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## A theory-based randomized controlled trial in promoting fruit and vegetable intake among schoolchildren: PROFRUVE study --Manuscript Draft--

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	<p>Results: FV intake increased significantly in the intervention group (+0.45 servings/day; 95% CI 0.17 to 0.74; p=0.001) but not in the control group (+0.01 servings/day; 95% CI -0.20 to 0.22; p=0.409) shortly after the intervention. Long-term measurement showed that one year after intervention finished, the intervention group maintained the effect (+0.52 servings/day from baseline; 95% CI 0.22 to 0.78; p=0.003). Multiple lineal regression showed that receiving the intervention (B=0.345, p=0.045) was associated with higher FV intake change after adjusting the model by FV baseline intake, gender and family social economic status (SES) (R<sup>2</sup>=0.196).</p> <p>Conclusions: The intervention program based on TPB seems to be moderately effective in increasing FV intake and successful in maintaining the effect of the reached increase. Moreover, baseline FV intake determines the effect size of the intervention.</p> <p>Keywords: Fruit, vegetable, children, theory of planned behavior, nutritional education, school.</p>
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# A theory-based randomized controlled trial in promoting fruit and vegetable intake among schoolchildren: PROFRUVE study

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## 1. Abstract

**Purpose:** The main objective of the PROFRUVE study is to evaluate the effectiveness of a TPB-based intervention program at increasing fruit and vegetable (FV) consumption in schoolchildren aged 7 to 10.

**Methods:** Eight eligible classrooms were randomly assigned to the intervention (classrooms n=4; children n=90) or control group (classrooms n=4; children n=95). The intervention group received 14 sessions of one hour during an academic year (from October to June) but the control group did not. Sessions were based on the Theory of Planned Behavior (TPB) and focused on modifying FV intake. FV consumption was evaluated before, shortly after and one year after intervention ended using validated 7-day food records.

**Results:** FV intake increased significantly in the intervention group (+0.45 servings/day; 95% CI 0.17 to 0.74;  $p=0.001$ ) but not in the control group (+0.01 servings/day; 95% CI -0.20 to 0.22;  $p=0.409$ ) shortly after the intervention. Long-term measurement showed that one year after intervention finished, the intervention group maintained the effect (+0.52 servings/day from baseline; 95% CI 0.22 to 0.78;  $p=0.003$ ). Multiple lineal regression showed that receiving the intervention ( $B=0.345$ ,  $p=0.045$ ) was associated with higher FV intake change after adjusting the model by FV baseline intake, gender and family social economic status (SES) ( $R^2=0.196$ ).

43     **Conclusions:** The intervention program based on TPB seems to be moderately effective in increasing FV  
44     intake and successful in maintaining the effect of the reached increase. Moreover, baseline FV intake  
45     determines the effect size of the intervention.

46     **Keywords:** Fruit, vegetable, children, theory of planned behavior, nutritional education, school.

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## 2. Introduction

### 2.1. Background

Fruit and vegetables (FV) are essential components of a healthy diet. It has been evidenced that increased consumption of FV has a beneficial effects on bone density [1], cardiovascular disease [2-5], some cancers [5-8], diabetes [9] and obesity [10]. Taking into account that the habits acquired in childhood tend to last into adulthood, it seems reasonable to focus the effort on increasing the consumption of FV in the infant population [11].

#### 2.1.1 FV intake data

The ENALIA study [12] showed that only 31.7% of Spanish young people under 17 reached the recommended five servings of FV daily (3 servings of F and 2 servings of V). The COSI Study carried out between 2015 and 2017, showed that 29% of the Spanish child population (6 to 9) consumed F every day and only 9% ate V every day. In addition, 9% and 15% consumed one or fewer servings of FV respectively within the week. The latest study carried out in the Basque Country showed that children and youngsters aged 4 to 18 usually eat 98.9-114.2 grams of F per day (boys and girls respectively) and 90.3-86.5 grams of V. In Vitoria-Gasteiz, the capital of the Basque Country located in the north of Spain, only two in ten children and adolescents aged 6 to 17 eat the recommended three servings of F and only one in ten the recommended two servings of V daily. Average intake of F was 1.8 servings/day and 0.8 servings/day for V (unpublished data of Vitoria-Gasteiz City Council Nutritional Observatory, 2007). This context has reinforced the importance of developing effective strategies to promote the consumption of FV, which has become a priority challenge for public health.

#### 2.1.2 Behavioral nutrition education

Educational intervention seems to be necessary and the school environment is the ideal scenario for improving healthy eating habits. Moreover, both interventions in schools and in worksites or communities appear to be important for long-term behavior changes [13]. In addition, it is essential to involve parents, teachers [14, 15] and even classmates [16], as they are engaged in the education of children or influence them.

