Article

A Cluster Randomized Controlled Trial of the *Archena Infancia Saludable* Project on Adherence to 24-h Movement Guidelines and Mediterranean Diet among Schoolchildren: A   
Protocol Study

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| **Citation:** López-Gil, J.F.;  García-Hermoso, A.; Smith, L.;  Gallego, A.; Victoria-Montesinos, D.; Ezzatvar, Y.; Hershey, M.S.;  Gutiérrez-Espinoza, H.; Mesas, A.E.; Jiménez-López, E.; et al. A Cluster Randomized Controlled Trial of the *Archena Infancia Saludable* Project on Adherence to 24-h Movement Guidelines and Mediterranean Diet among Schoolchildren: A Protocol Study. *Int. J. Environ. Res. Public Health* **2023**, *20*, x. https://doi.org/10.3390/xxxxx  Academic Editor(s):  Received: 14 January 2023  Revised: 14 March 2023  Accepted: 15 March 2023  Published: date  A picture containing text, clipart  Description automatically generated  **Copyright:** © 2023 by the authors. Submitted for possible open access publication under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://creativecommons.org/licenses/by/4.0/). |

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**Abstract: Objective:** The objective of this paper is to describe the protocol of a cluster randomized controlled trial (RCT) that will evaluate the effectiveness of a lifestyle-based intervention. The *Archena Infancia Saludable* project will have several objectives. The primary objective of this project is to determine the 6-month effects of a lifestyle-based intervention on adherence to 24-h movement behaviors and Mediterranean diet (MedDiet) in schoolchildren. The secondary objective of this project is to test the intervention effects of this lifestyle-based intervention on a relevant set of health-related outcomes (i.e., anthropometric measurements, blood pressure, perceived physical fitness, sleep habits, and academic performance). The tertiary objective is to investigate this intervention’s “halo” effect on parents’/guardians’ adherence to 24-h movement guidelines and MedDiet. **Methods:** The *Archena Infancia Saludable* trial will be a cluster RCT submitted to the Clinical Trials Registry. The protocol will be developed according to SPIRIT guidelines for RCTs and CONSORT statement extension for cluster RCTs. A total of at least 154 eligible parents/guardians with schoolchildren aged 6-13 years (77 participants for each group) will be randomized into an intervention group or a control group. This project focuses on two fundamental pillars: 24-h movement behaviors and MedDiet. It will mainly focus on the relationship between parents/guardians and their children. Behavior change strategies for dietary and 24-h movement behaviors in schoolchildren will be based on healthy lifestyle education for parents/guardians through infographics, video recipes, brief video clips, and videos. **Conclusions:** Most of the current knowledge on 24-h movement behaviors and adherence to the MedDiet is based on cross-sectional or longitudinal cohort studies, warranting a need to design and conduct RCTs to obtain more robust evidence on the effect of a healthy lifestyle program to improve adherence to the MedDiet and increase 24-h movement behaviors in schoolchildren.

**Keywords:** physical activity; sedentary behavior; screen time; sleep duration; movement guidelines; movement recommendations; children; lifestyle; parents; family

1. Introduction

The 24-h movement guidelines for youth have shifted the focus from individual PA components to an integration of all movement-related behaviors in the 24-h time-use continuum [1]. These guidelines indicate that children and adolescents should engage daily in at least 60 min of moderate-to-vigorous PA, restrict their recreational screen time (≤120 min per day for children/adolescents), and obtain adequate sleep duration (e.g., 9–11 h per day for children, 8–10 h for adolescents) in a period of 24 h [1,2]. Thus, clustering and interactions between all 24-h movement guideline recommendations should be promoted to improve health outcomes [3]. Physical activity (PA), sleep duration, and sedentary behavior (including screen time) have been related to a wide range of essential health and developmental outcomes in a young population [4]. To date, most studies have studied these movement behaviors in isolation. However, recently, the focus has shifted to a more integrated approach, recognizing that 24-h movement behaviors are codependent and interrelated [3,5]. Such guidelines note that the clustering and interactions among all domains of 24-h movement behaviors should be targeted to improve health outcomes (e.g., lower risk of obesity, type 2 diabetes, depression) [3,6,7]. Despite these attributed health benefits, a recent meta-analysis reported a global rate of adherence to the 24-h movement guidelines of only 7.12% [8].

