

## Colombia Si Intervention Usaquén #2

Version: 11 July 2016

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## 1. Introduction

Cardiovascular disease (CVD) is a leading cause of mortality worldwide. According to the World Bank report, 56% of all deaths in low- and middle-income countries may be attributed to non-communicable diseases<sup>1</sup>, and by 2020, 80% of all deaths may be attributed to these diseases.<sup>2</sup>

Negative health behaviors initiated in childhood that persist through adulthood can be risk factors that predict CVD<sup>3 4</sup>. In Colombia, poor lifestyle factors affecting childhood are very prevalent: 50% live a sedentary lifestyle, 48% have high fat and carbohydrate consumption, 30% are exposed to passive smoking, 14% are overweight or obese, 15.8% have hypercholesterolemia, and 5% have hypertension<sup>5 6 7 8 9</sup>.

To modify the lifestyle factors initiated at childhood, early identification and understanding of behavioural and physiological variables related to CVD are essential, so that appropriate interventions can be targeted at this age<sup>10 11 12</sup>, with the expectation that such changes could drive modifications in cardiovascular risk factors and lessen the risk of developing these diseases during adulthood.

In Madrid-Spain<sup>13</sup>, was conducted a cluster-randomized controlled intervention trial involving 24 public schools (n=2062 children 3-5 years old) to evaluate the impact of the SI! Program that entails four lifestyle-related components: diet, physical activity, knowledge of the human body and heart, and management of the emotions, with a follow-up of 3 years. The authors concluded that the SI! Program is an effective strategy for instilling healthy habits among preschoolers, translating into a beneficial effect on adiposity, with maximal effect when started at the earliest age.

In Colombia, the SI! Program (Salud Integral), promotes cardiovascular health, instilling proper lifestyle behaviors at an early age, which, in turn, can be brought into adulthood. As part of this program, in May 2009, in Bogota, Colombia, was conducted a cluster randomized trial (kindergartens) in 1216 children between 3 and 5 years old, and 928 parents with the aim of evaluate a five months educational intervention to change knowledge, attitudes and habits related to a healthy diet and active lifestyle in preschoolers. The results showed that the intervention was feasible and effective<sup>14</sup>. Finally every 1216 children "cohort Usaquén" received the intervention, performing a follow-up at 18 and 36 months showing that the changes persisted over time<sup>15</sup>.

In 2016 the SI! Program will perform a new follow up of this cohort, in children between 9 and 12 years old, and under the assumption that the effects of this intervention have decreased, the researchers plan to evaluate through a randomized control trial the impact of a four months community educational intervention, in the cardiovascular health of these children and in knowledge, attitudes, habits and emotions towards a healthy lifestyle. The study will include children from the Usaquén's cohort who are contacted and children of a comparable cohort (n = 1200), in order to achieve sustainable changes in the cardiovascular health of children, that impact the burden of disease in their adulthood.

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Due to the high rate of migration within the country, given the social and economic difficulties faced by many Colombians, in 2015 the study population was scattered from 1 to 15 localities and from 14 kindergartens to more than 200 public and private schools, mostly in the Usaquén's locality, with great variability ranging from the facilities, resources, length of the school day, number of children in each classroom, to the training of teachers and their low motivation and availability time to perform any initiative (data obtained from focus groups conducted in schools).

For these reasons, it is not feasible to carry out a second educational intervention in schools. However, we believe that a community-based intervention is an excellent choice for tracking this population. There is evidence that support the community-based interventions, increasing the time of daily physical activity, nutritional behaviors, and decreasing body mass index (BMI) in children aged 9-15 years old.

The next phases of the study will answer the following **questions**:

### **Phase 1:**

1. Have the knowledge, attitudes and habits in heathy lifestyles administered to the Usaquén's cohort decreased overtime?
2. Are there differences in knowledge, attitudes and habits towards healthy lifestyles among children from Usaquén's cohort and a comparable cohort?
3. Are there differences in the cardiovascular health among children from Usaquén's cohort and a comparable cohort?
4. Are there differences in the cardiovascular health between parents from Usaquén's cohort, and a comparable parent cohort?

### **Phase 2:**

1. What is the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in children 9-12 years and their parents or caregivers?
2. What is the impact of a community pedagogical intervention in healthy lifestyles on knowledge, attitudes, habits and emotions towards healthy lifestyles in children 9-12 years old
3. What is the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in children aged 9 to 12 years old differentiating between children from Usaquén's cohort and a comparable cohort?
4. What is the impact of a community pedagogical intervention in healthy lifestyles in knowledge, attitudes, habits and emotions towards healthy lifestyles for children 9 to 1 years old differentiating between children from Usaquén's cohort and a comparable cohort?
5. What is the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in parents or caregivers differentiating between children from Usaquén's cohort and a comparable cohort?

## **2. Background**

In preparation for the design of the community based intervention, broad research was conducted, a summary follows:

In the document “Interventions on diet and physical activity: what works” the World Health Organization provides policy-makers and other stakeholders with a summary of tried and tested diet and physical activity interventions that aim to reduce the risk of chronic NCDs<sup>16</sup>. The evidence is presented under the eight categories: policy and environment, mass media, school settings, the workplace, the community, primary health care, older adults, and religious settings. In the category of the community, they identified as an effective interventions:

- Group-based physical activity programs or classes for a homogenous group of Individuals
- Multicomponent diet education programs that target high-risk groups
- Interventions that use an existing phone-in service to provide dietary advice
- Programs that target low-income/low literacy populations and include diet education in the standard programme.
- Computer/web-based interventions with interactive personalized feedback, targeting high-risk groups.
- Internet and electronic communication that provide the potential to create and sustain “virtual” communities of persons with common interests, challenges and needs.
- Supermarket tours and on-site educational programs to support the purchase of healthier foods.
- Prevention programs that work with promoters or group leaders involved in both the formative assessment and the cultural adaptation of the intervention that include educational classes and the participation in a walking club.

