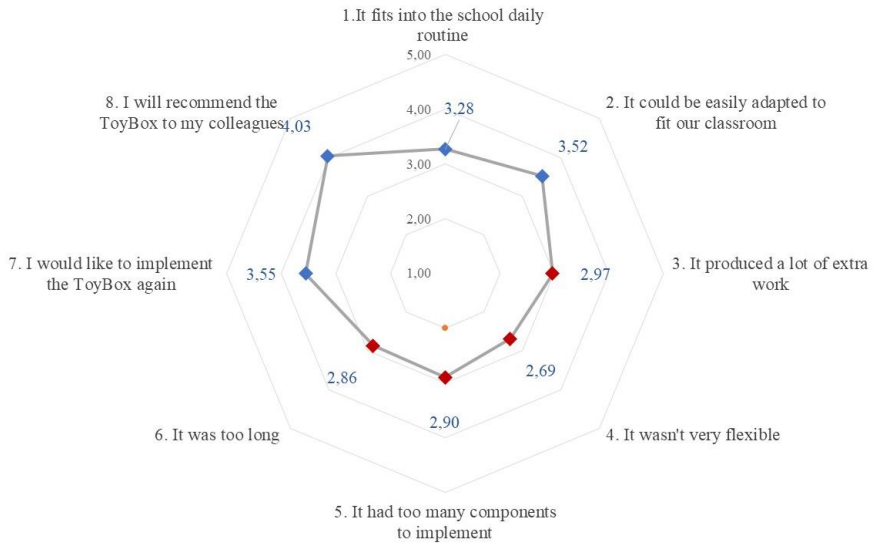
was too long' (2.86) 'It wasn't very flexible' (2.69). However, the mean values of the score result to be always lower than the scale's central value (3.00).

Among the positive aspects, the best was the fact that the teachers were favourable to the implementation of the ToyBox: 'I will recommend the ToyBox to my colleagues' (4.03), 'I would like to implement the ToyBox again' (3.55). Moreover, the respondents agreed on the fact that the programme 'could be easily adapted to fit our classroom' (3.52) and that 'It fits into the school daily routine' (3.28).

Table 41. General judgment on the ToyBox Program by the teachers on interval scale from 1 ('strongly disagreed') to 5 ('strongly agreed').

The ToyBox programme….	No.	Mean	St. Dev.
1.It fits into the school daily routine	29	3.28	1.10
2.Could be easily adapted to fit our classroom	29	3.52	0.83
3. Produced a lot of extra work	29	2.97	1.09
4. Wasn't very flexible	29	2.69	0.89
5.Had too many components to implement	29	2.90	0.90
6.Was too long	29	2.86	1.03
7.I would like to implement the ToyBox again	29	3.55	0.87
8.I will recommend the ToyBox to my colleagues	29	4.03	0.73

Figure 31. Radar chart to plot the judgement on the ToyBox programme by the teachers on an interval scale from 1 ('strongly agreed') to 5 ('strongly disagreed).



Judgement on the educational materials and on the satisfaction of the activities performed confirm and exceed the general judgement, as reported in Table 42 and in Figure 32. The

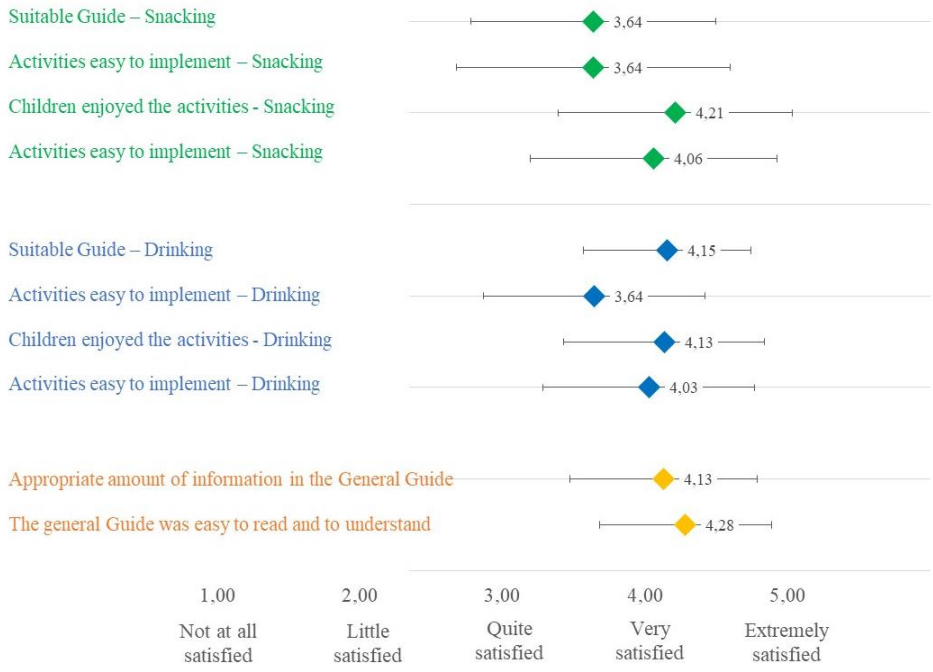
General Guide was deemed easy to read and suitable as compared to the amount of information included (scores on a scale from 1 to 5, corresponding to 4.28 and 4.13, respectively, with low indices of variability, that is values of the standard deviation at 0.60 and 0.66).

With regard to the ease of implementation of the activities, the judgments are almost similar for the two sections (4.03 for the drinking behaviour and 4.06 for snacking behaviour), and for the satisfaction of the teachers (4.13 for the drinking behaviour and 4.2 for the snacking behaviour) and for the children (3.64 for both sections). Instead, the thematic Guides were appreciated differently, the guide on the snacking behaviour received a higher score (4.15) as compared to the guide on the drinking behaviour (3.64) and such difference was statistically significant to the non-parametric Wilcoxon paired t-test ($p<0.01$).

Table 42. Judgement on the educational materials and on the appreciation of the activities by the teachers on an interval scale from 1 ('very satisfied') to 5 ('not at all satisfied').