The main factors that contribute to the effectiveness of nutritional education interventions include those considered in studies that are behaviorally focused and behavioral theory-based [13, 17]. In particular, the most effective programs that have attempted to modify the pattern of infant feeding in terms of FV have been those that include the determinants of eating behavior. In fact, according to a meta-analysis that studied the influence of behavioral theory based interventions on children's FV intake, the effectiveness of theory based and non-theory based studies differed significantly [18]. The results were more positive when the interventions were theory-based, irrespective of the number of theories used for the interventions and FV consumption. Furthermore, it was concluded that the quality of the study is more important than the theory itself or the number of theories used [18]. One of the theories used in these types of interventions is the theory of planned behavior (TPB). According to this theory, three types of determinants guide human behavior, including food choice and intake: attitude toward the behavior, perceived social pressure or subjective norm, and perceived behavioral control. These determinants lead to the formation of a behavioral intention, the previous step for final behavior. Generally, the more favorable the attitude and subjective norm, and the greater the perceived control are, the stronger the intention of the person to carry out the behavior in question, in our case eating more FV [19].

## 2.2. Hypothesis

An intervention program to promote FV intake among schoolchildren aged 7 to 10 and based on TPB increases FV intake and its effect is maintained one year after.

## 2.3. Objectives

The main objective of this study is to evaluate the short-term effectiveness of an intervention program based on TPB in increasing FV intake in schoolchildren aged 7 to 10.

Secondary objectives of the study are (i) to examine the impact of the intervention program on FV intake one year after, and (ii) to study the association of social demographic variables on children's FV intake change.

# 3. Materials and Methods

## 3.1. Study design

A cluster randomized controlled community trial was carried out over an academic year at school level in Vitoria-Gasteiz, the capital of the Basque Country. Clustering of classrooms from the same school was performed as previously described in the study protocol [20]. Clustering was chosen because this is the easiest way to implement an intervention program at school level. Additionally, the phenomenon of contamination among children from the same classrooms is avoided. Contact between the research group and schools was made by the City Council.

Inclusion criterion included there being a minimum of 24 children per classroom aged 7 to 10. Exclusion criteria were both schools for children who are unable to benefit from ordinary schooling because they have special education needs and schools that were carrying out some other programs related to health promotion in the same period. Having carried out previous nutritional programs was not an exclusion criterion as the greater part of schools has participated in different programs organized by the City Council.

The control group was necessary in order to analyze the direct effect of the intervention and to discard increased FV intake by seasonality (first measurements in October and final ones in June) or other factors. The study was approved by the Ethic Committee of the University of the Basque Country (CEISH/262/2014/RODRIGUEZRIVERA) and all parents or legal guardians, school principals and teachers were sent an informed consent before the study started. After the receipt of informed consent, baseline data collection was carried out followed by the randomized allocation of classrooms. Eligible classrooms from the school were randomly assigned to the intervention or the control group, by a random sequence generated using IBM-SPSS Statistical software. The personnel responsible for randomizing were blinded to participants. Teachers, children and families were also blinded to their intervention or control group.

### 3.2. Participants

Following the published study protocol [20], sample size was calculated to provide a power of 90% to detect an effect size (Cohen's *d*) of at least 0.5 servings/day: 172 participants (86 in the intervention group and 86 in the control group) were required. Taking into account the dropout rate of similar studies [21-23], the final sample size was increased by 20% to reach 206 children (8 classrooms with a minimum of 26 children per class). Five of the sixteen schools proposed by the municipality met the inclusion criteria but

a single school agreed to participate respecting our requirements. Taking into account the problems in the recruitment of the schools that met the inclusion criteria and accepted to participate, the minimum number of students per class had to be reduced to 24 children. Finally, 192 children were recruited. The study was conducted in eight classrooms of 3<sup>rd</sup> and 4<sup>th</sup> grade (7 to 10) within the public school with most students in the city.

The recruitment of schools began in May 2015. Written informed consent followed by baseline data collection were performed in September 2015.

### 3.3. Intervention

The intervention program lasted one academic year and was designed by a multidisciplinary team. All materials, sessions and the program design were based on TPB and were respectful of gender, culture or religion. After randomization, meetings were held with teachers of each classroom to describe the specific program to be carried out by each classroom without telling them which group they would belong to (control or intervention) and to set the dates of sessions and evaluation procedures. Teachers of the intervention groups received some training, as they are models for children, after which the intervention group started receiving program lessons every 15 days. This group received 14 sessions of one hour over an academic year, from a trained nutritionist.

Combining different theories in the program was discarded. This choice was based on a meta-analysis that analyzed the influence of behavioral theories on FV intervention effectiveness among children and found no association between the number of theories and consumption [18]. To make the program more effective, sessions were designed based on learning taxonomies [24], active learning methodologies and persuasion techniques (ELM: Elaboration Likelihood Model) [25]. All sessions had their own script for the nutritionist involved and all the scripts had the same structure (objectives, methodology, argument and resources). The script was followed by the nutritionist with the aid of an audiovisual presentation, sheets for students, work sheets for families, a goal-diary, FV's folder, album and stickers, and material for specific sessions (e.g. FV as rewards at the end of each session and the "Fruitmeter").



The strategy proposed had three axes of action: a) school activities, b) outside activities and c) home activities.

