LIVELY: MuLtidimensional school-based and family Involved interVentions, to promote a hEalthy and sustainable LifestYle for the childhood obesity primary prevention, a Study Protocol

Sara Basilico, Maria Vittoria Conti, Ilaria Ardoino, Chiara Breda, Federica Loperfido, Elena Klaic, Linda Spialtini, Andreana Foresta, Francesca Orsini, Maria Luisa Ojeda Fernandez, Stefano Conca Bonizzoni, Elisabetta Modena, Yasamin Tootoonchi, Federica Villa, Hellas Cena, Marta Baviera, Carlotta Franchi

Submitted to: JMIR Research Protocols
on: February 19, 2024

Table of Contents

LIVELY: MuLtidimensional school-based and family Involved interVentions, to promote a hEalthy and sustainable LifestYle for the childhood obesity primary prevention, a Study Protocol

Sara Basilico[1]; Maria Vittoria Conti[1]; Ilaria Ardoino[2]; Chiara Breda[1]; Federica Loperfido[1]; Elena Klaic[1]; Linda Spialtini[1]; Andreana Foresta[3]; Francesca Orsini[2]; Maria Luisa Ojeda Fernandez[3]; Stefano Conca Bonizzoni[4]; Elisabetta Modena[4]; Yasamin Tootoonchi[4]; Federica Villa[4]; Hellas Cena[1, 5]; Marta Baviera[3]; Carlotta Franchi[2, 6]

[1]Laboratory of Dietetics and Clinical Nutrition, Department of Public Health, Experimental and Forensic Medicine University of Pavia Pavia IT
[2]Laboratory of Pharmacoepidemiology and Human Nutrition, Department of Health Policy Istituto di Ricerche Farmacologiche Mario Negri IRCCS Milan IT
[3]Laboratory of Cardiovascular Prevention, Department of Health Policy Istituto di Ricerche Farmacologiche Mario Negri IRCCS Milan IT
[4]Department of Humanities University of Pavia Pavia IT
[5]Clinical nutrition Unit, General Medicine ICS MAUGERI IRCCS Pavia IT
[6]Italian Institute for Planetary Health Milan IT

Corresponding Author:
Sara Basilico
Laboratory of Dietetics and Clinical Nutrition, Department of Public Health, Experimental and Forensic Medicine
University of Pavia
Via Agostino Bassi 21
Pavia
IT

Abstract

Background: Childhood obesity has become a significant public health concern over the past two decades, posing multifactorial challenges that include modifiable factors like dietary habits and physical activity. Prevention efforts require a comprehensive approach, including educational interventions, collaboration among multidisciplinary teams, and community engagement. Given that schools play a central role in children's lives, they are an ideal setting for promoting healthy habits.

Objective: The LIVELY study focuses on assessing the prevalence of overweight and obesity in primary school children and identifying contributing factors within families. Additionally, it aims to implement and evaluate a multidimensional, multidisciplinary intervention to foster a sustainable and healthy lifestyle, ultimately working towards preventing obesity in school-aged children.

Methods: The study is being conducted at Istituto Comprensivo "Luigi Cadorna", a public primary school in Milan, Italy, and it will last one full school year, from October 2023 until October 2024. At baseline (T0), data regarding children's (clinical history, anthropometric measures, and lifestyle habits) and their families (socio-economic status, environmental influences, and behavioral determinants) have been collected throughout a set of structured questionnaires. All the data collected at baseline will be assessed at six (T1) and at twelve months (T2) from the beginning of the study to evaluate possible changes in relation to the intervention. At T1 the feasibility of the intervention will be assessed in terms of satisfaction, learning, and organization through ad-hoc questionnaires addressed to teachers, families, and children.
During the school year, each class will be individually involved in a multidimensional educational intervention that will cover the topics of healthy and sustainable nutrition and lifestyle. Children will also be involved in a multimedia lab to create an animated cartoon. The lectures will act on several fronts using frontal teaching, games and drawing activities to stimulate and maximize children's learning and involvement.

Results: Data collection began in October 2023 and will last until October 2024. A sample of 227 children from 14 classes was included in the study. The mean age was 8.9±1.2 years (min 6; max 12 yo); 48% were males. Among the overall sample, 18.1% (95% CI: 13.7%-23.7%) presented overweight, while 5.3% (95% CI: 3.0%-9.0%) presented obesity. Males had higher prevalence of obesity than females (9.1% vs 1.7%, p=0.03 respectively). Otherwise, the prevalence of central obesity was similar between the two sexes (p=0.329). Data analysis and presentation of the complete results will be available after the end of 2024.

Conclusions: The authors believe that the study could lead to the structuring of an educational intervention model in school settings aimed at preventing childhood obesity. Moreover, it could help raise awareness of the issue of childhood obesity and it could help prevent such an evident public health problem. Clinical Trial: ClinicalTrials.gov NCT05966051

(JMIR Preprints 19/02/2024:57509)
DOI: https://doi.org/10.2196/preprints.57509

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

LIVELY: MuLtidimensional school-based and family Involved interVentions, to promote a hEalthy and sustainable LifestYle for the childhood obesity primary prevention, a Study Protocol

Sara Basilico[1], Maria Vittoria Conti[1], Ilaria Ardoino[2], Chiara Breda[1], Federica Loperfido[1], Elena Klaic[1], Linda Spialtini[1], Andreana Foresta[3], Francesca Orsini[2], Maria Luisa Ojeda Fernandez[3], Stefano Conca Bonizzoni[4], Elisabetta Modena[4], Yasamin Tootoonchi Hamedani[4], Federica Villa[4], Hellas Cena[1,5], Marta Baviera[3], Carlotta Franchi[2,6]

