



Rationale and design of the SI! Program for health promotion in elementary students aged 6 to 11 years: A cluster randomized trial

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Unhealthy habits in children are increasing at an alarming rate. The school provides a promising setting for effective preventive strategies to improve children's lifestyle behaviors. The SI! Program is a multilevel multicomponent school-based educational intervention aimed at all stages of compulsory education in Spain.

Here, we present the design of the SI! Program for Elementary School cluster-randomized controlled trial, targeting children aged 6 to 11 years. This trial aims to study the impact of different timings and intensities of exposure to SI! Program activities on elementary school children and their immediate environment (parents/caregivers, teachers, and school).

The trial includes 1770 children from 48 public elementary schools in Madrid (Spain), together with their parents and teachers. Schools and their children were randomly assigned to the intervention group (the SI! curriculum-based educational program over 3 or 6 academic years) or to the control group (standard curriculum). The primary outcomes are the change from baseline at 3-year and 6-year follow-up in children's scores for knowledge, attitudes, and habits (KAH) and health factors (blood pressure, height, weight, waist circumference, and skinfold thickness). Secondary outcomes include 3-year and 6-year changes from baseline in lifestyle questionnaire scores for parents/caregivers and teachers, and in the school environment questionnaire.

The overarching goal of the SI! Program is to provide an effective and sustainable health promotion program for the adoption of healthy behaviors in children. The present trial will address the impact and the optimal timing and duration of this educational intervention in the elementary school setting. (*Am Heart J* 2019;210:9-17.)

The proliferation of cardiovascular risk factors worldwide has made cardiovascular disease the largest single contributor to global mortality and morbidity.¹ Remarkably,

most of these risk factors are modifiable by changes in behavior.² Childhood, a period dominated by behavioral learning, is an excellent window of opportunity for promoting health.³⁻⁵ Schools offer a promising setting to achieve this goal because children spend the majority of their day there.⁶ Many school-based interventions have been conducted; however, few have been tested in randomized trials. Most studies have focused on preventing weight gain by addressing only one lifestyle component such as diet or physical activity, with modest overall intervention effect sizes.⁷⁻⁹ Moreover, few studies have included a long-term follow-up to assess their sustainability or evaluate the effect of different exposure durations. These results highlight the need to test optimized school-based interventions¹⁰ that target not only children, but also their families,¹¹ teachers,¹² and the school environment.¹³

The SI! Program (*Salud Integral* – Comprehensive Health) is a multilevel multicomponent educational intervention designed by the Foundation for Science, Health and Education (SHE Foundation)¹⁴ in collaboration with

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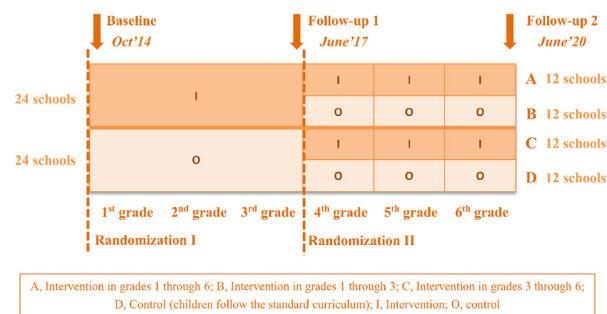
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Figure 1

Study design of the SI! Program for Elementary School.

the Spanish National Center for Cardiovascular Research (CNIC).¹⁵ The SI! Program adapts the principles of the transtheoretical model of behavior change¹⁶ with the goal of promoting a lifelong healthy lifestyle and cardiovascular health. Its content aligns with the scholar curriculum, including adaptations to each educational stage from preschool to secondary school. Uniquely, the intervention introduces the topic of emotion management as a cohesive component to enhance uptake of healthy behaviors and prevent drug abuse and addiction. While this educational strategy has shown promising results in preschool children from diverse socioeconomic backgrounds,¹⁷⁻²⁰ so far it has not been tested in older children.

Here, we describe the rationale and design of a cluster-randomized controlled trial evaluating the impact of the SI! Program for Elementary School in a large sample of primary schools in Madrid, Spain. The goal of this study is to evaluate the effect of different timings and intensities of exposure to the SI! Program activities on elementary school children (aged 6-11 years) and their immediate environment (parents/caregivers, teachers, and school).

