# 2022 Informe Anua **Annual Report**



SHE Foundation for Science, Health and Education

Fundación "la Caixa"



«Se destinan millones al tratamiento de la enfermedad cardiovascular, pero no suficientes en educar y promover la salud. Ambos aspectos son fundamentales para prevenir una enfermedad que ya es la primera causa de muerte en el mundo» Dr. Valentín Fuster



# Índice

Carta del presidente		4
Corazones sanos	Promoción de la salud. Una declaración de intenciones Publicaciones	8 10
Proyectos propios	Programa SI!	14
	Programa Fifty-Fifty	18
	Healthy Communities	20
Proyectos en colaboración	Estados Unidos, New York	
	Harlem – Programa «FAMILIA»	24
	5 Boroughs - Programa «CHILDREN»	25
	Colombia, Bogotá	
	Programa «Healthy Habits for Life»	26
	América Latina	
	Programa «Listos a Jugar»	27
	España	
	«Iniciativa VIVE» - Programa «FAMILIA»	28
La Fundación		32
Año 2022	«Los hábitos de vida saludables» Dra. Gloria Santos	38
	Memoria de actividades	
	Programa SI!	42
	Healthy Communities	44
	10 Aniversario	45
	Transparencia	
	El año 2022 en cifras	46
	Transparencia. Origen y destino de los recursos	47
Texts in english version		49
Anexo	Aportación a la comunidad científica	
	Conferencias y congresos	60
	School-Based Cardiovascular Health Promotion in Adolescents: A Cluster Randomized Trial. JAMA Cardiol. 2023; 8(9):816-824.	65
	Magnetic resonance imaging reference values for cardiac morphology, function and tissue composition in adolescents EClinicalMedicine 2023;57:101885.	75
	Sleep duration and its association with adiposity markers in adolescence: a cross-sectional and longitudinal study. Eur J Prev Cardiol 2023;30(12):1236-1244.	92
	Lessons Learned From 10 Years of Preschool Intervention for Health Promotion: JACC State-of-the-Art Review. J Am Coll Cardiol 2022;79:283-298.	105

# **Carta del presidente** «Si realizamos una investigación y no se publica en una revista científica de alto impacto, podemos considerar que hemos fracasado.» Dr. Valentín Euster

La Fundación SHE (Science, Health and Education) cumplió 10 años de existencia el pasado 2020. La celebración de dicha efeméride tenía previstos varios acontecimientos de conmemoración que el coronavirus nos obligó a aplazar. A pesar del decalaje producido por la pandemia, hemos mantenido las actividades previstas y las hemos llevado a cabo este año 2022, que será para siempre el año de nuestro décimo +2 aniversario. Un año muy especial.

Muchas gracias a todas las autoridades y personalidades que nos han honrado con su apoyo y asistencia a los diferentes eventos y actos que encontrarán detallados en el apartado correspondiente de este Informe Anual de actividades, además de a todo el equipo SHE que lo ha hecho posible.

10+2 años son muchos y además de animarnos a mirar el futuro con optimismo nos obligan a hacer balance y a acordarnos de muchas e importantes contribuciones.

Somos **CIENCIA**. Nos definimos como una fundación que dedica sus recursos a validar hipótesis científicas y a generar conocimiento para ser publicado en revistas científicas de impacto internacional, para contribuir así a promocionar la salud, especialmente entre niños y jóvenes. Con este fin hemos desarrollado 3 grandes intervenciones que se desarrollan ampliamente más adelante, el Programa SI! dirigido a la etapa escolar, el Programa Fifty-fifty para adultos y el Programa Healthy Communities para comunidades, como su nombre indica. Así, en estos años de existencia hemos invertido más de 11 Millones de Euros € en investigación, un 90% de nuestro presupuesto total disponible excluyendo gastos de estructura que están en un promedio del 20-25% esta es nuestra inequívoca declaración de prioridades e intenciones.

Siempre he defendido que lo que no se publica no existe y por tanto lo primero que se debe hacer al repasar nuestra travectoria es enumerar los 33 congresos en los que hemos estado presentes e impartido ponencias o la importante lista de publicaciones que verán más adelante. La Dra. Santos, responsable del equipo científico de Fundación SHE ha seleccionado 4 textos íntegros de entre los 31 disponibles, que considera relevantes por su impacto o actualidad y que adjuntamos al final de esta memoria. En el artículo de lecciones aprendidas en 10 años de promoción de salud en preescolares, describimos elementos clave en la promoción de la salud cardiovascular en el entorno escolar, que son los equipos multidisciplinares, contenido que incorpora varios componentes, estrategias dirigidas a distintos niveles de la población, coordinación local de la implementación y evaluación científica mediante ensayos clínicos aleatorizados. Adjuntamos también los resultados principales del último estudio del Programa SI! en adolescentes, donde pese al impacto de la pandemia en la marcha del proyecto hemos encontrado un factor determinante en la intensidad y la distribución del currículum impartido. Además, hemos incluido dos artículos en adolescentes que son de gran relevancia clínica, uno analiza el último factor de riesgo cardiovascular que ha incluido la AHA en sus métricas, el sueño,

y constata su asociación con indicadores de obesidad, y el otro aporta valores de referencia de dimensión y función cardiaca y propiedades del tejido miocárdico obtenidos mediante resonancia magnética.

Tras muchos años de actividad profesional combatiendo la enfermedad cardiovascular, mi presidencia de la Asociación Americana del Corazón (AHA) y de la Federación Mundial del Corazón (WHF) hace ya 20 años, me hicieron ver la importancia de la promoción de la salud a nivel global frente a la prevalencia de las enfermedades del corazón. Desde entonces, tengo el convencimiento de que un cambio en el estilo de vida de la población es el único camino para evitar la extensión de las enfermedades cardiovasculares, una verdadera epidemia, primera causa de mortalidad en el mundo. El principal factor de riesgo cardiovascular es la obesidad y sus derivadas, como la diabetes y la hipertensión, como consecuencia de una alimentación inadecuada y el sedentarismo. También influyen hábitos de vida poco saludables como el alcohol o el tabaquismo. – Por ese motivo decidí impulsar la creación de la Fundación SHE. Una fundación sin ánimo de lucro que, basándose en la investigación básica y clínica (Science), tiene como objetivo promover los hábitos saludables (Health) mediante la comunicación y la educación (Education) en la población. - Con este propósito, la Fundación SHE dedica sus esfuerzos a crear un marco de referencia de lo que significa y comporta una educación que incida en la adquisición de hábitos saludables des la infancia. La finalidad es promover un mundo donde desde niños, jóvenes y adultos tengan la capacidad de actuar positivamente hacia su SALUD.

Esto no hubiera sido posible sin el apoyo desinteresado de muchos particulares. La filantropía tiene aún mucho camino por recorrer en Europa en general y en España en particular. No obstante, en la Fundación SHE hemos sido muy afortunados y contado con el apoyo muy importante de Patronos y benefactores. Por orden conológico y empezando por mi esposa los patronos fundadores, Maria Angels Guals, Carles Vilarrubí, nuestro primer Vicepresidente, Rosa Mª Guals, Lluís Torres, Javier Solana y Joan Font, patrono Secretario. Patronos de mérito como José Mª Castellano Ríos, Isak Andic, Sol Daurella, Marc Puig, Jorge Miarnau, Emilio Ferré, Mauricio Botton Carasso, Josep Oliu, Artur Carulla e Isabel Carvajal. Benefactores como Jacques A. Nahmias y Marina Carasso, Alicia Koplowitz, José Ferrer Sala. Capítulo aparte merecen Mariano Puig y su esposa Maria Guasch por su generosa contribución a las infraestructuras necesarias para el proyecto Healthy Communities en Cardona. Gracias a todos.

Ello nos permitió encarar una fase de consolidación que se inició en 2017 con la incorporación de la Fundación "la Caixa" para poder así dar continuidad a nuestra labor investigadora como socio de referencia. Desde ese momento el nombre de la Fundación SHE se asocia a la imagen de la Fundación "la Caixa". Muchas gracias a aquellos Patronos designados por Fundación "la Caixa" que lo han hecho posible, a Àngel Font por su permanente acompañamiento, a nuestros patronos actuales Javier Solana, Esther Planas e Higini Clotas. Y sobre todo a la confianza que han depositado en mi persona y en nuestra labor a Antoni Vila, Director General de Fundación "la Caixa" y Vicepresidente de Fundación SHE y a Isidre Fainé, Presidente de la Fundación "la Caixa".

El futuro se nos presenta lleno de retos y posibilidades. 2022 es un año fundamental en nuestra corta historia. No solamente por la celebración de nuestro décimo aniversario, sino porque ha sido el ejercicio en el que han confluido dos importantes factores.

De un lado, el diseño del ensavo clínico que va a tener lugar en Madrid sobre Programa SI! va a responder a la pregunta de la sostenibilidad de las intervenciones escolares. ¿Es necesario reintervenir? El diseño científico aúna todo lo aprendido en estos más de 12 años de trabajo en el campo de la promoción de salud cardiovascular con el objetivo de mantener el efecto a largo plazo, por una parte reforzando el contenido y la estrategia para impactar en el entorno inmediato de los estudiantes (familia y ambiente escolar), y por otra parte haciendo recordatorios de los mensajes clave en las edades en las que los estudiantes van ganando autonomía y forjando sus propios hábitos. Este nuevo estudio abarcará las edades más críticas, empezando en los 7 años cuando los estudiantes ya son capaces de incorporar conceptos más abstractos como el cuidado de la salud reinterviniendo en el aula a los 10 años cuando empieza su fase más autónoma donde ya comienzan a tomar decisiones que serán relevantes para su salud en el presente y el futuro. La Dra. Santos nos da más detalles más adelante en el Informe Anual.

De otro, el momento clave del programa comunitario Healthy Communities (HC) en el que se transiciona de una fase de acompañamiento a la comunidad en la educación sobre hábitos saludables a una etapa de mayor autonomía y empoderamiento. HC busca animar los ciudadanos a tomar decisiones más saludables sobre cómo se mueven, qué comen y cómo utilizan el entorno que los rodea, para mejorar la salud mental y la felicidad. - La hipótesis es que una ciudad saludable repercutirá positivamente sobre los habitantes con la mejora de los índices de salud cardiovascular y de actividad física, la salud mental y el bienestar. ¿Lo conseguiremos? Ambas respuestas las tendremos a lo largo de estos próximos 7 años.

Decíamos al principio que el acrónimo SHE, además de llamar la atención sobre la mujer, tradicionalmente olvidada en la investigación cardiovascular, reflexiona sobre la Educación de la Salud desde la Ciencia.

Pues bien, si de **EDUCACIÓN** se trata, no quisiera finalizar estas líneas sin un último recuerdo muy sentido a mi alter ego el Dr. Ruster. Un muppet creado por Sesame Workshop que además de mi flequillo, bata y estetoscopio, quiero creer que toma lo mejor de mí. Aconseja y cuida a los personajes de Barrio Sésamo para que lleven una vida más saludable. De esta forma también se introduce la figura del médico a los niños para que entiendan que es un perfil que ayuda y proporciona información para mantener y mejorar la salud. Nuestras investigaciones han demostrado que es una exitosa forma de mostrar el papel de los profesionales de la salud y sus batas blancas a los niños de todo el mundo. Me llena de orgullo poder decir que su existencia se debe a un acuerdo de colaboración entre Fundación SHE y Sesame Workshop para producir 26 capítulos para la serie audiovisual "Monstruos Supersanos" que ha saltado fronteras y aparte de nuestro país, ha intervenido posteriormente en programas de promoción de la salud en EE.UU., México, Colombia, Brasil y el resto de Centro y Sudamérica.

El New York Times publicaba una estadística que relacionaba causa de mortalidad en EEUU y cobertura en medios de comunicación. El 30.2% de las defunciones en el país se debieron a la enfermedad cardiovascular mientras que solo el 2.5% del total de las informaciones en medios hacían referencia a las enfermedades del corazón. En contraste, el 35.6% del espacio en los medios lo ocupaba el terrorismo cuando su mortalidad era inferior al 1.8%.

Queda mucho por hacer. Move on!

Valentín Fuster Presidente Fundación SHE

# **Corazones sanos** Promoción de la salud. Una declaración de intenciones.

Tras toda una vida dedicada a la medicina y la investigación, el Dr. Valentín Fuster de Carulla, tiene el convencimiento de que un cambio en el estilo de vida de la población es el único camino para evitar la extensión de las enfermedades cardiovasculares, una verdadera epidemia y la primera causa de mortalidad en el mundo.

Factores tales como la obesidad, la adicción al alcohol, el tabaquismo y otras drogas se han convertido en los principales factores de riesgo de la enfermedad cardiovascular y provocan que año tras año aumente considerablemente el número de personas que la padecen

Los expertos coinciden en que el único modo de evitar la extensión de estas enfermedades pasa por un cambio en el estilo de vida de la población y una concienciación sobre la necesidad de promover hábitos saludables.

El reto es cómo pasar del tratamiento de la enfermedad al cuidado preventivo de la salud Las enfermedades cardiovasculares son la primera causa de mortalidad en el mundo.

- El principal factor de riesgo cardiovascular, tanto en adultos como en niños, es la obesidad y sus factores asociados como la diabetes y la hipertensión, fruto de una alimentación inadecuada y de unos bajos niveles de actividad física.

 Las adicciones al alcohol, tabaquismo y otras drogas también son importantes factores de riesgo de la enfermedad cardiovascular. La proliferación de estos hábitos inadecuados entre la población aumenta el número de enfermos cardiovasculares año tras año.

 Una esperanza de vida más larga, gracias a la medicina más avanzada y las nuevas tecnologías, está provocando una carga social y económica insostenible para nuestra sociedad.



8 Carta del presidente

Proyectos en colaboración Anexo

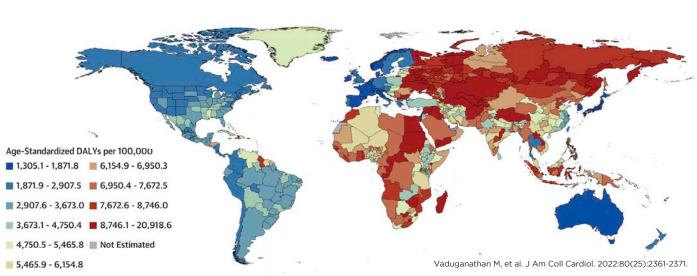
Año 2022

## «¿Qué pasaría si la sociedad fuera capaz de modificar sus rutinas actuales y adquirir hábitos saludables?»

Dr. Valentín Fuster

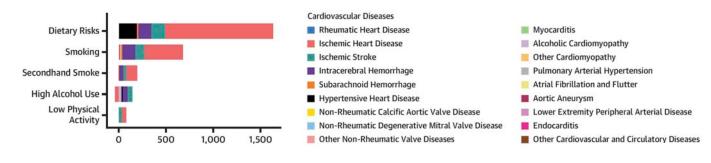
Las enfermedades cardiovasculares (ECV), que consisten en cardiopatía isquémica, accidente cerebrovascular, insuficiencia cardíaca, enfermedad arterial periférica y otras afecciones cardíacas y vasculares, constituyen la principal causa de mortalidad mundial y contribuyen en gran medida a la reducción de la calidad de vida. En 2017, las enfermedades cardiovasculares causaron aproximadamente 17,8 millones de muertes en todo el mundo, lo que corresponde a 330 millones de años de vida perdidos y otros 35,6 millones de años vividos con discapacidad.

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#### **Global Burden of Cardiovascular Diseases and Risks**

#### **Behavioral Risks**



# **Corazones sanos** Publicaciones

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- 2. de Cos-Gandoy A, Santos-Beneit G, Bodega P et al. The role of socioeconomic background on cardiovascular health promotion in early childhood. J Am Coll Cardiol 2023;In Press.
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# **Proyectos propios** Programa SI!

### Hipótesis

La adquisición de hábitos saludables desde la infancia reduce los riesgos de la enfermedad cardiovascular y mejora la calidad de vida

Los datos demuestran que en nuestras sociedades existe una persistencia de estilos de vida poco saludables, que comienzan en la infancia y se perpetúan en la edad adulta.

El principal factor de **riesgo cardiovascular**, tanto en adultos como en edad infantil, es la **obesidad** y sus factores asociados (diabetes e hipertensión), fruto de una alimentación inadecuada y de unos bajos niveles de actividad física. Los datos epidemiológicos indican que estos factores se presentan cada vez en edades más tempranas y que los estilos de vida poco saludables que se adquieren en la infancia, se perpetúan hasta la vida adulta.

Además, otros factores de riesgo cardiovascular, como la adicción al alcohol, el tabaco y otras drogas, también empiezan a estar presentes en la población preadolescente española. La investigación en salud pública ha señalado que las iniciativas de promoción de la salud deben comenzar en la infancia para conseguir un cambio de comportamiento duradero y eficaz. El Programa SI! consiste en una intervención en centros educativos para promocionar la salud cardiovascular desde la etapa preescolar. Su objetivo es demostrar que la adquisición de hábitos saludables desde la infancia reduce los riesgos de la enfermedad cardiovascular y mejora la calidad de vida en la edad adulta. Las cuatro áreas básicas que se trabajan en el programa son:

- » Adquisición de hábitos de alimentación saludable
- » Desarrollo de la actividad física
   » Conocimiento del funcionamiento del cuerpo y del corazón
- » Gestión de las emociones

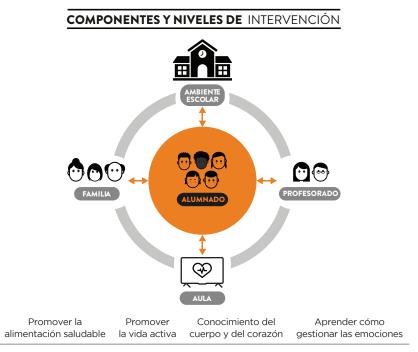


Figura 1. Componentes y niveles de intervención del Programa SI!