1. Laboratory of Dietetics and Clinical Nutrition, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy
2. Laboratory of Pharmacoepidemiology and Human Nutrition, Department of Health Policy, Istituto di Ricerche Farmacologiche Mario Negri IRCCS Milan, Italy
3. Laboratory of Cardiovascular Prevention, Department of Health Policy, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy
4. Department of Humanities, University of Pavia, Pavia, Italy
5. Clinical nutrition Unit, General Medicine, ICS MAUGERI IRCCS, Pavia, Italy
6. Italian Institute For Planetary Health, Milan, Italy

Abstract

Background: Childhood obesity has become a significant public health concern over the past two decades, posing multifactorial challenges that include modifiable factors like dietary habits and physical activity. Prevention efforts require a comprehensive approach, including educational interventions, collaboration among multidisciplinary teams, and community engagement. Given that schools play a central role in children's lives, they are an ideal setting for promoting healthy habits.
Objective: The LIVELY study focuses on assessing the prevalence of overweight and obesity in primary school children and identifying contributing factors within families. Additionally, it aims to implement and evaluate a multidimensional, multidisciplinary intervention to foster a sustainable and healthy lifestyle, ultimately working towards preventing obesity in school-aged children.
Methods: The study is being conducted at Istituto Comprensivo "Luigi Cadorna", a public primary school in Milan, Italy, and it will last one full school year, from October 2023 until October 2024. At baseline (T0), data regarding children's (clinical history, anthropometric measures, and lifestyle habits) and their families (socio-economic status, environmental influences, and behavioral determinants) have been collected throughout a set of structured questionnaires. All the data collected at baseline will be assessed at six (T1) and at twelve months (T2) from the beginning of the study to evaluate possible changes in relation to the intervention. At T1 the feasibility of the intervention will be assessed in terms of satisfaction, learning, and organization through ad-hoc questionnaires addressed to teachers, families, and children.
During the school year, each class will be individually involved in a multidimensional educational intervention that will cover the topics of healthy and sustainable nutrition and lifestyle. Children will also be involved in a multimedia lab to create an animated cartoon. The lectures will act on several fronts using frontal teaching, games and drawing activities to stimulate and maximize children's learning and involvement.
Results: Data collection began in October 2023 and will last until October 2024. A sample of 227 children from 14 classes was included in the study. The mean age was 8.9±1.2 years (min 6; max 12 yo); 48% were males. Among the overall sample, 18.1% (95% CI: 13.7%-23.7%) presented overweight, while 5.3% (95% CI: 3.0%-9.0%) presented obesity. Males had higher prevalence of

obesity than females (9.1% vs 1.7%, p=0.03 respectively). Otherwise, the prevalence of central obesity was similar between the two sexes (p=0.329). Data analysis and presentation of the complete results will be available after the end of 2024.
Conclusions: The authors believe that the study could lead to the structuring of an educational intervention model in school settings aimed at preventing childhood obesity. Moreover, it could help raise awareness of the issue of childhood obesity and it could help prevent such an evident public health problem.

Trial Registration: ClinicalTrials.gov NCT05966051

Keywords:

childhood obesity; school education; family education; healthy lifestyle; sustainability; primary prevention; nutritional intervention; nutrition; children.

Introduction

Background

Childhood overweight and obesity have emerged as a public health crisis, reaching a global dimension [1]. Overweight and obesity prevalence estimates from the fifth round of COSI data collection (2018-2020), conducted in 33 countries of the WHO European Region, indicate that 29% of 7-9 years old children are living with overweight, including 12% with obesity, with Italy “winning” fourth place in the rankings [2].

Primary factors contributing to obesity in Europe—unhealthy dietary habits and lack of physical activity—stand as prominent drivers of preventable fatalities, chronic illnesses, and economic health burdens among the youth. These modifiable determinants have been particularly challenged during the COVID-19 pandemic, across all population age groups, including children. The lockdown affected children’s lifestyle habits with an increased sedentary lifestyle and screen time, and high calorie-dense and sugary food consumption [3].

This scenario is calling for the execution of more evidence-based policies, economic investments, and integrated programs [4,5]. As a matter of fact, it is undeniable that in the past decades several childhood abatement interventions have been executed to contain the issue but increasing regional and global prevalence trends display how those have had little success [2,6,7]. Scientific evidence described how the ‘eat less, move more’ attitude is too simplistic, and no single intervention can be successful in halting the advancement of the obesity epidemic. Therefore, modern policy actions have been prompted into executing integrated programs, which takes into consideration: 1) multi-component approaches (nutrition, physical activity, sleep hygiene, etc.); 2) multi-level efforts (individual children, families, school); 3) multi-settings interventions (primary care clinics, homes, community centers) to prevent, contain and manage childhood overweight and obesity [2,8,9].

Adherence to the Mediterranean Diet (MD) and lifestyle, primary prevention strategy for obesity recognized by many relevant scientific societies [10], has decreased in the past decades in most WHO Member States, including countries in the Mediterranean basin, and among younger individuals belonging to low social classes [11-13]. According to estimates of the most recent COSI data collected (2018-2020), in the WHO European Region less than half (43%) of children consumed fresh fruit daily and even less (34%) ate vegetables daily [2]. According to these data, level of

physical activity remains poor as well: overall, 40% of children did not spend any time during the week doing sports while 43% of children aged 6-9 years had at least two hours a day of screentime, with prevalence reaching 76% at weekends [2].