Methods

Study design and randomization process

The SI! Program for Elementary School study is a cluster-randomized open-label intervention in which the units of randomization, intervention, and analysis are the participating schools. Elementary schooling in Spain includes primary education from the end of preschool until the start of secondary school, that is, children aged from 6 to 11 years in grades 1 to 6. To evaluate the effects of different exposures to the Program, schools were allocated for intervention in A) all elementary-school levels, B) the first 3 levels (grades 1 to 3), or C) the last three levels (grades 4 to 6); a group of control schools continued their regular curriculum (D). Randomization was carried out in two pre-specified stages (Figure 1).

At baseline, 48 schools were allocated to intervention (n = 24 schools) or control (n = 24 schools) using a

simple randomization scheme. The second randomization was timed in the middle of the elementary school period, at the end of 3rd grade; this was a stratified randomization for control and intervention schools based on the percentage of children from immigrant families (according to quartiles) and was performed to ensure a balance in cultural background across final 4 groups (A, B, C, D). The allocation sequence was generated by an independent researcher who has no interaction with schools or participants during the study. This 2-step randomization will enable us to ascertain if knowledge, attitudes, and habits (KAH) acquisition takes place progressively and if it differs between the first elementary-school period (grades 1, 2, and 3) and the second (grades 4, 5, and 6).

The study has been approved by the Madrid Regional Ethics Committee for Clinical Research (CEIC-R). Schools were informed of their allocation group in the study by mail; participation was conditional on informed consent from teachers and children's parents or legal guardians. Informed consent forms were provided to the teachers, who distributed them to parents, collected the completed forms, and returned them to the research team. Collected information is handled according to Spanish Law 15/1999 on the Protection of Personal Data, ensuring the confidentiality of all of data submitted by the participants. The study is registered in [ClinicalTrials.gov](https://clinicaltrials.gov), number NCT02428634. The reporting of this study protocol adheres to the SPIRIT guidelines.^{21,22}

Intervention

The SI! Program for Elementary School is tailored to the curriculum content at this educational stage, with adaptation of strategies and materials. Materials were developed with support from the University of Barcelona Institute of Education Sciences. The core intervention comprises teacher-led classroom activities grouped into health challenges distributed across the different levels (grades 1 to 6). The minimum intervention load is 40 hours per year in 1st and 2nd grade and 30 hours per year in 3rd to 6th grades. The levels and components comprising the educational intervention are summarized in Table I.

Briefly, the SI! Program includes 4 interrelated components coordinated in a multidimensional approach: diet (D), physical activity (PA), human body and heart awareness (HB), and emotion management (E). Through components D and PA, children learn how a well-balanced diet and an active life are directly connected to a healthy heart. The HB component helps the children to understand how the body works and how it is affected by behavior and lifestyle. The last component, E, seeks to instill protective behavioral mechanisms against substance abuse later in life by working on self-awareness, self-esteem, decision-making, and listening and communication skills.

The health challenge topics are integrated into the curricular subjects (science, physical education, music

Table I. SI! Program for Elementary School: levels of intervention and goals

Level	Goal	Strategy	Supporting materials
Children	Instill a healthy lifestyle	Healthy activities at school and at home	- Classroom materials: challenges (including audiovisual resources), Alicia's cooking workshops, Healthometer. - Family challenges - Healthy Fair
Families	Instill a healthy lifestyle in participating families	Healthy family activities and recommendations Participation in the school Healthy Fair	- Family challenges - Healthy tips for the home - SI! Program website
Teachers	Instill a healthy lifestyle in teachers	Formal training Continued counseling from the SHE Foundation educational team	- Teaching guide - Guide for emotion management in the classroom - Classroom materials: challenges (including audiovisual resources), Alicia's cooking workshops, Healthometer. - Proposal for the Healthy Fair - SI! Program website
School	Promote a healthy school environment	Healthy recommendations for schools	- Healthy School Management - Guidance for the Healthy Fair - SI! Program website

and art classes, etc.). All teachers in the intervention group have online access to program materials and a detailed teaching guide on the SI! Program website (a password for each school is provided at the beginning of the academic year).