In 2016, the World Health Organization <sup>17</sup> developed a new comprehensive, integrated package of recommendations to address childhood obesity. Some recommendations that support the community interventions are:

- Provide guidance to children and adolescents, their parents, caregivers, teachers and health professionals on healthy body size, physical activity, sleep behaviors and appropriate use of screen based entertainment.
- Provide guidance to caregivers on appropriate nutrition, diet and portion size for this age group.
- Provide guidance on appropriate sleep time, sedentary or screen-time, and physical activity or active play
- Engage whole-of-community support for caregivers and child care settings to promote healthy lifestyles for young children.
- Make food preparation classes available to children, their parents and caregivers
- Develop and support appropriate weight management services for children and adolescents who are overweight or obese that are family based, multicomponent (including nutrition, physical activity and psychosocial support) and delivered by multi-professional teams with appropriate training and resources.

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A recent publication<sup>18</sup> made a systematic literature search, including two meta-analysis that found strong evidence to support beneficial effects of child obesity prevention programs on BMI. These reviews<sup>19 20</sup> included three studies targeting children 8-15 years old that evaluate a community and home-based interventions and show improvements in physical activity, nutrition behaviors and in BMI for age.

The first one<sup>21</sup>, a cluster randomized controlled trial conducted in Fort Collins, Colorado, USA, evaluated the impact of a 13 weeks intervention, in families with at least one 8- to 12-year old child who was at-risk-for-overweight or overweight, including 82 families in the intervention group and 23 in a control group. The intervention consisted in two small lifestyle changes: increasing their daily walking by 2000 steps/day above baseline levels, and consuming 2 servings/day of ready-to-eat cereal, one at breakfast and one for a snack. The families were provided with a step counter and a group-specific step and cereal log and free cereal. Families in the intervention also met with study staff on three occasions during the course of the study. The intervention was successful in increasing walking (steps) and cereal consumption, and had positive, significant effects on percentage BMI-for-age and percentage body fat for target children and weight, BMI, and percentage body fat for parents.

The second study<sup>22</sup>, other randomized control trial conducted in Minneapolis, Minnesota, USA, evaluated the impact of a 1 year intervention in families with at least one child ages  $\geq 5$  years and two members ages  $\geq 12$  years that residence in a private house, including 45 families in the intervention group and 45 families in the control group. The intervention program included 6 monthly face-to-face group sessions, telephone calls, monthly newsletters, and 12 home-based activities. The intervention included both households (HH) environment and individual-level behavioral components. The HH environment intervention included a placement of TV time-limiting devices on all HH TV sets; provision of guidelines about HH food availability; and provision of a home scale for daily self-weighing (adults only). The individual behavioral intervention component promoted specific individual behavior changes related to weight control that were consistent with the HH-level intervention. Control HHs received no intervention. Intervention HHs significantly reduced TV viewing, snacks/sweets intake, and dollars per person spent eating out, and increased dietary intake of fruit and vegetable and moderate/vigorous physical activity (min/day) in adolescents. Additionally increase in adults PA and self-weighing frequency compared with control HHs. No significant intervention effects were observed for change in HH BMI-z score.

The last study<sup>23</sup>, a randomized controlled trial conducted in San Diego County, California, in primary care with follow-up at home, evaluated the impact of a 1 year intervention in eight hundred seventy-eight adolescent girls and boys aged 11 to 15 years. The intervention included a primary care, office-based, computer-assisted diet and Physical activity (PA)

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assessment and stage-based goal setting followed by brief health care provider counseling, and 12 months of monthly mail and telephone counseling. The control group addressed sun exposure protection. Girls and boys in the diet and PA intervention significantly reduced sedentary behaviors (intervention vs control change, 4.3 to 3.4 h/d vs 4.2 to 4.4 h/d for girls, respectively [ $p = .001$ ]; 4.2 to 3.2 h/d vs 4.2 to 4.3 h/d for boys, respectively [ $P = .001$ ]). Boys reported more active days per week (intervention vs control change: 4.1 to 4.4 d/wk vs 3.8 to 3.8 d/w, respectively [ $p = .01$ ]), and the number of servings of fruits and vegetables for girls approached significance (intervention vs control change, 3.5 to 4.2 servings/d vs 3.5 to 3.9 servings/d, respectively [ $p = .07$ ]). No intervention effects were seen with percentage of calories from fat or minutes of PA per week. Percentage of adolescents meeting recommended health guidelines was significantly improved for girls for consumption of saturated fat (intervention vs control change, 23.4% to 41.0% vs 18.5% to 31%, respectively [relative risk, 1.33; 95% confidence interval, 1.01-1.68]) and for boys' participation in d/wk of PA (intervention vs control change, 45.3% to 55.4% vs 41.9% to 38.0%, respectively [relative risk, 1.47; 95% confidence interval, 1.19-1.75]). No between-group differences were seen in body mass index.

### 3. PHASE 1

#### 3.1. OBJECTIVES

##### 3.1.1. GENERAL OBJECTIVE

1. To assess differences at baseline in healthy lifestyles between children from Usaquén's cohort and a comparable cohort.

##### 3.1.2. SPECIFIC OBJECTIVES

1. To assess differences at baseline in knowledge, attitudes, habits and emotions towards a healthy lifestyles between children from Usaquén's cohort and a comparable cohort.
2. To assess differences at baseline in cardiovascular health between children from Usaquén's cohort, and a comparable cohort.
3. To assess differences at baseline in cardiovascular health between parents from Usaquén's cohort, and a comparable cohort.

#### 3.2. METHODOLOGY

##### 3.2.1. Design

Cross-sectional study.

The unit of analysis will be the children.

##### 3.2.2. Participants

- Children 9-12 years old from the original Usaquén's cohort
- Children 9-12 years old who are not included in the original cohort (comparable cohort)
- Parents of participating children will be evaluated.

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### 3.2.3. Recruitment

#### 3.2.3.1. Children 9-12 years old from the original Usaquén's cohort.

As part of a feasibility study conducted during 2015, the research group located 650 children/families of the 1216 children who belonged to the Usaquén's cohort (assembled in 2009) (Table 1), 530 (81.5%) from the Usaquén and Suba localities, in private and public schools (n= 70 schools).