Italy is no exception: the transition toward western dietary patterns, based on ultra-processed foods, and sedentary lifestyle is the consequence of many socio-cultural and economic factors, such as increased cost of living, changes in gender roles in society, urbanization, and globalization [14]. In particular, children of migrant background often change for the worse their traditional eating habits while increasing consumption of processed food often because of economic barriers [13,14]. Given that as of January 1, 2020, Italy was counting 1.3 million children of migrant background aged 0-17, it's clear how the imprinting of nutritional and healthy lifestyle education among this population group is determinant to curb childhood obesity prevalence in future years [15].

Since the consolidation of healthy dietary habits at an early age may prevent the onset of chronic diseases later in adulthood, schools have been recognized as powerful settings to instill nutritional and healthy lifestyle education and execute targeted interventions [8,16].

Archero et al. [17] conducted a two-month cross-sectional study in Novara, including three primary and two secondary schools to assess the MD association with the weight status. The authors found a higher prevalence of overweight and obesity and a lower adherence to MD in children attending primary school, compared to the others. Another cross-sectional study was conducted by Paduano et al. [18] with the aim to investigate physical/sedentary activities of first-year primary school children in Modena, and their association with overweight/obesity and dietary habits. The authors found that three out of four children spent in physical activities less than 7 h/week, while 63.9% dedicated to sedentary activities two or more hours/day. Recently, Italian National Institute of Health, in collaboration with the Ministry of Health, implemented a project, called "Maestra Natura" [19] aimed at promoting healthy lifestyles and improving knowledge about food and nutrition in elementary school children. The results showed a significant improvement in knowledge ($p < 0.001$) in the intervention group with respect to the control group.

Despite several actions carried out to counteract childhood obesity on Italian soil [17-19], the rising incidence of obesity demonstrates that the measures adopted were not so effective in achieving their short and long run goals [20]. In this context, the LIVELY study (MuLtidimensional school-based and family Involved interVentions, to promote a hEalthy and sustainable LifestYle for the childhood obesity primary prevention) aims to set up and evaluate the feasibility of a multidimensional school-

based educational intervention for prevention of childhood obesity.

Study Objectives

The study's primary objectives include:

1. To investigate prevalence of overweight and obesity among primary school children and its determinants related to children (clinical history, lifestyle habits) and their families (socio-economic status, environmental influences, and behavioral determinants).
2. to set up and to evaluate the feasibility of a multidimensional school-based educational intervention promoting a healthy and sustainable lifestyle and therefore aim at preventing childhood obesity.
3. the assessment of possible changes in children's diet and lifestyle, as well as in family behavioral attitudes, at 6 and 12 months from the execution of the interventions.

Methods

Study design and overview

The LIVELY is a single arm pre -post study (without control). It was approved by the *Comitato Etico Fondazione IRCCS Istituto Neurologico Carlo Besta* (protocol 11) in January 2023.
The study is conducted in accordance with the principles of the Declaration of Helsinki, with relevant institutional regulations. LIVELY is being conducted by a multidisciplinary team consisting of researchers from the *Istituto di Ricerche Farmacologiche Mario Negri IRCCS* (IMN) of Milan and the Laboratory of Dietetics and Clinical Nutrition (LDNC) of the University of Pavia.

Setting

LIVELY is being carried out at *Istituto Comprensivo "Luigi Cadorna"*, a public primary school with a strong multiethnic component in the North-West of Milan, Italy. The study will last from October 2023 until October 2024. **Figure 1** shows the timeline of the study.

Selection criteria

The target population for the study were children from 5 to 12 years of age, of both sexes and any ethnicity, and their families. Only children whose parents or legal guardians approved and signed the informed consent were included.

Recruitment

The multidisciplinary team organized an initial meeting at the participating school to introduce the project to the dean and teachers. Teacher representatives took charge of presenting the project to the families of the various classes. Interested families were provided with a study information sheet which was translated in different languages (Arabic and English) due to the high multiethnicity, especially Arabian, of the school. Teachers in participating classes gave informed consent and privacy forms to each child in the family's native language. Signed documents were required from all children’s families before their enrollment in the study.

Outcome measures

Details of data collected from both children and their families throughout the study period are summarized in **Table 1**.

Anthropometric measurements and weight status classification

A team of trained nutritionists managed the assessment of children anthropometric measurements, which were obtained at T0 and will be assessed also at T1 and at T2.

Children's weight was measured using the same digital scale (Tanita BC545N). Before standing on the scale, children were asked to remove their shoes and to wear just trousers and t-shirt. Body weight was recorded to the nearest 0.1 kilogram. Height was measured using a portable altimeter (Seca 213) and recorded to the nearest millimeter. Waist circumference (WC) was measured midway between the lower rib and the iliac crest to the closest 0.5 cm, while the circumference of the non-dominant bicep was measured with the forearm flexed 90°, between the acromion process and the olecranon to the closest 1.0 cm.

Body Mass Index (BMI) was expressed as BMI z-score by referring to the growth curves proposed by the WHO that classify children as having underweight, normal weight, overweight (BMI by sex and age greater than 2 standard deviation) or obesity (BMI greater than 3 standard deviations) [21]. The software Anthro® and AnthroPlus® was used to calculate BMI z-score [22].

Waist-to-height ratio (WHtR) was calculated as WC divided by height, both expressed in centimeters. For the definition of central distribution of adiposity, we adopted the discriminatory value of 0.5 for WHtR [23,24], which corresponds to the 85th percentile of our sample [25,26]. Pupils were separated into two groups: the first one included children with WHtR <0.5 (normal distribution of adiposity), while the second one included children with WHtR ≥0.5 (central obesity).

Data collection

A case report form (CRF) was used to collect information regarding the children and their household and to investigate all the determinants of overweight and/or obesity. Referring teachers distributed the CRF, in paper format, to each child participating in the study, in the family's native language, and then took charge of collecting them once they were filled out by the parents.