Año 2022

Anexo



El programa actúa en cuatro niveles: ambiente escolar, profesores, familias y alumnos.

La intervención a nivel del ambiente escolar se realiza mediante comunicaciones periódicas al equipo directivo y al dinamizador del centro para su posterior distribución entre profesorado.

La actuación a nivel del profesorado pretende por un lado concienciar al equipo docente de la realidad de la enfermedad cardiovascular y de la importancia de su contribución como formadores en la adquisición de hábitos saludables en la población escolar y, por otro lado, formar al profesorado en hábitos saludables y en la metodología a seguir para impartir el programa en el aula y facilitarles materiales y herramientas de trabajo a los alumnos. Esta formación, de 30 horas, para los profesores encargados de impartir los contenidos está acreditada por las distintas Administraciones Autonómicas. Los contenidos del programa en su desarrollo fueron contrastados por psicopedagogos y por el profesorado de los centros, además de ajustarse al currículum escolar. Se hace especial hincapié en la implicación de los mismos para conseguir cambios de rutinas y hábitos en el entorno familiar.

La Fundación SHE ha realizado varios estudios científicos en distintas Etapas Educativas para demostrar la hipótesis del Programa SI!.

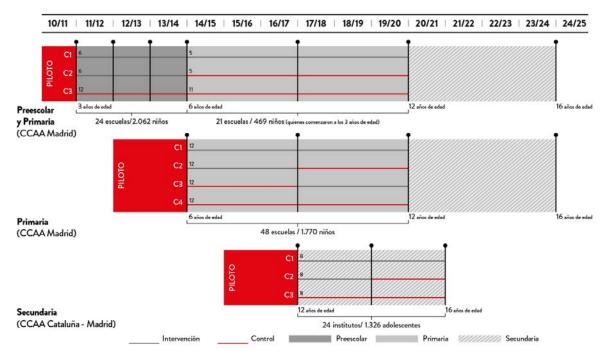


Figura 2. Estudios Científicos del Programa SI! en Etapa Infantil, Primaria y Secundaria.

# **Proyectos propios** Programa SI!

### Etapa Educativa de Infantil

Se llevó a cabo de 2011 a 2014 en 24 escuelas públicas de Madrid mediante un estudio controlado, aleatorizado. La mitad de los colegios que participaron en el estudio fueron asignados aleatoriamente al grupo intervención, cuyos alumnos realizaron un mínimo de 30 horas de actividades por curso académico en torno a los componentes del programa sobre gestión de emociones, actividades adicionales los fines de semana con los familiares, ferias anuales de salud etc. Los alumnos de los colegios restantes (control) continuaron con su currículum habitual.

Una decena de investigadores del Centro Nacional de Investigaciones Cardiovasculares y del Hospital Mount Sinai evaluaron la eficacia del **Programa SI!** en 2.062 niños de 3 a 5 años. Los resultados del estudio mostraron que la implantación del programa produjo un incremento significativo por parte de los niños en los conocimientos, actitudes y hábitos saludables, así como una mejora de los marcadores de adiposidad. En conclusión, el **Programa SI!** aporta nuevos y valiosos datos sobre los beneficios de una intervención temprana en la edad preescolar para fomentar hábitos de vida saludables. Según el Dr. Fuster, *"el programa tiene sus bases en que entre los 3 y 6 años de edad desarrollamos nuestra conducta como adultos; la enfermedad cardiovascular tiene mucho que ver con la conducta, con lo cual es la ventana de la oportunidad"*.

Este estudio, además, utiliza un diseño innovador, ya que amplía el papel de los médicos para abarcar también la comunidad educativa. Asimismo, incorpora un protocolo y una evaluación estructurada, algo que suele faltar en las intervenciones de salud pública comunitarias. El programa además coordina las familias y los educadores a través de los alumnos, lo que puede garantizar la sostenibilidad de la intervención.

En la actualidad, el **Programa SI!** se ha extendido a más de 125 escuelas de la Comunidad de Madrid, Cataluña y Galicia.

### Etapa Educativa de Primaria

Se llevó a cabo un estudio aleatorizado, en Madrid, de 2014 hasta 2020 en niños de 6 a 11 años. Participaron 48 colegios públicos de 16 municipios del sur de Madrid, con un total de 1.770 niños, sus familias y sus profesores. Se realizó una aleatorización en 4 grupos de colegios con distinta exposición al Programa SI!. Con este diseño se pretendió evaluar el efecto del programa en distintos momentos y con distinta intensidad. De forma adicional, se hizo un seguimiento de los niños participantes en el estudio de la Etapa Infantil. De esta forma, se pretende evaluar el efecto del Programa a largo plazo y con distinta intensidad de exposición a la intervención.



### Etapa Educativa de Secundaria

El proyecto, de 2017 hasta 2021, que adjudicó la Marató de TV3 en colaboración con la Universidad de Barcelona y el Centro Nacional de Investigaciones Cardiovasculares. Incluía 1.326 adolescentes de 12 a 16 años de 24 institutos públicos del norte de Madrid, Barcelona y Baix Llobregat. Al inicio del estudio, la mayoría de los adolescentes jóvenes inscritos en el ensayo del Programa SI! tenían una salud cardiovascular mala o intermedia, y sólo el 11% de ellos presentaba una salud cardiovascular ideal. El componente individual con menor puntuación fue el de los hábitos alimentarios, ya que sólo el 0,6% de los adolescentes cumplía las recomendaciones ideales. El estatus de bajos ingresos familiares auto declarados, el bajo nivel educativo de los padres y la condición de inmigrante se asociaron con una peor salud cardiovascular de los adolescentes. Las intervenciones de promoción de la salud deben aplicarse a edades tempranas, con especial atención a los hábitos dietéticos y a los entornos socioeconómicos bajos.

Actualmente se están analizando los datos recogidos en los estudios.

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# Proyectos propios **Programa Fifty-Fifty**

#### **Hipótesis**

Si se capacita a los adultos en conocimientos, habilidades y actitudes sobre un estilo de vida saludable. entre iguales, estos mejorarán sus hábitos de salud cardiovascular y el autocontrol de los factores de riesgo

La primera causa de mortalidad o discapacidad en España y en el mundo son las enfermedades cardiovasculares.

La asociación Americana del Corazón define que en España la salud cardiovascular es pobre, y menos del 1% de la población presenta un estilo de vida saludable, es decir, sólo ese pequeño porcentaje de la población alcanza valores ideales en los 7 indicadores de la salud cardiovascular. Algunos de los factores de riesgo para el desarrollo de enfermedades cardiovasculares y que padecen los adultos en España son sobrepeso (36%), obesidad (17%), sedentarismo (37%), tabaquismo (27%) o tensión arterial elevada (Figura 1).

La Fundación SHE, en colaboración con la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AESAN) pusieron en marcha el estudio científico del Programa Fifty-Fifty, diseñado por el Dr. Valentín Fuster, que tiene como objetivo mejorar la salud integral en adultos de entre 25 y 50 años, ayudándoles a autocontrolar los principales factores de riesgo para estas patologías.

Después de un estudio piloto en Cardona, el Dr. Fuster desarrolló el estudio científico en 7 localidades españolas (Figura 2) en la colaboración de la Federación Española de Municipios y Provincias (FEMP), y los ayuntamientos de los municipios participantes. Participaron 543 personas (71% mujeres) con al menos un factor de riesgo cardiovascular.

La intervención se basó en elementos de la Teoría Cognitiva Social que incluyen el aprendizaje observacional, el refuerzo, el autocontrol y la autoeficacia. Al inicio los participantes recibieron talleres dirigidos a promover hábitos de vida saludables, como gestión del estrés, cesación tabáquica y autocontrol de la tensión arterial, entre otros. Posteriormente los participantes fueron divididos aleatoriamente en dos grupos (1:1). El grupo de intervención, siguió dinámicas de grupo durante 12 meses de duración, y el grupo control, del que simplemente se hizo seguimiento durante el mismo periodo de tiempo.

Se realizaron valoraciones continuadas a los participantes durante el estudio: al inicio del programa, después de los talleres formativos, a los 12 meses (después de las dinámicas de grupo) y a los 40 meses.

El resultado principal evaluado en el estudio fue el cambio medio en una puntuación compuesta relacionada con presión arterial, el ejercicio, el

Sedentarismo







Obesidad

Tensión arterial

Tabaquismo

Figura 1. Factores de riesgo cardiovasculares

Alimentación no saludable



#### 🕻 Fundación "la Caixa"

peso, la alimentación y el consumo de tabaco (puntuación Fuster-BEWAT).

Los resultados obtenidos del estudio, acompañados de una evaluación científica rigurosa, confirman que educar a los adultos en conocimientos, habilidades y actitudes sobre un estilo de vida saludable, acompañado del apoyo entre iguales, mejora los hábitos de salud cardiovascular y el autocontrol de los factores de riesgo, además, confirma la importancia de dar continuidad a las dinámicas de apoyo.

Algunas empresas españolas como Port Aventura (parque temático) y AMPO (fundición de acero) han aplicado el Programa Fifty-Fifty con el objetivo de dar herramientas que permitan mejorar la salud cardiovascular de sus trabajadores.

Aplicar estos programas de promoción de hábitos saludables suponen una ayuda para sensibilizar a la población, debido a que, en palabras del Dr. Fuster «no hay que prevenir enfermedades, hay que promover la salud».

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# **Proyectos propios** Programa Healthy Communities

### Hipótesis

En el Programa Healthy Communities son los miembros de la misma comunidad quienes promueven el cambio del paradigma de salud en su ciudad

La epidemia de enfermedades cardiovasculares son el resultado de la sociedad de consumo en la que vivimos. Deben ser abordadas mediante estrategias multisectoriales de promoción de la salud y prevención primaria que fomenten un estilo de vida saludable y reduzcan los **factores de riesgo cardiovascular**, la morbilidad y la mortalidad.

Aunque la mortalidad por enfermedades cardiovasculares ha mostrado una tendencia decreciente en los países desarrollados, confirmada también en España, la combinación de factores como la mayor esperanza de vida de la población, el incremento de la supervivencia de los pacientes después de un evento cardiovascular, o la urbanización y sus efectos derivados (como el sedentarismo, la obesidad, los cambios en hábitos dietéticos y el tabaquismo) contribuyen a que la prevalencia de estas enfermedades siga siendo alta. Ante esta situación, es necesario focalizar los esfuerzos no solo en el tratamiento de las enfermedades cardiovasculares, sino en la promoción de la salud y de estilos de vida

saludable. Por ello, los expertos defienden que los programas de intervención comunitaria de promoción de la salud integral pueden tener un impacto significativo en la salud cardiovascular.

El Programa **Healthy Communities,** implementado en la ciudad de Cardona (Barcelona, España) cuenta con la colaboración del Ayuntamiento de la localidad.El programa pretende promover el desarrollo de estilos de vida saludables a lo largo de todas las etapas de la vida y de contribuir a favorecer la calidad de vida, a corregir los hábitos de salud y a autocontrolar los principales factores de **riesgo de las enfermedades cardiovasculares**, como el sobrepeso, la obesidad, la inactividad física, la presión arterial o el tabaquismo.

Se pretende convertir la ciudad de Cardona en un modelo de ciudad saludable a seguir, dando prioridad a sus habitantes, a partir



Proyectos en colaboración

#### Foundation for Science, Health and Education HC Healthy Communiti

 <u>Fundación "la Caixa"</u>

de la creación de entornos físicos (urbanismo saludable) y sociales (entorno) que promuevan la salud y pueda llegar a ser un modelo replicable para el desarrollo de municipios. En la fase piloto del proyecto se organizaron actividades comunitarias que involucraron a los vecinos de Cardona según sus capacidades, se organizaron conferencias sobre salud y se impartieron talleres formativos y motivacionales, por "promotores de salud" formados específicamente para el programa, para la promoción de hábitos de vida saludables.

Por otra parte, el programa incluyó un ambicioso plan urbanístico para promover la actividad física entre la población. En este estudio piloto, aproximadamente el 10% de la población de la ciudad de Cardona fue evaluada longitudinalmente en los años 2014 (inicio del estudio piloto), 2016 (impacto de las actividades piloto de promoción de la salud) y 2018 (sostenibilidad, fin del estudio piloto). Los resultados preliminares fueron prometedores y mostraron mejoras en los componentes de actividad



# **Proyectos propios** Programa Healthy Communities

física y dieta. Estos resultados justificaron el desarrollo de la siguiente fase del proyecto donde el impacto de la creación de una Ciudad Saludable será evaluado adecuadamente mediante un estudio cuasi experimental y resultados relevantes, de modo que el modelo pueda ser aceptado y replicado en otros lugares. Se trata del **Programa Healthy Communities (HC-2030)**.

El **Programa Healthy Communities (HC-2030)**, iniciado en otoño de 2021, al promover un estilo de vida más activo, debería animar a los ciudadanos a tomar decisiones más saludables sobre cómo se mueven, qué comen y cómo utilizan el entorno que les rodea para mejorar la salud mental y la felicidad.

La hipótesis es que una ciudad saludable repercutirá positivamente en sus habitantes mejorando los índices de salud cardiovascular y de actividad física, la salud mental y el bienestar. Para ello, se ha iniciado un estudio de intervención longitudinal controlado basado en la comunidad con 2.000 participantes (1.000 en la ciudad de intervención que es Cardona y 1.000 en la de ciudad control que es Sallent) a partir de 12 años durante un periodo de 5 años.

### El **Programa Healthy Communities** es una

iniciativa multidisciplinar que dará lugar a un conjunto de herramientas para una intervención de promoción de la salud, impulsada por la comunidad, que podría reproducirse en ciudades y pueblos tanto a nivel nacional como internacional.

El criterio de valoración primario será la diferencia entre grupos (ciudad intervenida frente a la ciudad de control) para el cambio en la puntuación Fuster-BEWAT, que consiste en una escala de 0 a 15 para los comportamientos/factores de salud relacionados con la presión arterial, el ejercicio, el peso, la alimentación (dieta) y el consumo de tabaco (fumar).

El núcleo de la intervención se basará en los anteriores programas de promoción de la salud desarrollados y evaluados por la Fundación: el **Programa SI!** para niños y adolescentes, y el **Programa Fifty-Fifty** para adultos.

3 – 5 SI! Infantil 6 – 11 SI! Primaria

12 - 16 a SI! Secundaria 17 - 24 Fifty-Action 25 – 50 Fifty-Fifty

51 – 66 Fifty-Plus I +66 Fifty-Plus II

| 22

Carta del presidente Proyectos en colaboración La Fundación Año 2022

El efecto de estas intervenciones fue comprobado mediante ensayos aleatorios y los resultados fueron publicados en revistas de alto impacto (Journal of the American College of Cardiology, American Heart Journal, American Journal of Medicine, etc.).





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# **Proyectos en colaboración** Programa «FAMILIA» Programa «CHILDREN»



Estados Unidos, New York, Harlem Programa «FAMILIA»

El estudio incluyó a 562 niños de entre 3 y 5 años de 15 colegios de la ciudad de Nueva York en la comunidad de alto riesgo de Harlem, junto con 1.000 adultos, con el objetivo de demostrar que la educación en **hábitos de vida saludables** desde una edad temprana mejora los conocimientos, actitudes y hábitos de los más pequeños y una intervención en adultos puede reducir el riesgo de enfermedades cardiovasculares y mejorar la calidad de vida. El estudio integró 3 proyectos de investigación distintos:

1) Evaluación del impacto en la salud cardiovascular de un programa educativo comunitario de promoción de la salud integral (Programa SI!) focalizado en cuatro áreas (alimentación, conocimiento del cuerpo y corazón, actividad física y gestión emocional), dirigido a niños en edad preescolar y a sus padres o tutores.

 2) Análisis de múltiples estrategias de intervención en el estilo de vida en adultos.

Evaluación de posibles
 cambios genéticos ligados a los
 cambios de conducta en los niños y
 los padres o tutores.

☐ <u>https://fundacionshe.org/har-</u> lem-new-york-programa-familia/

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Children's Lifestyle, Diet & Exercise Intervention

## Estados Unidos, New York, 5 Boroughs Programa «CHILDREN»

El Proyecto CHILDREN (CHIldren's Lifestyle, Diet and exeRcise intErveNtion) de Mount Sinai Heart, en la Escuela de Medicina Icahn, promueve la salud cardiovascular en los cinco distritos de Nueva York, proporcionando a los niños conocimientos y habilidades para evitar factores de riesgo cardiovascular a lo largo de sus vidas.

Este proyecto, tiene como objetivo comprender mejor cómo influye en el comportamiento de los niños su contexto socioeconómico y su entorno más inmediato, y en consecuencia, en los factores de riesgo cardiovascular.

El estudio **CHILDREN** pretende proporcionar un programa de promoción de salud cardiovascular (Programa SI!) a casi 2.000 colegios en los cinco distritos de Nueva York.

El proyecto **CHILDREN**, comenzó en el invierno de 2020 en un estudio piloto para cinco escuelas públicas de la ciudad de Nueva York y en otoño de 2021 se ha lanzado el estudio completo en Manhattan antes de expandirse a los cinco distritos.

El programa se basa en las iniciativas educativas de Sesame Workshop y la Fundación SHE

https://fundacionshe.org/proyecto-de-salud-infantil-e-implicaciones-socioeconomicas-children

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# **Proyectos en colaboración** Programa «Healthy Habits for Life» Programa «Listos a Jugar»



# Colombia, Bogotá Programa: «Healthy Habits for Life»

El Dr. Fuster puso en marcha un estudio en 2009 de intervención comunitaria en colaboración con «Barrio Sésamo» y «Plaza Sésamo».

El objetivo del programa, dirigido a niños de 3 a 5 años a padres y profesores, era promover el desarrollo de hábitos saludables perdurables hasta la edad adulta, a través de actividades lúdicoeducativas relacionadas con la nutrición, un corazón saludable y la importancia del ejercicio físico. El estudio, llevado a cabo en Bogotá, Colombia, incluyó a 1.216 niños de 3 a 5 años, 928 padres y a 120 profesores de 14 escuelas.

