

Design and Objectives of the South American Youth/Child Cardiovascular and Environmental (SAYCARE) Study

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Objective: The purpose of this paper is to introduce the overarching study design of the South American Youth/Child Cardiovascular and Environmental (SAYCARE) study, which is an observational multicenter feasibility study held in seven South American cities: Buenos Aires (Argentina), Lima (Peru), Medellin (Colombia), Montevideo (Uruguay), Santiago (Chile), and São Paulo and Teresina (Brazil). Children and adolescents (3-17 years of age) were studied.

Methods: The data management systems, quality assurance monitoring activities, standardized operating procedure manuals, and training and study management are addressed in this paper. Various quality controls to ensure the collection of valid and reliable data are also discussed.

Results and Conclusions: Data were obtained from 237 preschoolers and schoolchildren and 258 adolescents during the validation phase measurements. The results of the SAYCARE study are expected to provide higher accuracy in the assessment of cardiovascular disease risk factors, including eating behaviors, body composition, physical activity, sedentary behaviors, lipid profiles and cardiovascular health biomarkers, oral health, social conditions, environmental factors and home environment, and their determinants in children and adolescents from ages 3 to 17 in seven South American cities.

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Introduction

Several lifestyle variables are associated with nutritional status (1) and cardiovascular diseases (CVDs) (2,3); however, these behaviors are complex and vary by age, sex, seasonality, day of the week, and time of day. Moreover, they are influenced by biological, sociological, psychological, and environmental factors (4). The cluster of these factors is called the ecological model (4).

The ecological model indicates that the factors that determine the development of CVD are influenced by three mediators: biological (e.g., genetic or intrauterine growth factors), lifestyle (physical activity, sedentary and eating behaviors, hours of sleep), and environmental (socioeconomic factors, familiar and cultural, health systems, built environment factors) mediators (5). These mediators are responsible for the differences in the prevalence and incidence of obesity and CVD in different population groups (4).

From the epidemiological perspective, it is accepted that obesity and some factors associated with diet increase the noncommunicable disease (NCD) risk (6). It has also been established that exposure to such risk factors starts early in life, an example of which is childhood obesity, whose prevalence has increased substantially during the last 3 decades globally (7). For this reason, the World Health Organization (WHO) encourages its member countries to develop strategies that reduce the burden of disease associated with inadequate eating habits and physical inactivity (8) and places special emphasis on the prevention of childhood obesity (7). It is important to emphasize that although the group under 18 years of age is not the most affected by NCDs, this group is exposed to risk factors, and early control of these groups will result in a lower incidence of NCDs later in life (9).

Importantly, the methods used to obtain these data must be reliable, validated in the study population, and, if possible, amenable to comparisons between countries. Multicenter studies that use standardized methods, such as those developed in Europe to assess lifestyle and cardiovascular health in children and adolescents, appear to best allow for comparisons between countries (10,11).

From this point of view, to develop methods in South America, it seems to be important to maximize the data collection quality and thus to understand these factors among countries. Therefore, it is necessary to develop joint methods that allow for comparisons of cardiovascular health measurements and associated factors. The standardization of methods that respect different cultures across South American countries can become a reference for analytical studies.

No multicenter studies that use standardized and jointly developed methods between countries have been conducted in South America to assess lifestyle, cardiovascular health, and nutritional status in children and adolescents. To overcome this gap in the literature, the South American Youth/Child Cardiovascular and Environmental (SAYCARE) study aims to develop methods to collect reliable, comparable, and validated data about cardiovascular health biomarkers, lifestyles, and environmental, social, and familial factors. In addition, this project will study to evaluate the sociocultural characteristics of these countries, a valid and transcultural method for assessing cardiovascular health determinants, which has been rarely considered in the European studies. Therefore, the final the purpose

of this paper is to introduce the overarching study design of the SAYCARE study, which is an observational multicenter feasibility study held in seven South American cities: Buenos Aires (Argentina), Lima (Peru), Medellin (Colombia), Montevideo (Uruguay), Santiago (Chile), and São Paulo and Teresina (Brazil). The other papers in this supplement will present more details on specific protocols and measurements.

Methods

Study design

The SAYCARE study is an observational, multicenter, feasibility study, which was carried out in seven South American cities, as shown in Figure 1 (Buenos Aires, Lima, Medellin, Montevideo, Santiago, São Paulo, and Teresina). These cities were selected based on the presence of specialized research centers with experience in this area of research, a population of more than 500,000 inhabitants, and locations in different geographic areas.