Sociodemographic information

Sociodemographic and socioeconomic information of the family (household composition, ethnicity, parents' education, job, health, smoking and drinking habits and household food habits) and of the children (age, attended class, health conditions and practices related to child feeding) were collected through a structured questionnaire collected at the beginning of the school year (T0).

Diet and Lifestyle

Information regarding the child's eating habits and lifestyle were assessed at T0 through a structured

questionnaire. The same questionnaire will be administered at six months (T1) and 12 months (T2) after the beginning of the study to assess changes in children's eating and lifestyle habits in relation to the educational content addressed in the classrooms during the intervention.

Specifically, the Mediterranean Diet Quality Index for children and adolescents (KIDMED) [27,28] questionnaire was used to assess adherence to the Mediterranean Diet (MD) and to get an overview of the child's consumption of the main food groups (fruits, vegetables, pasta and cereals, legumes, fish, meat, and dairy products). To complete the questionnaire, information was requested regarding the number of meals consumed, whether children ate in the school cafeteria, whether they used sweeteners in tea or milk (e.g., sweetened cocoa, sugar, or honey), whether they consumed whole foods, and whether they made consumption of ultra-processed foods (NOVA classification) [29,30]. In the absence of a validated questionnaire to assess children's lifestyle, questions were structured based on the 2018 Centro di Ricerca Alimenti e Nutrizione (CREA) Guidelines [31] to assess hydration level and the WHO Guidelines [32] to assess physical activity, sleep habits, and screen time.

Multidimensional educational interventions

Lessons and games

During the school year, each class is individually involved in a multidimensional educational intervention that will cover the topics of healthy and sustainable nutrition and lifestyle. The educational intervention will be conducted by experienced staff such as nutritional biologists and registered dietitians. All classes will be conducted during regular school hours and included within the teaching of Civic Education. Six lessons from October 2023 up to April 2024 will be conducted on the following topics: macronutrients, micronutrients, the digestive system, food pyramid, healthy eating plate, lifestyle (sleep habits, screen time and physical activity). Each lesson, every four weeks and lasting 2 hours, will be divided into two parts: the first part of about 30-40 minutes of frontal teaching with the support of interactive slides, and the second part of about 80-90 minutes in which playful activities adapted to the target age group of children will be carried out.

Multimedia lab

After the first five lessons, in which children will have learned the basics of healthy and sustainable nutrition, a multimedia workshop will be conducted to create an animated cartoon. Children will be asked to draw a humanized food to which they will assign a name, distinguishing features,

personality, and clothing. Thanks to the multimedia support of the interdepartmental workshop Officine Creative of the University of Pavia (https://artivisiveperformative-lm.cdl.unipv.it/it/officine-creative), the drawings will be transformed into animated characters and included in a short cartoon that will be screened at the end of the school year.

Evaluation of the project

The evaluation of educational interventions will aim to analyze and interpret relevant aspects of the multidimensional intervention. It will involve both the school team (teachers) and the recipients (children and families) participating in the LIVELY project and will be evaluated at the end of the school year (T1).

The feasibility of the multidimensional educational intervention at school will be assessed in terms of satisfaction, learning, and organization. Three main areas of evaluation of educational interventions will be distinguished, namely, "satisfaction" (by children, families, and teachers), "learning" (by children), and "organizational" impact in the work context (by teachers).

The assessment of children's and their families' satisfaction will be collected through an ad-hoc questionnaire investigating the level of appreciation about the proposed activities. While the evaluation of the children's knowledge of the topics covered in the lessons (healthy and sustainable nutrition and lifestyle) will be collected through specific questionnaires (true/false items, multiple-choice items, insertion) or short compositions, depending on the child's age group. The overall satisfaction and organizational impact of the interventions will be evaluated by teachers through an ad-hoc structured questionnaire, which will explore the following issues: usefulness (definition and consistency/congruence of the multidimensional interventions with the project objectives, usefulness of the interventions and materials prepared), didactics (competence and appropriateness of the teaching techniques of the study teams addressed to the subjects, support received by the study teams during the implementation of the activities), organization and services (timing, facilities and appropriateness of the schools' premises). In addition, teachers will be asked to refer to the reproducibility of the intervention in other classrooms or schools. All items in the questionnaire will be rated on a Likert-type scale.

Sample size calculation

For this kind of study, it is not needed a sample size calculation, but we expected to enroll about 300/350 children aged 6/12 years within 15/20 classes (in primary school and in the first class of first grade secondary school) based on the availability/willingness of teachers to participate and of the resources.

This will allow us to estimate a prevalence of overweight and obesity of about 23-24% with a 20% relative precision and within a 95% confidence interval. This data is in line with those observed in the Okkio alla Salute 2019 survey in the Lombardy region [33].

Statistical analysis

Descriptive analysis will be performed to summarize the baseline characteristics of the involved children according to normal-weight, overweight and obese classification. Descriptive data were expressed as counts (percentages) for categorical data and as means standard deviation (SD), for continuous variables. The means for continuous variables were compared using independent group T-tests when the data were normally distributed, otherwise the Mann–Whitney test was applied. Categorical variables were compared using the Chi-square test. Main determinants of overweight/obesity among children will be investigated according to clinical conditions, dietary patterns, physical activity habits, environmental and behavioral (family) conditions, collected at the baseline, by means of logistic/multinomial regression models.

Specifically, according to questionnaires' results and to information collected in the CRF, children will be identified as 'Fully adherent', 'Partial adherent' or 'Poor adherent' to the WHO recommendation, regarding eating and lifestyle habits.