	No.	Mean	St. Dev.
The general Guide was easy to read and to understand	39	4.28	0.60
Appropriate amount of information in the General Guide	39	4.13	0.66
Activities easy to implement – drinking	39	4.03	0.74
I enjoyed the activities - drinking	38	4.13	0.70
Children enjoyed the activities - drinking	39	3.64	0.78
Suitable Guide – drinking	39	4.15	0.59
Activities easy to implement – snacking	33	4.06	0.86
I enjoyed the activities - snacking	33	4.21	0.82
Children enjoyed the activities - snacking	33	3.64	0.96
Suitable Guide – snacking	33	3.64	0.86

Figure 32. Graph representation of the judgement on the educational materials and on the appreciation of the activities by the teachers on an interval scale from 1 ('not at all satisfied') to 5 ('very satisfied').

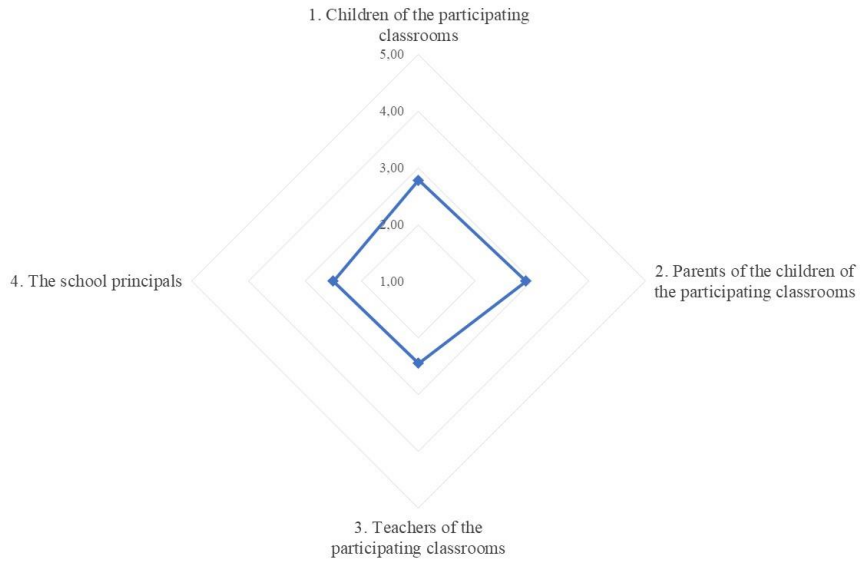


Conversely, the judgement on the impact of the ToyBox programme, that is how much the teachers believed that the ToyBox contributed to increasing the interest and awareness regarding the consumption of water and of healthy snacks, was less optimistic as reported in Table 43 and in Figure 33. For all the respondents, the agreement on a possible positive impact of the programme was lower than the median of the central tendency (<3.00) and was worst when referred to the school staff (teachers, 2.45 and school principals, 2.50) *vs* target (children, 2.89 and parents, 2.79).

Table 43. Judgment given by the teachers on the impact of the ToyBox programme on the groups of enrolled subjects on an interval scale from 1 ('not at all likely') to 5 ('extremely likely').

To what extent has the ToyBox contributed to increasing the interest and awareness regarding the consumption of water and healthy snacks among the following groups?	No.	Mean	St. Dev.
1.Children of the participating classrooms	28	2.79	0.74
2.Parents of the children of the participating classrooms	28	2.89	0.74
3.Teachers of the participating classrooms	29	2.45	0.83
4.The school principals	26	2.50	0.86

Figure 33. Radar graph on the judgment given by the teachers on the impact of the ToyBox programme on the groups of enrolled subjects on an interval scale from 1 (‘not at all likely’) to 5 (‘extremely likely’).



The questionnaire-log also included the collection of ‘open-ended’ questions, that required longer responses by the teachers on the following aspects:

1. Factors facilitating the performance of the activities
2. Any additional or ‘extra-curriculum’ activities
3. Suggestions
4. Additional costs
5. Remarks

A qualitative analysis was performed, first by sorting the responses by homogenous categories and then calculating the frequencies for each category.

Table 44 and Figure 34 report the summary in the absolute frequency by homogenous categories.

Among the facilitating factors, the use of the narration (stories with the Kangaroo) was reported as the most frequent factors by the teachers (23 times) followed by: the possibility to use telematic channels and multimedia resources such as video recordings, audio to share (10 times), the ‘structured programme’ and the availability of materials (9 times) and, finally, the practical activities such as arts and crafts and experiments (8 times).

The performance of additional activities as compared to the programme and the available materials was reported 23 times, with regard both to the section on the drinking behaviour and the snacking behaviour: some examples were the creation of cardboard templates, colouring-in templates, the production of audio, etc. Conversely, other respondents stated that they did not need to use any extra material to the ToyBox programme for an almost similar number of times (24).

Suggestions were very limited: the suggestion of including new activities was given 5 times (e.g., 'creating a table to record the number of glasses of water or soft drinks drunk during the day'); suggestions on the quality of the ToyBox materials were reported only 4 times (e.g., 'modifying some experiments that sometimes are too complicated to be understood by the children').