Population

Research subjects were selected in each city in two steps: (1) schools were selected based on the students' age, stratified for groups (preschool [3-5 years], schoolchildren [6-10 years], and adolescents [11-17 years]) and school types (public or private; socioeconomic status [SES] proxy) on the enrolled preschool, primary school, and high school and (2) random sampling was conducted by using student lists (all pupils from a selection of classes from the selected schools; only in Medellin, both steps were selection by convenience. Each sex was represented by 50% of participants.

The sample size was calculated based on the experience of other multicenter studies in which feasibility pilot studies were previously conducted and the reliability and validity of the used methods were evaluated (10,12,13).

Several sample size calculations were performed in order to enable reliability analyses of the questionnaires and to perform a validity/agreement assessment between the two measurement methods (objective and subjective) in the study population. Each sample size calculation was adapted for each work package variable. For example, the calculation parameters used to analyze the reliability of the SES questionnaire were a two-tailed α of 0.05 (type I error), a β or power (type II error) of 0.10, and a correlation coefficient and kappa coefficient of 0.80 each. From these parameters, we estimated a required sample of 28 individuals from each city for reliability/agreement analyses between the first and second measurement. Anticipating losses and rejections of 20%, we invited 240 children and 240 adolescents from each city, totaling approximately 580 research subjects. All sample size estimations are described in detail in the Supporting Information.

Exclusion and inclusion criteria

The study's exclusion criteria were pregnancy, the inability to complete the questionnaires, and the inability of the parents, guardians, and/or students to sign the informed consent form. Subjects who, for other reasons not covered, were eliminated after the start of the study were excluded. The study included all subjects between 3 and 18 years of age whose parents/guardians signed the informed



Figure 1 SAYCARE research centers by country.

consent form. Moreover, a signed assent form was obtained from all children and adolescents to indicate their approval to participate in the study.

Data collection

The headmasters of the selected schools received a formal and detailed application about the importance, objectives, and methods of the study, allowing them to voluntarily consent to collaborate with the project. The institutional research ethics committees of the six countries involved approved the study protocol.

Table 1 provides a list of the methods used to collect data, the measurements of interest, and the variables obtained and specifies in which center this information was collected. Specific variables for which data were obtained as measures of CVD risk factors are listed in the Supporting Information.

Fieldwork teams and evaluator training

To harmonize the methodology, seven fieldwork teams (one from each city) participated in a general training workshop that was held in Teresina (Brazil), between March 9 and March 13, 2015, with 40

hours of work in order to obtain the qualifications required for conducting the fieldwork. The principal researcher from each city attended the workshop together with their research team.

The training was standardized in all its proceedings and consisted of both theoretical and practical sessions. For the practical session, researchers from the Teresina team organized a visit to a school in order to simulate the fieldwork. Triplicate measurements were made in 10 children or adolescents per researcher, simulating the fieldwork. These previous sessions included the final version of the questionnaires, anthropometry, blood pressure, a sexual maturation test, logistics of the fieldwork, and evaluations of the interviewers' work.

All these measures were made in triplicate. Once the third measurement was made, appropriate statistical tests were performed to determine whether a second training session was needed. The values considered acceptable for intra-observer variability followed the WHO guideline (14).

The oral health assessment training was conducted by a "senior examiner" and was performed as follows: (1) a half-day slideshow was presented with discussion codes and protocols for analysis and (2) new examiners underwent 2 days of training.

The person in charge of the researchers' training determined the consistency of the applied criteria. The tests were repeated until sufficient agreements between examiners (kappa coefficient) were reached. This training did not involve blood collection.

These teams conducted anthropometric measurements (weight, height, and skinfold thickness), oral health assessments, delivery of questionnaires, and sexual maturation assessments. Each team was held responsible and consisted of the researchers, a doctor, and a nurse. The final number of researchers in these teams depends on the possibilities of each city, with a minimum of five researchers.

In both theoretical and practical sessions, some improvements were discussed. The decisions made were included in the final versions of the questionnaires, anthropometry, blood pressure measurements, sexual maturation tests, fieldwork logistics, and evaluations of the interviewers' work.