Sin embargo, se hizo una reintervención 7 años más tarde a 596 niños de entre 9 y 13 años del primer estudio, y se comparó con un grupo de 620 niños de la misma edad que no habían sido intervenidos en la etapa preescolar. No se encontraron diferencias estadísticamente significativas entre los grupos después de la intervención a los 9-13 años, por lo que parece importante que las estrategias de re-intervención se realicen a edades más tempranas para mantener un efecto sostenido de la intervención preescolar.

https://fundacionshe.org/colombia-healthy-habits-for-life/

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#### América Latina

# Programa: «Listos a Jugar»

Durante más de una década Sésamo ha colaborado con el Dr. Valentín Fuster para promover la salud y el bienestar cardiovascular, educando a los niños para que lleven estilos de vida más saludables en Colombia, España y Harlem (Nueva York). Conjuntamente, se creó un personaje (el Dr. Ruster), así como medios de comunicación y materiales de divulgación. Durante este periodo, el equipo del Dr. Fuster ha llevado a cabo una investigación rigurosa sobre los beneficios a largo plazo del uso de materiales de Barrio Sésamo en las intervenciones de promoción de la salud durante los años preescolares.

Sobre la base de este trabajo inicial, el programa «Listos a Jugar» de Sésamo se lanzó en 2019 como una respuesta regional a la alta incidencia de la obesidad y la diabetes en los niños de América Latina. El programa ha llegado a más de 11 millones de personas, principalmente a través de los medios de comunicación. Inicialmente financiado por socios públicos y privados, incluía una serie de televisión de 26 episodios, recursos digitales que incluían una aplicación y un sitio web, y recursos para cuidadores y educadores. Desde entonces, se ha distribuido en Bolivia, Brasil, Colombia, Ecuador, México y otros países de Centroamérica.

 <u>https://fundacionshe.org/pro-</u> grama-listos-a-jugar-america-latina/



# **Proyectos en colaboración** Iniciativa VIVE - Programa «FAMILIA»

# 

En marzo de 2011, la Fundación Pro CNIC y la Fundación SHE firmaron un convenio de colaboración bajo el nombre Iniciativa "VIVE", con el objetivo de aunar esfuerzos para mejorar la salud cardiovascular en población adulta. De esta firma nació un plan de coordinación conjunto liderado por el doctor Valentín Fuster, director del Centro Nacional de Investigaciones Cardiovasculares (CNIC).

#### España,

## Programa «FAMILIA»

En el marco de Iniciativa Vive, Salud en Familia es un programa de promoción de la salud cardiovascular dirigido a aquellas personas que quieren llevar a cabo cambios en sus hábitos de vida y en los de su entorno, con el objetivo de mejorar la salud de forma integral.

El programa está orientado para ser aplicado en familia porque practicar actividad física, comer saludable y hablar de nuestros estados emocionales, en definitiva, **ser saludable, es una forma de vida que se consigue en equipo**.

Gran parte de los hábitos de vida que tenemos en la edad adulta se desarrollan a partir de actitudes, conocimientos y conductas que adquirimos en la infancia y la adolescencia y que se establecen en la juventud. Los niños y las niñas no pueden ser saludables sin la ayuda de las personas de su entorno ya que **en estas edades no tienen autonomía para tomar decisiones sobre sus hábitos**. Además, las personas adultas **somos su referente y una fuente importante de aprendizaje** a través de la **imitación**.

A lo largo de las unidades que forman este programa se trabajan **contenidos relacionados con los principales factores de protección del corazón** a través de juegos, manualidades y actividades divertidas, con los que mayores y pequeños disfrutarán de tiempo juntos a la vez que cuidan su salud.



# Proyectos

# "Si se puede hacer en NYC, se puede hacer en cualquier lugar"

Dr. Valentín Fuster

# **ESTADOS UNIDOS**

GDP per capita USD 70,248 Familia (PSI! + Fifty-Fifty) 2015 Children PSI! 2023

MÉXICO GDP per capita USD 10,045 Fifty-Fifty 2016 PSI! Listos a Jugar Escuelas 2021

# COLOMBIA

GDP per capita USD 6,104 PSI! Infantil 2009

PSI! Primaria 2016

- PSI! Listos a Jugar Escuelas 2022
- PSI! Listos a Jugar Centros de Salud 2022

GRANADA

GDP per capita USD 9,010 Fifty-Fifty 2008

# BRASIL

GDP per capita USD 7,507 PSI! Listos a Jugar Escuelas 2022

**RENTA ALTA** 

# **ESPAÑA**

GDP per capita USD 30,103 PSI! Infantil 2011 PSI! Primaria 2014 PSI! Secundaria 2017 PSI Reintervención Primaria 2023 Fifty-Fifty 2013 Healthy Communities Cardona 2015 Healthy communities Cardona-Sallent 2021

**RENTA MEDIA ALTA** 

# La Fundación



El **Dr. Fuster** impulsa la creación de SHE en 2009, una fundación sin ánimo de lucro que, basándose en la investigación básica y clínica (*Science*), tiene el objetivo de promover los hábitos saludables (*Health*) mediante la comunicación y la educación (*Education*) a la población. En 2017, la Fundación "la Caixa" se incorporó al Patronato de la **Fundación SHE** para dar continuidad a su labor investigadora.

Con este propósito, la Fundación SHE dedica sus esfuerzos a crear un marco de referencia de lo que significa y conlleva una educación que incida en la adquisición de hábitos saludables desde la infancia, a fin de promover un mundo donde niños, jóvenes y adultos tengan la capacidad de actuar positivamente hacia su salud.

Porque si la sociedad reduce riesgos, también reduce el impacto de las enfermedades cardiovasculares.

Por ese motivo, la Fundación SHE se dedica a validar hipótesis científicas y a generar conocimiento que se publica en destacadas revistas, para promocionar la salud, especialmente entre niños y jóvenes. Para contribuir a este fin desarrolla varios programas de formación.



# Ciencia

Pretendemos ser un referente a nivel científico gracias a nuestro rigor y nuestros métodos en la evaluación de cualquier proyecto o programa de salud que promovamos desde la fundación.

# Salud

Promovemos la salud como prioridad incidiendo en los factores de riesgo que disminuyen la enfermedad cardiovascular y mejoran la calidad de vida.

# Educación

Queremos crear un marco de referencia sobre lo que significa y comporta una educación en salud que incida en a adquisición de hábitos saludables para toda la vida. «La prevención de la enfermedad y la promoción de la salud son la clave para reducir la prevalencia de la enfermedad cardiovascular en el mundo» Dr. Valentín Fuster

### Patronato

**Dr. Valentín Fuster de Carulla** Patrono fundador – Presidente

**Sr. Antonio Vila Bertrán** Patrono de mérito, Fundación "la Caixa" - Vicepresidente

**Sr. Carles Vilarrubí Carrió** Patrono fundador – Vicepresidente

**Excmo. Sr. Javier Solana de Madariaga** Patrono fundador

Sr. Lluís Torres Arro Patrono fundador **Sra. Isabel Carvajal Urquijo** Patrona de mérito

**Sr. Higini Clotas Cierco** Patrono de mérito, Fundación "la Caixa"

**Sra. Esther Planas Herrera** Patrona de mérito, Fundación "la Caixa"

**Sr. Joan Font Torrent** Patrono Secretario

Fundación "la Caixa" se incorporó en 2017 al patronato de la Fundación SHE para dar continuidad a su labor investigadora.



# La Fundación

# Equipo de la Fundación

# Área Pedagógica

# Dirección Pedagógica Isabel Carvajal

Licenciada en Biología. Especialidad en Genética y Fisiología. Universidad Complutense de Madrid.

# Equipo Pedagógico Domingo Haro

Licenciado en ciencias de la actividad física y el deporte. INEFC Barcelona - Universidad de Barcelona.

## Belén Blanco

Doble Grado: Derecho y Ciencias Políticas. Universidad Autónoma de Madrid.

## Carla Rodríguez

Licenciada en Psicología y Posgrados en Inteligencia Emocional y Psicología positiva. Universidad Complutense de Madrid.

# Xavier Òrrit

Doctorado en Educación física y del deporte. Universidad Autónoma de Barcelona.

#### Anna Badia Licenciada en CAFE y Magisterio Lenguas extranjeras. Universidad de Barcelona.

# Natalia Montilla

Licenciada en psicología. Universidad Autónoma de Barcelona.

# Área Científica

Dirección Científica **Gloria Santos** Doctora en Biología. Universidad Complutense de Madrid.

### Equipo Científico Patricia Bodega

Nutricionista (Universidad San Pablo CEU) y Doctoranda en Ciencias de la Salud y el Deporte (Universidad de Zaragoza).

## Amaya de Cos

Máster en Bioestadística y Doctoranda en Biología. Universidad Complutense de Madrid.

## Mercedes de Miguel

Licenciada en Biología y Máster en Gestión de Proyectos. Universidad de Salamanca.



Foundation for Science, Health and Education



# Administración

Administración general **Carles Peyra** Licenciado en ciencias empresariales y Máster

### Administración y finanzas **Rafael Badia**

en Dirección de Empresas (ESADE).

Diplomatura en ciencias empresariales Universidad de Barcelona y posgrado en dirección financiera (EADA)

## Ester Pla

Diplomatura en turismo. Escuela superior de Turismo Jesuitas Sant Ignasi.

# Colaboradores

Comunicación Olga Montilla Grado en Publicidad y Relaciones públicas. Universidad Pompeu Fabra.

Calidad **Pilar Altarriba** Gestión de Proyectos. Universidad Autónoma de Barcelona.

Pedagogía Vanesa Carral Doctorada en Psicología-Neurociencia. Universidad de Barcelona.

## Colaboradores





















Generalitat de Catalunya

Departament d'Educació

Atenció Primària Catalunya Central

Salut/Institut Català de la Salut/

Concello de OURENSE Educación









# Los hábitos de vida saludables Dra. Gloria Santos

Responsable equipo científico Fundación SHE

Los hábitos de vida saludables son una herramienta de indudable potencia para la prevención de la enfermedad cardiovascular. Muchos de los principales factores de riesgo cardiovascular son modificables y están estrechamente relacionados con los estilos de vida. Los programas de promoción de salud cardiovascular son fácilmente adaptables a las distintas edades, y puesto que cada persona intervenida puede impactar en su entorno inmediato, la propagación puede ser exponencial y estas iniciativas pueden impregnar un hogar, un aula, todo un centro escolar, el entorno laboral de una empresa o un municipio entero. Los proyectos del Dr. Fuster en materia de promoción de salud abarcan todas las edades y multitud de entornos.

El Programa SI! es un programa educativo escolar de promoción de la salud dirigido a niños de 3 a 16 años diseñado para retrasar la aparición y disminuir los factores de riesgo de enfermedad cardiovascular. Basado en una visión global de promoción de la salud, el contenido educativo del Programa SI! bascula entre cuatro componentes relacionados estrechamente con la salud cardiovascular: alimentación, actividad física, funcionamiento del cuerpo y del corazón, y gestión de las emociones. En 2009 en Bogotá (Colombia) se llevó a cabo el primer proyecto en entorno escolar del Dr. Fuster, liderado por Mount Sinai y la Fundación Cardioinfantil del Instituto de Cardiología de Bogotá, y en colaboración con Sesame Street, donde se aplicó una versión preliminar del Programa SI! en 7 colegios y se comparó el efecto con otros 7 colegios control. Un total de 1216 niños de 3 a 5 años participaron junto con sus familias y sus profesores y se obtuvo una mejora en conocimientos, actitudes y hábitos en relación con la alimentación y la actividad física favorable al grupo que recibió el programa educativo que se mantuvo durante 3 años pero que se terminó perdiendo 6 años más tarde.

En 2009, en España se incorporó un cuarto componente al Programa SI!, la gestión emocional, que se ha convertido en una de sus piezas fundamentales. Desde entonces, se ha ido adaptando el Programa a los distintos niveles educativos, realizando estudios aleatorizados con la colaboración del Centro Nacional de Investigaciones Cardiovasculares entre otras entidades en Educación Infantil (con más de 2000 niños y niñas de 3 a 5 años de edad), Educación Primaria (en casi 1800 estudiantes de 6 a 11 años) y Educación Secundaria (con 1300 adolescentes de 12 a 16 años). En todos estos estudios se aplicaron cuestionarios sobre aspectos relacionados con la salud cardiovascular y se llevaron a cabo mediciones de una serie de parámetros como la presión arterial, el perímetro de la cintura, la talla y el peso que progresivamente han sido más complejos siguiendo las recomendaciones que ha ido publicado la American Heart Association en el transcurso de los últimos años, incorporando parámetros en sangre como el colesterol y la glucosa. Este aspecto ha dotado a estos estudios de un gran interés para la comunidad científica aportando datos en población general juvenil que permiten estudiar en mayor detalle la evolución de la prevalencia de ciertos factores de riesgo que en edad adulta pueden desembocar en enfermedad cardiovascular u otras patologías asociadas.

Los artículos anexados a este texto son ejemplos de esta aportación a la comunidad científica, tanto en materia educativa en el contexto de la ciencia de la implementación con los resultados de la intervención en adolescentes o la compilación de lecciones aprendidas en 10 años de

Proyectos en colaboración intervenciones escolares de promoción de salud, como en el ámbito clínico con resultados como los valores de referencia de dimensión y función cardiaca en adolescentes, o la relación entre el sueño y parámetros de obesidad también en los participantes en el estudio del Programa SI! de Secundaria.

En todos estos estudios, los resultados del efecto de la intervención demuestran una mejora de los indicadores de salud cardiovascular de los estudiantes muy dependiente de la cantidad y la distribución del contenido educativo del Programa SI! que se implementa en el aula. El diseño del próximo proyecto en el entorno escolar de la Fundación SHE aúna todo lo aprendido en nuestros estudios previos implementando estrategias innovadoras a través de la participación más activa de familias y entorno escolar apoyándose en el concepto de salud colectiva. Con este nuevo enfoque, esperamos conseguir un efecto beneficioso del Programa SI! que sea más duradero gracias al refuerzo de mensajes clave en el aula y el entorno inmediato de los estudiantes en momentos críticos de su desarrollo cognitivo. Además, para este proyecto estamos desarrollando un índice de salud simplificado y específico para niños y adolescentes con el que, basados en las métricas más actuales recomendadas por la American Heart Association, logremos obtener una mayor sensibilidad al cambio de hábitos en línea con el objetivo del Programa SI!.

La Fundación SHE ha llevado a cabo proyectos de promoción de salud en población adulta con una estrategia de talleres formativos y grupos de apoyo entre iguales (Programa Fifty-Fifty) que ha demostrado un impacto positivo en la salud de los participantes que disminuye con el tiempo al dejar de acudir a los grupos de apoyo, reforzando la necesidad de la reintervención que se encontró también en los estudios del Programa SI!. Los proyectos de promoción de salud en adultos se han implementado en entornos muy diferentes desde su comienzo en 2005 en la Isla de Granada en colaboración con Mount Sinai, aplicándose en España junto con la Agencia Española de Consumo, Seguridad Alimentaria y Nutrición (AECOSAN) en distintos municipios y también en el entorno laboral, permitiendo definir un modelo de buenas prácticas que facilita su traslación a instituciones públicas y privadas y que a día de hoy se está aplicando con éxito en distintas empresas y entidades.

También en el marco de estos estudios, se desarrolló y validó un índice de salud cardiovascular simplificado, Fuster-BEWAT, incorporando presión arterial (Blood pressure), actividad física (Exercise), control del peso (Weight), dieta (Alimentation) y hábito tabáquico (Tobacco), proporcionando a la comunidad científica y a la población una nueva herramienta de monitorización de la salud cardiovascular simple y precisa.

Entre 2015 y 2017 se aplicó una adaptación del Programa SI! y el programa Fifity-Fifty a la comunidad educativa impulsado por la Icahn School of Medicine at Mount Sinai de Nueva York, en el que participaron 600 niños de 3 a 5 años, sus familias, profesores y personal laboral de 15 colegios del barrio de Harlem en Nueva York. Este estudio resultó ser un precursor del proyecto Healthy Communities que aglutina intervenciones todas las franjas de edad y ámbitos de la comunidad, con el objetivo de que finalmente sean los propios habitantes quien mantengan un ambiente saludable que perdure en el tiempo. Desde que comenzó el proyecto de Healthy Communities en Cardona se han llevado a cabo distintas actividades educativas de promoción de salud y en colaboración con el Ayuntamiento se han llevado a cabo acciones de recuperación y habilitación de espacios públicos para fomentar la vida activa. También se aplica el Programa SI! en todos los centros educativos del municipio que constituye el grupo intervención (Cardona), y se aplicará el Programa Fifty-Fifty a jóvenes de 17 a 24 años (con su versión adaptada Fifty-Action), a adultos de 25 a 50 (Fifty-Fifty) y a mayores de 50 (Fifty-Plus). Este estudio tiene un diseño aleatorizado con un municipio cercano como grupo control (Sallent) en el que se realizan las mismas mediciones directas de parámetros de salud cardiovascular así como cuestionarios, pero no se aplica ninguna intervención educativa. Con este estudio se podrá comprobar si la intervención en distintos estratos de la comunidad puede mantenerse en el tiempo de manera autónoma una vez que se ha dotado, tanto a la población individual como a las entidades, de herramientas y recursos relacionados directamente con los factores modificables de riesgo cardiovascular como la alimentación, el consumo de tabaco, la actividad física o el bienestar emocional.

Con todos estos programas de promoción de salud, la Fundación SHE contribuye en la labor que las administraciones públicas de la comunidad internacional junto con entidades privadas están situando como prioridad en materia de salud pública, en su caso educando a la población para poder adquirir y mantener un estilo de vida saludable.