- a) School activities: Nine sessions were held within the school (7 within the classroom and 2 FV cooking sessions in the dining room). Every month a “Fruitmeter” session took place. In this activity, each classroom was to write down their group FV mean intake during the last week using a tool called the “Fruitmeter”, which works by social pressure to reach the objective of eating more FV. The “Fruitmeter” has poster format and was hung in each classroom.
- b) Outside activities: Two visits to local product markets and two visits to local farmers were made. The last session was held in a local theatre as the final FV program party.
- c) Home activities: a goal-diary with objectives related to FV consumption that participants should reach, e.g. to try a new V this week or to eat F for breakfast three times per week, was filled in at home with participants’ parents. All worksheets that children used at school and reviewed at home were noted.

Following an ethical committee proposal, the control group only participated in two one-hour lessons during the academic year with general information about the benefits of FV intake. These sessions were led by a nutritionist and not based on behavioral theories.

### 3.4. Assessment

All intervention and control sessions were held by the same nutritionist, and data collection at baseline (T0: September) and shortly after intervention (T1: June) were performed by the same researcher. A year after intervention ended (T2: June +1 year), only intervention group’s FV intake was assessed as this group changed its FV pre-post intake, but not the control group.

#### 3.4.1. Primary outcome: FV intake

FV (excluding potatoes and legumes) consumption was measured by a validated self-administered 7-day food record [26]. It provides information about standard servings of FV intake (Four items: pieces of fresh F, natural non-commercial juice, raw V and cooked V) for 7 days. Codified surveys were sent through children inside codified sealed envelopes. These surveys were filled out at home by parents and returned to school.

### 3.4.2. Secondary outcomes: family social-demographic outcomes

Parental educational attainment, employment situation, family type and economic status data were collected by a questionnaire designed by the Department of Sociology 2 of the University of the Basque Country.

### 3.5. Data analysis

Descriptive statistics were carried out to describe baseline characteristics of intervention and control groups. Independent non-parametric and *chi*-square tests were conducted to ensure the equivalence of the groups. Intra-group and inter-group FV intake at baseline and follow-up, and differences between times were analyzed by Wilcoxon signed-rank test and Mann–Whitney U test. Intra-group analysis was made in long-term follow-up (one year after intervention).

Multiple lineal regressions were used to study the effectiveness of the intervention, adjusting for social demographic variables, family-related variables, FV baseline eating habits, age and gender. Statistical analyses were made by using STATA 14.0 (StataCorp LP, College Station, TX, USA) and SPSS 24.0 (IBM, Armonk, NY, USA) statistical software. CI of 95% and significance level of  $p < 0.05$  were assumed.

## **4. Results**

### 4.1. Descriptive statistics and test of homogeneity: baseline data and dropout.

Mean of age in years was 8.45 (SD=0.776). 56% of participants were male and 44% female. Baseline measures were compared between control and intervention group, and no significant differences were observed (table 1). Age, gender and FV intake distribution did not differ from one group to the other, neither did familiar educational attainment nor family, economic and employment situations.

(Table 1)

As described in the flow diagram (fig. 1), of the 192 children recruited, 4 parents did not sign the consents (n=188). 185 children filled out all questionnaires and food records at baseline (intervention group n=90; control group n=95). The dropout of the first follow-up in the intervention group was 26 children and 20 in the control group because they did not fill in the 7-day food record. In the second follow-up (only with the intervention group), the dropout was 21 children for the same reason. 3 children were eliminated from the

analysis as outliers, “extreme values” that are more than 3 box lengths from a hinge in the SPSS boxplot were eliminated.

The analysis of homogeneity between the dropout and others showed no differences at any time in the major part of variables ( $p>0.05$ ). Age is the variable that differs from dropouts at the first and the second follow-ups. Shortly after, dropouts had a mean of 8.96 (SD=0.56) and no-dropouts 8.18 (SD=0.917) ( $p=0.000$ ). One year after intervention finished, dropouts had a mean of 8.80 (SD=0.67) and no-dropouts 8.26 (SD=0.924) ( $p=0.011$ ). For that reason, although the differences are minimal, age was considered within multiple linear regression.

#### 4.2 Intervention effectiveness:

Means and standard deviations for the servings of the main food groups consumed (F, V and F+V) at baseline, follow-up and differences are shown in table 2. Differences for each group between baseline and follow-up showed that FV combined intake and F intake were higher in the intervention group after intervention, but not in the control group. Regarding V consumption, pre-post analysis showed a non-significant increase neither in control nor in intervention group. Similar but not identical baseline intake, led us to compare intake differences between two groups and it was shown that F+V combined intake, F intake and V intake changes after intervention were significantly higher in intervention compared with control group changes.

(Table 2)

Table 3 describes subgroups according to how both F and V are consumed. F is divided into servings of fresh F and homemade F juices. V is divided into servings of consumed raw or cooked V. Analyzed separately, both fresh F and juice intake were increased in the intervention group, but not in the control. In terms of V consumption, there was a significant increase of raw V in the intervention group, but not in the control. Cooked V were maintained in the intervention group and significantly decreased in control ones.