Data collection

Several measuring instruments/methods were used and were classified in two main groups: (1) objective measurements (anthropometry, blood pressure assessments, accelerometer use, blood sample collection, physical fitness tests, and oral health evaluation) and (2) subjective measurements (questionnaires). Once the schools had all the study information and agreed to participate, the data collection occurred in five school visits:

- First visit: explanation of the project and delivery of informed consent to be signed by parents/guardians or the adolescents themselves.
- Second visit: delivery of the core questionnaires (parental and adolescent self-completion questionnaires) to children or adolescents, anthropometric measurements, response to the Tanner stages on the self-reported questionnaire, and delivery of accelerometers. On this day, an appointment for the collection of blood samples was

TABLE 1 Overview of measurements and variables collected in the SAYCARE study

Method	Measure of interest	Variables
<i>Core protocol (measured in all survey centers)</i>		
Parental and adolescent self-completion questionnaire	Pregnancy information of child	Birth weight, birth length, gestation period, cesarean section, smoking during pregnancy, early infant nutrition
	Medical history	Diseases in the family, current medications
	Socioeconomic and sociodemographic questionnaire	Socioeconomic status, parental education, parents' occupations, number of people living in their household, people who live in their household
	Environmental factors	Social environment and infrastructure of the area of residence, quality of public spaces, appropriate environments for physical activity, perceived violence in the area, frequency of garbage collection
Teacher/caretaker self-completion questionnaire	Energy expenditure	Time spent in physical activity, sedentary behavior, sleep
	Energy intake	Food frequency questionnaire, 24-h dietary recall
	Dietary determinants	Perception of body image, self-esteem and emotional well-being, behavior related to food, family atmosphere and environment of school, supplementary feeding, advertising and mass media programs
Tanner stages, self-reported	School environment and physical education class	Attitudes, behavior, and nutrition of teachers, school policy on physical education
Oral health questionnaire	Sexual maturation	Prepuberty, puberty, and postpuberty
Anthropometric	Oral health habits	Self-reported oral health
Omron automatic monitor (Omron Healthcare Inc., Kyoto, Japan) and sphygmomanometer column of mercury	Body composition of child or adolescent	Measured weight, height, skinfold thickness (tricep, subscapular, and suprailiac), circumferences (neck, upper arm, waist, and hip), self-reported weight and height of parents
		Systolic and diastolic blood pressure, pulse rate
<i>Extended protocol (restricted to subsamples of children or adolescents)</i>		
Actigraph uniaxial accelerometer	Blood pressure and pulse rate of child or adolescent	Physical activity and sedentary time counts in 5-s/1-min intervals over 4 d (measured in São Paulo, Teresina, Medellin, and Lima)
Blood samples	Physical activity levels	Hematological profile, lipid profile, metabolic-nutritional profile, anti-inflammatory and inflammatory markers (measured in São Paulo, Buenos Aires, Teresina, Medellin, and Lima)
Fitness tests and questionnaire	Biological markers in fasting venous	Flamingo balance test, back-saver sit and reach, handgrip strength, standing broad jump, 40-m sprint and shuttle-run test (measured in only Teresina)
DMFT Index; International Caries Detection System and Evaluation Index II; Periodontal Condition Index, O'Brian Index; hypomineralization	Physical fitness (coordination, motor fitness, speed, and cardiorespiratory fitness)	Dental caries, periodontal disease, biofilm, pulp complication (measured in São Paulo, Teresina, Lima, and Santiago)
DMFT Index; International Caries Detection System and Evaluation Index II; Periodontal Condition Index, O'Brian Index; hypomineralization	Oral health	

DMFT, Decayed, Missing, and Filled Teeth; SAYCARE study, South American Youth/Child Cardiovascular and Environmental study.

scheduled, and the participants were informed of which procedures to perform on the day before the blood collection.

- Third visit: collection of completed questionnaires and accelerometers, blood collection, and oral health evaluation.
- Fourth visit: second delivery of the core questionnaires in order to assess their reliability.
- Fifth visit: collection of completed questionnaires (second application) and submission of reports to children or adolescents. In the event that any of the results were abnormal, this report was used as a guideline for a basic health unit to provide primary health care.