At least 1 teacher from each intervention school receives a 30-hour formal training from the SHE Foundation's educational team and acts as the contact person for other teachers in the school. All the classroom activities end with a family-challenge set as homework. Families also receive key messages about children's health, including the importance of adequate sleep time and eating breakfast every day. The school environment intervention takes the form of an annual Health Fair and a series of recommendations provided by the SHE Foundation. The Healthy Fair is an annual week-long program of events planned and carried out by the schools that involves the whole center in health-related play activities. Schools are provided with a model itinerary for the week, including content and activities designed to include all family members and encourage their full participation.

The SI! Program differs in several respects from the standard curriculum. First, the SI! Program explores the health-related content of the standard curriculum in greater detail, with a focus on cardiovascular health; moreover, the approach used spreads the content across all subjects, giving children a global sense of the importance of health. Second, the SI! Program promotes family involvement through shared activities, such as trips to the market to buy fresh products, cooking a healthy breakfast at the weekend, or interpreting emotional expressions together. Family activities such as these do not normally form part of the standard curriculum. Third, the SI! Program places a major emphasis on fostering an awareness of emotions through the promotion of body knowledge, providing guidelines to help teaching staff and families accompany the children in this learning process. Thus, the SI! Program fosters the

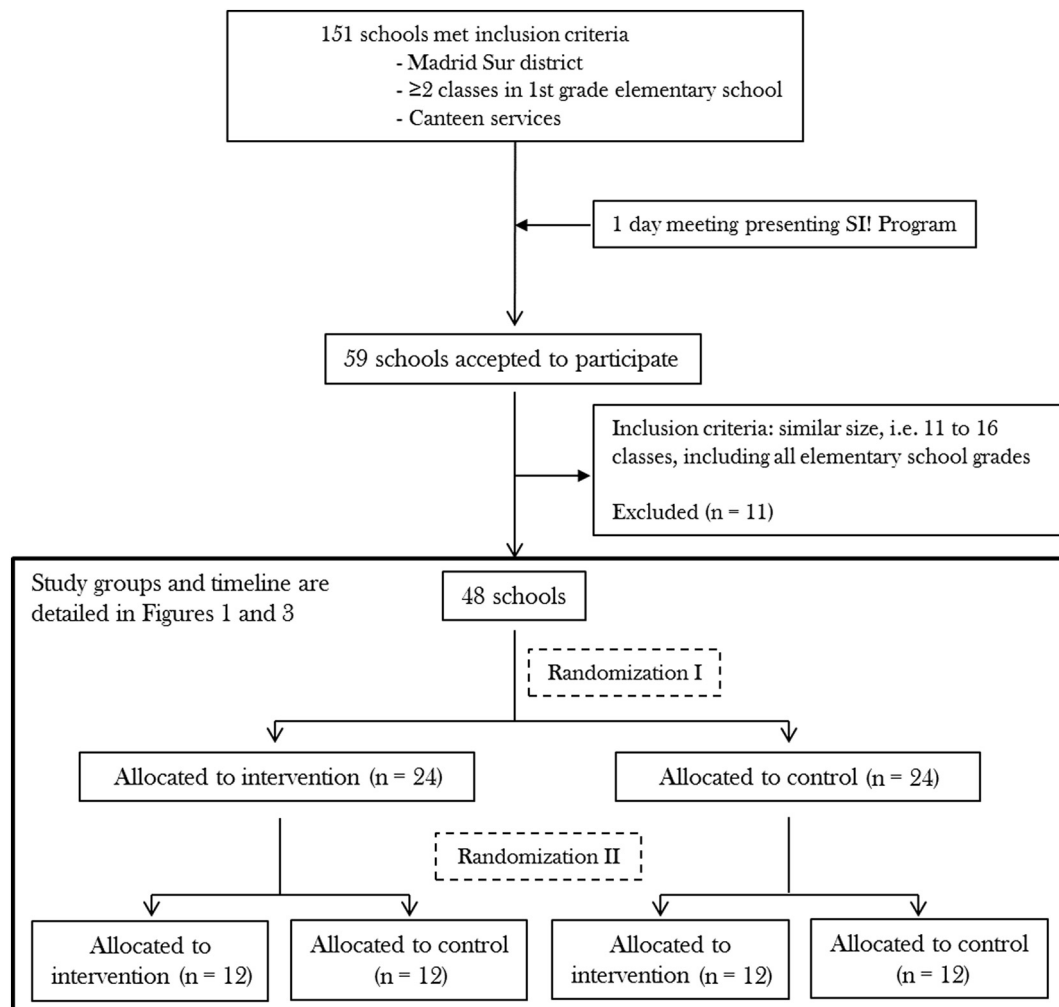
practice of activities that focus on corporeal sensations, especially through breathing, contrasting the emphasis on physical fitness that characterizes the standard curriculum. Similarly, the SI! Program seeks a broad development of attitudes and habits, eschewing the narrow focus on factual knowledge that characterizes the standard curriculum. The intervention encourages children to develop a critical attitude regarding healthy vs. unhealthy and junk food; to be aware of heart rate during physical activity; to take active breaks during class hours; and to develop self-knowledge and identify personal strengths. Finally, the intervention is supported with an animated character (*Cardio*) and his friends, who confront a number of different situations; these stories introduce children to abstract health concepts in an easy, non-intimidating way.