(Table 3)

#### 4.3. Long-term effectiveness:

One year after intervention finished, intervention group outcomes were re-measured (n=66). Only this group was evaluated, due to the fact that control group did not change its FV intake after intervention. Even so, it was ensured that intervention group received no FV related educational or intervention processes during this year within the school setting.

As shown in table 4, intervention group consumed 2.81 servings/day one year after intervention. This group maintained its FV, F and V intake with a subtle but not significant increase comparing with the data shortly after intervention (+0.52 servings/day comparing with baseline). The intake of the subgroups (fresh F, juice and raw/cooked V) remained unchanged.

(Table 4)

#### 4.4. Influence on FV intake change: shortly after intervention

After adjusting the model for baseline FV intake (servings/day), age (years), gender and family social economic status (SES) (low-middle low or high/middle high), multiple linear regression showed an association between a higher FV pre-post change shortly after intervention and having received the intervention (table 5).

(Table 5)

In the adjusted model the intervention increased FV intake by 0.345 servings/day, remaining significant ( $p=0.045$ ). In addition, baseline FV intake proved to be significant ( $p=0.000$ ) in the adjusted model, showing that increasing baseline FV intake in one serving, intervention effect decreased in 0.383 servings/day.

Although age, gender and family SES were not significant outcomes in the adjusted model, there was a tendency for FV change to be greater among girls ( $B=0.141$ ;  $p=0.408$ ) and for SES to affect FV change negatively after intervention when the SES is higher.

## 5. Discussion

As far as we know, PROFRUVE is the first intervention of this type to achieve such positive results within Spain. The effect of the program is moderate, increasing from baseline 0.45 servings of FV shortly after in the intervention group ( $p=0.001$ ). More precisely, intervention group increased F consumption by 0.31

servings ( $p=0.000$ ) and 0.14 servings of V ( $p=0.080$ ), in the unadjusted model. These results are in agreement with those published in different systematic reviews and meta-analyses that studied the influence of FV intervention effectiveness among children. A review that studied school-based interventions to improve daily FV intake in children aged 5-12 years showed moderate results in most of the interventions: an improvement by 0.32 portions/day of FV (95% CI 0.14 to 0.50), 0.24 portions/day of F (95% CI 0.05 to 0.43) and 0.07 portion/day of V (95% CI -0.03 to 0.16) [27]. A meta-analysis of the influence of behavioral theories on the effectiveness of interventions which aimed to increase FV intake, also showed the interventions to have moderate effects on F intake ( $g=0.322$ ; 95% CI, 0.186 to 0.458;  $p<0.05$ ), the effect on V intake being low but significant ( $g=0.174$ ; 95% CI, 0.073 to 0.276;  $p=0.001$ ), and the effect on FV moderate ( $g=0.471$ ; 95% CI 0.309 to 0.634;  $p<0.01$ ) [18]. Generally speaking, different systematic reviews and meta-analysis observed that interventions within a school setting improved FV intake from 0.14 to 0.99 servings/day [28-30]. In broad terms, better results are obtained in the promotion of the consumption of F than V.

By contrast, the AFLY 5 study, a large cluster randomized controlled trial, performed in 60 primary schools and aimed to improve FV intake and physical activity, did not demonstrate the effectiveness of the intervention (difference of FV change between groups: 0.08 servings/day; 95% CI -0.12 to 0.28) [31]. The large heterogeneity of the results could be due to different aspects. First of these might be the variables taken into account within study outcomes, for example, by counting potatoes and legumes as V or juice as F. In our study, potatoes and legumes were excluded, but homemade F juices were not. A systematic review showed an increase of intake by 0.25 servings of FV when F juice were excluded, with an increase of 0.32 portions when it was included [27]. In comparison, our data showed greater increases: 0.45 servings of FV with juice and 0.34 servings without it. It is important to highlight that the improvement of total F consumption in our study was based on fresh F rather than on juice. This fact is an important aspect, as WHO advises limiting the consumption of free sugars, including those present in F juices [32].

Baseline FV intake is a variable that affected the effectiveness of the program on FV intake and it is in concordance with a meta-analysis of school-based interventions [28]. In our study, baseline FV intake was 2.27 servings/day within intervention group and 2.35 servings/day in the control group. As may be seen in the adjusted model, intervention effect decreased 0.345 servings/day when baseline FV intake increased from 0 to 1 serving/day, making the program less effective the higher the FV consumption before the program.

In our study, long-term evaluation showed that the results obtained were maintained without intervention for one year. Few studies have measured 12-month follow-up as long-term effect evaluation, the large AFLY-5 study found no effect one year after intervention had finished [33]. Nevertheless, Pro-children study, a school-based intervention carried out in different European countries, also measured FV intake one year after intervention in the Spanish population and the results showed a decrease in FV consumption. By contrast, the same study showed positive results in Norwegian children, where intervention group increased significantly its FV intake from baseline one year later compared with control group [22]. The difference between our study and Pro-children is that our results remain positive without any intervention after one year and Pro-children used a less intensive intervention between the main intervention and the second follow-up.