Dra. Gloria Santos

l 40 Carta del presidente

Proyectos en colaboración



# **2022 – Programa SI!** Memoria de actividades

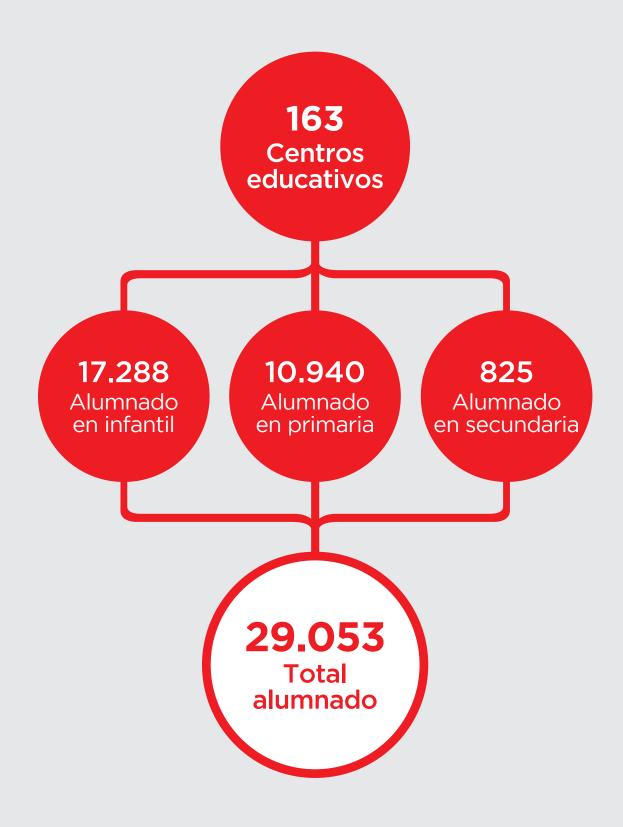
→ Durante el curso 2021-2022 algunos de los centros participantes en el estudio científico continúan implementando el PSI! en Educación Secundaria. → Se han analizado los datos recogidos en el estudio científico y se está preparando la publicación de resultados. → En el último trimestre de 2022 se ha empezado a diseñar el estudio de Reintervención del Programa SI! de Primaria que se llevará a cabo a partir del curso 2023-2024.

23	2023/2024	2024/2025	2025/2026	2026/2027	2027/2028	2028/2029	2029/2030
/2023 <b>)TO</b>	1º Primaria	2º Primaria	3º Primaria	4º Primaria	5º Primaria	6º Primaria	1º Secundaria
2022/ PILC	FP	I	E	E	R	E	0
- 5	0	0	0	FP	T	E	0

- FP Formación del profesorado y planificación de la implementación
- I Intervención en el aula y en el entorno
- E Refuerzo de los mensajes clave en entorno (familias, profesorado, ambiente escolar)
- R Reintervención en aula y entorno
- 0 No intervención

- Mediciones completas
- Cuestionario simple

# **2022 – Programa SI!** Beneficiarios del Programa SI!



# **2022 – Healthy Communities** Memoria de actividades



→ Durante los meses de enero a junio de 2022 se siguió realizando el reclutamiento y las mediciones basales de los participantes en Cardona, como municipio de intervención y Sallent como municipio control.

→ Todos los participantes recibieron un informe con los resultados de las mediciones y un librito con recomendaciones de estilos de vida saludable.



→ Para el reclutamiento se enviaron 4239 cartas.



→ Se midieron un total de 1810 personas (907 en Cardona y 903 en Sallent) de entre 12 y 84 años.

→ Una vez finalizadas las mediciones, se ha realizado un análisis descriptivo preliminar de la muestra del estudio. → De enero a diciembre se iniciaron los talleres formativos dirigidos a los participantes del programa en la población intervención. Los contenidos que se han impartido son:

- Motivación por el cambio de hábitos
- Alimentación saludable
- Bienestar emocional
- Gestión del estrés
- Actividades física
- Prevención del consumo de sustan-
- cias tóxicas como el tabaco y el alcohol





→ Durante el año se han organizado distintas actividades como conferencias con la participación del Dr. Fuster, talleres formativos, scape room, pilates y charlas con profesionales de la salud.

# **2022 - 10 Aniversario** Memoria de actividades



Fundación SHE cumplió su décimo aniversario el pasado 2020.

Esta efeméride tenía previstos varios eventos de conmemoración que el coronavirus obligó a aplazar. A pesar de ello, Fundación SHE mantuvo las actividades previstas para el décimo aniversario tras 10+2 años de existencia.

Se organizó un concurso escolar entre los colegios que forman parte del Programa de SI! de Barcelona, Madrid y Ourense. Los premios se entregaron en un evento familiar en el Planetario de Madrid. El acto institucional de celebración del 10 aniversario tuvo lugar en Cosmocaixa (Barcelona).

En estos 10 años la Fundación SHE ha conseguido hitos importantes en su labor científica, divulgativa y formativa, que se pueden concretar en las siguientes cifras:

### Más información en: fundacionshe.org/10-aniversario/



**31** Artículos

31 artículos publicados en revistas científicas de alto impacto

### Congresos Participación en

33

Participación en 33 congresos

## **37m** Alumnos

Más de 37.000 alumnos han participado en las actividades educativas del Programa SI!

### 2.000 Profesores

Más de 2.000 profesores han recibido la formación para aplicar el Programa SI!

### 235 Centros Más de 235 centros

educativos han implementado el Programa SI!

## **Año 2022** Transparencia. El año 2022 en cifras.

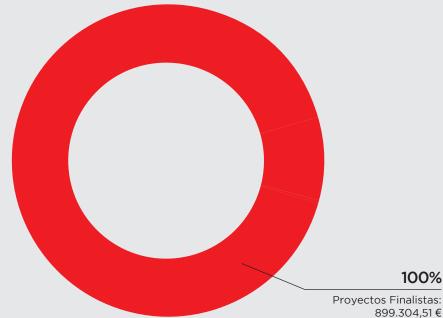


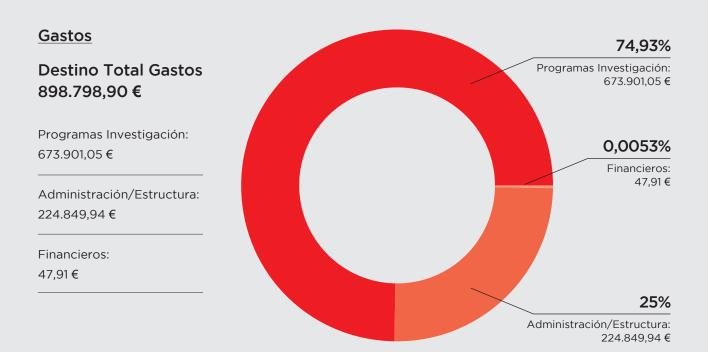
## Año 2022 Transparencia. Origen y destino de los recursos.

Ingresos

**Origen Ingresos Totales** 899.304,51€

Proyectos Finalistas: 899.304,51€





Informe Anual 2022 47 |

100%

# **Text in English**







#### Letter from the president

The SHE Foundation (Science, Health and Education) celebrated its tenth anniversary in 2020. Several commemorative events were planned for the celebration of this anniversary, but the coronavirus pandemic forced us to postpone them. Despite the delay caused by the pandemic, we went ahead with the planned activities and carried them out in 2022, which will forever be the year of our tenth (+2) anniversary. A very special year.

Many thanks to all the authorities and personalities who have honoured us with their support and attendance at the different events and acts that you will find detailed in the corresponding section of this Annual Activity Report, as well as to all the SHE team that has made it possible. Ten (+2) years is a long time so, as well as encouraging us to look to the future with optimism, it forces us to reflect and remember many important contributions. We are SCIENCE. We define ourselves as a foundation that dedicates its resources to validating scientific hypotheses and acquiring knowledge to be published in internationally recognised scientific journals in order to contribute to promoting health, especially among children and young people. To this end, we have developed three major initiatives that are described in detail below: the SI! Programme (aimed at school students), the Fifty-Fifty Programme (for adults), and the Healthy Communities Programme (for communities, as its name indicates).

Thus, throughout these years of operation, we have invested more than 11 million in research. This represents 90% of our total available budget (excluding structural costs which are on average 20-25%) – an unequivocal statement of priorities and intentions of ours.

I have always defended the idea that what is not published, does not exist. Therefore, the first thing to do when reviewing our trajectory is to list the 34 congresses at which we have been present and given lectures or the important list of publications that you will see below. Dr Santos, head of the SHE Foundation's scientific team, has selected four full texts from the 19 available, which she considers relevant due to their impact or relevance today which are attached at the end of this report. In the article on lessons learned in ten years of health promotion at nursery schools, we describe key elements in the promotion of cardiovascular health in school environments, which are multidisciplinary teams, content that incorporates various components, strategies aimed at different levels of the population, and local coordination of implementation and scientific evaluation through randomised clinical trials. We also attach the main results of the latest SI! Programme study in adolescents, where, despite the impact of the pandemic on the project's progress, we have found a decisive factor in the intensity and distribution of the curriculum taught. In addition, we have included two articles on adolescents that are of great clinical relevance. One of which analyses the latest cardiovascular risk factor included by the AHA in its metrics: sleep (noting its association with obesity indicators). The other provides reference values for cardiac size and function and myocardial tissue properties obtained by magnetic resonance imaging.

After many years of professional activity in the fight against cardiovascular disease, my presidency of the American Heart Association (AHA) and the World Heart Federation (WHF) 20 years ago made me realise the importance of global health promotion in the face of the prevalence of heart disease. Since then, I have been convinced that a change in the population's lifestyle is the only way to prevent the spread of cardiovascular diseases – a true epidemic and the world's leading cause of death. The main cardiovascular risk factor is obesity and its derivatives, such as diabetes and hypertension, as a consequence of an inadequate diet and a sedentary lifestyle. Unhealthy lifestyle habits such as consuming alcohol and tobacco also play a role. That is why I decided to promote the creation of the SHE Foundation. A non-profit foundation that, based on basic and clinical research (Science), aims to promote healthy habits (Health) through communication and education (Education) in the population. To this end, the SHE Foundation dedicates its efforts to creating a framework for what education means and entails in the acquisition of healthy habits from childhood onwards. The aim is to promote a world where children, young people and adults all have the capacity to act positively towards their HEALTH.

This would not have been possible without the selfless support of many individuals. Philanthropy still has a long way to go in Europe in general and in Spain in particular. However, at the SHE Foundation, we have been very fortunate and have had the very important support of patrons and benefactors. In chronological order (starting with my wife), the founding trustees are Maria Àngels Guals, Carles Vilarrubí (our first Vice-President), Rosa Mª Guals, Lluís Torres, Javier Solana and Joan Font (our Trustee Secretary). The following are some of our patrons of merit: José Mª Castellano Ríos, Isak Andic, Sol Daurella, Marc Puig, Jorge Miarnau, Emilio Ferré, Mauricio Botton Carasso, Josep Oliu, Artur Carulla and Isabel Carvajal. The following are some of our benefactors: Jacques A. Nahmias, Marina Carasso, Alicia Koplowitz and José Ferrer Sala. Mariano Puig and his wife Maria Guasch deserve a special mention for their generous contribution to the infrastructure necessary for the Healthy Communities Programme in Cardona. Thanks to all of them.

This allowed us to face a phase of consolidation that began in 2017 with the incorporation of the "la Caixa" Foundation in order to be able to continue our research work as a leading partner. Since then, the name of the SHE Foundation has been associated with the image of the "la Caixa" Foundation. Many thanks to those trustees appointed by the "la Caixa" Foundation who have made this possible, to Àngel Font for his constant support, to our current trustees Javier Solana, Esther Planas and Higini Clotas. Above all, to the trust placed in me and in our work by Antoni Vila, Managing Director of the "la Caixa" Foundation, and Isidre Fainé, President of the "la Caixa" Foundation.

The future is full of challenges and possibilities. 2022 is a crucial year in our short history. Not only because we are celebrating our tenth anniversary, but also because it has been the year in which two important factors have come together.

On the one hand, the design of the clinical trial that will take place in Madrid on the SI! Programme will answer the question of the sustainability of school initiatives. Is it necessary to revisit the participating schools? The scientific design brings together all that has been learned in more than 12 years of work in the field of cardiovascular health promotion with the aim of maintaining the effect in the long run, by reinforcing the content and strategy to impact students' immediate environment (family and school environment), but also by reminding them of the key messages at the ages when students are becoming independent and forming their own habits. This new study will cover the most critical ages, starting at seven years of age when students are already able to incorporate more abstract concepts such as healthcare, and then revisiting them in the classroom when they start their most independent phase – at 10 years of age – during which they begin to make decisions that will be relevant to their health in the present and the future. Dr Santos gives more details later in the Annual Report.

On the other hand, the Healthy Communities (HC) Programme's key moment is the transition from a phase of accompanying the community in educating them about healthy habits to a more independent and empowered phase. HC aims to encourage citizens to make healthier choices about how they move, what they eat and how they use the environment around them, to improve mental health and happiness. The hypothesis is that a healthy city will have a positive impact on inhabitants by improving cardiovascular health and physical activity rates, mental health and wellbeing.

Will we achieve this? We will have both answers over the next seven years.

We said at the beginning that the acronym SHE, as well as drawing attention to women, traditionally forgotten in cardiovascular research, reflects on Health Education from a scientific perspective. Well, if we are talking about EDUCATION, I would not like to end these lines without one last heartfelt remembrance of my alter ego Dr Ruster. A muppet created by the Sesame Workshop who, in addition to sharing my fringe, gown and stethoscope, I want to believe that he represents the best of me. He advises and cares for the Sesame Street characters to lead a healthier life. In this way, the figure of the doctor is also introduced to children so that they understand that it is a profile that helps and provides information to maintain and improve health. Our research has shown that this is a successful way to show the role of health professionals and their white coats to children all over the world.

I am proud to say that its existence is due to a collaboration agreement between the SHE Foundation and the Sesame Workshop to produce 26 chapters for the audio-visual series *Monstruos Supersanos* (Superhealthy Monsters), which has crossed borders and, apart from our country, has subsequently been used in health promotion programmes in the USA, Mexico, Colombia, Brazil, and the rest of Central and South America. The *New York Times* published a statistic relating the cause of death in the USA to media coverage. Cardiovascular disease accounted for 30.2% of deaths in the country, while only 2.5% of all media reports referred to heart disease. In contrast, 35.6% of media space was taken up by terrorism when its mortality rate was less than 1.8%.

Much remains to be done. Let's move on!

### Valentín Fuster President of the SHE Foundation

### **Healthy Hearts**

Health promotion. A declaration of intentions. "What would happen if society were able to modify its current routines and acquire healthy habits?" Dr. Valentín Fuster

After a lifetime devoted to medicine and research, Dr. Valentín Fuster de Carulla is convinced that a change in the population's lifestyle is the only way to avoid the spread of cardiovascular diseases, which are a real epidemic and the main cause of death in the world. Factors such as obesity, alcohol addictions, smoking and other drugs have become the main risk factors for cardiovascular disease and year after year cause a considerable increase in the number of people who suffer from it.

Experts agree that the only way to avoid the spread of these diseases is a change in the lifestyle of the general public and awareness-raising of the need to promote healthy habits.

The challenge is how to move on from treating the disease towards preventive health care. Cardiovascular diseases are the leading cause of death in the world.

- The main cardiovascular risk factor for both adults and children is obesity and its associated factors, such as diabetes and high blood pressure, which stem from an inadequate diet and low levels of physical activity.

- Addictions to alcohol, smoking and other drugs are also important risk factors for cardiovascular disease. The proliferation of these unsatisfactory habits among the general population increases year after year the number of cardiovascular diseases.

- Longer life expectancy, due to more advanced medicine and new technologies, is causing an unsustainable social and economic burden on our society.

### Our Own Projects

### Programa SI!

### Hypothesis

"The acquisition of healthy habits from childhood reduces the risk of cardiovascular diseases and improves the quality of life in adulthood" The main cardiovascular risk factor, in both adults and children, is obesity and its associated conditions (diabetes and arterial hypertension), resulting from poor eating habits and a low level of physical activity. The epidemiological data indicate that cardiovascular risk factors are present from increasingly on early ages, and that the poor eating habits acquired in childhood persist on into adult life.

In addition, other cardiovascular risk factors such as alcohol abuse, smoking and the use of other drugs are also beginning to manifest in the Spanish (pre)-adolescent population. Public health research has shown that health-promoting initiatives should start in childhood in order to secure lasting and effective behavioral changes.

The SI! Program consists of an intervention in educational centres to promote cardiovascular health from the pre-school stage. Its aim is to demonstrate that the acquisition of healthy habits from childhood reduces the risks of cardiovascular disease and improves quality of life in adulthood.

The SI! Program consists of four basic, interrelated components:

- 1. Acquisition of Healthy eating habits
- 2. Active living
- 3. Knowledge of the body and heart
- 4. Management of emotions

The program operates at four levels: school, environment, teachers, families and pupils.

The intervention at the school environment level is carried out through regular communications to the management team and the school coordinator for subsequent distribution amongst the teaching staff.

The action at the teacher level aims, on the one hand, to make the teaching staff aware of the reality of cardiovascular disease and the importance of their contribution as educators in the acquisition of healthy habits in the school population and, on the other hand, to train teachers in healthy habits and in the methodology to be followed to teach the program in the classroom and provide them with materials and tools to work with students. This 30-hour training course for teachers in charge of teaching the contents is accredited by the different Autonomous Administrations.

The contents of the program were checked by educational psychologists and teachers at the centres, as well as being in line with the school curriculum. Special emphasis is placed on their involvement in order to achieve changes in routines and habits in the family environment.

The SHE Foundation has carried out several scientific studies in different Educational Stages to demonstrate the hypothesis of the SI! Program.