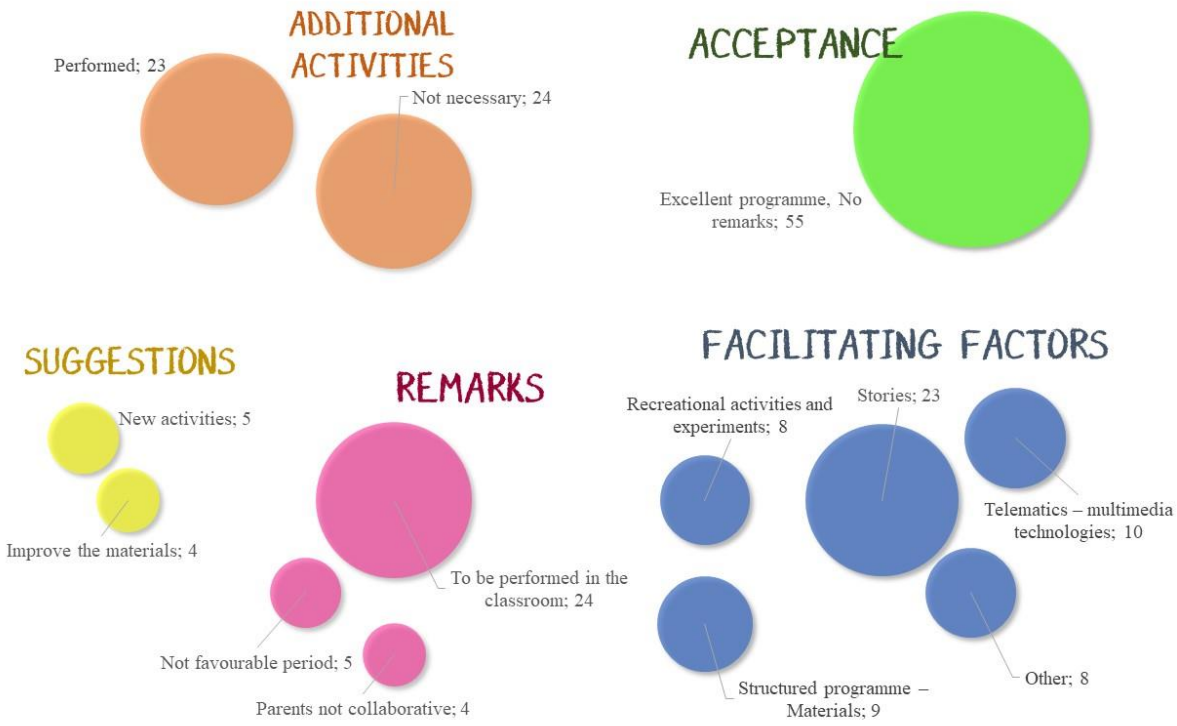
The most frequently reported remark (24 times) was that the intervention should be performed in the classroom and, in this regard, many teachers wished they could replicate the ToyBox programme in this modality. Further remarks (5 times) concerned the quarantine period of the performance of the ToyBox (May – June 2020) which was deemed not suitable, and the poor participation/collaboration of the parents (4 times).

Finally, the extremely favourable judgement (a mean of about 1.5 times per teacher) on the ToyBox was given 55 times, acknowledged as an 'optimal programme.'

Table 44. Absolute frequency of open-ended questions given by the teachers on the aspects of the process sorted by homogeneous categories.

Investigated aspects	Categories	No. items
FACILITATING FACTORS	Stories	23
	Telematics – multimedia technologies	10
	Structured programme - Materials	9
	Other	8
	Recreational activities and experiments	8
ADDITIONAL ACTIVITIES	Not necessary	24
	Performed	23
SUGEGSTIONS	New activities	5
	Improve the materials	4
	To be performed in the classroom	24
REMARKS	Not favourable period	5
	Parents not collaborative	4
	No remark - Excellent programme	55

Figure 34. Bubble chart on the absolute frequency of open-ended questions replied by the teachers on the on the aspects of the process sorted by homogeneous categories.



4.6.4.3 Satisfaction of the parents

Ninety-two percent of the 25 parents who completed the questionnaire (23/25) gave a positive judgement on the ToyBox Programme, saying that they 'enjoyed' it (19/25) or 'enjoyed it very much' (4/25).

Eighty-four percent (21/25) of the respondents confirmed the accessibility of the materials provided (newsletters, tip cards, posters) and reported that their contents were 'very easy' (14/25) or 'easy' (7/25) to understand; two parents reported they had not received the materials and 1 parent reported that the material was 'a little difficult'.

With regard to the contents of the materials, 56.0% found the information given 'significantly correct' (14/25), 20.0% (5/25) 'moderately correct', whereas the remaining part found it 'little' or 'not all correct'.

Eighty percent of the parents found the suggestions on the intake of beverages and snacks useful ('very useful'14/25 and 'quite useful' 6/25), whereas 2 parents found them 'little useful' or 'not at all useful'.

About half of the sample of respondents reported that they had introduce the recommended activities 'always (4/25) or 'often' (8/25), the remaining part reported ‘sometimes’ (7/25), 'rarely’ (3/25) or ‘never’ (2/25).

Eighty percent of the sample reported that they and their children appreciated the ToyBox programme, whereas the remaining percentage reported that they did not carry out any of the activities of the intervention or that they did not appreciate it (4 in total/25).

The amount of information and contents in the materials provided (newsletters, tip cards) was evaluated ‘fair’ by 72% of the parents, while the remaining part reported it was ‘excessive’ (3/25), 'poor’ (1/25) or they reported they had not received the materials.

Those who received the materials gave a positive or very positive judgement of the design (colour, layout, font, etc.) (22/25).

Seventy-two percent of the parents acknowledged that managing the educational activities of their child was ‘simple’ (16/25) or ‘very simple’ (2/25) because of the quarantine, whereas 24% reported that it was a ‘little difficult’.

Tables 45 and 46 and Figure 35 reported the proportion of parents who carried out the different activities involved in the programme regarding the drinking behaviour and the snacking behaviour.

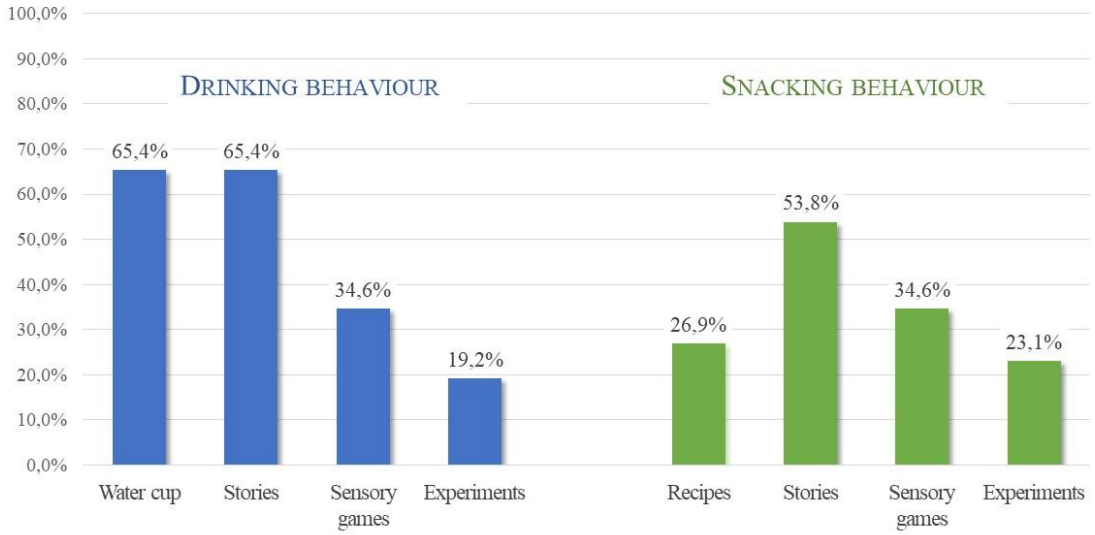
Table 45. Proportion of activities implemented on the drinking behaviour referred to the parents (26 respondents).