The obesogenic environment will be investigated by summarizing all information collected with a proper index by assigning a score ranging from 0 – least obesogenic - to 100 – most obesogenic - assigning a score to each item. Variables that were considered positive aspects of the environment – grocery, stores/superstores, exercise opportunities – were reverse-scored such that a lower score for these variables indicated a healthier environment. Variables that were considered negative aspects – fast-food restaurants and/or affordability at home, using a car to go to school – were scored as is, such that a higher score indicated an unhealthy environment.

Indices for each dimension and an aggregate index will also be calculated to assess the level of satisfaction referred to the training intervention, learning and overall knowledge of the topic and of the overall organization and reproducibility of the intervention. Multivariate statistical analysis will be used to investigate general and specific quality dimensions and factors and it will be correlated with the other measures illustrated above. Changes in dietary and lifestyle habits in children, behavioral attitudes in their families and children's anthropometric measurements will be assessed at 6 (T1) and 12 months (T2) starting from baseline. All the results will be stratified by sex and age groups.

Preliminary results

Recruitment lasted throughout the month of October 2023. From the 275 children afferent to the 14 classes participating in the project, 227 whose parents approved and signed the informed consent were included in the study.

The mean (std.dev) age was 8.9 years (1.2 years,), 48% (n=110) were males. Children from the 14 classes were distributed as follows: 5.3% (n=12 children) from the second year (1 class), 33.9% (n=77 children) from the third year (5 classes), 15.9% (n=36 children) from the four year (2 classes) and 44.9% (n=102 children) from the fifth year (6 classes). No first-year class took part in the project. Data related to demographic data, including age, weight, height, BMI z-score, and WHtR are shown for total population and by sex in **Table 2**.

The percentage of normal weight, overweight and obesity, defined by BMI z-score, and of central obesity according to the WHtR cut-off is reported in **Table 3**. Among the overall sample, 18.1% (95% CI: 13.7%-23.7%) presented overweight, while 5.3% (95% CI: 3.0%-9.0%) presented obesity. Males had higher prevalence of obesity than females (9.1% vs 1.7%, p=0.03 respectively). Conversely, the overall prevalence of central obesity was similar between males and females, respectively (31% vs 37%, p=0.329).

Data analysis and presentation of the complete results will be available after the end of 2024.

Discussion

The rising prevalence of obesity worldwide represents a growing burden of Non-Communicable Diseases (NCDs) and a significant public health issue due to increasing public service health costs [6,11,34]. To prevent the early onset of NCDs in younger populations, additional policies, treatments, and financial investments must be made to contrast the growing pandemic of childhood obesity [35-37]. Based on scientific research [8], preventing childhood obesity requires a multifaceted approach including multiple areas of intervention. Therefore, it is essential to develop and carry out integrated programs that could cover a variety of topics (nutrition, physical activity, sleep hygiene, etc.) at various levels (individual, family, school, and institutional) [38].

The LIVELY study enrolled 226 school-age children attending an elementary school belonging to a highly multiethnic neighborhood in the North of Milan, Italy. Classes from the second to the fifth year were involved. No first-year class joined the project because the availability of children to follow the lesson could not be optimal. This was since during the first year of elementary school, children are just beginning to learn how to read and write, leading primary school teachers to abstain from participating in the project.

In line with previous studies [17-19], our preliminary results showed a high prevalence of overweight/obesity among enrolled children with it being 24% among males and 23% among females, with a higher prevalence of obesity among males (p=0.007). Interestingly, the prevalence of central obesity was similar between the two sexes (p=0.329).

A child's diet and physical activity can be greatly influenced by their surroundings, particularly family and school [39]. To date, many programs have been developed to prevent obesity in children, but the overall impact of these are questionable and do not include long-term follow up measurements [17-19]. Thus, the Lively study has significant strengths such as: 1) Multidimensional interventions involving different actors (children, families, teachers) and multidisciplinary professional expertise will be implemented, allowing for addressing of the different determinants of childhood obesity; 2) Frontal lectures and games inherent to the subject matter will be adapted to the age group, dividing the children between two years (first and second grade) and three years (third to fifth grade). The strong multicultural component of the sample will be considered by involving them in stimulating and bonding activities; 3) An interactive digital lab will be developed to maximize learning outcomes by exploiting children’s digital skills; 4) Attention will be given to the opinion of all participants (children, parents, teachers) to assess the feasibility and reproducibility of the project.

There are several possible obstacles to this research in real-world contexts; some ones could be foreseen now, and others will be managed as they arise. The authors already encountered two main challenges. The first regarded the active involvement and participation of teachers as some of them found it difficult to include new modules into the already tight teaching schedule as all classes will be conducted during regular school hours and included within the teaching of Civic Education. However, it was possible to overcome this obstacle by involving the school principal and explaining to teachers the importance and impact of the project since the topics covered are not part of the regular school curriculum and will cover current and important issues such as sustainability and Planetary Health. Moreover, this approach fits with the Sustainable Development Goals (SDGs) described in the 2030 Agenda for Sustainable Development, adopted by all United Nations Member States, and whose study has been introduced since 2020 by the Italian Ministry of Education in the field of Civic Education. The second concerned the large multicultural component of the sample, as language barriers can play a crucial role. To minimize this obstacle, most of the tools concerning completion by families (informed consent, releases, and questionnaires) were translated into three different languages (Italian, English and Arabic).

The authors may encounter challenges with the compliance of the families to fill the questionnaires auto administered. To address this, phone calls to the families to fill in the questionnaires or enter the missing data with the support of trained staff will be planned. Another difficulty may lie in the failure to collect data at 12 months from children moving from 5th grade to 6th grade who will change school sites. Authors plan to mitigate this issue by maintaining contact with teachers and parents. In addition, through satisfaction questionnaires, the various stakeholders of the project will be given a voice with the aim of highlighting the strengths and any critical issues of the project from different perspectives.