Objective measurement methods

Anthropometry. The anthropometric variables were analyzed according to the reference manual of anthropometric standardization of the WHO (15) as follows: weight, height, waist circumference, hip circumference, neck circumference, and skinfold thickness (bicep, tricep, subscapular, and suprailiac). All anthropometric variables were measured once in this order, and then the measurements were repeated one or two more times in the same order. The third measure was performed only in case of an error of 5% between the first and the second measure. The evaluations were conducted in a private room at the school. All measures were taken in underwear or with as few clothes as possible and without shoes.

Blood pressure and heart rate assessment. Blood pressure measurements were performed following the recommendations of the American Heart Association (16). Systolic and diastolic blood pressure and resting heart rate were measured twice, with an interval of two minutes between both measurements, according to international guidelines (17). If the values of the second measurement varied by more than 5% in relation to the first, a third measurement was necessary.

Accelerometers. Physical activity and sedentary time were objectively evaluated by using Actigraph MTI accelerometers (model GT3X; Manufacturing Technology Inc., Fort Walton Beach, Florida).

Blood sample collection procedures. The blood sample collections were conducted by using a Vacutainer system (Becton Dickinson, Oxford, United Kingdom). The experimental conditions included blood sampling early in the morning (by arrangement with the school) after an overnight fast of 12 hours. Families were instructed to keep the participants fasted on the morning of the collection day and were informed that after blood collection, a breakfast for the children and adolescents would be offered.

At all schools in each city, samples were collected by a laboratory technician, who transferred the samples under optimum transport and time conditions to a hired specialized laboratory, which performed the analyses. The samples from each subject were divided in thirds into three cryotubes. The samples from Buenos Aires and Teresina were analyzed twice to evaluate the reliability and stability of biomarkers after transportation. The first analysis was carried out in the city of origin (two cryotubes), and the third tube was sent by a specialized transportation company, ideally at -70°C , to São Paulo for review. The hematological and metabolic profile data were obtained.

Physical fitness field tests and questionnaires. We evaluated the general physical fitness based on cardiorespiratory fitness,

muscular fitness, speed-agility, and flexibility levels by two methods performed twice, and the best result was recorded; the two methods included (1) physical fitness field tests and (2) the International Fitness Scale questionnaire. To assess the reliability of the questionnaire, measurements were taken from the same subjects on two occasions with a 2-week interval between measurements (18,19). Concurrent validity was estimated from the level of agreement between the test and retest of the questionnaire compared to the physical test (19,20).

Oral health. Recently, some studies have shown that the association between this condition and periodontal disease is well established (21,22) and occurs especially via bacteremia, endotoxemia, and a systemic inflammatory burden (23,24). According to these presumptions, we measured several oral health indicators, according to the WHO recommendations, and the following indicators were assessed:

- the Decayed, Missing, and Filled Teeth Index (indicating the presence of caries);
- the International Caries Detection and Assessment System Index II;
- the Pulp, Ulceration, Fistula, and Abscess Index;
- the Periodontal Screening and Recording System; and
- the Index of Plaque.

Subjective measurement methods (collection of data through questionnaires)

The SAYCARE questionnaires were developed by adapting questionnaires designed and validated in European multicenter studies to the realities of South America (13,14,16,17). Previously, the questionnaire underwent cross-cultural adaptations into Portuguese and Latin American Spanish versions according to the universalistic methodology proposed by Herdman et al. (18). The questionnaire consists of two stages: the assessment of conceptual and item equivalence (first stage) and the evaluation of semantic equivalence (second stage) (19). This process of cultural adaptation during the planning of the SAYCARE study was performed by the Youth/Child Cardiovascular Risk and Environmental and Growth, Exercise, Nutrition and Development research groups and with participation and adaptation by all the countries involved. For the dietary determinants questionnaire, this procedure was performed by the research group of Professor Laura González-Zapata. This process began in August 2013, was completed in April 2014, and included face-to-face discussions with all center coordinators participating in the SAYCARE study. The questionnaires used in our study were the end result of this cross-cultural adaptation process. To access and/or use the SAYCARE questionnaires, contact the General Coordinator of the SAYCARE study by email: ycare_fmusp@yahoo.com.

For children aged 3 to 10 years (preschool and primary school), it was recommended that the parents or guardians fill out the questionnaires (15). Adolescents (11-17 years) answered the questions themselves. The questionnaires collected the following information:

- Environmental factors questionnaire: The 14 questions of this questionnaire measured the social and infrastructure characteristics of the area of residence.
- Demographic factors questionnaire: This questionnaire addressed sex and age.