Intervention design could also contribute to the heterogeneity among results of different studies. PROFRUVE encompasses different components that sometimes have been employed independently or in smaller groups: nutritional education, sensorial and culinary lessons, grocery shopping and gardening activities. In general, it seems that multi-component interventions show better improvement regarding FV consumption compared with single-component programs [27, 30]. Implementation rate and study quality must be the base of the intervention and they could be the reason for the differences among studies. The quality of PROFRUVE study is justified by different aspects described below, concretely in the “strengths” section.

## LIMITATIONS AND STRENGTHS

**Strengths:** This is a theory-based randomized control community trial in real condition whose application of the intervention program is a remarkably easily implementable tool. The protocol study was published following the CONSORT statements [34] and considering aspects of Cochrane Risk of Bias Tool [35]. The intervention is an extensive and multicomponent intervention, consisting of 14 sessions with a professional nutritionist. Methodologically, those people responsible for collecting the data were the same people in every class and were blinded to the intervention, thus reducing the risk of bias. Moreover, the 7-day food record used is a validated tool. One of the most interesting things is that long-term effectiveness was measured, confirming that the effect of the intervention was maintained, a key aspect.

**Limitations:** Contamination bias appears when both intervention and control group classrooms are within the same school. Nutritionists were not blinded to the intervention or control group, so performance bias

could take place. Although the intervention involved families, it should be more directly and deeply put into place since they are responsible of children's feeding, determining the accessibility and availability of FV in their homes, so they can block the positive effect obtained in children. Furthermore, it is a challenge to measure the diet in this population.

## **6. Conclusions**

PROFRUVE intervention program was moderately effective in increasing children's FV intake shortly after the intervention and maintaining this effect in a long term. Nevertheless, there are some factors that limit the effect of the intervention, of which the most significant is baseline FV consumption. We are able to conclude that the program can be useful among low FV eaters, so we can apply our focus and efforts to those populations with that characteristic. F intake is more easily increased with this program, so in future studies it may be useful to work on V intake improvement, which seems to be more difficult to achieve. In general, even if the intervention is effective, the objective of achieving the goal of 5 servings/day is still far away.

## **7. Other information**

**Trial Registration:** This study has been registered at ClinicalTrials.gov. Identifier: NCT03400891. Data registered 17/01/2018

**Protocol:** The study protocol was published elsewhere: <https://doi.org/10.1186/s12889-018-5748-3> [20].

**Ethics approval:** The study was approved by the Ethic Committee of the University of the Basque Country UPV/EHU (CEISH/262/2014/RODRIGUEZRIVERA). Parents or legal guardians, school directors and teachers completed a written consent form before the study commences.

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## References

1. Wosje KS, Khoury PR, Claytor RP et al. (2010) Dietary patterns associated with fat and bone mass in young children. *Am J Clin Nutr.* 92: 294-303.
2. Hartley L, Igbinedion E, Holmes J et al. (2013) Increased consumption of fruit and vegetables for the primary prevention of cardiovascular diseases. *Cochrane Database Syst Rev.* doi: 10.1002/14651858.CD009874.pub2.
3. Alissa EM, Ferns GA. (2017) Dietary fruits and vegetables and cardiovascular diseases risk. *Crit Rev Food Sci Nutr.* 57: 1950-62.
4. Zhan J, Liu YJ, Cai LB et al. (2017) Fruit and vegetable consumption and risk of cardiovascular disease: A meta-analysis of prospective cohort studies. *Crit Rev Food Sci Nutr.* 57: 1650-63.
5. Aune D, Giovannucci E, Boffetta P et al. (2017) Fruit and vegetable intake and the risk of cardiovascular disease, total cancer and all-cause mortality—a systematic review and dose-response meta-analysis of prospective studies. *Int J Epidemiol.* 46: 1029-56.
6. Wang Y, Li F, Wang Z et al. (2015) Fruit and vegetable consumption and risk of lung cancer: A dose-response meta-analysis of prospective cohort studies. *Lung Cancer.* 88(2): 124-30.
7. Key TJ, Schatzkin A, Willett WC et al. (2004) Diet, nutrition and the prevention of cancer. *Public Health Nutr.* 7: 187-200.



380 8. Maynard M, Gunnell D, Emmett P et al. (2003) Fruit, vegetables, and antioxidants in childhood and  
381 risk of adult cancer: The boyd orr cohort. *J Epidemiol Community Health*. 57(3): 218-25.

382 9. Wu Y, Zhang D, Jiang X et al. (2015) Fruit and vegetable consumption and risk of type 2 diabetes  
383 mellitus: A dose-response meta-analysis of prospective cohort studies. *Nutr Metab Cardiovasc Dis*. 25:  
384 140-7.

385 10. Ledoux TA, Hingle MD, Baranowski T. (2011) Relationship of fruit and vegetable intake with  
386 adiposity: A systematic review. *Obes Rev*. 12(5): e143-50.