Concerning eating habits, the World Health Organization (WHO) advises a healthy diet to help protect against malnutrition as well as noncommunicable diseases such as cancer, cardiovascular diseases, stroke, and type 2 diabetes [9]. However, the need to improve dietary quality on a global scale has recently been highlighted [10]. In this sense, the Mediterranean Diet (MedDiet) is a healthy eating pattern well known worldwide for its distinctive characteristics and health benefits [11,12]. The MedDiet includes an eating pattern rich in fruits and vegetables (seasonal), legumes, whole grains, nuts, and olive oil as the main dietary fat with a greater intake of white or lean meats rather than red or processed meats, moderate consumption of dairy products (cheese, milk), moderate consumption of fish, eggs, and small intakes of wine with meals (only in adults) [13]. Supporting this notion, scientific evidence has demonstrated the inverse relationship between the MedDiet and noncommunicable diseases in adults (e.g., cancer, metabolic syndrome, hypertension, and cardiovascular diseases) [14]. Specifically, among young people, greater adherence to the MedDiet has been associated with greater anti-inflammatory potential [15]. Unfortunately, despite being an evidence-based healthy dietary pattern, a systematic review has pointed out the clear trend of decreasing adherence to the MedDiet in Mediterranean countries, especially among children [16,17]. For instance, Cabrera et al. [16] reported an overall rate of only 10% with high adherence to the MedDiet among a young population. As possible reasons for this trend, westernization of diets [18], urbanization [19], lifestyle changes [20,21], economic factors [22], and lack of knowledge and education [23] (among others) have been proposed.

Previous studies have found an association between meeting the 24-h movement guidelines and healthier dietary patterns [24,25]. Regarding MedDiet, only one previous cross-sectional study (in adolescents) has found that meeting all three 24-h movement guidelines has been related to greater adherence to the MedDiet compared to those who did not meet these guidelines [26]. It is possible that the low prevalence of 24-h movement guidelines reported worldwide [8] and in Spain [24] may be another factor to be taken into account in the low adherence to the MedDiet currently described [16,17]. Although the need for interventions focusing on improving adherence to the 24-h movement guidelines [8] and MedDiet [21] has been previously suggested, the literature on this topic is limited. More specifically, to our knowledge, no previous randomized controlled trial (RCT) has verified the effect of a healthy lifestyle program on both adherence to 24-h movement behaviors and the MedDiet in schoolchildren. In addition, although associations between 24-h movement behaviors or adherence to the MedDiet and several health-related outcomes (e.g., blood pressure, obesity-related indicators, physical fitness, sleep quality) have been previously reported, there is a lack of clinical evidence on the effect of healthy lifestyle interventions, including their interaction effects on particular health-related outcomes in addition to academic performance, when both are implemented at the same time. This also denotes the need for well-designed RCTs focused on this matter.

The objective of this paper is to describe the protocol of a cluster RCT that will evaluate the effectiveness of a lifestyle-based intervention. The *Archena Infancia Saludable* project will have several objectives. The primary objective of this project is to determine the 6-month effects of a lifestyle-based intervention on adherence to 24-h movement guidelines and MedDiet in schoolchildren. In addition, the secondary objective of this project is to test the intervention effects of this lifestyle-based intervention on a relevant set of health-related outcomes (i.e., anthropometric indicators, active transportation, resting blood pressure and heart rate, sleep problems, health-related quality of life, perceived physical fitness, and academic performance). Likewise, the tertiary objective of this study is to verify this intervention’s “halo” effect on adherence to 24-h movement guidelines and MedDiet. We hypothesize that the *Archena Infancia Saludable* project will achieve improvements with small-to-medium effects on adherence to 24-h movement guidelines and MedDiet in schoolchildren.

2. Materials and Methods

2.1. Design

The *Archena Infancia Saludable* (Figure 1) project will be a cluster-randomized, parallel group, clinical trial. The protocol was developed according to SPIRIT guidelines for RCTs [27] and CONSORT statement extension for cluster RCTs [28].

Una caricatura de una persona

Descripción generada automáticamente con confianza baja

**Figure 1.** The Archena Infancia Saludable Project.

2.2. Setting

2.2.1. Procedure

The unit of randomization, intervention, and cluster analysis are the participating parents/guardians with schoolchildren aged 6−13 years, who will be randomized into an intervention group or a control group. The study will be conducted at four different times during one academic year:

1. *First phase.* For four months, we will prepare protocols, set up measurement techniques, enroll the study participants, and collect the baseline data from both parents/guardians and their children.
2. *Second phase*. The intervention program will be conducted for six months.
3. *Third phase*. For one month, we will collect postintervention data from both parents/guardians and their children.
4. *Fourth phase*. In the last month, the control group will receive all the contents of the healthy lifestyle program upon completion of the program by the intervention group.

2.2.2. Rationale for the Age Group Selected

This project will target schoolchildren aged 6−13 years. This age group was selected because childhood is a critical period for adopting daily routines and habits. In addition, the *Archena Infancia Saludable* program will be focused on parents/guardians because they are in a key position to encourage healthy behaviors among their children [29]. Furthermore, an additional reason that justifies this choice of study population lies in the low adherence to MedDiet [16,17,21] and meeting all the 24-h movement guidelines [4,8] found in schoolchildren.

2.2.3. Schoolchildren Eligibility

Regarding the inclusion criteria, schoolchildren aged 6−13 years will be eligible. The exclusion criteria will be defined as follows: (a) participants with any pathology that contraindicates exercise or that requests special attention; (b) participants under pharmacological treatment that prevents them from receiving the contents of the activities of the program; (c) participants or parents/legal guardians presenting Spanish learning difficulties in understanding the contents of the questionnaires; (d) participants not authorized by the parents/guardians to be included in the research project; or (e) participants who do not agree to take part in the research project.