### Infant Education Stage

This was carried out from 2011 to 2014 in 24 state schools in Madrid through a randomized, controlled study. Half of the schools that participated in the study were randomly assigned to the intervention group, whose students carried out a minimum of 30 hours of activities per academic year focusing on the program components on emotion management, additional weekend activities with family members, annual health fairs, etc. Students in the remaining (control) schools continued with their usual curriculum.

A dozen researchers from the National Centre for Cardiovascular Research and Mount Sinai Hospital evaluated the effectiveness of the SI! Program in 2,062 children aged 3-5 years. The results of the study showed that the implementation of the program led to a significant increase in children's knowledge, attitudes and healthy habits, as well as an improvement in markers of adiposity.

In conclusion, the SI! Program contributes new and valuable information on the benefits of an early intervention targeted to pre-school children, referred to the promotion of healthy life habits. According to Dr. Fuster, "the basis of the program is the fact that it is between 3-6 years of age when we develop our future behavior as adults. Cardiovascular disease has a lot to do with behavior, and so here we have our window of opportunity". This study moreover uses an innovating design since it expands the role of physicians to also encompass the teaching community. On the other hand, it involves a protocol with structured evaluation, something that is usually lacking in community public health interventions. The program moreover coordinates families and educators through the pupils, which may serve to guarantee the sustainability of the intervention. Currently, the SI! Program has been extended to more than 125 schools in the Community of Madrid, Catalonia and Galicia.

### Primary Education Stage

In Madrid, a randomized study was carried out from 2014 to 2020 in the primary education stage (children aged 6 to 11 years). Forty-eight public schools from 16 municipalities in the south of Madrid participated, with a total of 1,770 children, their families and teachers. A randomization was carried out in 4 groups of schools with different exposure to the SI! Program. The aim of this design was to evaluate the effect of the SI! Program at different times and with different intensities. Additionally, the children participating in the randomized study of the SI! Program were followed up. In this way, it will be possible to evaluate the effect of the SI! Program in the long term and with different intensity of exposure to the intervention.

### Secondary Education Stage

SI! Program has been applied in Secondary Education through a randomized design from 2017 to 2021. The project, awarded by the Marató of TV3 in collaboration with the University of Barcelona, the National Center for Cardiovascular Research and SHE-la Caixa Foundation, has included 1,326 adolescents aged 12 to 16 years from 24 public high schools in the north of Madrid, Barcelona and Baix Llobregat. Most early adolescents enrolled in the SI! Program for Secondary School trial had a poor or intermediate cardiovascular health at baseline, with just 11% of them demonstrating ideal cardiovascular health [16]. The lowest scoring individual component was dietary habits, with only 0.6% of adolescents meeting ideal recommendations. Self-reported low-income family status, low parental education, and migrant condition were associated with worse adolescent cardiovascular health. Health promotion interventions should be implemented at young ages, with a particular focus on dietary habits and low socioeconomic settings. The data collected in the studies are currently being analysed.

### Fifty-Fifty Program

#### Hypothesis

"If adults are trained in peer groups and provided with the knowledge, skills and attitudes a healthy lifestyle requires, their cardiovascular health habits and their own self-control of the risk factors will improve." Dr. Valentín Fuster

In Spain, cardiovascular diseases are the leading cause of mortality or disability.

The American Heart Association defines that cardiovascular health is poor in Spain. Less than 1% of all Spaniards reach ideal values for the 7 cardiovascular health indicators and thus have a healthy lifestyle. In Spain the prevalence in adults of overweight is: 36%, obesity: 17%, smoking: 27% and sedentary life: 37%. The SHE Foundation and the Spanish Agency of Consumer Affairs, Food Security and Nutrition (AESAN) from the Spanish Ministry of Consumer Affairs, promoted the introduction of the Fifty-Fifty Program. This Program constitutes a community intervention trial designed by Dr. Valentín Fuster with the aim of improving comprehensive health in adults, helping them to establish self-control of the main risk factors for such diseases. The participants in the study were healthy adults between 25-50 years of age and with at least one cardiovascular risk factor.

Based on previous scientific learnings, Dr. Fuster initiated a pilot project in the town of Cardona (Barcelona, Spain). The good results obtained facilitated the conduction of a larger study in another 7 Spanish cities and towns: Barcelona, Cambrils, Guadix, Manresa, Molina de Segura, San Fernando de Henares and Villanueva de la Cañada. This study involved 543 volunteers (71% females), each with at least one cardiovascular risk factor. The intervention was based on elements of Social Cognitive Theory. The key elements of this theory include observational learning, reinforcement, self-control and self-efficacy.

In a first phase, all the participants were enrolled in educational and motivational workshops designed to promote healthy living habits. The

meetings were used to address motivations for change, stress management, smoking cessation, healthy eating habits, regular physical exercise, and blood pressure self-control.

Then, in a second phase lasting 12 months, the participants were randomized to two groups (1:1): an intervention group, involving peer group activities; and a control group, simply subjected to follow-up during the same period of time.

The investigators have performed a new analysis of cardiovascular risk factors: at baseline, after workshops, 12 months (after peer group) and 40 months after the end of the study to assess the progression of the participants.

The main outcome assessed in the study was the mean change in a composite score related to blood pressure, exercise, weight, diet and tobacco consumption (Fuster-BEWAT score).

The results obtained from the study, accompanied by a rigorous scientific evaluation, confirm that educating adults in knowledge, skills and attitudes about a healthy lifestyle, accompanied by peer support, improves cardiovascular health habits and self-management of risk factors, and confirms the importance of giving continuity to support dynamics.

The Fifty-Fifty Program has also been applied in Spanish companies PortAventura and AMPO with the aim of providing tools to improve the cardiovascular health of their workers.

It is essential to implement programs to promote healthy habits which, like this one, are of great value in raising public awareness, since, in the words of Dr. Fuster, "we must not prevent disease, we must promote health".

### **Healthy Communities**

"In the healthy communities program it is the members of the community itself who promote the change of the health paradigm in their town" Dr. Valentín Fuster

The current worldwide epidemic of cardiovascular diseases is the outcome of the consumerist society we live in. The major increase in the prevalence of these diseases must be addressed by means of multi-sector health promotion and primary prevention strategies that encourage a healthy lifestyle and reduce cardiovascular risk factors, morbidity and mortality.

Although mortality by cardiovascular diseases has decreased in the developed countries, also confirmed in Spain, the combination of factors such as the population's greater life expectancy, increased patient survival after a cardiovascular event, or city development and its derived effects (such as a sedentary lifestyle, obesity, changing eating habits and smoking) keep the prevalence of these diseases high. In view of the situation, we must focus our efforts not only on the treatment of cardiovascular disease, but also on primary prevention by means of multi-sector strategies to promote health and healthy lifestyles. Thus, the experts hold that community intervention programs promoting integrated health may have a significant impact on cardiovascular health.

The Healthy Communities Program, implemented in collaboration with the City Council of Cardona, aims to promote the development of healthy lifestyles throughout all stages of life and to contribute to promoting quality of life, correcting health habits and self-management of the main risk factors for cardiovascular diseases, such as overweight, obesity, physical inactivity, blood pressure and smoking.

Consequently, the aim is to turn Cardona (Barcelona, Spain) into a healthy city, that means, a city that prioritizes the health of its inhabitants in all its actions, including the creation of physical (healthy urbanism) and social environments (environment) that promote health. The idea is to be able to create a replicable model for the development of healthy municipalities. During the pilot phase of the project community activities were organized, involving the residents of Cardona according to their capacities, conferences about health were organized and motivational workshops were held by "health promoters", trained specifically for the program, to promote healthy lifestyles.

Moreover, Cardona's program included an ambitious urban development plan designed to provide an atmosphere that promotes physical activity among the population. In this pilot study approximately 10% of the city population was longitudinally assessed in years 2014 (beginning of the pilot study), 2016 (impact of pilot health promotion activities) and 2018 (sustainability, end of the pilot study). Preliminary results were promising and showed in the first 18-month period (intervention period) a trend toward improvement of their health scores, mainly driven by improvements in the physical activity and dietary components. These findings justified the development of the next stage of the project in which the impact of the creation of a Healthy City will be appropriately tested through a quasi-experimental study design and relevant outcomes, so the model could be accepted and replicated elsewhere: Healthy Communities 2030.

By promoting a more active lifestyle, the Healthy Communities Program (HC-2030), launched in fall 2021, should encourage people to make healthier decisions about how they move, what they eat and how they use the environment around them and also provide opportunities to improve mental health and happiness. We hypothesize that a healthy city will impact positively to their inhabitants by improving cardiovascular health and physical activity indices, mental health and wellbeing. For such a purpose, a controlled longitudinal community-based intervention study will be carried out on 2,000 participants (1,000 in the intervention, which is Cardona, and 1,000 in the control town, which is Sallent) 12 years or older over a period of 5 years.

The primary endpoint will be the between group (intervened town vs control town) difference for the change in the Fuster-BEWAT score [4] which consists of a 0-15 scale for behaviors/health factors related to blood pressure, exercise, weight, alimentation (diet), and tobacco use (smoking).

The Healthy Communities Program is a multidisciplinary health-promotion initiative. The project will result in a toolkit for a community-driven health promotion intervention that could be replicated in cities and towns both nationally and internationally. The core of the intervention will be based on the previous health promotion programs developed and evaluated by the Science, Health and Education (SHE) Foundation: the SI! Program for children, and the Fifty-Fifty Program for adults.

The effect of these interventions was proven through randomized trials and the results were published in high-impact journals (Journal of the American College of Cardiology, American Heart Journal, American Journal of Medicine, etc.).

### **Collaborative Projects**

### United States | New York, Harlem | «FAMILIA» Program

The study enrolled 562 children aged 3-5 in 15 of New York City's preschools in the high-risk community of Harlem along with 1,000 adults with the aim of demonstrating that education in healthy living habits from an early age improves the knowledge, attitudes and habits of children and intervention in adults can reduce the risk of cardiovascular diseases and improve quality of life.

Three different inter-related and synergic research projects were proposed within the "FAMILIA" Program:

1) Evaluation of the cardiovascular health impact of a community-based educational program for the comprehensive promotion of health (Programa SI!) centered on four areas (eating habits, knowledge of the body and heart, physical activity, and the management of emotions) and targeted to pre-school children and their parents or caregivers.

2) Analysis of multiple lifestyle intervention strategies in adults.

3) Evaluation of possible genetic changes linked to behavioral changes in children and their parents or caregivers.

https://fundacionshe.org/en/harlem-new-york-familia-program/

### United States | New York, Harlem | «CHILDREN» Program

The (CHIldre's Lifestyle, Diet and exeRcise intErveNtion (CHILDREN) Project of Mount Sinai Heart at Icahn School of Medicine is to promote cardiovascular health in the five boroughs of New York city's by providing children with the knowledge and skills to avoid cardiovascular risk factors throughout their lives. This project aims to better understand how childhood socioeconomic context and their immediate environment intersect to children's behavior, and consequently, cardiovascular risk factors.

The CHILDREN study aims to provide a cardiovascular health promotion program (SI! Program) to nearly 2,000 schools in the five boroughs of New York. The CHILDREN Project began in the winter of 2020 for a Pilot study in five NYC public schools. In fall of 2021, the full study will launch, initially recruiting in Manhattan before expanding to all five boroughs.

The program is based on and adapted from educational initiatives by Sesame Workshop and the SHE Foundation. https://fundacionshe.org/en/new-york-children/

#### Colombia, Bogotá | «Healthy Habits for Life» Program

In 2009, Dr. Fuster designed a community intervention study in collaboration with "Sesame Street" and "Plaza Sesamo".

The aim of the program, targeted to children between 3-5 years of age, their parents and teachers, was to promote the development of healthy habits that persist into adult life, through leisure-educational activities focusing on nutrition, a healthy heart and the importance of physical exercise.

The study carried out in Bogotá, Colombia, included 1,216 children aged 3 to 5 years, 928 parents, and 120 teachers from 14 schools. However, a reintervention was made 7 years later to 596 children between 9 and 13 years old from the first study and compared with a group of 620 children of the same age who had not been intervened in the preschool stage. No statistically significant differences were found between the groups after the intervention at 9-13 years old, so it seems important that re-intervention strategies are carried out at an earlier age to maintain a sustained effect of the preschool intervention.

https://fundacionshe.org/en/colombia-healthy-habits-for-life/

#### Latin America | «Listos a Jugar» Program

For more than a decade Sesame has collaborated with Dr. Valentín Fuster to promote cardiovascular health and well-being by educating children to lead healthier lifestyles in Colombia, Spain and Harlem. Jointly, a muppet was created (Dr. Ruster) as well as media and outreach materials. Over this period of time Dr. Fuster's team has conducted rigorous research on the long-term benefits of using Sesame Street materials in preschool health promotion interventions has during the preschool years.

Building on this initial work, Sesame's Listos a Jugar program launched 3 years ago as a regional response to the high incidence of obesity and diabetes in children in Latin America. The program has reached over 11 million people largely through mass media distribution. Initially funded by public and private partners, included a 26-episode television series, digital assets including an app and a website, and resources for caregivers and educators. Since then, it has been distributed in Bolivia, Brazil, Colombia, Ecuador, Mexico, and other Central American countries. https://fundacionshe.org/en/latin-america-listos-a-jugar-program/

#### Spain | «Iniciativa VIVE» -«FAMILIA» Program

March 2011, the Pro CNIC Foundation and the SHE Foundation signed a collaboration agreement under the name "VIVE" Initiative, with the aim of joining forces to improve the cardiovascular health of adulthood. This agreement gave rise to a joint coordination plan led by Dr. Valentí Fuster, director of the National Centre for Cardiovascular Research (CNIC).

Within the framework of Iniciativa VIVE, "Salud en Familia" is a cardiovascular health promotion program aimed at people who would like to make changes to their lifestyle and those around them, with the aim of improving their health in a comprehensive way. The program is designed to be applied to the whole family because doing physical activity, eating healthily and talking about our emotions, in short, being healthy, is a way of life that is achieved with teamwork.

The majority of our lifestyle habits in adulthood are developed from attitudes, knowledge and behavior acquired during childhood and adolescence and later established during our youth. Children cannot be healthy without the help of the people around them, because at this age they do not have the autonomy to make decisions about their habits. Furthermore, adults are their reference point and an important source of learning through imitation. Throughout the units of this program, we work on content related to the main factors of heart protection with games, crafts and fun activities, during which adults and children enjoy time together while taking care of their health.

### The Foundation

"The prevention of disease and the promotion of health are the key to reducing the prevalence of cardiovascular disease in the world" Dr. Valentín Fuster

Dr. Fuster promoted the creation of SHE in 2009, a non-profit foundation that, focused on basic and clinical research (Science), is aimed at promoting healthy habits (Health) through communication and Education of the population. In 2017, the "Ia Caixa" Foundation joined the board of trustees of the SHE Foundation to give continuity to its research work.

With this purpose, the SHE Foundation devotes its efforts to creating a frame of reference for what an education in health, stressing the acquisition of healthy habits from childhood, means and involves, to promote a world in which children, young people and adults have the ability to act positively regarding their health. Because if society reduces risks, the impact of cardiovascular diseases will be also reduced.

The SHE Foundation is dedicated to validating scientific hypotheses and generating knowledge for publication in leading journals to promote health, especially for children and young people. To achieve this goal, it develops various training programs.

Science | We aim to be a scientific reference due to our rigorous methods in the assessment of any health project or program that is promoted by the foundation. Health | We promote health as a priority, influencing the risk factors that reduce cardiovascular disease and improve the quality of life. Education | We want to create a frame of reference for what having an education in health, stressing the acquisition of healthy habits for life, means and involves.

### **Board of Trustees**

Dr. Valentín Fuster de Carulla, Founding Trustee – Chairman Sr. Antonio Vila Bertrán, Trustee, "la Caixa" Foundation – Deputy Chairman Sr. Carles Vilarrubí Carrió, Founding Trustee – Deputy Chairman Excmo. Sr. Javier Solana de Madariaga, Founding Trustee

### Team

Pedagogical Area <u>Pedagogical management</u> Isabel Carvajal Degree in Biology. Madrid Complutense University. Specialty: Genetics and Physiology.

### Pedagogical Area

Domingo Haro Degree in Sciences of Physical Activity and Sport (INEFC Barcelona -University of Barcelona).

Belén Blanco Bachelor's Degree in Law and Political Science. Universidad Autónoma de Madrid.

#### Carla Rodríguez

Bachelor's Degree in Psychology and Postgraduate degree in Positive Psychology and Emotional Intelligence. Universidad Complutense de Madrid.

Xavier Òrrit PhD in physical activity and sport from the Autonomous University of Barcelona

Anna Badia Degree in Physical Activity and Sport Sciences from the INEFC University of Barcelona.

Natalia Montilla Bachelor's degree in psychology. Universidad Autónoma de Barcelona. Scientific Area

### Scientific Area

<u>Scientific management</u> Gloria Santos Ph.D. degree in Biology by the Complutense. University of Madrid.

<u>Scientific Team</u> Patricia Bodega

BSc in Human Nutrition and Dietetics (Universidad San Pablo CEU and PhD student in Health Science and Sports (Universidad de Zaragoza).

Sr. Lluís Torres Arro, Founding Trustee Sra. Isabel Carvajal Urquijo, Trustee Sr. Higini Clotas Cierco, Trustee, "la Caixa" Foundation Sr. Esther Planas Herrera, Trustee, "la Caixa" Foundation Sr. Joan Font Torrent, Secretary Trustee

<u>Scientific Team</u> Amaya de Cos BSc in Biology (Universidad Autónoma de Madrid), MSc in Biostatistics (Universidad Complutense de Madrid), and PhD student in the biomathematics field at the Biodiversity, Ecology and Evolution Department (Universidad Complutense de Madrid).

Mercedes de Miguel BSc in Biology (University of Salamanca, 2001), Master in Proj. Management.

### Collaborators

<u>Comunication</u> Olga Montilla Bachelor's degree in Advertising and Public Relations. U. Pompeu Fabra.