387 11. Lloyd JJ, Wyatt KM, Creanor S. (2012) Behavioural and weight status outcomes from an exploratory  
388 trial of the healthy lifestyles programme (HeLP): A novel school-based obesity prevention programme.  
389 *BMJ Open*. doi: 10.1136/bmjopen-2011-000390.

390 12. AECOSAN. Encuesta ENALIA: Encuesta nacional de alimentación en la población infantil y  
391 adolescente (2018).

392 13. Pomerleau J, Lock K, Knai C et al. (2004) Effectiveness of interventions and programmes promoting  
393 fruit and vegetable intake. background paper for the joint FAO/WHO workshop on fruit and vegetable for  
394 health.

395 14. Pearson N, Biddle SJ, Gorely T (2009) Family correlates of fruit and vegetable consumption in  
396 children and adolescents: A systematic review. *Public Health Nutr*. 12: 267-83.

397 15. Yee AZ, Lwin MO, Ho SS (2017) The influence of parental practices on child promotive and  
398 preventive food consumption behaviors: A systematic review and meta-analysis. *Int J Behav Nutr Phys*  
399 *Act*. 14: 47,017-0501-3.

400 16. Salvy SJ, de la Haye K, Bowker JC et al. (2012) Influence of peers and friends on children's and  
401 adolescents' eating and activity behaviors. *Physiol Behav*. 106: 369-78.

402 17. Contento IR (2010) *Nutrition Education: Linking Research, Theory, and Practice*. Jones & Bartlett  
403 Publishers.

404 18. Diep CS, Chen TA, Davies VF et al. (2014) Influence of behavioral theory on fruit and vegetable  
405 intervention effectiveness among children: A meta-analysis. *J Nutr Educ Behav.* 46: 506-46.

406 19. Ajzen I (1991) The theory of planned behavior. *Organ Behav Hum Decis Process.* 50: 179-211.

407 20. Arrizabalaga-López M, de Jáuregui DR, Portillo M et al. (2018) A randomised controlled trial of a  
408 program based on the theory of planned behavior to promote fruit and vegetable intake among  
409 schoolchildren: PROFRUVE study protocol. *BMC Public Health.* 18: 827.

410 21. Christian MS, Evans CE, Ransley JK et al. (2012) Process evaluation of a cluster randomised  
411 controlled trial of a school-based fruit and vegetable intervention: Project tomato. *Public Health Nutr.* 15:  
412 459-65.

413 22. Te Velde S, Brug J, Wind M et al. (2008) Effects of a comprehensive fruit-and vegetable-promoting  
414 school-based intervention in three european countries: The pro children study. *Br J Nutr.* 99: 893-903.

415 23. Lehto R, Määttä S, Lehto E et al. (2014) The PRO GREENS intervention in finnish schoolchildren—  
416 the degree of implementation affects both mediators and the intake of fruits and vegetables. *Br J Nutr.*  
417 112: 1185-94.

418 24. Krathwohl D (2002) A Revision of Bloom's Taxonomy: An Overview. *Theory Pract.* 41 (4): 212–8.

419 25. Petty RE, Cacioppo JT (1986) The elaboration likelihood model of persuasion. *Advances in*  
420 *Experimental Social Psychology.* 19: 123-205.

421 26. Rodríguez VM, Elbusto-Cabello A, Alberdi-Albeniz M et al. (2014) New pre-coded food record form  
422 validation. *Rev Esp Nutr Hum Diet.* 18: 118-26.

423 27. Evans CE, Christian MS, Cleghorn CL et al. (2012) Systematic review and meta-analysis of school-  
424 based interventions to improve daily fruit and vegetable intake in children aged 5 to 12 y. *Am J Clin Nutr.*  
425 96: 889-901.

426 28. Howerton MW, Bell BS, Dodd KW et al. (2007) School-based nutrition programs produced a  
427 moderate increase in fruit and vegetable consumption: Meta and pooling analyses from 7 studies. *J Nutr*  
428 *Educ Behav.* 39: 186-96.

429 29. Knai C, Pomerleau J, Lock K et al. (2006) Getting children to eat more fruit and vegetables: A  
430 systematic review. *Prev Med.* 42: 85-95.

431 30. de Sa J, Lock K (2008) Will european agricultural policy for school fruit and vegetables improve  
432 public health? A review of school fruit and vegetable programmes. *Eur J Public Health.* 18(6):558-68.

433 31. Kipping RR, Howe LD, Jago R et al.(2014) Effect of intervention aimed at increasing physical  
434 activity, reducing sedentary behaviour, and increasing fruit and vegetable consumption in children:  
435 Active for life year 5 (AFLY5) school based cluster randomised controlled trial. *Bmj.* 348: g3256.

436 32. World Health Organization (2015) Guideline: Sugars Intake for Adults and Children. World Health  
437 Organization.