2.2.4. Recruitment and Randomization

Recruitment will be performed in one school randomly selected from *Archena* (Region of Murcia, Spain). Previously, we contacted the directors of both public and private schools of *Archena* (Region of Murcia, Spain), and we will publish advertisements in the local media. Any parent/guardian with a child who meets the inclusion criteria indicated above will be invited to participate. A blinded randomization of the participants into the intervention or control group will be performed using the list of encrypted codes of the participants using Statistical Package for Social Sciences (SPSS) Statistics for Windows, version 28.0 (Armonk, NY, USA). To decrease the risk of selection bias during the assessments, a researcher who will not participate in either the data collection or in the statistical analysis will be responsible for randomizing the groups after the intervention. This process will be performed immediately after the collection of baseline data. The researchers who will participate in the data collection will not know to which group the schoolchildren belong, neither at the baseline nor at the postintervention measurements.

2.3. Intervention

The intervention group will complete the *Archena Infancia Saludable* interdisciplinary program for six months. The interdisciplinary research team comprised nutritionists, physicians, PA and sports science professionals, physical education teachers, nurses, and psychologists. The investigators responsible for carrying out the intervention program will not be involved in data collection or statistical analysis, so they will not be aware of the participants’ group assignment.

The *Archena Infancia Saludable* project will focus on two fundamental pillars: 24-h movement behaviors and MedDiet. Some examples of the contents of the intervention program are shown in Figure 2. The project will mainly focus on the relationship between parents/guardians and their children. Furthermore, the program includes a behavioral approach (i.e., nutritional education), which encourages the responsibility among all the participants to maintain healthy behavioral changes over the long term [15,30].

A picture containing text, parking, screenshot

Description automatically generated

**Figure 2.** Examples of infographics used in the *Archena Infancia Saludable* Project.

The nutritional approach will follow the MedDiet model [12]. We will not impose any caloric restriction since we aim to establish a healthy diet based on the MedDiet [11,21]. Concerning the 24-h movement behaviors, parents/guardians will be told to encourage their children to adopt an active lifestyle with a daily balance of PA, sedentary behavior, and sleep that supports their healthy development [1]. Dietary and 24-h movement behavior changes in schoolchildren will be based on healthy lifestyle education for parents/guardians by infographics, video recipes, information pills, and videos. The contents of these materials have been created by the research team following international and national guidelines for PA [1,31,32], sedentary behavior [1], sleep duration [1,33], MedDiet [34], and healthy eating guidelines [35,36].

The intervention will be performed by the communication application for schools TokApp (TokApp Online S.L., Vigo, Spain). All the contents of the intervention programs will be delivered online. In line with our hypothesis, only parents/guardians will receive the contents of the intervention. We will try to verify whether intervening in parents/guardians has an impact on adherence to 24-h movement guidelines and MedDiet in their children. Thus, parents/guardians will receive three different contents weekly (i.e., infographics, video recipes, information pills, or videos) related to 24-h movement behaviors (i.e., PA, sedentary behavior, sleep duration) or MedDiet. In addition, each launched content will be available until the end of the intervention for those who have not been able to view it at the time of its launch. To not discriminate participants from the control group, all project materials will be offered to parents/guardians allocated to the control group at the end of the intervention phase as well. The researchers responsible for sending the contents of the intervention program through the communication application TokApp will not participate in data collection or statistical analysis after the intervention.

The length of the intervention (24 weeks during a school-academic year) is within the timeframe used in the previous RCTs on this topic (i.e., 20 weeks [37] and 60 weeks [38]). It has been previously described that when an intervention program is delivered, it can have a compensatory effect, so that participants discontinue other physical activities that they would normally have done otherwise. To address this issue, we will assess PA using activity monitors (i.e., accelerometers) for seven days at two different times during the study: at baseline and postintervention. Finally, any adverse effects will be documented and reported with trial outcomes.

2.4. Strategies to Enhance Compliance and Adherence to the Program

Parents/guardians will be verbally invited to participate in the intervention program and to refer to all the assessment and contents. They will receive a reminder if they have not viewed the content sent after one week. Our goal will be that parents/guardians engage in at least 80% of the weekly content, which will be considered a successful attendance rate. This evaluation will be possible because the communication application TokApp allows us to know the interaction with the content sent. However, we will encourage the schoolchildren and their families to visualize all contents weekly whenever possible.