<u>Quality</u> Pilar Altarriba Project Management, Universidad Autónoma de Barcelona.

<u>Pedagogy</u> Vanesa Carral PhD in Psychology. Universidad de Barcelona.

### Management

<u>General Management</u> Carles Peyra MBA and Graduated, ESADE Business Administration School – Universitat Ramon Llull, Barcelona.

<u>Management and finances</u> Rafael Badia Bachelor's degree in Business Sciences (Universidad de Barcelona) and postgraduate in financial management (EADA)

Ester Pla Bachelor's degree in Tourism. Escuela superior de Turismo Jesuitas Sant Ignasi (Barcelona).

### Healthy lifestyle habits Dr. Gloria Santos - SHE Foundation Scientific Team Manager

Healthy lifestyle habits are a powerful tool for the prevention of cardiovascular disease. Many of the major cardiovascular risk factors are modifiable and closely related to lifestyle. Cardiovascular health promotion programmes are easily adaptable to different ages, and since each person involved can have an impact on their immediate environment, the spread can be exponential and these initiatives can reach homes, classrooms, entire schools, workplaces or an entire municipality. Dr Fuster's health promotion projects cover all ages and a variety of settings.

The SI! Programme is a school-based educational health promotion programme aimed at children aged 3 to 16 and designed to delay the onset and reduce the risk factors of cardiovascular disease. Based on a global vision of health promotion, the educational content of the SI! Programme is based on four components closely related to cardiovascular health: nutrition, physical activity, body and heart functionality, and emotional intelligence. Dr Fuster's first school-based project, led by Mount Sinai and the *Fundación Cardioinfantil del Instituto de Cardiología de Bogotá* and in collaboration with Sesame Street, was conducted in 2009 in Bogotá, Colombia, where a preliminary version of the SI! programme was implemented in seven schools and the effect was compared with seven monitored schools. A total of 1216 children aged three to five years participated together with their families and teachers and an improvement in knowledge, attitudes and habits in relation to diet and physical activity was achieved in favour of the group that received the educational programme, which was maintained for three years but ended up being lost six years later.

In 2009, in Spain, a fourth component was added to the SI! Programme: emotional intelligence. This has become one of its key components. Since then, the programme has been adapted to different educational levels, carrying out randomised studies with the collaboration of the *Centro Nacional de Investigaciones Cardiovasculares* (National Centre for Cardiovascular Research) amongst other entities in infant education (with more than 2000 children aged between three and five), primary education (with almost 1800 students aged between six and 11) and secondary education (with 1300 teenagers aged between 12 and 16). In all these studies, questionnaires were completed on aspects related to cardiovascular health and measurements of a series of parameters were taken such as blood pressure, waist circumference, height and weight, which have become progressively more complex following the recommendations published by the American Heart Association over the last few years, incorporating blood parameters such as cholesterol and glucose. This aspect has made these studies of great interest to the scientific community, providing data on the general population of young people which allows us to study in greater detail the evolution of the prevalence of certain risk factors that in adulthood may lead to cardiovascular disease or other associated pathologies. The articles attached to this text are examples of this contribution to the scientific community, both in the educational field in the context of implementing science with the results of the intervention in teenagers or the compilation of lessons learned in ten years of school health promotion initiatives, and in the clinical field with results such as the reference values of cardiac dimension and function in teenagers, or the relationship between sleep and obesity parameters in participants of the SI! Programme study.

In all these studies, the results of the initiative show an improvement in the cardiovascular health indicators of the students which is highly dependent on the amount and distribution of the educational content of the SI! Programme implemented in the classroom. The SHE Foundation's next school project's design brings together all the lessons learned in our previous studies by implementing innovative strategies through the more active participation of families and the school environment based on the concept of collective health. With this new approach, we hope to achieve a longer-lasting beneficial effect of the SI! Programme by reinforcing key messages in the classroom and in students' immediate environment at critical stages of their cognitive development. In addition, we are developing a simplified and specific health index for children and teenagers for this project with which, based on the most current metrics recommended by the American Heart Association, we will raise greater awareness of habit changing in line with the SI! Programme's objective.

The SHE Foundation has carried out health promotion projects in the adult population with a strategy of educational workshops and peer support groups (Fifty-Fifty Programme) that has demonstrated a positive impact on the health of participants that diminishes over time as they stop attending the support groups, reinforcing the need for revisiting that was also found in the SI! programme studies. The adult health promotion projects have been implemented in very different environments since their inception in 2005 on the island of Grenada in collaboration with Mount Sinai, being applied in Spain together with the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) in different municipalities and also in the workplace, enabling the establishment of a good practice model that facilitates its transfer to public and private institutions which is currently being successfully applied in different companies and organisations.

Also within the framework of these studies, a simplified cardiovascular health index (Fuster-BEWAT), was developed and validated, incorporating blood pressure, physical activity, weight control, diet and tobacco consumption, which provides the scientific community and the population with a new, simple and accurate cardiovascular health monitoring tool.

Between 2015 and 2017, an adaptation of the SI! programme and the Fifty-Fifty programme was applied to the educational community by the Icahn School of Medicine at Mount Sinai in New York, involving 600 children aged between three and five, their families, teachers and staff from 15 schools in New York's Harlem neighbourhood. This study proved to be a precursor to the Healthy Communities Programme, which brings together initiatives from all age groups and areas of the community, with the aim that it is ultimately the inhabitants themselves who maintain a healthy environment that lasts over time. Since the Healthy Communities project began in Cardona, various educational activities have been carried out to promote health and, in collaboration with the Council, actions have been carried out to recover and adapt public spaces to encourage active living. The SI! Programme is also implemented in all the schools in the municipality which constitute the intervention group (Cardona), and the Fifty-Fifty Programme will be implemented for young people aged 17 to 24 (with its adapted version Fifty-Action), to adults aged 25 to 50 (Fifty-Fifty) and to those over 50 (Fifty-Plus). This study has a randomised design with a nearby municipality as a control group (Sallent), in which the same direct measurements of cardiovascular health parameters and questionnaires are carried out, but no educational intervention is applied. With this study, it will be possible to check whether the intervention in different parts of the community can be independently maintained over time once both the individual population and the organisations have been provided with tools and resources directly related to modifiable cardiovascular risk factors such as diet, tobacco consumption, physical activity and emotional wellbeing.

With all these health promotion programmes, the SHE Foundation contributes to the work that the public administrations of the international community together with private entities are prioritising in the field of public health, in this case, educating the population to be able to adopt and maintain a healthy lifestyle.

Dr. Gloria Santos

### 2022 - SI! Program Activities

During the 2021-2022 academic year, some of the schools participating in the scientific study continue to implement the SI! Program in Secondary Education.

We continue to analyse data from the scientific study and prepare the publication of the results. In the last quarter of 2022, we have designed a reintervention study of the Primary Program, which will be carried out from the 2023-2024 academic year.

### Beneficiaries of the SI! Program

Centres 163 Children in preschool 17,288 Children in elementary 10,940 Adolescents in secondary 825 Total children 29,053

### 2022 - Healthy communities Activities

From January to June 2022, the recruitment and baseline measurements of participants continued to be carried out in Cardona, which was the intervention municipality. Sallent was the control municipality.

A total of 4,239 recruitment letters were sent out. Measurements were carried out on a total of 1,810 people (907 in Cardona and 903 in Sallent) between the ages of 12 and 84.

All participants received a report with the results of the measurements and a booklet containing healthy lifestyle recommendations. Once the measurements were completed, a preliminary descriptive analysis of the study sample was carried out.

From January to December, program participants from the intervention population took part in training workshops. The contents included: Motivation to change habits - Healthy eating - Emotional wellbeing - Stress management - Physical activities - Preventing the consumption of toxic substances such as tobacco and alcohol.

During the year, different activities were organized, such as conferences with participation from Dr. Fuster, training workshops, an Escape room, Pilates and talks with health professionals.

#### 2022 - 10 years of the SHE Foundation Activities

The SHE Foundation celebrated its 10th anniversary in 2020. Several commemorative events were planned for this anniversary, but the coronavirus forced them to be postponed. In spite of the delay caused by the pandemic, the SHE Foundation continued with the planned activities after 10+2 years of its existence.

A school competition was organised among the schools that form part of the SI! Program in Barcelona, Madrid and Ourense. The competition included a prize-giving ceremony at the Madrid Planetarium. The institutional event took place in Cosmocaixa, Barcelona.

In these 10 years the SHE Foundation has achieved important milestones in its scientific, informative and educational work, which can be summed up in the following figures:

31 articles published in high-impact scientific journals Participation in 33 congresses More than 235 educational centres have implemented the SI! Program More than 37,000 pupils have participated in the educational activities of the SI! Program More than 2,000 teachers have been trained to implement the SI! Program

### 2022 - Transparency. The year in figures.

Budget: 899.304,51€ Team: 16 Centres: 163 Children: 29.053 Trained teachers: 85 Teacher training hours: 30 Publications and Congresses: 14 Communities: 3 (Madrid, Catalonia and Galicia)

### Source and destination of resources

Income Source of total income: 899.304,51€

### Costs

Research Programs: 673.901,05€ Administration/Structure: 224.849,94€ Financiers: 47,91€









# **Conferencias y congresos**

### ISBNPA 2023, 22nd Annual Meeting of the International Society of Behavioral Nutrition and Physical Activity. 06-2023. Uppsala, Suecia.

- Comunicación oral: Body image satisfaction and food intake in adolescents from the SI! Program for Health Promotion in Secondary Schools. Bodega P, et al.
- Comunicación oral: Association between social vulnerability burden and cardiovascular health over adolescence using the novel Life's Essential 8 score. Martínez-Gómez J, et al
- Comunicación oral: A mediation analysis on the relationship between adolescents' migrant background and their body mass index. Beneito-Durá M et al.
- Comunicación oral: The accumulation of social vulnerabilities directly associates with obesity and weight gain over adolescence. Fernández-Alvira JM, et al.
- Póster: Influence of parental health on children's health behaviors from the SI! Program for Elementary Schools. de Cos-Gandoy A, et al.
- Póster: Impact of a school-based health promotion intervention in adolescents: primary results of the SI! Program cluster-randomized trial. Santos-Beneit G, et al.

### The First International Conference on Antioxidants: Sources, Methods, Health Benefits and Industrial Applications. 05-2023. Online.

• Comunicación oral: Gender Differences between Total Polyphenols in Urine and Cardiovascular Risk Factors in Spanish Adolescents using Structural Equation Modelling. Laveriano-Santos EP, et al.

### ESC Preventive Cardiology 2023, Annual Congress of the EAPC (European Association of Preventive Cardiology). 04-2023. Málaga, España.

- Comunicación oral: The role of socioeconomic background on cardiovascular health promotion in early childhood: insights from the SI Program for preschoolers. de Cos-Gandoy A, et al.
- Póster: Gender differences in cardiovascular health over adolescence using the novel Life's Essential 8 score. Martínez-Gómez J, et al.
- Póster: Nutritional status, body image satisfaction, and self-esteem in adolescents from the SI! Program for secondary school trial. Bodega P, et al.
- Póster: Cardiac magnetic resonance imaging derived reference values for ventricular anatomy and function and myocardial tissue characterization in adolescents: the EnIGMA study. Real C, et al.

### XXVII Jornadas Internacionales de Nutrición Practica y XVI Congreso Internacional de la SEDCA. 03-2023. Madrid, España.

• Póster: Urolithin metabotypes and blood lipid profile in adolescents. Laveriano-Santos EP, et al.

### SEC 2022. Congreso de la Salud Cardiovascular de la Sociedad Española de Cardiología. 10-2022. Palma de Mallorca, España.

• Comunicación oral: Tiempo de pantallas, patrones de sueño y su asociación con marcadores antropométricos en adolescentes incluidos en el Programa SI! en España. Martínez-Gómez J, et al.

### ESC Congress 2022. Annual Congress of the European Society of Cardiology (ESC). 08-2022. Barcelona, España.

- Póster moderado: Cardiac magnetic resonance imaging derived reference values for ventricular anatomy and function and myocardial tissue characterization in adolescents: the EnIGMA study. Real C, et al.
- Póster moderado: Absence of myocardial involvement after SARS-CoV2 infection or vaccination in asymptomatic adolescents assessed with cardiac magnetic resonance imaging: insights from the EnIGMA study. Párraga R, et al.
- Póster: Sleep duration and its association with cardiometabolic outcomes among adolescents enrolled in the SI Program in Spain. Martínez-Gómez J, et al.

### XIII-Congreso Internacional Dieta Mediterránea. Fundación Dieta Mediterránea. 04-2022. Barcelona, España.

- Conferencia invitada: El factor emocional en los hábitos saludables. Rodríguez C.
- Póster: Identification of metabotypes based on anthropometric measures, Mediterranean diet and physical activity and their association with nitric oxide in adolescents from the SI! Program for Secondary Schools. Ramírez-Garza SL, et al.

### ESC Preventive Cardiology 2022, Annual Congress of the EAPC (European Association of Preventive Cardiology). 04-2022. Online.

• Póster: Cardiovascular health trajectories among adolescents enrolled in the SI! Program in Spain: a longitudinal study. Martínez-Gómez J, et al.

XXVI Jornadas de Nutrición Práctica y XV Congreso Internacional de la Sociedad Española de Dietética y Ciencias de la Alimentación (SEDCA). 03-2022. Madrid, España.

 Comunicación oral: Flavonoids from cocoa-base products and obesity among Spanish adolescents: a crosssectional study. Laveriano-Santos EP, et al.

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### JAMA Cardiology | Original Investigation

### School-Based Cardiovascular Health Promotion in Adolescents A Cluster Randomized Clinical Trial

Gloria Santos-Beneit, PhD; Juan M. Fernández-Alvira, PhD; Anna Tresserra-Rimbau, PhD; Patricia Bodega, MSc; Amaya de Cos-Gandoy, MSc; Mercedes de Miguel, MSc; Sonia L. Ramírez-Garza, MSc; Emily P. Laveriano-Santos, PhD; Camila Arancibia-Riveros, MSc; Vanesa Carral, PhD; Xavier Orrit, PhD; Carla Rodríguez, MSc; Isabel Carvajal, MSc; Domenec Haro, MSc; Carles Peyra, MBA; Jesús Martínez-Gómez, MSc; Antonio Álvarez-Benavides, PhD; Ramón Estruch, PhD, MD; Rosa M. Lamuela-Raventós, PhD; Rodrigo Fernández-Jiménez, PhD, MD; Valentín Fuster, PhD, MD

**IMPORTANCE** School-based interventions offer an opportunity for health promotion in adolescence.

**OBJECTIVE** To assess the effect of 2 multicomponent educational health promotion strategies of differing duration and intensity on adolescents' cardiovascular health (CVH).

**DESIGN, SETTING, AND PARTICIPANTS** The SI! Program for Secondary Schools is a 4-year cluster randomized clinical intervention trial conducted in 24 secondary schools from Barcelona and Madrid, Spain, from September 7, 2017, to July 31, 2021. Eligible participants were adolescents enrolled in the first grade of secondary school.

**INTERVENTIONS** Schools and their participants were randomized to receive a health promotion intervention (SI! Program) over 4 school years (long-term intervention [LTI], 8 schools, 412 adolescents) or 2 school years (short-term intervention [STI], 8 schools, 504 adolescents) or to receive the standard curriculum (control, 8 schools, 441 adolescents).

MAIN OUTCOME AND MEASURES The primary end point was the between-group difference at 2 and 4 years in the change from baseline of the overall CVH score, as defined by the American Heart Association (range, 0-14 points, with a higher score indicating a healthier CVH profile). Intervention effects were tested with multilevel mixed-effects models. A complete-case intention-to-treat analysis was performed as the primary analysis.

**RESULTS** Of the randomized students, the study enrolled 1326 adolescents (684 [51.6%] boys, mean [SD] age, 12.5 [0.4] years at recruitment) with a study completion rate of 86.0%. Baseline overall CVH scores were 10.3 points in the LTI group, 10.6 points in the STI group, and 10.5 points in the control group. After 2 years, at halfway through the LTI and at the end of the STI, the difference in the CVH score change was 0.44 points (95% Cl, 0.01-0.87; P = .04) between the LTI group and the control group and 0.18 points (95% Cl, -0.25 to 0.61; P = .39) between the STI group and the control group. At 4 years, differences for the LTI and STI groups vs control were 0.12 points (LTI: 95% Cl, -0.19 to 0.43; P = .42) and 0.13 points (STI: 95% Cl, -0.17 to 0.44; P = .38). No adverse events were reported.

**CONCLUSIONS AND RELEVANCE** Overall, the tested school-based health promotion strategies in this randomized clinical trial had a neutral effect on the CVH of the adolescents. Although there was evidence of a marginal beneficial effect at a point halfway through implementation in the LTI group, such a benefit was not noted at 4 years. Further research is warranted into the efficacy of school-based health promotion programs.

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Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Authors: Rodrigo Fernández-Jiménez, PhD, MD, Centro Nacional de Investigaciones Cardiovasculares, Calle Melchor Fernández Almagro, 3, 28029 Madrid, Spain (rfernandez@cnic.es); Valentín Fuster, PhD, MD, The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, New York, NY 10029 (valentin. fuster@mountsinai.org).