The steps of the recruitment are:

- Phone call to families to invite them to an informational meeting (April-May, 2016)
- Informational meeting (June, 2016)
- Measurements in community centers (#6), in the Usaquén and Suba localities (July-August, 2016)

**Table 1. Localization of children from the Usaquén's cohort.**

Date	Activity	# children	Lost to follow-up from baseline	Localization
*May 2009	1° measurement	1216		14 kindergardens in the Usaquén locality
*Nov 2009	2° measurement	1116	n=100	
*Nov 2010	3° measurmeent	598	n=618	
*May 2012	4° measurement	596	n=620	
*Mayo 2014	Feasibility	754	n=462	Bogotá= 740 (98.1%) -Usaquen locality= 603 (80%), in 39 schools -Others 16 localities= 137(18.2%), in 60 schools  Other cities= 14 (1.9%), in 12 schools
*Mayo 2015	Feasibility	650	n=566	Bogotá= 635 (97.7%) -Usaquen locality= 490 (75.4%), in 50 schools -Suba locality= 40 (6.2%), in 20 schools -Others 16 localities= 105 (16.2%), in 78 schools } <b>530</b>  Other cities= 15(2.3%), in 13 schools



### **3.2.3.2. Children 9-12 years old from the comparable cohort**

The most feasible way for the selection of these population is from schools distributed proportionally to the localities where children of the Usaquén cohort live in Bogotá, aiming to have the most comparable population as possible (age, socioeconomical status, sex).

The steps of the recruitment are:

- Identification of the localities and schools where the children of the Usaquén's cohort live (April-May, 2016).
- Contact schools principals and obtain the permission to invite children and their parents to participate in the study (May-June, 2016)
- Phone call to families of the comparable cohort to invite them to an informational meeting (May-June, 2016)
- Informational meeting (June, 2016)
- Measurements in community centers (#6), in the Usaquén and Suba localities (July-August, 2016)

### **3.2.4. MEASUREMENTS AND EVALUATIONS**

See annex 1.

#### **3.2.4.1. Primary Outcome Measures**

1. Cardiovascular health in children<sup>24</sup>(Table 2)
2. Knowledge, attitudes, habits and emotions towards healthy lifestyles for children 9 to 12 years old.

#### **3.2.4.2. Secondary Outcome Measures**

1. Cardiovascular health in adults (Table 3)

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**Table 2. American Heart Association 2020 Strategic Impact Goals Definition of Poor, Intermediate, and Ideal Cardiovascular Health for Each Goal/Metric in children.**

Cardiovascular Health Goals/Metrics	Definitions		
	Poor	Intermediate	Ideal
Current smoking	Tried prior 30 days		Never tried; never smoked whole cigarette
Body mass index, kg/m <sup>2</sup>	≥95th Percentile	85th–95th Percentile	<85th Percentile
Physical activity	None	0 and 60 min of moderate or vigorous activity every day	60 min of moderate or vigorous activity every day
Healthy diet score components *	0–1	2–3	4–5
Total cholesterol, mg/dL	≥ 200	170 – 199	< 170
Blood pressure, mm Hg	≥95th Percentile	90th–95th Percentile or SBP 120 or DBP 80	<90th Percentile
Fasting plasma glucose, mg/dL	≥126	100–125	< 100

\*Fruits and vegetables: ≥4.5 cups per day

Fish: ≥two 3.5-oz servings per week (preferably oily fish)

Fiber-rich whole grains (≥1.1 g of fiber per 10 g of carbohydrate): ≥three 1-oz-equivalent servings per day

Sodium: <1500 mg per day\*

Sugar-sweetened beverages: ≤450 kcal (36 oz) per week.”

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**Table 3. American Heart Association 2020 Strategic Impact Goals Definition of Poor, Intermediate, and Ideal Cardiovascular Health for Each Goal/Metric for Adults >20 Years of Age**

Cardiovascular Health Goals/Metrics	Definitions		
	Poor	Intermediate	Ideal
Current smoking	yes	Former ≥12 mo	Never or quit ≥12 mo
Body mass index, kg/m <sup>2</sup>	≥30	25–29.9	<25
Physical activity	None	1–149 min/wk moderate intensity or 1–74 min/wk vigorous intensity or 1–149 min/wk moderate + vigorous	≥150 min/wk moderate intensity or ≥75 min/wk vigorous intensity or ≥150 min/wk moderate + vigorous
Healthy diet score components *	0–1	2–3	4–5
Total cholesterol, mg/dL	≥240	200–239 or treated to Goal	<200 untreated
Blood pressure, mm Hg	SBP ≥140 or DBP ≥90	SBP 120–139 or DBP 80–89 or treated to goal	<120/<80
Fasting plasma glucose, mg/dL	≥126	100–125 or treated to goal	<100

\*Fruits and vegetables: ≥4.5 cups per day

Fish: ≥two 3.5-oz servings per week (preferably oily fish)

Fiber-rich whole grains (≥1.1 g of fiber per 10 g of carbohydrate): ≥three 1-oz-equivalent servings per day

Sodium: <1500 mg per day

Sugar-sweetened beverages: ≤450 kcal (36 oz) per week.”

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3.2.5. Timeline.

Table 4. Timeline Phase 1

Activities	2016											2017				
	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
IRB Colombia and New York			x	x												
Contact with community centers	x	x	x	x	x	x										
Contact with families of children of the Usaquén's cohort			x	x	x	x	x									
Contact with families of children of the comparable cohort					x	x	x									
1st meeting with Usaquén's cohort						x										
1st meeting with Comparable cohort						x										
Informed consent							x	x								
Baseline measurements (children and parents)							x	x								
Data enter and analysis									x	x	x	x				
Report draft of the results													x			
Preparation of manuscript														x	x	x

### **3.2.6. Statistical Methods**

This cross-sectional study represent the baseline measurement of the Phase 2 of the study.