- Socioeconomic factors questionnaire: The 14 questions of this questionnaire included the presence of several consumer goods, domestic services, family income, parent educational level, and parent current occupation status (25).
- Dietary intake questionnaire: This questionnaire consisted of a food frequency questionnaire and a dietary recall over a 24-hour period.
- Physical activity questionnaire: This questionnaire asked about the frequency, duration, and intensity of physical activity of the child or adolescent at certain times of day, including during physical education classes, leisure time, and transportation.
- Sedentary behavior questionnaire: This structured questionnaire assessed how long the child or adolescent usually spends in front of a television or computer or playing video games, both on weekdays and on weekends.
- Sleep habits questionnaire: This structured questionnaire asked about sleeping time and sleep quality during the week and on weekends.
- Dietary determinants questionnaire: This structured questionnaire asked about six components related to dietary determinants: perception of body image, self-esteem and emotional well-being, food-related behavior, family atmosphere and school environment, complementary feeding, and advertising and mass media programs.
- Sexual maturation questionnaire: The maturation of sexual characteristics is a typical adolescent process that includes numerous physical and behavioral characteristics. For this reason, different stages were evaluated according to the method described by Tanner et al. (26). Children from age 11 and older were given demonstrative photos of different maturation stages and asked to qualify themselves.

Quality control

A premise of this multicenter study is to ensure that data collection is performed in a standardized way, thereby achieving a good representation of reality and allowing for comparisons of the data from different cities involved in the study.

The data management system was centralized and coordinated by the general coordinator of the project at the School of Medicine of the University of São Paulo. Reports were sent to São Paulo to verify data consistency. In addition, standardized procedures were used to ensure the accuracy and consistency of the results obtained during the study, such as manuals or standardized measurements, records protocols, and training and supervision of researchers through auditing protocols. Inconsistencies were quickly identified and corrected locally. This procedure allowed for previous diagnoses and resolution of difficulties during data collection and processing.

Reliability of measures

To assess the reliability of each variable, the measurements were performed in duplicate in the same individual at two different times at an interval of 15 days. For example, the physical activity questionnaire was applied on the second visit and the fourth visit.

Validity of measures

The validity of a measure is the ability of an instrument to correctly classify its subject matter, as evidenced by comparing subjective measures with objective measures. For example, the questionnaire on sedentary behavior was validated with the sedentary time

measured by the accelerometer. The variables selected for testing the reliability and validity of the measures, and their respective comparative methods, are described in Table 1 and Table 3.

Study management

The management of the SAYCARE study was designed to ensure effective collaboration and communication among the seven study centers involved in this observational, multicenter feasibility study. Investigators from each participating center were involved in the planning and development of the protocol, including the study design.

Two chairs (from São Paulo, Brazil) and a cochair (from Zaragoza, Spain) were responsible for the overall coordination of the study. Each city was managed by a local principal investigator, who was responsible for all aspects of data collection at the local level.

To facilitate data collection, entry, management, and analysis of the consistency of data, a secured Web-based system, the SAYCARE platform, was developed. A steering committee comprising members with extensive and diverse scientific backgrounds was created for the SAYCARE platform to assess the overall progress of the study and to provide guidance regarding the overall study direction and study goals.

The SAYCARE platform was created through a collaboration between the School of Medicine of the University of São Paulo and São Paulo State Technological College. Two researchers in São Paulo were responsible for the management of the central database and the specific software for managing the accelerometer data.

Results

Our final sample included pediatric populations (aged 3 to 18 years) of seven South American cities from six countries; in total, 237 children (preschoolers and schoolchildren) and 258 adolescents participated in the study (Figure 2). Participants were recruited from public and private schools. At least one school per type and age group was selected in each city except Montevideo, where almost all schools are public. Subjects with complete data were considered those with data about (1) sex, (2) birth date, and (3) weight, height, and waist circumference.

As previously mentioned, Table 2 shows an overview of the measurements and variables obtained. The core protocol included the parental/adolescent questionnaire, the teacher/caretaker questionnaire, anthropometric measurements, and blood pressure measurements. The extended protocol included accelerometer measurements, blood samples, fitness field tests, a fitness questionnaire, and an oral health clinical examination. The details for each procedure have been described in the specific published papers associated with this supplement.