Activity titles	
Water cup	65.4%
Stories with the Kangaroo: #1 #2 #3	65.4%
Sensory games on the intake of soft drinks: #1 #2	34.6%
Experiments: #1 #2	19.2%

Table 46. Proportion of activities implemented on the snacking behaviour referred to the parents (26 respondents).

Activity titles	
Recipes: #1 #2	26.9%
Stories with the Kangaroo: #1 #2 #3 #4 #5	53.8%
Sensory games on the intake of snacks: #1 #2 #3	34.6%
Experiments #1	23.1%

Figure 35 Proportion of activities implemented on the consumption of soft drinks and of snacks referred to parents (26 respondents).



5. DISCUSSIONS

Discussion - Phase 1

The collaboration of the European research team was relevant: a virtuous example of implementation of a good practice at cross-national level.

Obesity is widely acknowledged as a complex multifactorial disease (ISS d, 2020). To address this major public health problem, the involvement and collaboration of different stakeholders is fundamental in order to implement strategies at multiple levels (individual, community, etc.), in different settings (family, school, etc.) and with the use of multiple approaches (such as education, environmental political, infrastructural change, etc.) (Branca et al., 2007). There is a growing interest in building new collaborations with the different stakeholders to address major public health challenges, such as obesity. Establishing partnerships can benefit the different partners, enabling the exchange of information, skills, materials, etc. Partnerships provide a structure in which organizations can cooperate in producing activities designed to promote health and prevent disease (Mays & Scutchfield, 2010). The literature includes several studies aimed at preventing childhood obesity, but most of them were not conducted at an international level (Brown et al., 2019). Since obesity is global major public health issue, large-scale actions are required. However, it is not clear whether the interventions implemented on a local/national scale will be also successful on a large scale (Li et al., 2010). The ToyBox-study is a EU-funded multicentre trial study where multiple centres (listed in http://www.toybox-study.eu/?q=en/institutions) from six participating Countries collaborated for the development and implementation of the intervention. The coordination and collaboration took place through the different stages of the study, from the development to the implementation. The protocol and the procedures of the study were harmonised, standardized, and well planned in every centre to ensure a high level of validity and reliability of the measures. For example, standardised operational guides, devices of the same type and a data management system were used. Moreover, standardised procedures for the data quality control were put into place (Mouratidou et al., 2014). The ToyBox-study represents a virtuous example of the implementation of a good practice at international level aimed at finding strategies to prevent obesity and encourage people to adopt a healthy lifestyle.

Discussion on the data Phase 2

The test-rest validation of the CQ and FFQ questionnaires were conducted by following the procedures applied to the validation studies of the questionnaires during the planning and preparatory phase, prior to the implementation of the intervention (González-Gil et al.,2014) (Mouratidou et al., 2019). With regard to the CQ, the questionnaire was completed almost exclusively by the mothers. This aligned with other ToyBox investigations where only 12.1 % of the respondents were males (González-Gil et al., 2014).

The validation allowed to verify that the two questionnaires already used in the ToyBox-study represent an effective tool for the observation of the EBRs and of their determinants also in the Italian sample studied in this dissertation. The methodological test-retest study highlighted some criticalities in the stability of the single items, both in the CQ and in the FFQ. These criticalities include both the attitudes (in the first questionnaire) and the report on the frequencies and quantity of consumption. These observations can be ascribed to different hypothesis.

- The fact that in all the cases (except for one) the unacceptable correlations have low Spearman's rho values but not statistically significant might highlight a defect of the study effectiveness due to the small sample (only 48 CQs and only 40 FFQs repeated in the retest). Thus, a larger sample of the validation study would be required to confirm these criticalities.
- They may result from the propensity, sometimes also unaware, to give more 'positive' than real answers (the so-called 'Hawthorne effect') and, therefore, to cause higher level of confusion related to the little consistency in the responses given to the test and to the retest (Sedgwick & Greenwood, 2015). In the context of nutritional and physical activity interventions, the self reports of these behaviours are particularly vulnerable to these biases (Livingstone et al., 2006.).
- Moreover, they may highlight a low level of awareness on the family food habits as compared to still little-known contents (in particular, the consumption of water, the intake of healthy snacks such vegetables, yogurt, whole meal bread) and therefore a low capability to respond.

In the literature, apart from the ToyBox, the surveys and the questionnaires specifically designed for this age groups and focused on the ERBs are not numerous. Indeed, one of the strengths of the test-retest validation of the CQ in ToyBox was that for the first time in Europe a questionnaire on the ERBs among pre-schoolers was being validated (González-Gil et al., 2014). Huybrechts et al. (2009) conducted a validation study of a FFQ to use in a nutritional survey among pre-schoolers in the Fianders to estimate the intake of calcium and of foods (classified into food groups) (Huybrechts et al, 2009.). More recently, Esteban-Figuerola et al. (2020) built and validated a short FFQ, that is a reduced number of items (41), to estimate the energy intake, the nutritional intake and the frequency of food consumption in children from 3 to 6 years (Esteban-Figuerola et al., 2020). In 2017, in Finland the DAGIS project (Increased Health and Wellbeing in Preschools) (https://dagis.fi/in-english/) was implemented. The DAGIS is a research conducted among pre-schoolers (3-6 years), aimed at increasing the insights on the EBRBs, at examining the social and economic differences in the EBRBs, at promoting healthy EBRBs trying to reduce the social and economic differences in the EBRBs of the Finnish children (Ray et al., 2019). A FFQ was also designed (and validated) to estimate the consumption of food in children (Korkalo et al., 2019).