For sample size, see section 4.2.8.1 of statistical methods in the Phase 2.

#### **3.2.6.1. Analysis plan**

Data will be recorded in a 2010 version EXCEL database, and the analysis will be run with the STATA 13.0 version statistical package.

Descriptive statistics (mean, standard deviation, and percentiles), frequencies, tabulations, plots, graphics, and effect sizes will be produced.

For numeric variables (age, length, weight, total cholesterol, glucose), normality will be previously evaluated using the Kolmogorov-Smirnov (K-S) and Shapiro Wilk tests. If there is normality, Student's t-test for two independent groups will be used. In the event that the suppositions are not met, the Mann Whitney nonparametric asymptotic test will be used. For categorical variables proportions or frequency tables will be reported.

A comparison of the baseline characteristics between children and parents of the Usaquén's cohort and a comparable cohort will be done to determine possible differences. For each of the outcomes, we plan to run a multivariable models where other covariates will be included, to adjust for potential confounders. Variables in children models will be: Ideal Cardiovascular Health (ICH) and Knowledge, Attitudes, Habits and Emotions (KAHE) scores, age and sex of the child, age of the parents, and socioeconomic status. All analyzes will be considered significant for a value of  $p < 0.05$ .

Table 5. Analysis plan Phase 1

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**Specific objectives**

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1. Mean difference in scores and standard deviations in knowledge, attitudes, habits and emotions towards a healthy lifestyle at baseline between groups (cohort Usaquén and comparable cohort) will be determined in children, using a t-test. Multivariable models will be performed to adjust for potential confounders.
  
  2. Mean difference in scores and standard deviations in cardiovascular health (ICH) at baseline between groups (cohort Usaquén and comparable cohort) will be determined in children, using a t-test. Multivariable models will be performed to adjust for potential confounders.  
The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) at baseline in both groups (Usaquén's cohort and comparable cohort) will be determined. Possible differences between the prevalences will be evaluated using the chi2 test.
  
  3. In parents, mean difference in scores and standard deviations in cardiovascular health (ICH) at baseline in both groups (Usaquén's cohort and comparable cohort) will be determined, using a t-test. Multivariable models will be performed to adjust for potential confounders.  
The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) at baseline in both groups (Usaquén's cohort and comparable cohort) will be determined. Possible differences between the prevalences will be evaluated using the chi2 test.
-

**4. PHASE 2**

**4.1. OBJECTIVES**

**4.1.1. GENERAL OBJECTIVE**

1. To assess the impact of a community pedagogical intervention in healthy lifestyles in children 9-12 years old.

**4.1.2. SPECIFIC OBJECTIVES**

**Primary specific objectives**

1. To assess the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in children 9-12 years old in the comparable cohort.
2. To evaluate the impact of a community pedagogical intervention in healthy lifestyles on knowledge, attitudes, habits and emotions towards healthy lifestyles in children 9-12 years old in the comparable cohort.
3. To assess the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in children 9-12 years old in the Usaquén's cohort.
4. To evaluate the impact of a community pedagogical intervention in healthy lifestyles on knowledge, attitudes, habits and emotions towards healthy lifestyles in children 9-12 years old in the Usaquén's cohort.

**Secondary specific objectives**

1. To evaluate the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in intervened children in the Usaquén's cohort vs. intervened children in the comparable cohort.
2. To evaluate the impact of a community pedagogical intervention in healthy lifestyles in the knowledge, attitudes, habits and emotions towards a healthy lifestyle in intervened children in the Usaquén's cohort vs. intervened children in the comparable cohort.
3. To evaluate the impact of a community pedagogical intervention in healthy lifestyles on cardiovascular health in parents or caregivers, differentiating between parents in the Usaquén's cohort and a comparable cohort.

**4.2. METHODOLOGY**

**4.2.1. Design**

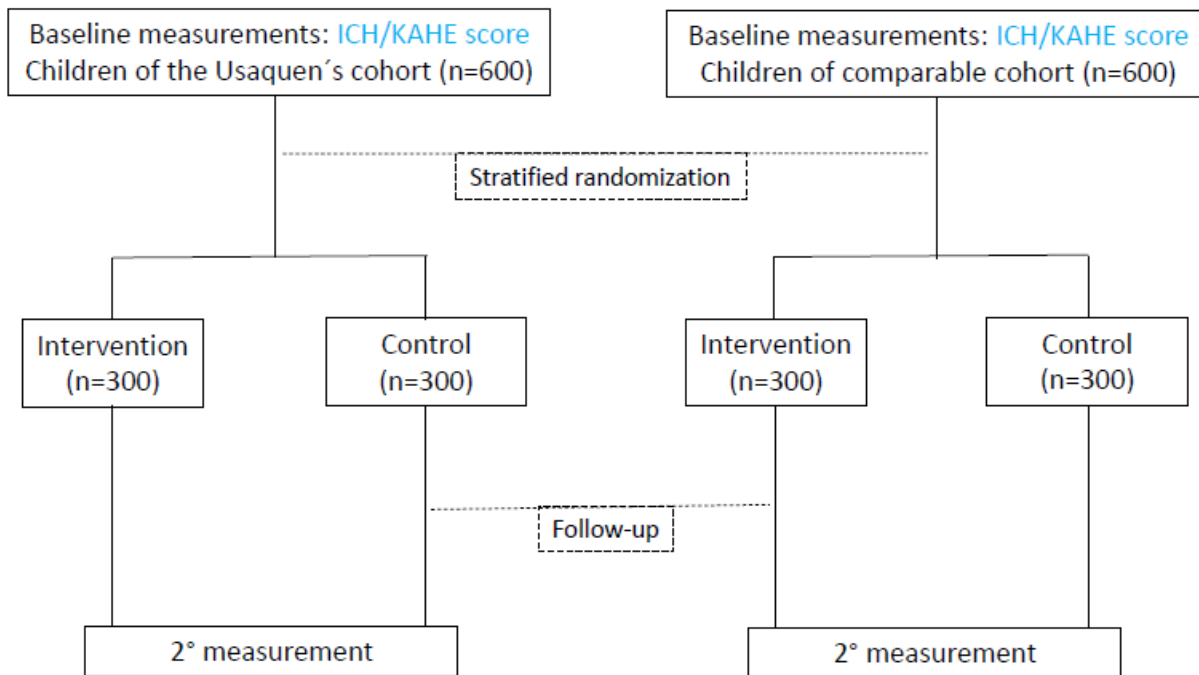
Randomized controlled trial. Intention-to-treat analysis will be used. Random allocation sequence (intervention or control) will be generated using a computer program (Stata 13.0) and will remain concealed until the intervention is assigned. Prior to randomization, standardized measurements by trained research staff will be conducted in all children