E1

### Research Original Investigation

School-Based Cardiovascular Health Promotion in Adolescents

ardiovascular (CV) disorders, principally ischemic heart disease and stroke, remain the leading cause of premature death and morbidity worldwide, mainly due to the high prevalence of unhealthy lifestyles and overweight and obesity.<sup>1</sup> Modifiable CV risk factors include high body mass index, elevated blood pressure, smoking, and an adverse lipid profile. A recent longitudinal study found that the presence of these CV risk factors from early childhood is associated with incident CV events and death from CV causes in midlife.<sup>2</sup> The same study also found that changes to these risk factors between early life stages and adulthood are important predictors of the risk of CV events later in life. This finding is consistent with prior evidence suggesting that overweight during puberty increases the risk of type 2 diabetes in middle and late adulthood.<sup>3</sup>

Adolescence is a crucial stage during which lifestyle choices become settled.<sup>4,5</sup> There is therefore a need for early preventive action on modifiable factors (eg, diet, physical activity [PA], tobacco use, and other substance use) to stem the adverse trends in CV health (CVH).<sup>6,7</sup> Schools are a favorable environment for this type of intervention.<sup>5,8,9</sup> However, to our knowledge, there have been few school-based health promotion trials conducted with adolescents, and most have focused on weight loss rather than overall CVH promotion, showing only modest improvements.<sup>10,11</sup> The Salud Integral Program (SI! Program) is a multidimensional educational intervention aimed at promoting lifelong CVH by instilling healthy lifestyle behaviors from early childhood through adolescence, while also involving families, teachers, and the school environment.<sup>12,13</sup> Based on previous SI! Program studies in preschoolers, the ideal timing to achieve sustained positive effects may depend on multiple factors, such as the intervention duration and intensity and especially the age of the targeted population.<sup>14</sup> This article reports the main results of the SI! Program for Secondary Schools trial in adolescence in Spain. The main aim of this randomized clinical trial was to assess the effect of 2 multicomponent educational health promotion strategies of differing duration and intensity on adolescents' CVH.

### Methods

### **Study Design and Population**

The design and rationale of the SI! Program for Secondary Schools trial has been published elsewhere.<sup>12</sup> Briefly, this study was designed as a cluster randomized controlled intervention to test the effect of a comprehensive lifestyle program on the CVH of adolescents aged 12 to 16 years in Spain. The trial was launched September 7, 2017, and finalized July 31, 2021. Cluster units were schools that met the following inclusion criteria: public schools located in the metropolitan areas of Barcelona or Madrid providing education from the first through the fourth secondary school grades, with 3 to 5 classes in the first grade. The education agencies of the Madrid and Catalonia regional governments invited all eligible schools to a presentation of the study. Schools that agreed to participate were randomly allocated 1:1:1 to receive a comprehensive educational program through a long-term (4-year) intervention (LTI), a short-term (2-year) intervention (STI), or the standard

### **Key Points**

**Question** What is the effect of 2 multicomponent educational health promotion strategies of differing duration and intensity on adolescents' cardiovascular health?

Findings In this cluster randomized clinical trial including 24 secondary schools in Spain, a neutral effect on adolescents' cardiovascular health was found regardless of the received intervention. Although there was evidence of a marginal beneficial effect at a time point halfway through implementation in the group who received the longer intervention, this was not sustained at 4 years.

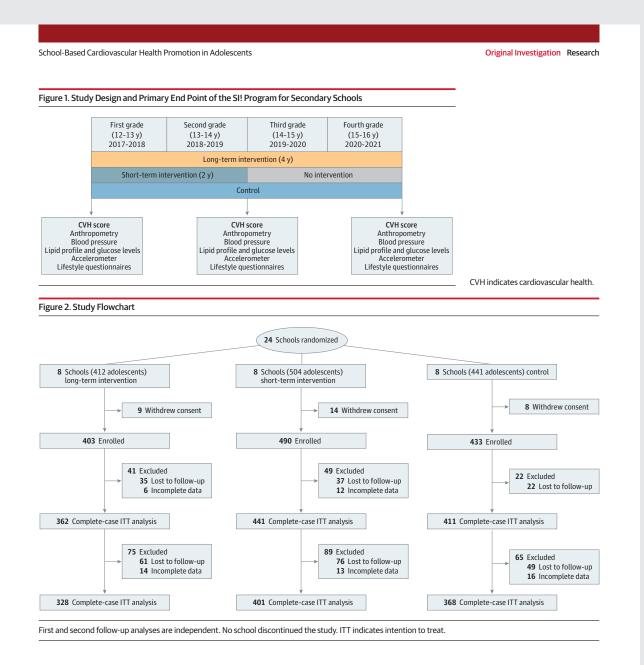
Meaning Further research is warranted into the efficacy of school-based health promotion programs with different intensities and reintervention strategies.

curriculum (control). A simple randomization scheme was used, ensuring an equal number of schools in each group (Figure 1). The allocation sequence was generated by an independent researcher who had no previous interaction with participating schools or adolescents. The study was approved by the corresponding committees for ethical research, and all participants gave their written informed consent to enroll in the study; participants did not receive financial compensation. The eligible adolescents were all students enrolled in the first grade of the secondary school at the participating schools. The study enrolled 24 secondary schools (17 in Barcelona and 7 in Madrid), corresponding to a total of 1326 adolescents (Figure 2).<sup>12</sup> The reporting of the results of this trial adheres to the Consolidated Standards of Reporting Trials Extension (CONSORT Extension) reporting guideline. The trial protocol can be found in Supplement 1.

#### Intervention

The SI! Program multidimensional educational intervention is based on the principles of the transtheoretical model of change<sup>15</sup> as applied to the promotion of healthy behaviors among adolescents and persons in their immediate environment (families, teachers, and school environment).<sup>16</sup> The SI! Program adopts a multicomponent approach based not only on the health effects of diet and PA, but also introducing emotion management focused on assertiveness, self-esteem, and other protective behavioral strategies against the use of tobacco and other harmful substances.<sup>13</sup> The intervention content was organized according to 2 strategies: LTI from first grade to fourth grade (ages 12-16 years) and the STI from first grade to second grade (ages 12-14 years). The curriculum incorporated 3 teaching units per school year: (1) healthy eating, (2) PA, and (3) protective factors against smoking and substance abuse. The curriculum was designed with an age-specific motivational theme developed through individual and group activities and interactive computer mini-games. Key messages were reinforced through newsletters distributed to families and school environment recommendations distributed to school leadership teams. All teaching activities for students were delivered in the classroom by their regular teachers after specific training provided by the Foundation for Science, Health, and Education. However, the implementation of the intervention in the third and fourth grades

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(which affected the LTI group) was modified due to the COVID-19 pandemic, including adaptation to remote learning and the cancellation of some activities involving PA. The description of the intervention follows the Template for Intervention Description and Replication guidelines<sup>17</sup> (eFigure 1, eTable 1, eTable 2, and the eMethods in Supplement 2 for additional information).

### **Data Collection**

Following American Heart Association recommendations, 7 health metrics were measured to determine the overall CVH of the adolescents (smoking status, body mass index, PA, diet, blood pressure, total cholesterol level, and blood glucose level).<sup>18</sup> Cardiovascular health was defined at 3 time points (baseline, 2-year follow-up at the end of the STI and halfway through the LTI, and 4-year follow-up at the end of the LTI and

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2 years after the end of the STI) using medical devices and/or self-report questionnaires. Adolescent participants were guided through questionnaires by a trained team of nutritionists and nurses or pharmacists, who also performed the clinical measurements during school hours according to a standardized protocol. Families (parents/caregivers) completed a survey with questions related to sociodemographic information (educational level, household income, and migrant status). No specific data on race and ethnicity were obtained.

Parental educational level was categorized according to the International Standard Classification of Education.<sup>19</sup> If more than 1 individual parental/caregiver educational level was reported, the highest one was used for analysis. Information on household income was collected and classified according to the most recently published Spanish average annual household income at the time of data collection.<sup>20</sup> Migrant

JAMA Cardiology Published online August 2, 2023 E3

Proyectos en colaboración

### Research Original Investigation

School-Based Cardiovascular Health Promotion in Adolescents

background was assigned if 1 or more parents/caregivers were born outside Spain. Missing values (if any) for socioeconomic variables used to create subgroups were not imputed (eMethods Supplement 2 for more details on data collection).

### **Definition of Health Scores**

The overall CVH score for each adolescent was calculated from 7 CVH metrics based on the American Heart Association criteria of ideal CVH in children and adolescents as reference values.<sup>18</sup> Each CVH metric was classified as ideal (score, 2), intermediate (score, 1), or poor (score, 0) (eTable 3 in Supplement 2). Overall scores were thus between 0 and 14 points, with a higher score indicating a better (healthier) CVH profile. The overall CVH score was also categorized as poor (overall CVH score, 0-7), intermediate (overall CVH score, 8-11), or ideal (overall CVH score, 12-14).<sup>21</sup> The analysis included all adolescents with valid data for at least 5 of the 7 individual CVH metrics. For participants with 1 or 2 missing individual health metrics, the overall CVH was calculated as the mean of the remaining metrics. The numbers of participants with missing values were as follows: 1 value was missing in 8 participants (0.60%) at baseline, 9 (0.75%) at 2-year follow-up, and 5 (0.44%) at 4-year follow-up and 2 values were missing in 45 participants (3.39%) at baseline, 10 (0.84%) at 2-year followup, and 13 (1.14%) at 4-year follow-up.

### **Outcomes and End Points**

The principal outcome measure was the overall CVH score (range, 0-14). The primary end points were the betweengroup differences in the change from baseline at 2-year follow-up and 4-year follow-up. Secondary end points included within-group changes in overall CVH over time and between-group differences in individual CVH metrics.

### **Qualitative Analysis**

At the end of the trial, students and teachers belonging to the LTI and STI schools from Madrid and Barcelona were invited to participate in online focus group discussions to share their personal experiences within the SI! Program. Four focus groups were conducted with fourth-grade students (11 girls and 13 boys), and 2 were conducted with 14 teachers (11 women and 3 men). Each session lasted 60 to 90 minutes, and the number of participants per session ranged from 4 to 9. Focus groups were led by a sociologist who conducted the interviews and the subsequent discursive analysis.<sup>22</sup>

### **Statistical Analysis**

The required trial sample size was estimated as previously described.<sup>12</sup> Continuous variables are presented as mean (SD), and categorical variables are presented as frequencies and percentages. Multilevel linear mixed-effects models that account for the hierarchical cluster randomized design were used to assess within- and between-group difference in overall CVH score as a continuous variable (range, 0-14 points) and for each of the 7 individual health metrics (range, 0-2 points). Similar models were built to assess the difference in the continuous variables that form the metrics of the CVH score. Stratified models were built according to socioeconomic variables of interest. Fixed effects

were the corresponding baseline score (as a continuous variable) and randomization group, whereas region (Madrid or Barcelona) and schools within each region were handled as random effects. Additional models were also adjusted for gender, age, household income, and migrant status. The Kenward-Roger method for small sample correction was used in all models.

Every attempt was made to follow up all enrolled participants, irrespective of allocation or treatment withdrawal. All participants were analyzed in the groups to which they were randomized. A complete-case intention-to-treat analysis was performed as the main analysis. As a sensitivity analysis, missing data were considered at random, and an analysis was performed including all enrolled participants after multiple imputation, using multivariate normal distribution. Further details of multiple imputation procedures performed can be found in the eMethods in Supplement 2. Statistical significance was set at 2-sided *P* < .05. All analyses were performed using Stata, version 15 (Stata Corp LLC).

### Results

### Participant Flow Diagram and Baseline Characteristics

The trial randomized and enrolled 1326 adolescents (684 [51.6%] boys, 642 [48.4%] girls) at 24 schools, with a study completion rate of 86.0%. Mean (SD) participant age at recruitment was 12.5 (0.4) years. No school withdrew from the trial during the study period, and no adverse events were reported.

A total of 1324 (99.8%) adolescents completed the baseline, 1214 (91.6%) completed the 2-year follow-up (median, 16.0; IQR, 15.2-16.9 months), and 1097 (82.7%) completed the 4-year follow-up (median, 40.4; IQR, 38.9-40.9 months) primary outcome assessments. These populations constituted the case-complete intention-to-treat analysis population (Figure 2; eFigure 2 in Supplement 2).

Adolescents were mainly classified as having intermediate overall CVH (65.5%), with a mean (SD) baseline CVH score of 10.5 (1.7) points and no significant differences between randomized groups (**Table 1**). Baseline information for participants included in the main analysis vs those with incomplete data and lost to follow-up is presented in eTable 4 and eTable 5 in Supplement 2.

### Primary End Points: Between-Group Changes in Overall CVH Score at 2- and 4-Year Follow-Up

Mean (SD) baseline overall CVH score was 10.3 (1.7) in the LTI group, 10.6 (1.5) in the STI group, and 10.5 (1.7) points in the control group. At 2-year follow-up, the mean difference between the control and LTI groups in the change in overall CVH score was 0.44 points (95% CI, 0.01-0.87; P = .04); for the comparison of the control and STI groups, the difference was 0.18 points (95% CI, -0.25 to 0.61; P = .39) (**Table 2**). At 4-year follow-up, the mean difference between the control and LTI groups in the change of overall CVH was 0.12 points (95% CI, -0.19 to 0.43; P = .42), and the difference between the control and STI groups was 0.13 points (95% CI, -0.17 to 0.44; P = .38) (**Table 3**). Overall results were similar in an analysis of all randomized enrolled participants after multiple imputation (eTable 6 in

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### School-Based Cardiovascular Health Promotion in Adolescents

### Table 1. Baseline Characteristics of Participants Enrolled in the SI! Program for Secondary Schools Trial<sup>a</sup>

Characteristic	Long-term intervention	Short-term intervention	Control	
Schools				
No. of schools	8	8	8	
No. of adolescents/school, mean (SD)	50.4 (10.5)	61.2 (21.8)	54.1 (14.6)	
amilies				
Region, No. (%)				
Barcelona	294 (73.0)	273 (55.7)	335 (77.4)	
Madrid	109 (27.0)	217 (44.3)	98 (22.6)	
Household income, No. (%)				
Low	156 (39.5)	150 (31.3)	130 (30.2)	
Average	141 (35.7)	143 (29.9)	126 (29.2)	
High	98 (24.8)	186 (38.8)	175 (40.6)	
Parental educational level, No. (%)				
Low	88 (22.2)	78 (16.3)	80 (18.5)	
Medium	171 (43.1)	183 (38.2)	183 (42.3)	
High	138 (34.8)	218 (45.5)	170 (39.3)	
Migrant background, No. (%)				
No	223 (56.3)	333 (69.5)	322 (74.5)	
Yes	173 (43.7)	146 (30.5)	110 (25.5)	
Adolescents				
No. of adolescents, No. (%)	403 (30.4)	490 (37.0)	433 (32.3)	
Age, mean (SD), y	12.6 (0.5)	12.5 (0.4)	12.5 (0.4)	
Gender, No. (%)				
Boys	210 (52.1)	250 (51.0)	224 (51.7)	
Girls	193 (47.9)	240 (49.0)	209 (48.3)	
Overall CVH score, mean (SD)	10.3 (1.7)	10.6 (1.5)	10.5 (1.7)	
Overall CVH score categorized, No. (%)				
Poor	29 (7.2)	19 (3.9)	26 (6.0)	
Intermediate	265 (65.8)	327 (66.9)	275 (63.7)	
Ideal	109 (27.0)	143 (29.2)	131 (30.3)	
Individual CVH metrics, mean (SD) <sup>b</sup>		1.0 (0.0)		
Smoking status	1.9 (0.5)	1.8 (0.6)	1.9 (0.5)	
Body mass index	1.6 (0.7)	1.7 (0.6)	1.6 (0.7)	
Physical activity	1.7 (0.5)	1.7 (0.4)	1.7 (0.4)	
Diet	0.6 (0.5)	0.6 (0.5)	0.6 (0.5)	
Blood pressure	1.8 (0.6)	1.7 (06)	1.7 (0.6)	
Total cholesterol level	1.6 (0.7)	1.7 (0.5)	1.5 (0.7)	
Blood glucose level <sup>c</sup>	1.2 (0.5)	1.4 (0.5)	1.4 (0.5)	

Abbreviation: CVH, cardiovascular health.

<sup>a</sup> The number of participants varied due to data availability.

<sup>b</sup> Individual CVH metrics range from 0 to 2 points. Overall CVH score (range, 0-14 points) was categorized as poor (overall CVH, 0-7), intermediate (overall CVH, 8-11), or ideal (overall CVH, 12-14).

<sup>c</sup> Although participants were instructed to fast overnight before the assessments, some of them may have had a nonfasting status at the time of measurements.

Supplement 2). In subgroup analysis, no consistent significant interaction effects were detected (eFigure 3 and eFigure 4 in Supplement 2).

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Original Investigation Research

### Secondary End Points: Within-Group Changes in Overall CVH and Between-Group Changes in Individual CVH Metrics

Many within-group changes over time in overall CVH score were larger in the intervention groups; however, no statistically significant within-group differences were observed in any group at any follow-up, and most between-group differences in the change in individual CVH metrics were nonsignificant (Tables 2 and 3). Similar changes were noted using continuous data for the metrics included in the CVH score (eTable 7 and eTable 8 in Supplement 2) and after adjusting for gender, age, household income, and migrant status (eTables 9 and eTable 10 in Supplement 2).

### **Qualitative Analysis of Focus Groups**

The participants were asked about their personal experience within the SI! Program. In all cases, the feedback was positive despite the complex situation due to the COVID-19 pandemic that affected mostly the last 2 years of implementation in the LTI group. The main qualitative results can be found in eTable 11 in Supplement 2.

### Discussion

The SI! Program for Secondary Schools cluster randomized clinical trial enrolled a large sample of adolescents and randomized them to receive 1 of 2 interventions differing in duration and intensity (LTI vs STI) or the control. The primary results of the trial showed an overall neutral effect of the 2 tested multicomponent educational health promotion strategies on adolescents' CVH. Although there was evidence of a marginal beneficial effect at a time point halfway through implementation in the LTI group, no such effect was noted at 4 years. To our knowledge, this is one of the largest trials to date evaluating a holistic school-based intervention for overall CVH promotion in adolescents.