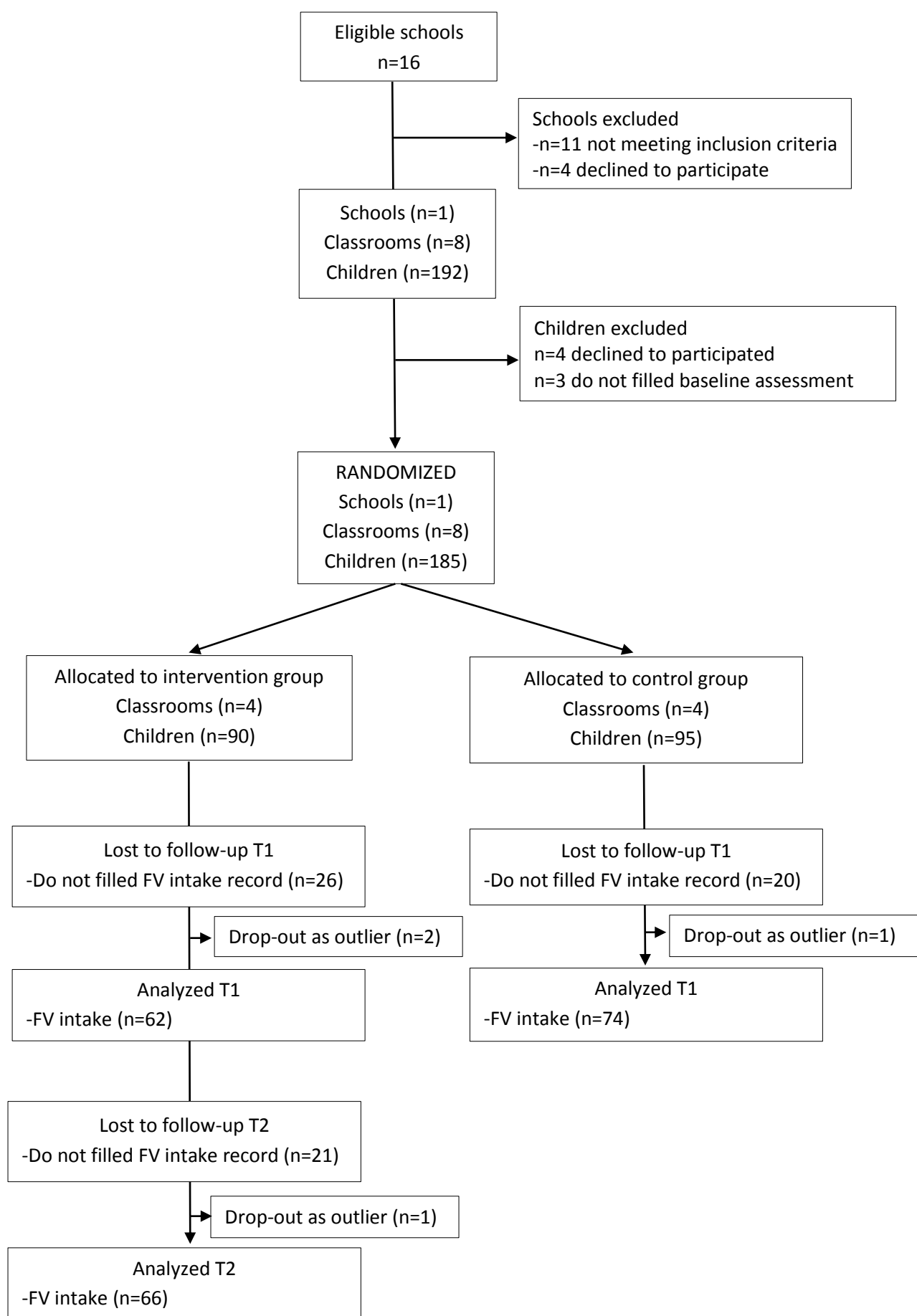
438 33. Lawlor DA, Howe LD, Anderson EL et al. (2015) The active for life year 5 (AFLY5) school-based  
439 cluster randomised controlled trial: Effect on potential mediators. *BMC Public Health.* 16: 68.

440 34. Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 statement: Updated guidelines for  
441 reporting parallel group randomised trials. *BMC Med* 8: 18.

442 35. Higgins JP, Altman DG, Gotzsche PC et al. (2011) The cochrane collaboration's tool for assessing  
443 risk of bias in randomised trials. *Bmj.* 343: d5928.

444

445 Fig 1. Flow diagram



446 Table 1: baseline characteristics and homogeneity between groups

	INTERVENTION (n=88)	CONTROL (n=94)	<i>p</i>
<b>GENDER</b>			
Female	44.3%	43.6%	0.924
Male	55.7%	56.4%	
<b>AGE (mean and SD)</b>	8.39 (0.903)	8.51 (0.635)	0.282
<b>FV INTAKE (mean and SD)</b>	2.27 (1.01)	2.35 (0.95)	0.966
<b>FAMILY TYPE</b>			
Living with both parents	89.2%	89.7%	0.994
Monoparental	9.6%	9.2%	
Living with parents and other relatives	1.2%	1.1%	
<b>PARENTS EDUCATIONAL ATTAINMENT</b>			
Primary	2.5%	6.9%	0.573
Secondary	72.8%	69.0%	
University	22.2%	20.7%	
NR/DK	2.5%	3.4%	
<b>PARENTS EMPLOYMENT SITUATION</b>			0.546
Employee	65.8%	70.2%	
Other situations	34.2%	29.8%	
<b>FAMILY SES</b>			0.769
Low or middle-low	36.3%	41.4%	
High or middle-high	52.5%	47.1%	
NR/DK	11.2%	11.5%	