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and their parents. The unit of randomization and intervention will be the cluster. The analysis will be take place both at cluster and individual levels. Figure 1, table 6.

**Figure 1. Flowchart of the randomized controlled trial**



ICH: Ideal Cardiovascular Health, KAHE: Knowledge, Attitudes, Habits, Emotions



#### 4.2.2. Participants

See the section 3.2.2. Participants in Phase 1.

#### 4.2.3. Community Intervention Sites

Given the sociocultural conditions of the study population the best option is a community pedagogical intervention outside schools that include families, in the community centers of the Zonal Planning Units in Usaquén and Suba localities (ZPU). The ZPU are an urban subdivision of Bogota, capital of Colombia. Its area is lower than the localities, but can group several neighborhoods (Annex 2). The ZPU have community spaces, where the intervention will take place.

In order to define the number of community centers where the intervention will be conducted, we decided to select the centers using a non-probabilistic method, proportional to the number of families/children in each ZPU, within the two localities.

#### 4.2.4. Recruitment

See the section 3.2.3. Recruitment in Phase 1.

The steps of the recruitment in Phase 2 are:

- Phone call to families to invite them to the beginning of the follow-up period (October, 2016)
- Randomization (November, 2016)

Currently, we plan to initially carry out the study in a total of 12 community centers.

*Once the project is approved and the contact with families starts, we will adjust the number of community centers proportionally to the number of families in each ZPU by locality.*

The follow up will take place in 12 community centers. Each community center will have capacity to gather 50 children and their parents every Saturday (25 in the morning and 25 in the afternoon). The study team will work with 600 children each Saturday in 12 community centers, with 2 meetings per month. The study population (n=1200 children) will be distributed in 48 clusters: 4 study groups consisted of 12 clusters per group (25 children per cluster). A total of 600 children will meet the 1° and 3° Saturday of the month, and the other 600 children will meet the 2° and 4° Saturday of the month. Table 6. To ensure engagement of the control groups, they will receive education content in different topics (assertive communication, maltreatment prevention, accident prevention) not related to the ones administered in the intervened groups.

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Table 6. Clusters by community centers

Comunity centers	1° and 3° Saturday of the month			2° and 4° Saturday of the month		
	Schedule	Children	Clusters	Schedule	Children	Clusters
1	am	25	→ 1	am	25	→ 25
	pm	25	→ 2	pm	25	→ 26
2	am	25	→ 3	am	25	→ 27
	pm	25	→ 4	pm	25	→ 28
3	am	25	→ 5	am	25	→ 29
	pm	25	→ 6	pm	25	→ 30
4	am	25	→ 7	am	25	→ 31
	pm	25	→ 8	pm	25	→ 32
5	am	25	→ 9	am	25	→ 33
	pm	25	→ 10	pm	25	→ 34
6	am	25	→ 11	am	25	→ 35
	pm	25	→ 12	pm	25	→ 36
7	am	25	→ 13	am	25	→ 37
	pm	25	→ 14	pm	25	→ 38
8	am	25	→ 15	am	25	→ 39
	pm	25	→ 16	pm	25	→ 40
9	am	25	→ 17	am	25	→ 41
	pm	25	→ 18	pm	25	→ 42
10	am	25	→ 19	am	25	→ 43
	pm	25	→ 20	pm	25	→ 44
11	am	25	→ 21	am	25	→ 45
	pm	25	→ 22	pm	25	→ 46
12	am	25	→ 23	am	25	→ 47
	pm	25	→ 24	pm	25	→ 48
TOTAL		600			600	

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Table 7. Summary of the Colombia SI Program Intervention components

POBLACIÓN	OBJETIVOS	ACTIVIDADES	MATERIALES	TIEMPO
NIÑOS/NIÑAS y FAMILIAS	Incrementar los conocimientos, actitudes y hábitos en los componentes del programa SI Colombia.	<p>Actividades pedagógicas por componentes SI:</p> <ul style="list-style-type: none"> <li>• Autocuidado del cuerpo y el corazón</li> <li>• Gestión de emociones</li> <li>• Alimentación saludable</li> <li>• Actividad física</li> </ul>	<p>Lugar: centros comunitarios</p> <p>Guías de actividades para los capacitadores</p>	<p>16 Retos (4/componente)</p> <p><b>Presenciales:</b> 2 retos / sesión 4 retos / mes Cada sesión: 4 horas 2 sesiones al mes Duración total: 4 meses (64 horas)</p>
	Mejorar el nivel de salud cardiovascular		<p>Lugar: hogar</p> <ul style="list-style-type: none"> <li>• Guía de actividad en familia</li> <li>• Actividades de soporte semanal (llamadas telefónicas, mensajes de texto, correo electrónico)</li> </ul>	<p>8 Retos (2/componente)</p> <p><b>No presenciales:</b> 1 reto quincenal 2 retos / mes Duración total: 4 meses (32 horas)</p>
			<p>Feria saludable</p> <ul style="list-style-type: none"> <li>• Autocuidado del cuerpo y el corazón (entrega resultados sobre nivel de salud cardiovascular)</li> <li>• Gestión de emociones</li> <li>• Alimentación saludable</li> <li>• Actividad física</li> </ul>	<p>Lugar: centro comunitario principal</p> <p>Material audiovisual Capacitadores Actividades por componentes</p>
CAPACITADORES	Incrementar los conocimientos, actitudes y hábitos en los componentes del programa SI Colombia	<p>Talleres cuyos temas son:</p> <ul style="list-style-type: none"> <li>• Propuesta pedagógica y didáctica</li> <li>• Autocuidado del cuerpo y el corazón</li> <li>• Gestión de emociones</li> <li>• Alimentación saludable</li> <li>• Actividad física</li> </ul>	<p>Lugar: FCI</p> <p>Guía de actividades para el capacitador</p>	<p>Entrenamiento inicial: 2 semanas (60 horas)</p> <p>Entrenamiento semanal: 6 horas, durante 3 meses (72 horas)</p>