- Phase 3 and phase 4 highlighted the need of more simple and acceptable tools by the participants in the study, in particular by the parents/caregivers of the children, with special regard to the assessment of the food habits. A possible alternative, in particular for the Italian context, could be represented by the KIDMED questionnaire, published for the first time in 2004, widely used and recently updated, which allows to assess the level of compliance with the Mediterranean Diet in children and adolescents, whose score can be easily calculated on a battery of 16 items (Serra-Majem et al., 2004) (Altavilla et al., 2019).

Discussions - Phase 4

Consumption adequacy of food groups as compared to the Guidelines

The comparison between the food habits of the children in the sample of this observational study with the guidelines for this age group highlighted some criticalities by defect or by excess:

- The extremely poor consumption of vegetables (only 3% of the children consume vegetables more than once a day); the inexistent intake of whole wheat pasta or rice (zero % of the sample) and of whole meal bread and bakery products (only 10% of the sample); the limited consumption of fish and legumes (less than half of the sample consume fish in the recommended quantities); the low intake of partially skimmed milk after three years of age (less than 30% of the sample); the low consumption of fruit (only 31% consume at least 3 servings per day);
- The excessive consumption of meat (on average 15% consume it 5-6 times per week) and cold cuts (45% consume them 2-4 times per week) and of cheese (more than half of the sample consume cheese 2-4 times per week and over).

Fruit and vegetables supply water, fibre, minerals and bioactive substances (eg. carotenoids and polyphenols), components that might contribute positively to health. Moreover, a high consumption of fruit and vegetables allows to reduce the energy density of the diet, both for their limited amount of fats and calories and for their greater satiety effect (CREA, 2018). In the United States, less than half of the children satisfy the intakes recommended by the American guidelines (Savoie-Roskos et al., 2017). Several European studies reported that the intake of fruit and vegetables in younger children is lower than the guidelines in particular the consumption of vegetables (de Lauzon-et al., 2019). We have extensively highlighted that food habits develop at an early age into adulthood. Many interventions have been developed at a European level (de Sa & Lock, 2008) and in other continents (Savoie-Roskos et al., 2017) to increase the consumption of fruit and vegetables in children and adolescents. In 2009, Italy started the initiative 'Fruit and vegetables in the schools'. This is a programme promoted by the European Union, developed by the Italian Ministry of Agricultural, Food and Forestry Policies and

targeted to children with the aim of increasing the consumption of vegetables and fruit and to raise the awareness on the benefits are they healthy diet. However, the programme is designed for children who attend primary school (6-11 years) (http://www.fruttanellescuole.gov.it/home).

Cereals and legumes play a fundamental role in the diet as a sort of nutrients and energy. Moreover, they contain different types of nutrients such as starch, fibre, proteins, minerals, vitamins and other substances (CREA, 2018). In several epidemiological studies the consumption was associated to a lower risk of developing cardiovascular diseases, type-2 diabetes and colorectal cancer. Moreover, the regular consumption of whole-grain products contributes to improving adiposity indices in children. Data from the INHES (Italian Nutrition & Health Survey), developed to acquire information on the food habits, on the factors that influence the choice of food and the awareness related to the relationship between nutrition and health in the Italian population, highlighted that among children/adolescents (5-19 years) 21,9% reported irregular consumption (once/week) of whole-grain products (Ruggiero et al., 2019). In Canada, the analysis of the data from the Canadian Community Health Survey-Nutrition 2015, a study aimed at investigating the patterns of whole-grain products of 6.400.000 children and adolescents (2-18 years), highlighted that whole-grain products and whole grain bread contribute to the daily energy intake for 12% (Hosseini et al., 2019). Legumes are an important food category for a healthy diet to prevent obesity and other chronic diseases associated with nutrition and lifestyle, such as diabetes, cardiovascular diseases and cancer. The zoom 8 study, a research part of the OKkio alla SALUTE on the food habits of Italian primary school children, highlighted that 53,7% of children never consume legumes and only 19.4% eat them 2-3 times per week (Ministero della Salute, 2013).

Fish to represent a food group relevant for health. It not only contributes with nutrients and proteins, minerals and vitamins, it is also an optimum source of fats, in particular of unsaturated fatty acids, such as the eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), polyunsaturated fatty acids essential for the normal functional development of the retina and brain and of great importance also for the prevention of cardiovascular and inflammation diseases (CREA, 2018). Kranz et al. (2017) reported the level of consumption of a fish in the UK paediatric population; this study highlighted that only

4.7% of the children satisfied the recommended consumption of at least two portions per week (Kranz et al., 2017).

The zoom 8 study by the OKkio alla SALUTE on the food habits of Italian primary school children highlighted that approximately 33% never or hardly ever consume fish (Ministero della Salute, 2013).

Meat represents a source of proteins but also of other fats and of micronutrients such as minerals and vitamins. However, there is a growing concern for the association between an excessive intake of meat (red and processed meat) and the susceptibility to a series of chronic diseases including cardiovascular diseases, diabetes and some types of cancer including colon cancer (Salter A., 2018). The IARC (International Agency for Research on Cancer) classified the consumption of red meat as 'probably carcinogenic to humans' and of processed meat as "carcinogenic to humans' (Bouvard et al., 2015). The zoom study highlighted that almost 14% of the primary school children exceeded the recommended levels for the consumption of cold cuts (Ministero della Salute, 2013).

This study allowed to detect the limits of the questionnaires used in the trial (in particular the FFQ of the ToyBox European study) and they need to integrate them with information more sensitive to the observation of characteristics for the diet also of children in early childhood that scientific evidence has identified as relevant for health (for example, whole wheat flour, olive oil, oleaginous fruit) (Scaglioni et al., 2016).

The administration of questionnaires to families and in the environment of the children (for example, the preschools) represents an exploratory tool: in fact, it can represent a useful tool of food education as it allows an insight into food habits and behaviours.