2.5. Statistical Procedures

2.5.1. Sample Size

The sample size calculation was performed following the indications by Donner et al. [39]. First, we calculated the sample sizes without adjustment for clustering (*N0*). For this purpose, the statistical analysis in this study involved several parameters, including the threshold probability for rejecting the null hypothesis (α), which represents the type I error rate, and the probability of failing to reject the null hypothesis under the alternative hypothesis (*β*), representing the type II error rate. In addition, the proportion of subjects in the intervention group (*q*1) and control group (*q*0), the effect size (Cohen’s *d*), and the standard deviation of the outcome in the population (*σ*) were calculated. Thus, established an *α* value (two-tailed) of 0.05 and a *β* value of 0.20, so that the standard normal deviation for *α* is *Zα* = 1.960 and for *β* is *Zβ* = 0.842. The proportion of subjects in both the intervention and control groups will be similar (*q*1 = 0.50; *q*0 = 0.50). Our study will be powered to detect medium-sized effects (i.e., Cohen’s *d* = 0.5), and the standard deviation of the outcome in the population will be 1.0.

|  |  |
| --- | --- |
| *N*0 |  |
| *N*0 |  |
| *N*0 = 125.58 ≈ 126 participants |  |

Second, we calculated the sample size with adjustment for clustering (*N*1). For previous studies in this specific population, we assumed an average household size (*m*) of 1.2 participants according to previous studies performed in the same region [40,41]. Moreover, the within-cluster correlation coefficient (*ρ*) was established as 0.5.

|  |  |
| --- | --- |
| Design effect = 1 + (*ρ* (*m* 1)) |  |
| Design effect = 1 + (0.5 (1.2 1)) = 1.1 |  |
| Clusters in IG = |  |
| Clusters in IG = = 57.75 ≈ 58 parents/guardians |  |
| Clusters in CG = |  |
| Clusters in CG = = 57.75 ≈ 58 parents/guardians |  |
| *N*1 = 116 parents/guardians |  |

Third, by assuming a percentage of losses we determined the number of participants (*N*2) and parents/guardians (*N*3) needed. Thus, we further expected a 10% drop-out rate, which was estimated using the following formula:

|  |  |
| --- | --- |
| *N*2 = *N*0/(1 % losses) |  |
| *N*3 = *N*1/(1 % losses) |  |
| *N*2 = = 153,33 ≈ 154 participants |  |
| *N*3 = = 128,89 ≈ 129 parents/guardians |  |

Rounding, a minimum sample of 130 eligible parents/guardians with schoolchildren aged 6–13 years (65 for each group) and 154 schoolchildren (77 for each group) will be needed to conduct this study.

2.5.2. Statistical Analysis

Means (*M*) and standard deviation (*SD*) or frequencies (*n*) and percentages (%) will be reported for all quantitative or qualitative variables, respectively. Data normality will be verified by a Kolmogorov–Smirnov’s test with Lilliefors correction, as well as the homogeneity of variances by Levene’s test. Thereafter, the data will be analyzed using Student’s *t* test or Mann–Whitney’s *U* test for two-group comparisons, depending on the compliance with the normality assumption. Associations between qualitative variables will be determined using Pearson’s chi-square test. For quantitative variables, the association will be determined through Pearson’s *r* or Spearman’s rho (*ρ*), according to the normality assumption. An exploratory analysis will be performed to determine the frequency, range, variability, and distribution type for each variable to use the most appropriate statistical test when comparisons are necessary. Since this RCT has an experimental design with two data collections of the primary and secondary outcomes and tertiary outcomes, the first at baseline (*t*0 = 0 weeks) and the second after intervention (*t*1 = 24 weeks) in both the intervention and control groups, we will apply a comparative analysis between these measures to establish differences between groups. To evaluate the intervention effect, multilevel mixed-effects regression models with repeated measures will be conducted for each dependent variable. Subsequently, multivariate analyses will be performed, considering the autocorrelation between repeated measures. Both intention-to-treat (ITT) (which measures the effect of assigning an intervention) and per-protocol (PP) analysis (which measures the effect of receiving an intervention) approaches will be applied for the data analysis. Data analysis will be carried out by the software SPSS (IBM Corp, Armonk, NY, USA) (version 25.0) and the software Stata (Stata, College Station, TX, USA) (version 17.0), both for Windows. A *p* value ≤ 0.05 will determine statistical significance.

2.6. Variables

The full set of primary, secondary, and tertiary outcomes will be assessed twice, at the time of enrollment and after the 24-week healthy lifestyle program. The measurements will be performed at school by evaluators previously trained to standardize the measurements and blinded to the group in which participants will be allocated. A summary of all the variables that will be examined in the *Archena Infancia Saludable* project is provided in Table 1.