Adherence to the program curriculum is monitored through annual reports prepared by the assigned contact teacher at the school and the school board.

The intervention materials and strategies were tested in 9 pilot schools in Catalonia and the Community of Madrid in 2014. The teachers implementing the SI! Program in their classes completed a survey with specific questions about the Program challenges, family challenges and the Healthy Fair. The results of this pilot study (not published) helped to improve the intervention materials and strategy before starting the randomized trial.

Sample size and participants

In line with the intraclass correlation range used in previous school-based interventions and in the preceding SI! Program for Preschool study,²³ 36 schools (48 children per school) were considered sufficient to detect overall KAH score differences of 0.8 points with a power greater than 80% and a type-I error of 0.05.²⁴ In anticipation of potential loss to follow-up due to the long study duration,²⁵ 48 schools were randomized in total.

Figure 2

SI! Program for Elementary School flow chart.

The study flow chart is shown in Figure 2. To be eligible, schools must meet all the inclusion criteria: status as a public school with canteen services located in the South Madrid Education Area, provision of education from grades 1 through 6, and at least 2 classes in grade 1. The Madrid regional government education committee invited all head teachers from eligible schools (a total of 151) to a 1-day presentation of the SI! Program study design. The final 48 schools were chosen from 59 schools that initially agreed to participate; the 11 excluded schools were either too large or too small (more than 16 or less than 11 elementary stage classes).

In the 48 selected schools, all 1st grade students, their families, and their teachers were invited to participate. Participating parents or caregivers, children, teachers, and school boards have the right to withdraw from the

study at any time. Based on adherence criteria established by the SHE Foundation coordination team, schools unable to deliver 75% of the program curriculum within 2 consecutive years may be excluded from the study. Concomitant health-related programs are discouraged during the course of the trial in all participating schools, whether they are in an intervention or the control arm. Schools are advised to inform investigators about any interest in other health-related programs, and investigators additionally monitor these periodically.

Study organization

The study will be centrally coordinated by the SHE Foundation. The authors are solely responsible for the drafting and editing of the manuscript and its final contents. There was no specific funding provided for the creation of this manuscript.

Figure 3

TIMEPOINT	STUDY PERIOD							
	Enrolment	Allocation		Postallocation				
	Apr'14	Jun'14	Sept'14	Oct-Dec'14	Apr-Jun'17	Jun'17	Sept'17	Apr-Jun'20
ENROLMENT:								
Eligibility screen	X							
Information meeting	X							
School recruitment	X							
School allocation		X				X		
Informed consent from participants			X					
INTERVENTIONS:								
SI! Program, grades 1-3				←→				
SI! Program, grades 4-6							←→	
ASSESSMENTS:								
Child KAH questionnaire				X	X			X
Child anthropometry and blood pressure measures				X	X			X
Parent questionnaire				X	X			X
Teacher questionnaire				X	X			X
School environment questionnaire				X	X			X

Enrolment, intervention, and assessment schedule in the SI! Program for Elementary School.