Food habits regarding drinks and snacks

- With regard to the food habits of children, data highlighted that 16% of them did not have breakfast every day, whereas three quarters of them drank between main meals (mostly water) and that two thirds ate between main meals: this data emphasizes the importance of changing the parental attitudes described above in order to make these moments healthier for the children.

Cardon et al. 2016 reported that in the ToyBox intervention, 10.3% of the normal-weight boys, 10.1% of the overweight/obese boys, 12.6% of the normal-weight girls and 15.9%

of the overweight/obese girls did not have breakfast every day. Moreover, 51.0% of the normal-weight boys, 53.7 % of the overweight/obese boys, 49.0% the normal-weight girls and 46.0% overweight/obese girls consume unhealthy snacks every day (≥47mg/day) (Cardon et al., 2016).

A Greek study aimed at examining the association between consumption of breakfast and weight status in children between 10 e 12 years, which accounted for socio-economic factors and lifestyle, reported that most children have breakfast every day. Specifically, 63.4% of the normal-weight children, 61.9% of the overweight children and 70.1% of the obese children (Champilomati et al., 2020).

Gibson et al. (2020) reported the existence in the ToyBox sample of an association between the parents' behaviour on the consumption of snacks and the snacks eaten by their children. The consumption of healthy and unhealthy snacks by the parents is associated with the intake of healthy and analysis snacks in children, respectively, but not vice versa. Moreover, permissiveness on the consumption of snacks promoted the intake only of unhealthy snacks, whereas the intake of healthy snacks was higher in children of less permissive parents on the consumption of unhealthy snacks (Gibson et al., 2020).

- The consumption of water appears to be frequent (96.9% ‘every day’), but it was poor in terms of a quantity as compared to the recommendations for this age group (1600 ml/day) (EFSA, 2010).

Pinket et. al (2016) also observed an average consumption of the total water in the ToyBox sample (consumed also from other drinks) below the recommendations, 1050,5 ml/day (Pinket et al. d, 2016).

- With regard to the consumption of light and sugary drinks, overall levels appeared to be low both in terms of frequency and of daily volume, however the consumption of pre-packed juices resulted to be higher, even if 75% of the sample did not exceed the frequency of 2-4 times per week and the quantity of 100-200 ml per day; they also were the most frequently consumed drinks during meals, after water and in higher quantity then homemade/fresh juices.
- The consumption of soft drinks in the ToyBox sample resulted to be limited, whereas pre-packed fruit juices after water and milk were the third source of water by importance (Pinket et al. d, 2016).

- White milk was widely consumed as compared to other dairy products; however, half of the sample drank it not more than 2-4 times per week and it was drunk between meals in little quantity even if higher than sweetened or flavoured milk.

In the ToyBox sample, almost a quarter of the consumption of water derives from milk. Milk, together with water, represents one of the main sources of intake of water in this age group (Pinket et al. d, 2016).

- Yoghurt was the most frequently consumed snack, however children consumed mostly sweetened/flavoured yoghurt; in fact, the frequency of consumption of white yoghurt is very low (half of the sample never or hardly ever consume white yoghurt).

Contrarily to our findings results, a British study, conducted to assess the association between the consumption of yoghurt and the intake of nutrients, the quality of the diet and the metabolic profile in children, highlighted that 38% of children between 4 and 10 years had not consumed yoghurt during the 4 days of completion of the food logbook (Hobbs et al., 2019).

- 50% of the children consumed fresh fruit up to a maximum of frequency of 5-6 times per week and 75% do not consume cooked or raw vegetable more than 2-4 times per week (half of the children never consume vegetables such as tomatoes, carrots etc. more than once a week, which however would be in excellent daily snack).
- Bread is consumed with a limited frequency (half of the sample do not exceed the frequency of 2-4 times per week) and, in particular, whole-grain bread was never consumed or was consumed less than once per month by half of the sample, however it was reported at the 4th place among the snacks eaten between main meals.

Among the whole grain products consumed by children/adolescents (5-19 years) of the above-mentioned INHES studies, the main source of wholegrain products resulted to be the whole wheat bread (42.3%) (Ruggiero et al, 2019).

A Brazilian study, aimed at assessing the consumption of food in relation to the degree of processing of the food, stratified by income and age group, in a sample of children with

age lower than 6 years, reported that the intake of bread accounted for 5.6% of the daily energy intake (2-year-old children or older) (Karnopp et al., 2017).

- Half of the children consumed sweet bakery products (cakes, biscuits) at least 5-6 times per week and these were at the third place in the snack ranking.
- Finally, even if on average the frequency of consumption of sweets, chocolate, cream spread and salty snacks was low (up to a maximum over once per week in half the sample), the value of the 3rd quartile highlighted that a quarter of the children ate them 2-4 times per week or more which cannot be considered a sporadic consumption, as recommended.

In the study by Karnopp et al. (2017), the overall contribution of the over-processed food (e.g. cakes and bakery products, biscuit, ice-creams confectionaries, crisps, etc.) to the daily energy intake was 36,1% (Karnopp et al., 2017). In another Brazilian study, the percentage of energy provided by over-processed foods consumed by children in pre-school age was 41.8%. The study showed the positive association between the consumption of over-processed foods and the risk of overweight and obesity and associated diseases, such as hypertension and cancer, even if only a limited number of studies investigated this association during childhood (Costa et al., 2019).

- In the general character of the sample of parents, the analysis of the attitudinal variables highlighted on average: 1) a good level of perception of the risks associated with the consumption of sugary drinks; 2) a sufficient awareness on the recommended/not recommended levels of intake of water/pre-packed drinks; 3) low level of perceived barriers to the consumption of water; 4) behavioural rules targeted to promote a healthy hydration of the children.

  However, the differences observed in some comparisons suggested that these attitudes and information are less favourable/correct among parents whose children consume sugary drinks, prepare pre-packed drinks and flavoured milk more frequently, thus indicating the possibility that these unhealthy food choices might be targeted to promote health in the household environment through more successful interventions.
- The completion of the FFQ resulted to be low, in particular with regard to the indication of the food quantity because the number of missing data resulted to be

particularly relevant. This did not allow to calculate the quantitative estimate of the consumption in terms of weight/volume.