It seems clear how the LIVELY study can benefit the study population and can convey through a multidisciplinary, multiprofessional and reproducible approach the basics of healthy and sustainable nutrition and lifestyle with the aim of preventing and/or reducing the prevalence of childhood obesity.

Acknowledgments

The authors thank the principal of the elementary school *Istituto Comprensivo "Luigi Cadorna*" for hosting the LIVELY project in her facility and all the teachers who allowed their classes to participate. In addition, the authors thank the children's families for their cooperation in data collection.

Authors' Contributions

CF, MB, IA and MVC conceived and designed the study and acquired funding. HC peer-reviewed the study design. SB and EK drafted and wrote the manuscript. All the authors critically reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Funder: Project funded under the National Recovery and Resilience Plan (NRRP), Mission 4 Component 2 Investment 1.3 - Call for proposals No. 341 of 15 March 2022 of Italian Ministry of University and Research funded by the European Union – NextGenerationEU.
Award Number: Project code PE00000003, Concession Decree No. 1550 of 11 October 2022 adopted by the Italian Ministry of University and Research, CUP D93C22000890001, Project title "ON Foods - Research and innovation network on food and nutrition Sustainability, Safety and Security – Working ON Foods".

Abbreviations

BMI: body mass index
COSI: Childhood Obesity Surveillance Initiative
CREA: Centro di Ricerca Alimenti e Nutrizione
CVD: cardiovascular disease
KIDMED: Mediterranean Diet Quality Index for children and adolescents
LIVELY: MuLtidimensional school-based and family Involved interVentions, to promote a hEalthy and sustainable LifestYle for the childhood obesity primary prevention
LDNC: Laboratory of Dietetics and Clinical Nutrition

MD: Mediterranean diet

NCDs: non communicable diseases

WC: waist circumference

WHO: World Health Organization

WHtR: Waist-to-height ratio

UNESCO: United Nations Educational, Scientific and Cultural Organization

Tables

Table 1. Summary of outcome measures collected from participating children and their families.

Outcome	Basal (T0)	6 months (T1)	12 months (T1)
Anthropometry measurements			
- Weight - Height - Waist circumference - Bicep circumference	X	X	X
Questionnaires			
Sociodemographic information related to the parents: - household composition - ethnicity - education - job - health - smoking and drinking habits - household food habits	X		
Sociodemographic information related to the children: - age - attended class - health conditions - practices related to child feeding	X		
Diet and Lifestyle related to the children. - Adherence to Mediterranean Diet - Consumption of ultra-processed foods - Water consumption - Sleep habits - Screen time habits	X	X	X
Project evaluation - Feasibility of the project (satisfaction, learning, organization)		X	

Legend Table 1:
Table 1 shows all the outcome measures that will be collected at baseline (T0), six months (T1) and 12 months (T2) after the start of the study from participating children and their families.

Table 2. Demographic characteristics of the study population

	Study Population			
	Total	**Males**	**Females**	
	n=227 100%	n=110 48%	n=117 52%	**p-value**
Age, years	8.9±1.2	8.9±1.2	8.9±1.1	0.975
Age range	6-12	6-12	7-12	
Place of birth				
Italy	170 (79.3)	83 (75.5)	97 (82.9)	
Europe	10 (4.4)	9 (8.2)	1 (0.9)	
South America	11 (4.8)	6 (5.5)	5 (4.3)	0.091
Africa	23 (10.1)	10 (9.1)	13 (11.1)	
Asia	3 (1.3)	2 (1.8)	1 (0.9)	
Attended class				
First year class	0 (0.0)	0 (0.0)	0 (0.0)	
Second year class	12 (5.3)	8 (7.3)	4 (3.4)	
Third year class	77 (33.9)	36 (32.7)	41 (35.0)	0.640
Fourth year class	36 (15.9)	17 (15.5)	19 (16.2)	
Fifth year class	102 (44.9)	49 (44.5)	53 (45.3)	
Anthropometric measurements				
Weight, kg	35.86±10.53	35.27±10.5	36.41±10.57	0.419
Height, cm	136.33±8.74	85.56±8.38	136.75±9.09	0.420
Waist circumference, cm	65.19±11.37	65.22±10.95	65.15±11.79	0.966
Bicep circumference, cm	22.11±4.01	21.72±4.12	22.47±3.89	0.159
WHtR	0.48±0.07	0.48±0.07	0.48±0.07	0.666
BMI z-score	0.85±1.42	0.85±1.55	0.84±1.30	0.971
BMI z-score classes				
Underweight	5 (2.2)	4 (3.6)	1 (0.9)	
Normal weight	169 (74.4)	80 (72.7)	89 (76.1)	0.025
Overweight	41 (18.1)	16 (14.5)	25 (21.4)	
Obesity	12 (5.3)	10 (9.1)	2 (1.7)	
Central obesity				
WHtR<0.5	150 (66.1)	76 (69%)	74 (63%)	0.329
WHtR≥0.5	77 (33.9)	34 (31%)	43 (37%)	

Legend Table 2:

Table 2 shows the demographic and anthropometric characteristics of the overall study population and then divided between males and females. Categorical variables presented as number (percentage), and continuous variables as mean (±SD). To compare variables between different groups, the Chi-squared test was used for categorical variables.

Body Mass Index (BMI); Waist-to-height ratio (WHtR).

Table 3. Weight status prevalence according to BMI z-score and their relation to Waist-to-Height Ratio (WHtR) in males and females.