Data collection

Questionnaires. Children's lifestyle is evaluated with a specific KAH questionnaire related to the 4 SI! Program components (D, PA, HB and E). This KAH evaluation system has been used in previous school-based interventions for health promotion as an indicator of improved lifestyle and thus as a marker of intervention effectiveness.²⁶⁻³⁰ The questionnaire was validated during the pilot study mentioned above. The questionnaire structure and validation procedure have been published elsewhere.³¹

Children's family habits and health behaviors are evaluated through a specific questionnaire related to the SI! Program's key messages for families, a general health questionnaire to calculate a cardiovascular health index,^{32,33} and a validated questionnaire about stress perception.³⁴ In addition, the survey for families includes validated questionnaires to assess children's habits (D,³⁵ PA,³⁶ and E³⁷). Teachers' lifestyles are evaluated by measuring adherence to the Mediterranean lifestyle through the Mediterranean lifestyle index (MEDLIFE)³⁸

and by the use of a validated stress perception questionnaire.³⁴ Finally, the school environment is evaluated with a questionnaire related to the recommendations provided by the intervention, including the type of food permitted on the school premises or activities to promote active travel to and from school (walking or bicycle). The pilot study also tested the questionnaires interrogating the school environment, families, and teachers.

A trained team of psychologists conducts interviews to complete children's questionnaires during school hours. Families, teachers, and school principals complete online questionnaires that are sent by e-mail through a dedicated data management application. Families without e-mail are provided with a paper questionnaire.

Anthropometric and blood pressure measurements. The SI! Program for Elementary School is evaluated according to its impact on cardiovascular health factors in participating children and selected anthropometric parameters. Body weight is measured with a Seca 803 electronic scale and height with a Seca 213 portable stadiometer, with the children wearing light

clothes and no shoes. Waist circumference is measured with a Holtain tape at the end of a gentle expiration. Triceps and subscapular skinfold thickness are measured on the right side of the body with a Holtain T/W Skinfold Caliper. Blood pressure is measured with an OMRON M6 monitor fitted with a CS2 cuff if required. Once the child is comfortable with the monitor, blood pressure is measured 3 times at 2–3 minute intervals. All measures are carried out at the school according to a standardized protocol by trained nutritionists.³⁹

All participants are evaluated at baseline and at 3 and 6 years thereafter with the same battery of questionnaires and measures. The schedule of enrolment, interventions, and assessments planned in the SI! Program for Elementary School is summarized in Figure 3, and is in accordance with SPIRIT 2013 recommendations.^{21,22} Every effort will be made to follow up all participants, including children no longer attending the original school.

Outcomes

The main overall goals of the SI! Program are to introduce an effective, sustainable health promotion program for the adoption of healthy behaviors in children, their families, and teachers and to improve the school environment. Primary outcomes are changes in children's questionnaire scores and cardiovascular health factors (blood pressure, height, weight, waist circumference, and triceps and subscapular skinfold thickness) between baseline and 3-year and 6-year follow-up. Secondary outcome measures are changes in family, teacher, and school environment questionnaire scores from baseline to post-intervention.

Statistical methods

To evaluate post-intervention changes, we will analyze data from children for the primary outcome (overall score and health factors) at baseline and at 3-year and 6-year follow-up. For each study component, we will determine the differences between the different interventions and control groups.^{19,23,40} The effect of the intervention will be tested using mixed-linear models. This methodology will allow us to account for the hierarchical cluster randomized design of the study and to adjust for baseline variables and the effect of clustering. The dependent variables analyzed for children will be the defined overall KAH score and each of the 4 components, as well as the individual health factors. Fixed effects in each model will be the corresponding baseline score and treatment group. Schools will be handled as random effects. Interaction models will be run to identify potential age-by-treatment or sex-by-treatment effects for the main outcome variable, as well as to study the influence of parental variables on the overall results. The same mixed-linear models strategy will be used to evaluate secondary outcomes. Both intention-to-treat and per protocol analyses will be performed.

The SI! Program for Elementary School study is a randomized trial consisting of repeated measurements. This design allows simultaneous testing of different hypotheses, for which investigators will draft a specific statistical analysis plan and select the appropriate data treatment and models to study associations and consider potential confounders. For every assessment time-point, cross-sectional associations between independent variables and outcomes of interest will be analyzed using multivariate linear regression models for continuous variables and logistic regression models for categorical variables. The adjustment variables will be defined a priori, depending on the research question, and will be entered into the model according to a combination of clinical and statistical criteria.

All statistical analyses will be performed using STATA version 12.0 or superior (STACORP, College Station, TX).