**Table 1.** Summary of the variables examined in the *Archena Infancia Saludable* project.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variables** | **Schoolchildren Variables** | | **Parents or Guardians Variables** | |
| **Measurement** | **Tool** | **Measurement** | **Tool** |
| Age | -Self-reported. | -Ad hoc questionnaire. | -Self-reported. | -Ad hoc questionnaire. |
| Sex | -Self-reported. | -Ad hoc questionnaire. | -Self-reported. | -Ad hoc questionnaire. |
| Socioeconomic status | -Objective. | -FAS-III. |  |  |
| Educational level |  |  | -Self-reported. | -Ad hoc questionnaire. |
| Immigrant status | -Objective. | -Ad hoc questionnaire. |  |  |
| Marital status |  |  | -Self-reported. | -Ad hoc questionnaire. |
| Perception of their child’s BMI status |  |  | -Self-reported. | -Ad hoc questionnaire. |
| Perception of their own BMI status |  |  | -Self-reported. | -Ad hoc questionnaire. |
| Active transportation | -Self-reported. | -PACO questionnaire. |  |  |
| Resting blood pressure and heart rate | -Objective. | -Omrom® EVOLV HEM-7600T-E. |  |  |
| Sleep-related problems | -Proxy-reported. | -BEARS scale. |  |  |
| Health-related quality of life | -Self-reported. | -CHU9D. |  |  |
| Self-reported physical fitness | -Self-reported. | -IFIS scale. |  |  |
| Academic performance | -Objective. | -School records. |  |  |
| Anthropometric measures | -Objective. | -Tanita BC-545, Leicester Tanita HR 001.  -Constant tension tape. | -Self-reported. | -Ad hoc questionnaire. |
| Physical activity | -Objective.  -Self-reported. | -Actigraph GT3x.  -YAP-S. | -Self-reported. | -IPAQ-short form. |
| Sedentary behaviors | -Objective.  -Self-reported. | -Actigraph GT3x.  -YAP-S. | -Self-reported. | -IPAQ-short form. |
| Recreational screen time | -Proxy-reported. | -Ad hoc questionnaire. | -Self-reported. | -IPAQ-short form. |
| Sleep duration | -Objective.  -Proxy-reported | -Actigraph GT3x.  -Ad hoc questionnaire. | -Self-reported. | -Ad hoc questionnaire. |
| *Siesta* | -Objective. | -Ad hoc questionnaire. |  |  |
| Adherence to the MedDiet | -Self-reported. | -KIDMED. | -Self-reported. | -PREDIMED questionnaire. |

BEARS, Bedtime Issues, Excessive Daytime Sleepiness, Night Awakenings, Regularity and Duration of Sleep, Snoring; BMI, body mass index; CHU9D, Child Health Utility 9D; FAS-III, Family Affluence Scale-III; IPAQ, International Physical Activity Questionnaire; KIDMED, Mediterranean Diet Quality Index for Children and Teenagers; MedDiet, Mediterranean diet; PACO, *Pedalea y Anda al Cole*; PREDIMED, PREvención con DIeta MEDiterránea; YAP-S; Youth Activity Profile—Spain.

2.6.1. Primary Outcomes (Schoolchildren)

**Adherence to the Mediterranean diet**

To assess adherence to the MedDiet, the Mediterranean Diet Quality Index for Children and Teenagers (KIDMED) index will be used, which has been previously validated in a young Spanish population[42]. The KIDMED index ranges from −4 to 12 and is based on a 16-question test. Items reporting unhealthy characteristics related to the MedDiet are scored with −1 point, and those reporting healthy characteristics with +1 point. The sum of all scores from the KIDMED test will be used to categorize into three different levels of adherence: (a) optimal MedDiet (>8 points), (b) improvement needed to adjust intake to Mediterranean patterns (4−7 points), and (c) very low diet quality (≤3 points) [42].

**24-h movement behaviors (accelerometers)**

PA and sedentary time will be assessed by accelerometers. A triaxial accelerometer (Actigraph GT3x, Pensacola, FL, USA) will be used to assess PA, sedentary time, and sleep duration over seven consecutive days. Participants will be instructed to wear the device attached to the nondominant wrist. Since there are nonwater-proof devices, schoolchildren will wear the accelerometers 24 h a day and will only be able to remove them while bathing or swimming. In addition, schoolchildren will have a paper-based diary log to record the time when they go to bed, wake up, and remove the device.

**24-h movement behaviors (self-reported)**

Self-report of PA levels and sedentary behaviors in youth will be assessed by the Youth Activity Profile—Spain (YAP-S). The YAP-S was designed to be a self-administered 7-day recall questionnaire suitable for use in schoolchildren [43]. Screen time will be assessed by asking parents/guardians the time that their children spent in different sedentary screen-based pursuits as follows: “Approximately, how much time does your child typically spend in front of a screen (on daily average), including computer, tablet, television, videos, video games or cell phone screen?”. This question will be asked individually for weekdays and weekends. A weighted sum of the three questions will be calculated (i.e., five weekdays and two weekend days). Sleep duration will be evaluated by asking parents/guardians for weekdays and weekend days separately: “What time does your child usually go to bed?” and “What time does your child usually get up?”. The average daily sleep duration will be computed for each participant as follows: [(average nocturnal sleep duration on weekdays × 5) + (average nocturnal sleep duration on weekends × 2)]/7. In addition, two ad hoc questions on *siesta* habits will be asked: (1) “Does your child usually take a *siesta*?”, with yes or no options, and (2) “How long does your child take a *siesta*?”, with answers ranging from (a) 0–15 min, (b) 15–30 min, (c) 30–45 min, (d) 45–60 min, (e) 60–75 min, (f) 75–90 min, (g) 105–120 min, or (h) 120 or more min. A siesta is a traditional short nap taken in the early afternoon, often after the midday meal. Such a period of sleep is a common tradition in some countries, particularly those where the weather is warm (e.g., Mediterranean region). The school timetable for all participants is from 09:00 a.m. to 14:00 p.m., which makes it possible to take a *siesta* after this time