SD: standard deviation; Age in years; FV intake: servings/day; SES: social economical level; NR/DK: no response or do not know

447

448 Table 2: scores of the main food groups (servings/day)

	Group	Baseline (mean and SD)	Follow-up (mean and SD)	<i>p</i>	Difference (mean and 95% CI)
<b>F+V intake</b>	Intervention	2.27 (1.01)	2.72 (1.15)	0.001	0.45 (0.17 to 0.74)
	Control	2.35 (0.95)	2.36 (1.04)	0.409	0.01 (-0.20 to 0.22)
	<i>p</i>	0.966	0.070		0.001
<b>F intake</b>	Intervention	1.49 (0.78)	1.80 (0.83)	0.000	0.31 (0.13 to 0.50)
	Control	1.55 (0.77)	1.57 (0.74)	0.736	0.02 (-0.13 to 0.16)
	<i>p</i>	0.886	0.183		0.001
<b>V intake</b>	Intervention	0.78 (0.40)	0.92 (0.53)	0.080	0.14 (-0.01 to 0.28)
	Control	0.80 (0.40)	0.79 (0.48)	0.305	-0.01 (-0.11 to 0.10)
	<i>p</i>	0.828	0.056		0.046

449

450 Table 3: Scores of the food subgroups within both F and V (servings/day)

	Group	Baseline (mean and SD)	Follow-up (mean and SD)	<i>p</i>	Difference (mean and 95% CI)
Fresh F	Intervention	1.16 (0.65)	1.36 (0.70)	0.004	0.20 (0.04 to 0.37)
	Control	1.07 (0.56)	1.10 (0.59)	0.525	0.04 (-0.07 to 0.14)
	<i>p</i>	0.269	0.021		0.035
F juice	Intervention	0.33 (0.32)	0.44 (0.37)	0.016	0.11 (0.03 to 0.19)
	Control	0.48 (0.44)	0.46 (0.40)	0.615	-0.02 (-0.12 to 0.08)
	<i>p</i>	0.303	0.519		0.020
Raw V	Intervention	0.33 (0.28)	0.48 (0.38)	0.006	0.15 (0.05 to 0.25)
	Control	0.34 (0.30)	0.39 (0.33)	0.172	0.05 (-0.02 to 0.11)
	<i>p</i>	0.910	0.093		0.175
Cooked V	Intervention	0.45 (0.26)	0.44 (0.31)	0.636	-0.01 (-0.09 to 0.07)
	Control	0.46 (0.29)	0.41 (0.27)	0.043	-0.05 (-0.12 to 0.02)
	<i>p</i>	0.740	0.801		0.350

451

Table 4: Scores (servings/day) of the main food groups and subgroups at baseline, shortly after and one year after intervention. Data only for the intervention group.

<b>n=66</b>	<b>Baseline (mean and SD)</b>	<b>First follow-up (mean and SD)</b>	<b>Long-term follow- up (mean and SD)</b>	<b><i>p</i></b>	<b>Difference (long- term follow-up - baseline) (mean and 95% CI)</b>
<b>F+V intake</b>	2.30 (0.94)	2.74 (1.11)	2.81 (1.30)	0.003	0.52 (0.18 to 0.85)
<b>F intake</b>	1.52 (0.72)	1.83 (0.76)	1.84 (0.91)	0.013	0.32 (0.08 to 0.56)
<b>V intake</b>	0.78 (0.41)	0.91 (0.55)	0.97 (0.55)	0.002	0.19 (0.05 to 0.34)
<b>Fresh F</b>	1.19 (0.62)	1.38 (0.66)	1.40 (0.69)	0.073	0.21 (0.02 to 0.40)
<b>Juice</b>	0.33 (0.29)	0.45 (0.36)	0.44 (0.43)	0.031	0.11 (0.00 to 0.23)
<b>Raw V</b>	0.34 (0.27)	0.48 (0.37)	0.44 (0.35)	0.001	0.11 (0.01 to 0.20)
<b>Cooked V</b>	0.44 (0.25)	0.43 (0.32)	0.53 (0.36)	0.241	0.09 (0.00 to 0.18)



456 Table 5: Adjusted multiple linear regression model.

Model	B coefficient	Standard error	95% CI	p
Constant	1.011	1.027	-1.025 to 3.047	0.327
<b>Intervention YES/NO</b>	0.345	0.170	0.007 to 0.682	0.045
Baseline FV intake	-0.383	0.087	-0.554 to -0.211	0.000
Age	0.001	0.113	-0.224 to 0.226	0.991
Gender	0.141	0.169	-0.195 to 0.477	0.408
Familiar SES	-0.087	0.172	-0.428 to 0.253	0.613

457 Dependent variable: FV intake difference between baseline and shortly after follow-up. R2=0.196.