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		<p>Feria saludable</p> <ul style="list-style-type: none"><li>• Autocuidado del cuerpo y el corazón</li><li>• Gestión de emociones</li><li>• Alimentación saludable</li><li>• Actividad física</li></ul>	<p>Lugar: FCI</p> <p>Material audiovisual</p> <p>Capacitadores</p> <p>Actividades por componentes</p>	<p>1 jornada de 4 horas</p>
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**.2.6. MEASUREMENTS AND EVALUATIONS****4.2.6.1. Procedures and Instruments**

See annex 2.

**4.2.7. Data Collection Schedule****Table 8. Data collection Schedule**

Measurements	September - October	February – May	June - August
	2016	2017	2017
Questionnaire of Knowledge, attitudes and habits toward a healthy lifestyle	✓		✓
Nutritional survey for children	✓		✓
Physical activity questionnaire: QAPACE	✓		✓
Height, weight	✓		✓
Blood pressure	✓		✓
Total Cholesterol, HDL, LDL	✓		✓
Triglycerides	✓		✓
Fast blood glucose level	✓		✓
Sociodemographic variables	✓		✓
Intervention	✓	✓	✓
Monitoring	✓	✓	✓
Nutritional survey (FFQ) for parents	✓		✓
IMC, Blood pressure for parents	✓		✓
Total cholesterol and Fasting glucose in adults	✓		✓

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Table 9. Timeline phase 2

Actividades	2016												2017												2018					
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Preparation of pedagogical intervention & materials	x	x	x	x	x	x																								
Adaptation of materials							x																							
Editing of materials & facilitators kit								x	x																					
Training of facilitators										x	x																			
Randomization												x																		
Follow-up & Intervention (only children)														x	x	x	x													
2nd measurement (children and parents)																		x	x	x										
Data enter and analysis																					x	x	x	x	x					
Report draft of the results																										x				
Preparation of manuscript																											x	x	x	

#### 4.2.8. Statistical Methods

##### 4.2.8.1. Sample size.

Taking into account the low probability that the children in the study meet all seven components of cardiovascular health to be categorized as poor or ideal according to the criteria of the AHA, we decided to calculate the sample size considering the ICH score as continuous variable as performed elsewhere (see annex 2). The sample size calculation needed to detect a mean difference between control and intervention groups of the same size has been performed by using the user-written command *nsize* (Stata v 12.0). Based on previous studies and considering a confidence level of 95%, a statistical power of 80%, a relevant difference to detect of 0.4 absolute points in the ICH score at the individual level (0.6 absolute points at the cluster level considering an intracluster correlation coefficient of 0.075), a common standard deviation of 1.5, and anticipated 20% of participants lost to follow-up, a sample size of 300 children should be included in each group. The unit of intervention will be the cluster, which will consist of 25 children (and their parents) each. Therefore, a total of 48 clusters (12 clusters of 25 children per group) will be included in the study.

Considering the prevalence of cardiovascular risk factors found in a study in the United States<sup>25</sup> and in Colombia<sup>26</sup> the following assumptions are made:

**Table 10. Sample size**

Variable	Assumptions				Sample size				TOTAL
	Percentage in the intervened group at the end of the study	Percentage in the control group at the end of the study	Intervened / control allocation	Significance test	Power	Intervened group	Control group	10% losses to follow-up	
-Overweight	13,5	20	1	95%	80	517	517	104	1138
-Sedentarysm	75	90	1	95%	80	199	199	40	438
-Unhealthy diet	75	85	1	95%	80	250	250	50	550
-Total cholesterol ≥ 200 mg/dl	10	16	1	95%	80	492	492	99	1083
-Exposure to tobacco	9	15	1	95%	80	460	460	92	1012
Variable	Mean difference to detect	Common standard deviation	Intervened / control allocation	Significance test	Power	Intervened group	Control group	10% losses to follow-up	TOTAL
Change in energy expenditure	80	150	1	95%	90	75	75	15	165

#### **4.2.8.2. Analysis plan**

Data will be recorded in a 2010 version EXCEL database, and the analysis will be run with the STATA 13.0 version statistical package. Intention to treat analysis will be done.

Descriptive statistics (mean, standard deviation, and percentiles), frequencies, tabulations, plots, graphics, and effect sizes will be produced.

For numeric variables (age, length, weight, total cholesterol, glucose), normality will be previously evaluated using the Kolmogorov-Smirnov (K-S) and Shapiro Wilk tests. If there is normality, Student's t-test for two independent groups will be used. In the event that the suppositions are not met, the Mann Whitney nonparametric asymptotic test will be used. For categorical variables proportions or frequency tables will be reported.

A comparison of the baseline characteristics between the intervention group and the control group will be done to determine the balance of randomization, which will be evaluated in terms of socio-demographic variables such as age, sex, socioeconomic status, etc. All analyzes will be considered significant for a value of  $p < 0.05$ .

For each of the primary outcomes, we plan to run a multivariable models where other covariates will be included, to adjust for potential confounders. Variables in children models will be: Ideal Cardiovascular Health (ICH) and Knowledge, Attitudes, Habits and Emotions (KAHE) scores, age and sex of the child, age of the parents, hours attended in contact activities.