Discussion

The present trial will evaluate the impact of the SI! Program on health promotion in elementary school children (aged 6–11 years). The SI! Program has first been tested in the preschool setting through several cluster-randomized controlled trials involving more than 3500 preschoolers in three countries (Colombia, Spain, and USA).^{17–20} The results are promising, showing larger increases in KAH scores toward a healthy lifestyle in the intervened children.^{17–19} Before launching the present trial, the SI! Program for Elementary School was tested in a pilot study that provided a qualitative assessment of materials, educational strategies, and evaluation tools, principally the KAH questionnaire.³¹ Children beginning their elementary schooling have to make the transition to a new environment and adjust to different teaching approaches. In this age range, children develop their abilities to make conscious choices and become less dependent on external factors. Parents/caregivers and teachers are crucial to providing support and encouragement to children, including access to healthy food and opportunities for physical activity.⁴¹

Previous school-based intervention trials in this age group have shown conflicting results.^{42–45} Two recent large trials conducted in primary schools, which included long-term follow-up, failed to prevent obesity or promote healthy habits in children.^{46,47} The evidence suggests that school-based health promotion interventions might require intensive behavioral interventions with children and upstream interventions at the level of the family and the school environment.^{10–12} Incorporating these ideas, the SI! Program involves not only the participating children but also key elements of their immediate environment (family, teachers, and school). Moreover, the intervention adopts a global view of health promotion that, unlike many childhood interventions, is not limited to the prevention of obesity through fitness education or dietary advice.⁴⁸

The major limitation of the present trial is its long duration, which might increase the risk of significant loss to follow-up and dropout. However, this long duration can also be seen as a strength because it will allow assessment of different exposure durations, long-term trends, and delayed effects. Another limitation is the regular changeover in school boards, which usually takes place every 4 years, introducing the possibility of changing priorities. Likewise, teacher mobility in Spain is high and could require re-initiation of the training and familiarization process. Also, families may move home during the study period, causing study drop outs. To minimize the impact of these issues, the sample size calculation factors in potential loss to follow-up and dropout, and additional intention-to-treat analysis is carried out for baseline population characteristics. Because the included population consists of healthy children, the outcome/endpoint does not include clinical events. However, outcomes in adulthood may have their origins during childhood; therefore, primordial prevention strategies promoting healthy behaviors in childhood and adolescence are especially encouraged in current guidelines.⁴⁹⁻⁵¹ Despite the limitations listed above, we plan to implement strategies allowing us to follow up participants beyond the end of the study period.

The SI! Program study also has significant strengths. These include the accessibility of materials on the SI! Program website, the projected low relative cost when implemented on a large scale, the inclusion of emotion management as an important behavioral component, and the implementation of the program by the children's own teachers. The SI! Program is flexible and can easily be adapted to different countries, income settings, languages, and children's cognitive function level.¹⁷⁻²⁰ These characteristics make the SI! Program highly suitable for worldwide implementation. The program thus offers the potential to curtail the current cardiovascular disease epidemic through the promotion of healthier behaviors and lifestyles from early childhood.

Declarations

Ethics approval and consent to participate

The study has been approved by the Madrid Regional Ethics Committee for Clinical Research (CEIC-R): Ref. 47/324474.9/14. Informed consent is required from teachers and parents or legal guardians for children's participation in the study. Thorough information about the study and its content is given to parents and children in written form and in conversation with study researchers. Parents are also informed of their right to withdraw from the study at any time. All collected information is handled in accordance with Spanish Law 15/1999 for the Protection of Personal Data, ensuring the confidentiality of all data submitted by the participants.

Availability of data and material

The data and materials presented and referred to in SI! Program publications can be requested from the principal investigator.

Declaration of interest

None.

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Author contributions

GS, EG-P, BO and JL-P helped in study design and initial coordination. GS drafted the first version of the manuscript. PB, MdM and AdC assisted with study coordination and data collection and helped to write the manuscript. CR, VC, XO, DH, and IC contributed to the study design and the implementation of the educational program. AdC, JM-F, BI, and RF-J made substantial conceptual contributions to the study and helped to write the manuscript. VF designed and conceived the overall study. All authors revised the manuscript critically for intellectual content and approved the published version.

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Appendix. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ahj.2018.12.011>.

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