2.6.2. Secondary Outcomes (Schoolchildren)

**Anthropometric measurements**

The body weight of the schoolchildren will be measured using an electronic scale (with an accuracy of 0.1 kg) (Tanita BC-545, Tokyo, Japan), while height will be determined by a portable height rod with an accuracy of 0.1 cm (Leicester Tanita HR 001, Tokyo, Japan). Body mass index (BMI) will be calculated by dividing body weight (in kg) by height (in squared meters). Furthermore, BMI z score will be computed by the WHO age-specific and sex-specific thresholds [44], as well as the International Obesity Task Force Criteria [45]. Subsequently, the BMI z scores obtained will be used to determine excess weight. Waist circumference will be measured to the nearest 0.1 cm at the level of the umbilicus using a constant tension tape. Moreover, the waist-to-height ratio (WHtR) will be calculated, and therefore, a value ≥ 0.5 will be used as a cutoff point to establish abdominal obesity [46].

**Active transportation**

Active transportation to and from school is evaluated by a self-report questionnaire of the PACO (*Pedalea y Anda al Cole*) project [47]. Participants answer the following questions: “How do you usually go to school?”, and “How do you usually come back from school?”. Additionally, the second set of questions refers to the way of commuting to and from school during a week. The possible responses will include walking, by bike, motorbike, car, bus, or other transport (requesting specific open-ended information in this case).

**Resting blood pressure and heart rate**

Resting blood pressure and heart rate will be measured using an automated blood pressure monitor with a fittingly sized cuff (Omrom® EVOLV HEM-7600T-E, Health-care Co, Kyoto, Japan). First, schoolchildren will be seated in a quiet room for 10 min with their feet on the ground and their back supported. Two readings will be taken, with the second blood pressure reading taken five minutes after the first. The average of the two measurements for systolic blood pressure and diastolic blood pressure was retained. Subsequently, mean arterial pressure will be computed by the following formula: diastolic blood pressure + [0.333 × (systolic blood pressure–diastolic blood pressure)]. Blood pressure categorization will be performed by age-, sex-, and height-specific cutoff points by the European Society of Hypertension guidelines for the management of high blood pressure in children and adolescents [48]. High-normal blood pressure will be considered systolic blood pressure and/or diastolic blood pressure ≥ than the 90th percentile but < than the 95th percentile for young people aged 0–15 years. Hypertension and percentile hypertension will be considered systolic blood pressure and/or diastolic blood pressure ≥ than the 95th percentile for young people aged 0–15 years.

**Sleep-related problems**

Sleep-related problems will be evaluated by the BEARS (B = Bedtime Issues, E = Excessive Daytime Sleepiness, A = Night Awakenings, R = Regularity and Duration of Sleep, S = Snoring) scale, a screening tool created to screen the most common sleep disorders in the young population (aged 2–18 years) in the context of a clinical interview [49]. This instrument contains questions that evaluate sleep-related areas such as bedtime problems (e.g., difficulties going to bed and falling asleep), excessive daytime sleepiness (e.g., behaviors usually related to somnolence during the day), awakening during the night, regularity and duration of sleep, and snoring. A previous study showed the concurrent validity of the Spanish translation of the BEARS to screen sleep disorders in pediatric evaluations [50]. This variable will be proxy-reported by parents/guardians.

**Health-related quality of life**

Health-related quality of life will be measured by the Child Health Utility 9D (CHU9D) [51,52]. This questionnaire was designed for use in children aged 7–11 years, but with interviewer assistance, it can be used in children 6 years of age [53]. The CHU9D consists of 9 dimensions: worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine, and ability to join in activities, with five different levels representing increasing levels of severity within each dimension. Furthermore, CHU9D scores will be used in cost-utility analyses [54]. In addition, cost-effectiveness will be assessed by an ad hoc questionnaire answered by parents/guardians, including the number of days in the hospital, pediatrician visits, medicine use and its cost, and study days lost due to health problems during the last 24 weeks.

**Self-reported physical fitness**

Self-reported physical fitness will be assessed by the International Fitness Scale (IFIS), which is composed of 5-point Likert-scale items asking about the children’s perceived global physical fitness, cardiorespiratory fitness, muscular fitness, speed-agility, and flexibility in comparison with their counterparts’ physical fitness (very poor, poor, average, good, and very good) [55].

**Academic performance**

Academic records will be provided at the end of the academic year by the school. Academic performance will be assessed in two different ways. First, academic performance will be evaluated according to the grade obtained in Language, Mathematics, Language and Mathematics (combined), English, as well as the grade point average of these three subjects. Previous studies have used these measurements as an indicator of academic performance [56,57]. Second, academic performance will be assessed by computing the average of all the subjects taken by the schoolchildren [58].