Table 2 describes the descriptive analyses for the first application of the questionnaire (Q1) and the second application of the questionnaire (Q2) according to demographic and socioeconomic variables. In children, the socioeconomic and demographic variables were different for age and school type, respectively. In adolescents, maternal education and school type in adolescents were different in Q2 when compared with Q1.

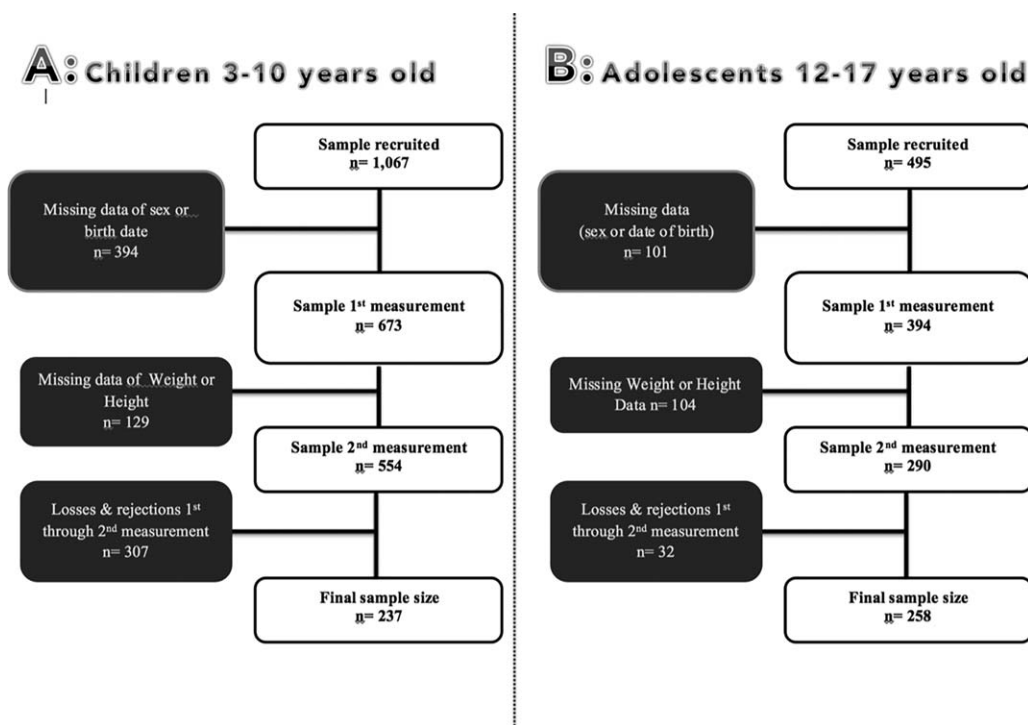


Figure 2 Final SAYCARE study sample size flowchart by age group.

Discussion

The SAYCARE study provides important information about reliable, valid methods for several social determinants, environmental factors, energy balance–related behaviors, and cardiovascular health indicators and was successful in setting up an important sample of children and adolescents (Q1: 1,067 and Q2: 495). The recruitments were performed carefully by using a standardized procedure aiming for the inclusion of low, medium, and high SES groups from seven South American cities. To the best of our knowledge, this is the first project that proposes the development, standardization, and testing of the reliability and validity of subjective and objective methods used to determine the cardiovascular health of pediatric populations in South America. The study allowed for the identification of noninvasive cardiovascular measures that best predict risk and suggested new approaches to prevent the progression of unhealthy lifestyle behaviors and cardiovascular risk. Thus, it is hoped that the results will be applicable to epidemiological studies and public health practices.

The ethnic and cultural diversity of the SAYCARE sample, albeit limited to a small number of groups and relatively small in some centers, is a unique feature and major strength of our study, as this diversity permitted testing of the reliability and validity insights in different social contexts. However, the relationships between SES (27,28), behaviors (29), and cardiovascular health (30) may vary across countries at different levels of SES development.

An important result is that the highest proportions of losses/refusal were from individuals with lower SES, indicating that future studies

in South America should oversample this SES class. This difficulty is attributed to the fact that because the questionnaire is extensive, the parents of the children and adolescents may have lost the motivation to respond to the same questionnaire twice in a short time period.