- Some remarks on the consumption of certain foods, particularly snacking and drinking between meals, resulted to be contradictory as compared to the expectations. In particular, the fact that the frequencies of consumption of some high energy density foods (eg. cakes, biscuits) where higher among the children of mothers with a higher level of education as compared to the children of mothers with a lower level of education, among the children of normal-weight mothers as compared to the children of overweight or obese mothers and among the mothers born in Italy compared to the mothers born in another country. With regard to the consumption of soft drinks, in ToyBox, the children whose mother had a lower level of education consumed more water through soft drinks as compared to the children whose mother had a higher level of education (Pinket et al. b, 2016). A possible explanation, which should be the topic of future research, is the fact that attitudinal determinants, and the level of awareness of the risks, prevail over these potential 'predisposing' factors, as already observed.
- In conclusion, this study highlighted the risk in early years (3-6 years) associated with the consumption of foods containing free sugars such as pre-packed juices that resulted to be the most frequently consumed drinks between meals.
- This observation is particularly relevant not only in terms of prevention interventions but also to guide the industrial production towards healthier and still enjoyable foods, as a strategy to promote health.

Anthropometry

The values of the anthropometric measures which were detected in the sample of children highlighted a general excess body weight status as compared to the expectations. These values resulted to be higher in almost all these stratified comparisons by sex and age, by the international percentile standards, in particular the BMI and the waist circumference values, which therefore indicate a higher prevalence of the excess of body fat. Indeed, the surplus deviation, as compared to height, is less obvious and there are a series of

comparison where the percentile values measured in the sample were lower than the standards.

The classification of the weight status based on the cut-offs of Cole and Lobestein (2012), allows the comparison with the literature, in particular with the data observed during the validation phase of the ToyBox European project: a more than twofold prevalence of (overweight + obesity) emerged in our sample (35.2% *vs* 14,1%) as compared to the total European sample of children aged 3,5-5,5 years (Pinket et al. c, 2016). In the ToyBox study, the prevalence of overweight and obesity was higher in the regions of southern and eastern Europe as compared to the northern and western countries, for example it was higher in Spain or in Greece compared with Belgium (van Stralen et al., 2012). These results aligned with the findings yielded by the COSI study, which highlighted the presence of an increasing gradient North-South, where the prevalence of overweight and obesity was higher in the countries of southern Europe (WHO h, 2018). These differences might be partly due to socio-economic or socio-cultural factors. In surveys conducted on adult population (18-65 years), Italy presented dietary and socio-economic development patterns similar to Spain (van Stralen et al., 2012). The prevalence of overweight in our study in fact was much closer to that of Spain (15.5%) or of Greece (19.7%) than of Belgium (11.8%) (Pinket et al. c, 2016). Moreover, in the analyses conducted in the ToyBox sample it was detected a higher prevalence of overweight and obesity in girls as compared to boys (van Stralen M M, 2012). Conversely, the World Obesity Federation in the first Atlas of childhood obesity (2019), published the estimates of the prevalence of obesity by country, age group and sex and the risks scores for future obesity (Lobstein & Brinsden, 2019). Although it is not discussed in the Atlas, a difference in the prevalence of obesity among the sexes across all age groups resulted to be relevant. In children from 5 to 9 years of age, a higher prevalence of obesity was detected in males as compared to girls (Shah et al., 2020). In our trial, we did not find any statistically significant difference in the prevalence of overweight and obesity between the two sexes. However, the prevalence of fat excess estimated through the percentile thresholds of the waist circumference highlighted a difference between boys and girls which instead did not emerge with the BMI method. The prevalence of boys with waist circumference value higher than 90th percentile results almost twofold as compared to girls, whereas the prevalence of obesity is homogenous. However, in the study by Gutièrrez Hervàs on

children between 2 and 7 years, no significant differences were reported between the waist circumference values between males and females, therefore, this aspect might be an interesting topic of future research focussed on this early age group (Gutiérrez Hervás et al., 2017). A limited literature exists on the possible reasons for the differences in the prevalence of childhood obesity between the two sexes (Shah et al., 2020). We might assume that in this age group the fat deposition is different between the two sexes, higher in boys than in girls, and therefore, the early exposure to a risk factor for the metabolic syndrome (higher in boys than in girls) might be different. Further studies might clarify the higher prevalence of obesity across males than females (Shah et al., 2020).

With regard to paragraph 4.5 (Phase 4), 'satellite' studies were conducted on the association between weight status of the children and variables related to specific contexts, in particular the family environment. An in-depth study focuses on the misperception of the children's weight: about 40% of the mothers, in our ToyBox sample, underestimated the weight of their child. Such misperception, assesses in a multiple causal model, resulted to be higher among the mothers with excess body weight and with reference to older children (Cesarini V. et al., 2019). Since parents play a key role in the prevention and treatment of childhood obesity, particularly at an early age, effective educational strategies are crucial to improve their awareness.

Discussion - Phase 5

The need for prevention interventions resulted to be even more urgent during the COVID-19 emergency, because home confinement exacerbates the risk of overweight and/or obesity.

After the outbreak of COVID-19, in April 2020, the University of L'Aquila (Italy), Department of Life, Health and Environmental Sciences, developed an innovative project, with the approval of the Scientific Supervisor of the European Study, Professor Yannis Manios of the University of Harokopio in Athens (Greece), 'ToyBox in Quarantine' adapting then the ToyBox to the global emergency and conducting a to assess the process and its effectiveness, to know its feasibility and the impact on the attitudes and food behaviours of the children and of their families during the quarantine.

The assessment of the process who's conducted by completing on-line questionnaires (Google Modules) targeted to teachers and parents following e specific time plan. The study involved more than 300 children and their families and about 40 preschool teachers, for a total of 8 schools. The compliance with the programme resulted to be high and the judgements of feasibility and satisfaction by the teachers were positive. Thus, the intervention can be applied to distance teaching. However, an in-person modality resulted to be more appreciated. A high acceptability of the ToyBox intervention was reported by a study conducted to assess the acceptability of the programme adapted to the Scottish setting, the overall score of acceptability was 80% (Malden et al., 2020).