2.6.3. Tertiary Outcomes (Parents/Guardians)

24-h movement behaviors (self-reported)

The level of PA and sitting time will be assessed by the International Physical Activity Questionnaire-short form (IPAQ-SF) [59]. The IPAQ-SF captured the number of days and time spent on PA in vigorous-intensity, moderate-intensity, and walking of at least 10 min duration over the last seven days and included time spent sitting over the last seven weekdays. The IPAQ-SF sum score will be expressed in Metabolic Equivalent of Task (MET)-minutes per day or week. Participants will be categorized as those meeting or not meeting the PA guidelines, moderate-vigorous PA minutes (≥150 or <150 moderate-vigorous PA minutes per week), and vigorous-intensity PA (≥75 or <75 min per week) will be dichotomized. For the sitting time, participants will be questioned about their sitting time separately for weekdays and weekend days. The 24-h movement guidelines provide a specific recommendation about recreational screen time: ≤3 h daily as a subcomponent of the sedentary recommendation (i.e., in addition to the 8-h sedentary time recommendation) [60]. In this project, recreational screen time will be self-reported using the following questions in the household interview about sedentary activities during leisure time: (a) “In a typical week in the past three months, how much time did you usually spend on a computer, tablet or iPad including watching videos, playing computer games, emailing or using the Internet?”; (b) “In a typical week in the past three months, how much time did you usually spend playing other types of video games on a game console or hand-held electronic device?”; (c) “In a typical week in the past three months, how much time did you usually spend watching television, DVDs or videos?” Respondents will be provided with a continuous response option. The time spent on each screen-based activity will be summed to yield a total daily recreational screen time estimate. Screen time will be categorized as a binary variable based on meeting (vs. not meeting) the recommendation. Sleep duration will be self-reported by using the following question for weekdays and weekends independently: “How many hours do you usually spend sleeping in a 24-h period, excluding time spent resting?” Responses will be reported as a continuous variable and rounded to the nearest half-hour by the interviewer. Sleep duration will be categorized as a binary variable to compare parents/guardians meeting age-specific sleep recommendations (i.e., 7–9 h daily for adults aged 18–64 years; 7–8 h daily for adults aged ≥65 years) with those not meeting that recommendation [60].

**Adherence to the Mediterranean diet**

Parents/guardians will also be administered a 17-item Mediterranean dietary questionnaire, a modified version of the previously validated questionnaire used in the PREDIMED (*PREvención con DIeta MEDiterránea*) trial designed to assess adherence to the MedDiet. Meeting with each of the 17 items relating to characteristic food habits will be scored with zero or one point. Therefore, the total score will range from 0 to 17 points, with 0 points denoting no adherence to the MedDiet and 17 indicating maximum adherence to the MedDiet [61].

2.6.4. Covariates

Age and sex will be self-reported by schoolchildren and parents/guardians, respectively. Parents/guardians will be asked for country birth (of their children and themselves) and their marital status. The somatic maturity of the schoolchildren will be estimated by following the prediction models by Moore et al. [62]. Socioeconomic status (SES) will be assessed by the Family Affluence Scale (FAS-III) [63], which will be responded to by parents/guardians. The FAS-III score will be calculated by the sum of the responses from six different items related to vehicles, bedroom, computers, bathrooms, dishwashers, and family travel. The final score ranges from 0 to 13 points. Thus, three different categories will be established: (a) low SES (0–2 points), (b) medium SES (3–5 points), and (c) high SES (≥6 points). Parents/guardians will be asked about their educational level. Possible options will be (a) incomplete primary education, (b) complete primary education, (c) incomplete secondary education, (d) complete secondary education, (e) incomplete higher education, or (f) complete higher education. The body weight and body height of the parents/guardians will be self-reported. Body mass index (BMI) will be computed by dividing body weight (in kg) by height (in squared meters). Subsequently, BMI status will be established by the WHO criteria [64] as follows: underweight <18.5, normal weight 18.5–24.99, overweight 25–29.99, or obesity ≥ 30. Parents’/guardians’ perception of their child’s body mass index status will be evaluated with the following question: “In relation to his/her height, which of the following options best describes your child’s body weight?: (1) substantially above normal, (2) slightly above normal, (3) normal, (4) below normal”[65]. This same question will be done four their perception of their own body mass index status as follows: “According to your height, which of the next options best describes your body weight: (1) substantially above normal, (2) slightly above normal, (3) normal, (4) below normal?” [65].

2.7. Ethical Considerations and Dissemination

The *Archena Infancia Saludable* project has been previously registered in (ClinicalTrials.gov ID NCT05620303) and has been approved by the Ethics Committee of the Albacete University Hospital Complex and the Albacete Integrated Care Management (ID 2202-132). Similarly, this trial will be performed in accordance with the Helsinki Declaration and respecting the human rights of the participants involved.

All study participants will receive written informed consent. All participants will be informed that they have the right to withdraw from the study at any point without giving reason. The results of this project will be disseminated to academic audiences by presentations at national and international conferences and through peer-reviewed publications in relevant journals. The results will be disseminated to the general population, academic audiences, and policy makers and through seminars, social networks, and press releases.