Males	Total n=110 (100%)	WHtR <0.5 n=76 (69%)	WHtR ≥0.5 n=34 (31%)
BMI z-score (WHO)			
Underweight	4 (3.6)	4 (5.3)	0 (0.0)
Normal weight	80 (72.7)	71 (93.4)	9 (26.5)
Overweight	16 (14.5)	1 (1.3)	15 (44.1)
Obesity	10 (9.1)	0 (0.0)	10 (29.4)
Females	Total n=117 (100%)	WHtR <0.5 n=74 (63%)	WHtR ≥0.5 n=43 (37%)
BMI z-score (WHO)			
Underweight	1 (0.9)	1 (1.4)	0 (0.0)
Normal weight	88 (75.9)	71 (95.9)	18 (41.9)
Overweight	25 (21.6)	2 (2.7)	23 (53.5)
Obesity	2 (1.7)	0 (0.0)	2 (4.7)

Legend Table 3:
Table 3 shows the weight status prevalence according to BMI z-score and their relation to Waist-to-Height Ratio (WHtR) in both sexes. Data are expressed as counts (percentages). Body Mass Index (BMI); Waist-to-Height Ratio (WHtR); World Health Organization (WHO).

Figures

Figure 1. Lively Study Flow Chart

References

1. Thomas-Eapen N. Childhood Obesity. Prim Care. 2021 Sep;48(3):505-515. doi: 10.1016/j.pop.2021.04.002. Epub 2021 Jul 8. PMID: 34311854.
2. Report on the fifth round of data collection, 2018–2020: WHO European Childhood Obesity Surveillance Initiative (COSI). Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO.
3. Cuschieri S, Grech S. COVID-19: a one-way ticket to a global childhood obesity crisis?. J Diabetes Metab Disord. 2020;19(2):2027-2030. Published 2020 Nov 6. doi:10.1007/s40200-020-00682-2
4. Di Cesare M, Sorić M, Bovet P, et al. The epidemiological burden of obesity in childhood: a worldwide epidemic requiring urgent action. BMC Med.
5. Yadav HM, Jawahar A. Environmental Factors and Obesity. In: StatPearls. StatPearls Publishing; 2023. Accessed October 17, 2023. http://www.ncbi.nlm.nih.gov/books/NBK580543/
6. World Health Organization. Report of the Commission on Ending Childhood Obesity. Geneva: WHO, 2016.https://iris.who.int/bitstream/handle/10665/204176/9789241510066_eng.pdf?isAllowed=y&sequence=1 (viewed December 3, 2023)
7. Report of the Commission on Ending Childhood Obesity. Implementation plan: executive summary. Geneva: World Health Organization; 2017 (WHO/NMH/PND/ECHO/17.1). Licence: CC BY-NC-SA 3.0 IGO (viewed December 3, 2023)
8. Wickramasinghe K, Chatterjee S, Williams J, Weber MW, Rito AI, Rippin H, Breda J. Childhood overweight and obesity abatement policies in Europe. Obes Rev. 2021 Nov;22 Suppl 6:e13300. doi: 10.1111/obr.13300. Epub 2021 Nov 4. PMID: 34738306.
9. Specchia ML, Barbara A, Campanella P, Parente P, Mogini V, Ricciardi W, Damiani G. Highly-integrated programs for the prevention of obesity and overweight in children and adolescents: results from a systematic review and meta-analysis. Ann Ist Super Sanita. 2018 Oct-Dec;54(4):332-339. doi: 10.4415/ANN_18_04_10. PMID: 30575570.
10. Visseren FLJ, Mach F, Smulders YM, et al. 2021 ESC Guidelines on cardiovascular disease prevention in clinical practice. *Eur Heart J*.
11. WHO European Regional Obesity Report 2022. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/europe/publications/i/item/WHO-EURO-2022-6594-46360-67071
12. Mendonça N, Gregório MJ, Salvador C, Henriques AR, Canhão H, Rodrigues AM. Low Adherence to the Mediterranean Diet Is Associated with Poor Socioeconomic Status and Younger Age: A Cross-Sectional Analysis of the EpiDoC Cohort. Nutrients. 2022;14(6):1239. doi:10.3390/nu14061239
13. Lauria, L., Spinelli, A., Buoncristiano, M. et al. Decline of childhood overweight and obesity in Italy from 2008 to 2016: results from 5 rounds of the population-based surveillance system. BMC Public Health 19, 618 (2019). https://doi.org/10.1186/s12889-019-6946-3
14. Bottalico, F., Medina, X., Capone, R., El Bilali, H., & Debs, P. (2016). Erosion of the Mediterranean diet in Apulia Region, South-eastern Italy: exploring socio-cultural and economic dynamics. J Food Nutr Res, 4(4), 258-66.
15. Mussino, E., Ortensi, L.E. Childcare in Italy among migrants and natives: who uses which type and why?. Genus 79, 16 (2023). https://doi.org/10.1186/s41118-023-00197-7
16. Andueza N, Martin-Calvo N, Navas-Carretero S, Cuervo M. The ALINFA Intervention Improves Diet Quality and Nutritional Status in Children 6 to 12 Years Old. Nutrients. 2023 May 18;15(10):2375.

doi: 10.3390/nu15102375. PMID: 37242258; PMCID: PMC10221220.