The effect of the intervention will be calculated using generalized estimating equations models. Changes between baseline and end-of study scores will be modeled as the outcome, randomization assignment as the independent predictor variable of interest, and subject's cluster as the clustering variable.



**Table 11. Analysis plan Phase 2**

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**Primary specific objectives**

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1. Mean difference in scores and standard deviations in cardiovascular health (ICH) at the end of the study between children in the intervened and control groups in the comparable cohort will be determined, using a t-test. Multivariable models will be performed to adjust for potential confounders.  
The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened and control groups in the comparable cohort.  
Possible differences between changes in prevalences will be evaluated using the chi2 test.
  
  2. Mean and standard deviation of the score of knowledge, attitudes, habits and emotions towards a healthy lifestyle in children will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened and control groups in the comparable cohort. Possible differences between changes in means will be assessed using test t-test. Multivariable models will be performed to adjust for potential confounders.
  
  3. Mean difference in scores and standard deviations in cardiovascular health (ICH) at the end of the study between children in the intervened and control groups in the Usaquén's cohort will be determined, using a t-test. Multivariable models will be performed to adjust for potential confounders.  
The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened and control groups in the Usaquén's cohort.  
Possible differences between changes in prevalences will be evaluated using the chi2 test.
  
  4. Mean and standard deviation of the score of knowledge, attitudes, habits and emotions towards a healthy lifestyle in children will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened and control groups in the Usaquén's cohort. Possible differences between changes in means will be assessed using test t-test. Multivariable models will be performed to adjust for potential confounders.
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**Secondary specific objectives**

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1. Mean difference in scores and standard deviations in cardiovascular health (ICH) at the end of the study between intervened children in the Usaquén's cohort and intervened children in the comparable cohort, will be determined, using a t-test. Multivariable models will be performed to adjust for potential confounders.

The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened children in the Usaquén's cohort and intervened children in the comparable cohort.

Possible differences between changes in prevalences will be evaluated using the chi2 test.

2. Mean and standard deviation of the score of knowledge, attitudes, habits and emotions towards a healthy lifestyle will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened children in the Usaquén's cohort and intervened children in the comparable cohort. Multivariable models will be performed to adjust for potential confounders.

Possible differences between changes in means will be assessed using test t-test.

3. In parents, mean difference in scores and standard deviations in cardiovascular health (ICH) at the end of the study between intervened and control groups will be determined, using a t-test, differentiating between parents in the Usaquén's cohort and a comparable cohort. Multivariable models will be performed to adjust for potential confounders.

The prevalence (CI 95%) of each of the 7 components of cardiovascular health rated as poor (risk factor) will be determined, calculating the difference found between the baseline measurement and the measurement at the end of the study in intervened and control groups differentiating between parents in the Usaquén's cohort and a comparable cohort. Possible differences between changes in prevalences will be evaluated using the chi2 test.

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**5. Annexes**

**Annexe 1. Procedures and Instruments**

Measurement	Instrument
Cardiovascular health (Table 4 and 5)	<p>According to the AHA, a construct of <i>ideal cardiovascular health</i>, is defined as:</p> <p>a) The simultaneous presence of 4 favorable health behaviors (abstinence from smoking within the last year, ideal body mass index [BMI], physical activity at goal, and consumption of a dietary pattern that promotes cardiovascular health).</p> <p>b) The simultaneous presence of 4 favorable health factors (abstinence from smoking within the last year, untreated total cholesterol &lt;200 mg/dL, untreated blood pressure &lt;120/&lt;80 mm Hg, and absence of diabetes mellitus).</p> <p>c) The absence of clinical CVD (including CHD, stroke, heart failure, etc).</p> <p>Using the metrics and criteria for individual ideal health factors and behaviors, we will calculate the <b>ideal cardiovascular health score (ICH)</b>. A value of 1 will be assign for each metric if the criterion for ideal cardiovascular health is met, and a value of 0 if the criterion is not met. The range of the scores is 0 to 7, with a higher score indicating a better cardiovascular health profile<sup>27 28</sup>.</p>
Physical activity questionnaire	A physical activity questionnaire: QAPACE <sup>29</sup>
Children’s healthy diet score	<p>Food frequency questionnaires (FFQ) Students self-report dietary intake using a semi-quantified food frequency questionnaire which solicits information from the past week (approximately 100 food items).</p> <p>Food frequency questionnaires (FFQ) are the most commonly used tool in nutritional epidemiology<sup>30</sup></p>
Body mass index (BMI)	BMI = weight (kg) / height (m) <sup>2</sup>
Nutritional status	<p>Using the Centers for Disease Control and Prevention growth charts for age (in months) and sex for body mass index (BMI)<sup>31</sup>, with children classified:</p> <ul style="list-style-type: none"> <li>-Malnourished if BMI was &lt;-2 standard deviation (SD)</li> <li>-Risk of malnourishment -2 SD and &lt; -1 SD</li> <li>-Eutrophic -1 SD and +1 SD</li> </ul>

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	-Overweight > +1 and +2 SD -Obese > +2 SD.
Blood pressure <sup>32</sup>	After resting quietly in a sitting position for 5 minutes, blood pressure measurements will be taken. The average of 3 readings will be used and converted to percentiles to ages to standardize the values. Blood pressure will be categorized as ideal, intermediate or por (Table 2).
Family history of early atherosclerotic cardiovascular disease.	Family history of premature coronary heart disease in a first-degree relative (heart attack, treated angina, percutaneous coronary catheter interventional procedure, coronary artery bypass surgery, stroke, or sudden cardiac death in a male parent or sibling before the age of 55 years or a female parent or sibling before the age of 65 years) <sup>33</sup>
Exposure to tobacco	Active or passive exposure to tobacco, using an instrument for evaluating knowledge, attitudes and practices towards a healthy lifestyle in children (Colombian version). <b>Appendix 1 and 2.</b> Questions 26 and 27.
Total cholesterol (mg/dL)	acceptable: < 170 borderline: 170-199 abnormal: ≥ 200 alert: > 300
High density lipoproteins or HDL (mg/dL)	acceptable: > 35 borderline: 30-35 abnormal: < 30
Low density lipoproteins or LDL (mg/dL)	acceptable: < 110 borderline: 110-129 abnormal: > 130 alert: > 190
Triglycerides (mg/dL)	acceptable: < 130 borderline: 130-150 abnormal: > 150 alert: > 500
Fasting glucose or blood sugar (mg/dL)	normal: < 100 alert: 110-125 alert (diabetes): > 125
Children with conditions predisposing to accelerated atherosclerosis and early CVD.	<b>High risk:</b> -T1DM and T2DM -Chronic kidney disease/end stage renal disease/ post–kidney transplant -Post–heart transplant -Kawasaki disease with current coronary artery aneurysms  <b>Moderate risk:</b> -Kawasaki disease with regressed coronary aneurysms -Chronic inflammatory disease