- Among the facilitating factors mostly reported by the teachers, there were the use of educational narrative tools (the stories of the kangaroo) particularly suitable to the target age group; a positive feedback on the stories was also given by the parents. Phase I of the programme, carried out in May, resulted to be better due to its ease of implementation, probably because the Phase II was carried out in June, at the end of the school year. In fact, many teachers suggested to perform such projects at the beginning of the school year.
- The assessment given by the parents is probably influenced by a bias of selection: only 25 parents participated in the assessment (less than 10% of the sample) who probably had also a more positive impact and therefore they provided non representative judgement of the overall study sample.

- The most comforting aspect was the wish explicitly expressed by the teachers to replicate the experiment in the future, therefore giving their positive evaluation of the project.

Limitations

The research has several limitations related to the methods (design of the study, enrolled sample, completeness of the statistical analysis), to the contents (we did not consider all the EBRBs and all the effectiveness measures) and to the modality of implementation in quarantine:

- In the face validity test of the materials (Phase 2) the judgment of the expert is not reported and addressed with a structured method (for example, the Delphi method), and we did not use the back-translation for the questionnaires due to the remarkable length and complexity;
- In the validation of the intervention assessment tools (Phase 3) we considered only one of the questionnaires (in particular, the validation of the intervention effectiveness questionnaire referred to the knowledge and the attitudinal variables of the teachers was not performed);
- The test-retest analysis on the questionnaires completed by the caregivers (Phase 3) was partial (it was referred only to general data and to contents on nutrition) and it did not include the application of statistical methods for the assessment of any impact of socio-demographic factors on their reliability (e.g., through the multilevel analysis and calculation of the ICC);
- The samples of children, caregivers and teachers, through the different phases, are uneven and not comparable;
- Enrolment was on a voluntary basis, without randomization neither of the schools, nor of the children and caregivers;
- The sample size was small (108 children for the validation of the questionnaires – Phase 3, 332 in the cross-sectional epidemiological analysis – Phase 4, 372 in the assessment of the project's feasibility in quarantine – Phase 5). Therefore, the sample cannot be considered representative of the population of Italian pre-schoolers, neither at local nor at national level; the strength of the study

(considering an alpha error=0.05), indeed resulted always to be lower than 80% both when assessed in the statistically significant comparisons on diet behaviours (consumption of yogurt higher in younger children, strength equal to 61%; consumption of meat sorted by geographic areas, strength equal to 74%; consumption of fruit higher in children of mothers with a higher level of education, strength equal to 47%) both in those on the weight status of the children (higher prevalence of overweight among the children of obese/overweight mothers, strength equal to 54%).

- An epidemiological analysis on the association between the measurements of the EBRBs (dietary habits) and the weight status of the children was not conducted (for example through multiple logistic models applied to the cross-sectional study – Phase 4);
- The feasibility assessment was not referred to the 'traditional' ToyBox intervention, but it was adapted to the COVID-19 emergency and difficulty in enrolling schools (Phase 5);
- The percentage of questionnaires completed and returned was high among the teachers (90.7%), but very poor among the parents (only 6.7%), therefore there may be a bias of selection as compared to the satisfaction of the families of the ToyBox in quarantine.

6. CONCLUSIONS

In conclusion, the research carried out for this doctoral dissertation allowed to reproduce and make available the ToyBox intervention within the Italian school setting for the early prevention of childhood obesity, which has already proved its effectiveness in other European countries.

Some of its limitations are related to the fact that the trial did not have any dedicated funding, and this has reduced the possibility to expand the project geographically as well the target sample size for the hand-on activities.

Further studies should be conducted in the future on a much larger scale to assess the reproducibility, sustainability and equity (addressing health and economic inequalities), necessary for the post-pandemic recovery. This objective is crucial for public health, because the COVID-19 pandemic might bring about an excessive burden on children and families, particularly on the socially and economically disadvantaged, thus increasing their vulnerability to food insecurity and to paediatric obesity (Tester et al., 2020).

Moreover, the pandemic has highlighted the need to reformulate some paradigms on the time spent at school/home and of the screen-time, on the availability of spaces and occasions of movement in public settings, on the same concept of 'household' or 'school' environment. The change in the habits and behaviours required to limit the pandemic urges us to reflect upon new patterns of life as compared to the past (e.g., working from home, rethinking the spaces, etc.). In this regard, the ToyBox in quarantine, in the current situation of social distancing and closure of schools, has revealed additional possibilities of the programmes and has demonstrated the feasibility and the acceptability by the families and the teachers in its 'distance' implementation.

The study has also involved the aspects of the communication and of the distribution of original educational contents on nutrition and lifestyles at an early age, outside the structured programme, in particular through the social networks (WhatsApp, Facebook).

We should also point out that there are not many studies that focused on this age group. The Italian health monitoring system provides for studies focused on childhood and early childhood, such as OkKio alla Salute (https://www.epicentro.iss.it/okkioallasalute/) and

ZeroDue (https://www.epicentro.iss.it/sorveglianza02years/), however, there is a paucity of studies on preschool age.

In relation to the unexpected acceleration of all these factors, and after almost 10 years from the propaedeutic study phases for the development of the ToyBox programme by the European research team, a review of the scientific evidence of the intervention is now considered crucial to address key issues in public health needs by supporting effective, sustainable and fair policies to strengthen health promotion.

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ANNEXES (available at the following link https://drive.google.com/drive/folders/19KoUQSNzo-UpmAaR50yXBV2o3XBU0f1S?usp=sharing):

- Annex 1 - Teachear's Questionnaire -Italian [Teachers' Profile] Annexed Log
- Annex 2 - Teachers' weekly logbook [Weekly Logbook] Annexed Core-Questionnaire
- Annex 3 - Post-Teacher's-Italian [Feasibility]
- Annex 4 - ToyBox Core Questionnaire – Italian
- Annex 5 - ToyBox FFQ Questionnaire - Italian
- Annex 6 - Post-Evaluation Parental Questionnaire - Italian [Satisfaction]
- Annex 7 - Post-Evaluation Teachers' Questionnaire - Italian [Satisfaction]