17. Archero F, Ricotti R, Solito A, et al. Adherence to the Mediterranean Diet among School Children and Adolescents Living in Northern Italy and Unhealthy Food Behaviors Associated to Overweight. *Nutrients*. 2018;10(9):1322. Published 2018 Sep 18. doi:10.3390/nu10091322

18. Paduano S, Greco A, Borsari L, et al. Physical and Sedentary Activities and Childhood Overweight/Obesity: A Cross-Sectional Study among First-Year Children of Primary Schools in Modena, Italy. *Int J Environ Res Public Health*. 2021;18(6):3221. Published 2021 Mar 20. doi:10.3390/ijerph18063221

19. Varì R, d'Amore A, Silenzi A, et al. Improving Nutrition Knowledge and Skills by the Innovative Education Program MaestraNatura in Middle School Students of Italy. *Nutrients*. 2022;14(10):2037. Published 2022 May 12. doi:10.3390/nu14102037

20. The Lancet Diabetes Endocrinology. Childhood obesity: a growing pandemic. *Lancet Diabetes Endocrinol*. 2022;10(1):1. doi:10.1016/S2213-8587(21)00314-4

21. WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards based on length/height, weight and age. Acta Paediatr Suppl. 2006 Apr;450:76-85. doi: 10.1111/j.1651-2227.2006.tb02378.x. PMID: 16817681.

22. WHO (2009) WHO AnthroPlus for Personal Computers Manual: Software for Assessing the Growth of the World's Children and Adolescents. WHO, Geneva. https://www.who.int/tools/growth-reference-data-for-5to19-years/application-tools. Accessed in November 2023.

23. Maffeis C, Banzato C, Talamini G. Waist-to-Height ratio, a useful index to identify high metabolic risk in overweight children. J Pediatr 2008; 152:207e13. https://doi.org/10.1016/j.jpeds.2007.09.021. e2.

24. Browning LM, Hsieh SD, Ashwell M. A systematic review of waist-to-height ratio as a screening tool for the prediction of cardiovascular disease and diabetes: 0.5 could be a suitable global boundary value. Nutr Res Rev 2010;23:247e69. https: //doi.org/10.1017/S0954422410000144.

25. Bacopoulou F, Efthymiou V, Landis G ,Rentoumis A, Chrousos GP. Waist circumference, waist-to-hip ratio and waist-to-height ratio reference percentiles for abdominal obesity among Greek adolescents. BMC Pediatr 2015;15:50. https://doi.org/10.1186/s12887-015-0366-z.

26. de Pádua Cintra I, Zanetti Passos MA, Dos Santos LC, da Costa Machado H, Fisberg M. Waist-to-height ratio percentiles and cutoffs for obesity: a cross-sectional study in Brazilian adolescents. J Health Popul Nutr 2014;32:411e9

27. Serra-Majem L, Ribas L, Ngo J, et al. Food, youth and the Mediterranean diet in Spain. Development of KIDMED, Mediterranean Diet Quality Index in children and adolescents. Public Health Nutr. 2004;7(7):931-935. doi:10.1079/phn2004556

28. Altavilla C, Caballero-Pérez P. An update of the KIDMED questionnaire, a Mediterranean Diet Quality Index in children and adolescents. Public Health Nutr. 2019;22(14):2543-2547. doi:10.1017/S1368980019001058

29. Rauber F, da Costa Louzada ML, Steele EM, Millett C, Monteiro CA, Levy RB. Ultra-Processed Food Consumption and Chronic Non-Communicable Diseases-Related Dietary Nutrient Profile in the UK (2008−2014). Nutrients. 2018;10(5):587. doi:10.3390/nu10050587

30. Monteiro CA, Cannon G, Moubarac JC, Levy RB, Louzada MLC, Jaime PC. The UN Decade of Nutrition, the NOVA food classification and the trouble with ultra-processing. Public Health Nutr. 2018;21(1):5-17. doi:10.1017/S1368980017000234

31. CREA. Linee Guida per Una Sana Alimentazione. Centro Di Ricerca Alimenti e Nutrizione. Revisione 2018. https://www.crea.gov.it/web/alimenti-e-nutrizione/-/linee-guida-per-una-sana-alimentazione-2018

32. Chaput JP, Willumsen J, Bull F, et al. 2020 WHO guidelines on physical activity and sedentary behaviour for children and adolescents aged 5-17 years: summary of the evidence. Int J Behav Nutr Phys Act. 2020;17(1):141. doi:10.1186/s12966-020-01037-z

33. Istituto Superiore di Sanità, EpiCentro - L'epidemiologia per la sanità pubblica, Indagine 2019: dati regionali. https://www.epicentro.iss.it/okkioallasalute/indagine-2019-report-regionali. Acessed in November 2023.

34. Tremmel, M.; Gerdtham, U.G.; Nilsson, P.M.; Saha, S. Economic Burden of Obesity: A Systematic Literature Review. Int. J. Environ. Res. Public Health 2017, 14, 435.

35. Koliaki C, Dalamaga M, Liatis S. Update on the Obesity Epidemic: After the Sudden Rise, Is the Upward Trajectory Beginning to Flatten? Curr Obes Rep. Published online October 2, 2023. doi:10.1007/s13679-023-00527-y

36. Buoncristiano M, Spinelli A, Williams J, et al. Childhood overweight and obesity in Europe: Changes from 2007 to 2017. Obes Rev. 2021;22 Suppl 6:e13226. doi:10.1111/obr.13226

37. Monteagudo C, Mariscal-Arcas M, Rivas A, Lorenzo-Tovar ML, Tur JA, Olea-Serrano F. Proposal of a Mediterranean Diet Serving Score. PLoS One. 2015;10(6):e0128594. doi:10.1371/journal.pone.0128594

38. Fornari E, Brusati M, Maffeis C. Nutritional Strategies for Childhood Obesity Prevention. Life. 2021;11(6):532. doi:10.3390/life11060532

39. Haddad J, Ullah S, Bell L, Leslie E, Magarey A. The Influence of Home and School Environments on Children's Diet and Physical Activity, and Body Mass Index: A Structural Equation Modelling Approach. Matern Child Health J. 2018;22(3):364-375. doi:10.1007/s10995-017-2386-9

Supplementary Files

Figures

The figure shows the flow chart of Lively study.