The particular challenge of the SAYCARE study was the need to collect data twice from the same children, parents, and adolescents within a short time interval (2 weeks), which was prescribed by the complex study design. Because of the large variables we measured, the losses/refusal rate between Q1 to the Q2 was approximately 53.6%, but the sample size we retrieved was sufficient to test the validity and reliability of all proposed methods. Taking this outcome into consideration, the proportion of participation may be considered quite good.

Data collections at the field centers were transmitted to the SAYCARE coordination center by using an online platform system. The SAYCARE intranet site was used by all study centers and allowed for error rates in data entry (Q1 vs. Q2) that were quite low, ranging from 0.19% in Buenos Aires to 6.29% in Lima. The coordination center reported the errors in data entry for each individual to each center for correction. After all data were collected (including the error checking phase), the data were cleaned and distributed to the coordination centers.

The diverse geographic origin of the samples, the use of several objective measures to assess the cardiovascular determinants, and the transcultural adaptation of the subjective methods are some of

TABLE 2 Distribution of sample in terms of demographic and socioeconomic variables of the SAYCARE study in both questionnaire applications

	Q1 (N = 673), %	Q2 (N = 237), %	P1	Adolescents	Q1 (N = 290), %	Q2 (N = 258), %	P1
Children				Adolescents			
<i>Research center</i>			< 0.001	<i>Research center</i>			0.096
São Paulo	15.2	11.0		São Paulo	17.3	15.6	
Teresina	33.0	0.0		Teresina	14.6	0.0	
Buenos Aires	5.4	12.7		Buenos Aires	4.4	6.0	
Medellin	16.1	32.5		Medellin	16.1	16.1	
Lima	12.6	5.5		Lima	25.2	29.2	
Montevideo	10.7	16.9		Montevideo	8.9	11.1	
Santiago	7.1	13.5		Santiago	13.6	16.6	
<i>Sex</i>			0.150	<i>Sex</i>			
Male	47.8	60.0		Male	50.0	39.4	0.643
Female	52.2	40.0		Female	50.0	60.6	
<i>Age</i>			< 0.001	<i>Age</i>			
3-5 y	55.5	34.5		11-14 y	51.9	46.2	0.115
6-10 y	44.5	65.5		15-18 y	48.1	53.8	
<i>Maternal education level</i>			0.702	<i>Maternal education level</i>			
Incomplete high school	6.4	3.1		Incomplete high school	1.4	21.4	< 0.001
High school	3.5	12.5		High school	7.1	3.6	
Technical education	10.8	12.5		Technical education	12.9	17.9	
University degree	55.1	60.9		University degree	47.1	42.9	
<i>School type</i>			< 0.001	<i>School type</i>			
Public	61.5	21.8		Public	30.8	36.8	< 0.001
Private	38.5	78.2		Private	69.2	63.2	

Significant values are in bold.

P1, χ^2 goodness of fit test for comparison between the sample in Q1 and Q2; Q1, first application of the questionnaire; Q2, second application of the questionnaire; SAY-CARE study, South American Youth/Child Cardiovascular and Environmental study.

TABLE 3 Diagrammatic presentation of the proposed procedures regarding the reliability and validity of the measures

Reliability ^a	Measurement
Questionnaires	Socioeconomic Environmental Physical activity Sedentary behavior Sleep time Food frequency questionnaire IFIS questionnaire Oral health questionnaire
Validity	Reference (objective)
Physical activity	Accelerometers
Sedentary behavior	
Food frequency questionnaire	24-h recall
IFIS questionnaire	Physical fitness field tests
Blood pressure automatic monitor	Mercury column

^aApplied in two different times at an interval of 15 days. IFIS, International Fitness Scale.

the main strengths of our study. Because the methods of this study will provide a robust examination in the identification of the risk and/or protection factors of the outcome in question, this will make it possible to measure these factors more consistently, with a minimum of measurement bias.

In summary, the SAYCARE study is a novel multicenter study carried out in South American countries and has used a set of harmonized methods to generate several methods for measuring social and environmental factors, energy balance-related behaviors, and biological cardiovascular health indicators in pediatric populations (3-17 years old) from six countries. The SAYCARE study thus provides valuable methods for measuring and analyzing the interactions between macro determinants (environmental and social) and energy balance-related behaviors that currently affect the cardiovascular health of pediatric populations. **O**

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