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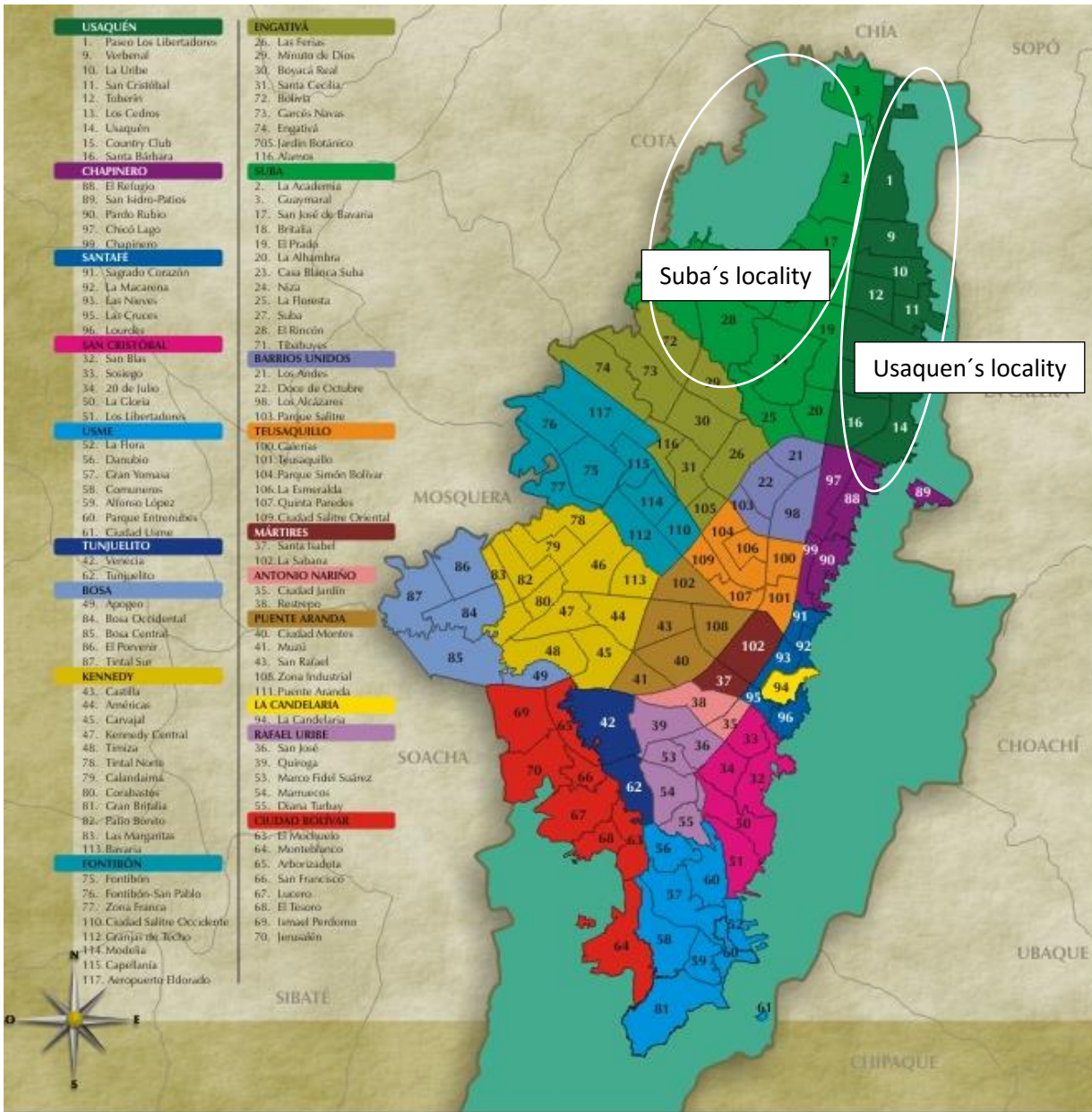
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	<ul style="list-style-type: none"><li>-HIV</li><li>-Nephrotic syndrome</li><li>-Preterm birth</li></ul>
Knowledge, attitudes, habits and emotions towards healthy lifestyles for children 9 to 12 years old.	<p>Using an instrument for evaluating knowledge, attitudes and practices towards a healthy lifestyle in children (Colombian version. This will be the result of the validation process).</p> <p>The instrument has 37 items:</p> <ul style="list-style-type: none"><li>-Items by domains: knowledge (10), attitudes (12) and habits (15)</li><li>-Items by areas: Nutrition (13), Physical activity (11) and Body and heart (13).</li><li>- Scores range from 0 to 100.</li></ul>
Parents healthy diet score	<p>Food frequency questionnaires (FFQ)</p> <p>Self-report dietary intake using a semi-quantified food frequency questionnaire which solicits information from the past week (approximately 100 food items).</p>
Total cholesterol (mg/dL) and Fasting glucose (mg/dL) in adults	Standardized Capillary sample. Accu-chek, Accutrend

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## Annexe 2. Localities and Zonal Planning Units (ZPU) in Bogotá.



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