3. Discussion

The *Archena Infancia Saludable* project will verify, for the first time, whether a cluster RCT based on 24-h behaviors and adherence to the MedDiet aimed at parents produces improvements in these healthy behaviors among their children. In childhood, unhealthy lifestyle behaviors (e.g., physical inactivity, excessive sedentary time, short sleep duration, unhealthy diet) share several factors in common [66]. They are (1) cumulative; (2) associated with poorer health in adulthood and increased risk of chronic diseases; (3) preventable and a consequence of not carrying out daily health-promoting activities; and (4) influenced by parenting confidence and skills. Despite this, it has been found that most parents/guardians have positive intentions to support their children’s health behaviors, and yet many are unable to promulgate this support [67]. Therefore, parents need innovative and attractive strategies that are not time-consuming and are adapted to the stressful pace of life today.

Childhood is a unique opportunity to implement primordial prevention lifestyle strategies [68,69]. For children, the school environment may be the most appropriate choice for a behavioral intervention, as it constitutes the most reliable means of effective transfer of knowledge and appropriate educational strategies [70,71]. In the best-case scenario, the school-based intervention will also encompass the children’s families to create a supportive environment at home and enhance its effect [72]. In general, interventions have tended to focus on health education and the provision of guidelines or recommendations with limited or no training of parents and little recognition of the importance of the role of parents in developing healthy lifestyle habits [66]. In this sense, the *Archena Infancia Saludable* program will seek to provide parents/guardians with numerous practical resources based on 24-h movement behaviors and MedDiet that can be applicable and feasible for their children on a daily basis and adjusted to their real context, beyond theoretical concepts and contents.

Guidelines or recommendations from institutions and scientific experts strongly encourage a MedDiet as a healthy eating pattern that could diminish the risk of chronic noncommunicable diseases since childhood [34,35]. This fact is also consistent with the recommendation of meeting with 24-h movement guidelines [1,73], since the current evidence suggests that these recommendations may have essential implications for health and are linked with several desirable health outcomes in young [61] and adult populations [6,7]. Based on the low levels of the young population meeting the 24-h movement guidelines as well as low adherence to the MedDiet (especially in this region of Spain [41]), it is clear that knowledge, awareness, and implementation of these healthy behaviors by the general population need to be improved in combination with one another for their potential synergistic effect [4,8,24,74].

On the other hand, the United Nations and the WHO defined nine global targets for noncommunicable diseases to reach by 2025 [75]. In line with this, the aim of Sustainable Development Goal 3.4 is to reduce premature mortality from noncommunicable diseases by one-third and promote mental health and well-being by 2030 [76]. Unhealthy diet and physical inactivity are among the leading risk factors for disability and are responsible for a large proportion of the burden of chronic noncommunicable diseases globally [10,77,78]. Providing intervention programs based on scientific evidence (such as the *Archena Infancia Saludable* program) to improve dietary patterns and lifestyles seems necessary, as it could play an important role in public health.

Additionally, it is worth mentioning that in this first edition of the *Archena Infancia Saludable* project, only one school will be selected. This decision is based mainly on the intention to carry out this intervention program as a pilot test in order to obtain a more consolidated and effective version of the *Archena Infancia Saludable* program. For this purpose, we will try to obtain feedback from parents/guardians and teachers on the functioning of the project, such as suggestions for improvement, and barriers to adherence to the intervention program. We will also try to seek additional sources of funding to increase the resources and methodological quality of this cluster RCT. The ultimate goal of this first edition of the project is to consolidate the intervention program to be implemented on a scaled basis in all schools in the municipality in future editions, as is being done in projects carried out in secondary schools in Archena that include a larger sample [40].

4. Conclusions

Most of the current knowledge on 24-h movement behaviors and adherence to the MedDiet is based on cross-sectional or longitudinal cohort studies, which warrants further evidence by conducting well-designed RCTs to assess the effect of a healthy lifestyle program on adherence to 24-h movement behaviors and the MedDiet in schoolchildren.

**Author Contributions:** Conceptualization, J.F.L.-G.; methodology, J.F.L.-G.; writing—original draft preparation, J.F.L.-G.; writing—review and editing, J.F.L.-G., A.G.-H., L.S., A.G., D.V.-M., Y.E., M.S.H., H.G.-E., A.E.M., E.J.-L., P.A.S.-M., A.L.-B., L.M.-G., S.C., J.B.-S., A.F.-M., P.E.A., J.M.P.R., P.J.T.-L. and S.N.K.; supervision, J.F.L.-G.; project administration, J.F.L.-G. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research has been funded by the *Ayuntamiento de Archena*.

**Institutional Review Board Statement:** The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Albacete University Hospital Complex and the Albacete Integrated Care Management (ID 2202-132) for studies involving humans.

**Informed Consent Statement:** Informed consent was obtained from the parents/legal representatives of all the participants involved in the study.

**Data Availability Statement:** Not applicable.

**Acknowledgments:** The author would like to express their gratitude to *Ayuntamiento de Archena*, as well as the participation of all the adolescents, parents/legal guardians, physical education teachers, schools, and staff implicated, and wishes to thank them for the information provided. JFL-G is a Margarita Salas Fellow (Universidad de Castilla-La Mancha—2021-MS-20563). A.G.-H. is a Miguel Servet Fellow (Instituto de Salud Carlos III–CP18/0150).

**Conflicts of Interest:** The authors declare no conflict of interest.

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