### The Effect of Intervention Duration and Intensity on Health Promotion

One of the main objectives of the trial was to assess the effect of different timings and intensities of educational health promotion in adolescents. Although the curriculum of the 2 interventions was similar, the STI condensed all the content into 2 years, whereas LTI distributed that content over 4 years, thus requiring the dedication of fewer hours per school year (eTable 3 in Supplement 2). Focus groups conducted during the course of the trial and feedback received after completion revealed that teachers found the content very difficult to implement in just 2 years (eTable 11 in Supplement 2). This finding is unsurprising since educational innovation programs are usually consolidated in the third year, after teachers become familiar with the content and begin to include it effectively during the first 2 years. In addition, teachers have to pay attention to other academic and administrative tasks, so a more intense intervention increases the risk that these responsibilities might conflict with implementation.13

Moreover, while the marginal effects observed at 2-year follow-up were not affected by the pandemic, the results at the

JAMA Cardiology Published online August 2, 2023 E5

### Research Original Investigation

Table 2. Changes in the Overall CVH Score and Individual CVH Metrics at 2-Year Follow-up, Within and Between Randomization Groups

	Mean difference (95% CI)								
	Within-group <sup>a</sup>			Between-group <sup>b</sup>					
Variable	Long-term intervention			Control vs long-term intervention P value		Control vs short-term intervention	P value		
2-y Follow-up									
Overall CVH score	0.13 (-0.40 to 0.66)	-0.13 (-0.65 to 0.39)	-0.31 (-0.84 to 0.22)	0.44 (0.01 to 0.87)	.04	0.18 (-0.25 to 0.61)	.39		
ndividual metric									
Smoking status	-0.36 (-0.61 to -0.11)	-0.42 (-0.67 to -0.17)	-0.47 (-0.73 to -0.22)	0.11 (-0.07 to 0.30)	.21	0.05 (-0.13 to 0.24)	.56		
Body mass index	0.01 (-0.06 to 0.08)	0.07 (0.01 to 0.14)	0.01 (-0.05 to 0.08)	-0.00 (-0.06 to 0.05)	.86	0.06 (0.00 to 0.11)	.05		
Physical activity	-0.08 (-0.14 to -0.02)	-0.09 (-0.15 to -0.04)	-0.04 (-0.10 to 0.02)	-0.04 (-0.13 to 0.05)	.38	-0.06 (-0.15 to 0.03)	.21		
Diet	0.07 (0.00 to 0.13)	0.01 (-0.05 to 0.07)	-0.01 (-0.07 to 0.05)	0.08 (-0.01 to 0.17)	.09	0.02 (-0.07 to 0.12)	.59		
Blood pressure	0.09 (0.03 to 0.14)	0.04 (-0.01 to 0.10)	0.01 (-0.04 to 0.07)	0.07 (-0.01 to 0.16)	.09	0.03 (-0.06 to 0.12)	.48		
Total cholesterol	0.06 (-0.13 to 0.25)	0.01 (-0.18 to 0.19)	0.09 (-0.10 to 0.28)	-0.03 (-0.21 to 0.15)	.71	-0.08 (-0.26 to 0.10)	.34		
Blood glucose <sup>c</sup>	0.32 (-0.02 to 0.66)	0.27 (-0.06 to 0.61)	0.12 (-0.22 to 0.46)	0.20 (0.03 to 0.37)	.03	0.15 (-0.02 to 0.33)	.08		

Abbreviation: CVH, cardiovascular health.

<sup>a</sup> Mean marginal within-group differences (change from baseline to follow-up in each group) and 95% CI were derived from linear mixed-effects models. Fixed effects were baseline CVH score and randomization group, whereas region (Madrid or Barcelona) and schools within each region were handled as random effects. The Kenward-Roger method for small sample correction was used.

<sup>b</sup> Mean between-group differences (difference between groups in the change from baseline to follow-up) and 95% CI derived from linear mixed-effects models. Fixed effects were baseline CVH score and randomization group, while region (Madrid or Barcelona) and schools within each region were handled as random effects. The Kenward-Roger method for small sample correction was used.

<sup>c</sup> Although participants were instructed to fast overnight before the assessments, some of them may have had a nonfasting status at the time of measurements.

	Mean difference (95% CI)								
	Within-group <sup>a</sup>			Between-group <sup>b</sup>					
'ariable	Long-term Short-term intervention intervention		Control	Control vs long-term intervention	P value	Control vs short-term intervention	P value		
-y Follow-up									
Overall CVH score	-0.35 (-1.11 to 0.40)	-0.34 (-1.09 to 0.41)	-0.47 (-1.22 to 0.28)	0.12 (-0.19 to 0.43)	.42	0.13 (-0.17 to 0.44)	.38		
ndividual metrics									
Smoking status	-0.66 (-0.79 to -0.52)	-0.74 (-0.87 to -0.61)	-0.79 (-0.93 to -0.66)	0.14 (-0.05 to 0.32)	.14	0.05 (-0.14 to 0.24)	.58		
Body mass index	0.03 (-0.04 to 0.10)	0.09 (0.02 to 0.16)	0.06 (-0.01 to 0.13)	-0.03 (-0.10 to 0.03)	.31	0.03 (-0.04 to 0.10)	.38		
Physical activity	-0.31 (-0.40 to -0.21)	-0.29 (-0.38 to -0.19)	-0.27 (-0.36 to -0.17)	-0.04 (-0.14 to 0.06)	.43	-0.02 (-0.12 to 0.08)	.69		
Diet	0.04 (-0.03 to 0.11)	0.04 (-0.02 to 0.11)	0.07 (0.01 to 0.14)	-0.03 (-0.13 to 0.07)	.50	-0.03 (-0.13 to 0.07)	.55		
Blood pressure	0.02 (-0.22 to 0.27)	0.02 (-0.22 to 0.26)	-0.02 (-0.26 to 0.22)	0.04 (-0.06 to 0.15)	.40	0.04 (-0.07 to 0.14)	.48		
Total cholesterol	0.07 (0.01 to 0.12)	0.11 (0.06 to 0.16)	0.16 (0.11 to 0.22)	-0.10 (-0.18 to -0.02)	.02	-0.05 (-0.13 to 0.03)	.20		
Blood glucose <sup>c</sup>	0.43 (0.23 to 0.64)	0.44 (0.24 to 0.64)	0.37 (0.17 to 0.57)	0.07 (-0.03 to 0.17)	.19	0.07 (-0.03 to 0.18)	.14		

Abbreviation: CVH, cardiovascular health.

<sup>a</sup> Mean marginal within-group differences (change from baseline to follow-up in each group) and 95% CI were derived from linear mixed-effects models. Fixed effects were baseline CVH score and randomization group, whereas region (Madrid or Barcelona) and schools within each region were handled as random effects. The Kenward-Roger method for small sample correction was used. models. Fixed effects were baseline CVH score and randomization group, while region (Madrid or Barcelona) and schools within each region were handled as random effects. The Kenward-Roger method for small sample correction was used.

<sup>c</sup> Although participants were instructed to fast overnight before the assessments, some of them may have had a nonfasting status at the time of measurements.

<sup>b</sup> Mean between-group differences (difference between groups in the change from baseline to follow-up) and 95% CI derived from linear mixed-effects

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4-year follow-up can only be interpreted as a surrogate of the planned intervention. The implementation of the intervention in third and fourth grades was affected due to the associated work overload, periods of self-quarantine, and burnout of teachers and students. Despite combined efforts from schools and the study team to adapt the intervention contents to the pandemic situation, adolescents only attended schools every other week during the last year of the study, and some intervention activities (those related to PA) were canceled during lockdown and in the following school year. Unquestionably, the switch to digital instruction was a major hurdle for teachers and students, and also for their families.

### Effect of the Intervention on CVH Components

The deterioration of the overall CVH score identified through the within-group changes over time (Tables 2 and 3) is unsurprising, particularly in relation to the evolution of the PA score and smoking status, since adolescence is a critical behavioral phase when PA tends to decrease and smoking often starts.<sup>5,23-25</sup> The between-group differences in the change of overall CVH score were likely the result of the accumulation of small or nonsignificant differences in individual health metrics. For example, although between-group differences in the change of smoking status were not statistically significant, they were consistently larger in the intervention groups, and thus the intervention may have reduced the use of tobacco to some extent. The SI! Program curriculum included assertiveness, selfesteem, and socioemotional skills necessary to make healthy decisions and avoid substance use.

A significant difference in the glucose metric, with a higher score noted in the LTI group vs the other groups, was observed at 2-year follow-up; however, this difference may reflect assessment of some participants in nonfasting conditions, thus introducing a variable that may have randomly affected different groups to differing extents. In addition, although the difference was nonsignificant, a higher dietary score in the LTI group was found at 2-year follow-up, suggesting a modest improvement in dietary habits in at least some of the intervention participants. The results of focus groups with teachers and adolescents showed that participation in the trial assessments may have played a fundamental role in raising health awareness in all randomized groups (including controls), mostly regarding eating habits. In addition, the expected wide acceptance of the Mediterranean lifestyle in participating families may explain the lack of significant differences between groups.

### Health Promotion Interventions in Adolescents

There are no discernible patterns in the literature suggesting effective mechanisms for school-based health promotion. Moreover, there is a lack of multidimensional interventions, with most previous health promotion approaches in adolescents focusing on specific modifiable lifestyle factors, such as diet or PA, and considering specific related outcomes. A systematic review of meta-analyses on adolescent obesity prevention noted that most behavioral/educational interventions focused on a single component showed no statistically significant differences in weight-related outcomes, so that combined interven-

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tions seemed to represent greater benefits.<sup>10</sup> However, another recent systematic review found some evidence of support for PA-only interventions and limited evidence for diet-only and combined PA and diet interventions.<sup>26</sup>

In contrast, the SI! Program used a multicomponent intervention to achieve a holistic approach to health promotion in school settings. The curriculum aims to increase health literacy and individual empowerment by providing students with tools to make general healthy lifestyle decisions and take action on behalf of themselves and others. Although beneficial changes in health factors such as blood pressure and total cholesterol levels are difficult to achieve over a short period, the overall CVH score was chosen ambitiously as the main trial outcome because of its clinical relevance. Nevertheless, we also observed no beneficial effects for some key modifiable lifestyle factors. Because of the categorization of the CVH components, the score might not capture smaller improvements. In any case, to achieve significant changes in the overall CVH score, the greatest changes need to occur first in the behavioral components. Results from diverse health promotion strategies in adults report that positive outcomes possibly related to health promotion interventions tend to disappear over time, <sup>27,28</sup> suggesting the value of reintervention strategies. Consequently, this kind of educational program may require a more suitable primary end point and a reintervention to achieve sustained behavioral effects that may therefore result in a meaningful effect on biological parameters.

### Limitations

This trial has limitations. A major unpredicted limitation to implementation was the general lockdown due to the COVID-19 pandemic and the subsequent changes in school routines. The long duration of the trial increased the difficulty of retaining participants throughout the study. However, potential loss to follow-up and dropouts were factored into the sample size calculation, and the trial enrolled more participants than expected. Furthermore, the primary analysis was supplemented by a series of sensitivity analyses, and overall results were similar.

Regarding CVH measurements, some participants were likely assessed in nonfasting conditions, therefore affecting recorded blood glucose levels. However, an additional sensitivity analysis excluding the blood glucose metric from the overall CVH score calculations did not alter the overall direction of the results (eTable 12 in Supplement 2). In addition, adolescents were often asked by trainers and teachers to remove accelerometers for security reasons during training and competition, and therefore PA might have been underestimated in some cases.

#### Conclusions

The SI! Program for Secondary Schools cluster randomized clinical trial showed an overall neutral effect on adolescents' CVH regardless of the received school-based health promotion intervention. Although the LTI had a marginal beneficial effect at a time point halfway through implementation

Proyectos en colaboración

#### Research Original Investigation

(2-year follow-up), the COVID-19 pandemic affected its implementation afterward, and the 4-year follow-up results might not reflect the full potential of the LTI. Cardiovascular health usually worsens with age, with adolescence being a particularly vulnerable behavioral period. Therefore, educational programs may need to include an age-tailored reintervention phase to achieve sustained behavioral effects, paying special attention to the curriculum intensity.

#### ARTICLE INFORMATION

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Author Affiliations: Foundation for Science, Health and Education, 08011 Barcelona, Spain (Santos-Beneit, Bodega, de Cos-Gandoy, de Miguel, Carral, Orrit, Rodríguez, Carvajal, Haro, Peyra, Fuster); The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, New York (Santos-Beneit, Peyra, Fuster); Centro Nacional de Investigaciones Cardiovasculares, Madrid, Spain (Fernández-Alvira, Bodega, de Cos-Gandoy, de Miguel, Martínez-Gómez, Fernández-Jiménez, Fuster); Departament de Nutrició, Ciències de l'Alimentació i Gastronomia, Xarxa d'Innovació Alimentària. Facultat de Farmàcia i Ciències de l'Alimentació, Institut de Nutrició i Seguretat Alimentària, Universitat de Barcelona, 08921 Santa Coloma de Gramenet, Spain (Tresserra-Rimbau, Ramírez-Garza, Laveriano-Santos, Arancibia-Riveros, Lamuela-Raventós); Consorcio CIBER, M.P. Fisiopatología de la Obesidad y Nutrición, Instituto de Salud Carlos III, Madrid, Spain (Tresserra-Rimbau, Laveriano-Santos Estruch, Lamuela-Raventós); Departamento de Sociología III: Tendencias Sociales. Facultad de Ciencias Políticas y Sociología, Universidad Nacional de Educación a Distancia, Madrid, Spain (Álvarez-Benavides); Department of Internal Medicine, Hospital Clínic, Institut d'Investigacions Biomèdiques August Pi I Sunyer, University of Barcelona, Barcelona, Spain (Estruch); Centro de Investigación Biomédica En Red en enfermedades CardioVasculares, Madrid, Spain (Fernández-Jiménez); Hospital Universitario Clínico San Carlos, Madrid, Spain (Fernández-Jiménez). Author Contributions: Ms de Cos-Gandoy had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. These authors contributed equally: Drs Santos-Beneit, Fernández-Alvira, and Tresserra-Rimbau. Concept and design: Santos-Beneit, Fernández-Alvira, Tresserra-Rimbau, de Miguel, Ramírez-Garza, Carral, Rodriguez, Carvajal, Haro, Peyra, Estruch, Lamuela-Raventós, Fernández-Jiménez, Fuster. Acquisition, analysis, or interpretation of data: Santos-Beneit, Fernández-Alvira, Tresserra-Rimbau, Bodega, de Cos-Gandoy, Ramírez-Garza, Laveriano-Santos, Arancibia-Riveros, Orrit, Martínez-Gómez, Álvarez-Benavides, Estruch, Fernández-Jiménez, Fuster. Drafting of the manuscript: Santos-Beneit,

Fernández-Alvira, Tresserra-Rimbau, Lamuela-Raventós, Fernández-Jiménez, Fuster. Critical revision of the manuscript for important intellectual content: Santos-Beneit, Tresserra-Rimbau, Bodega, de Cos-Gandoy, de Miguel, Ramírez-Garza, Laveriano-Santos, Arancibia-Riveros, Carral, Orrit, Rodríguez, Carvajal, Haro, Peyra, Martínez-Gómez, Álvarez-Benavides, Estruch, Fernández-Jiménez, Fuster. *Statistical analysis*: Tresserra-Rimbau, Bodega, de Cos-Gandoy, Orrit, Martínez-Gómez, Fuster. *Obtained funding*: Santos-Beneit, Fernández-Alvira, Tresserra-Rimbau, Peyra, Estruch, Lamuela-Raventós, Fernández-Jiménez. *Administrative, technical, or material support:* Santos-Beneit, Tresserra-Rimbau, de Miguel, Ramírez-Garza, Laveriano-Santos, Arancibia-Riveros, Carral, Rodríguez, Haro, Peyra, Estruch.

Supervision: Santos-Beneit, Bodega, de Cos-Gandoy, de Miguel, Ramírez-Garza, Orrit, Rodríguez, Carvajal, Estruch, Lamuela-Raventós, Fernández-Jiménez, Fuster.

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#### THE PRESENT AND FUTURE

JACC STATE-OF-THE-ART REVIEW

## Lessons Learned From 10 Years of Preschool Intervention for Health Promotion

### JACC State-of-the-Art Review

Gloria Santos-Beneit, PhD,<sup>a,b,c</sup> Rodrigo Fernández-Jiménez, MD, PhD,<sup>c,d,e</sup> Amaya de Cos-Gandoy, MSc,<sup>a,c</sup> Carla Rodríguez, MSc,<sup>a</sup> Vanesa Carral, PhD,<sup>a</sup> Patricia Bodega, MSc,<sup>a,c</sup> Mercedes de Miguel, MSc,<sup>a,c</sup> Xavier Orrit, PhD,<sup>a</sup> Domenec Haro, BA,<sup>a</sup> José L. Peñalvo, PhD,<sup>f</sup> Juan Miguel Fernández-Alvira, PhD,<sup>c</sup> Carles Peyra, BA, MBA,<sup>a,b</sup> Jaime A. Céspedes, MD,<sup>g,h</sup> Alexandra Turco, BS,<sup>b</sup> Marilyn Hunn, BS,<sup>b</sup> Risa Jaslow, MS, RDN,<sup>b</sup> Jorge Baxter, PhD,<sup>i</sup> Isabel Carvajal, MSc,<sup>a</sup> Valentin Fuster, MD, PhD<sup>a,b,c</sup>

#### ABSTRACT

Implementing a health promotion program for children is a complex endeavor. In this review, we outline the key lessons learned over 10 years of experience in implementing the SI! Program (Salud Integral-Comprehensive Health) for cardiovascular health promotion in preschool settings in 3 countries: Colombia (Bogotá), Spain (Madrid), and the United States (Harlem, New York). By matching rigorous efficacy studies with implementation science, we can help bridge the divide between science and educational practice. Achieving sustained lifestyle changes in preschool children through health promotion programs is likely to require the integration of several factors: 1) multidisciplinary teams; 2) multidimensional educational programs; 3) multilevel interventions; 4) local program coordination and community engagement; and 5) scientific evaluation through randomized controlled trials. Implementation of effective health promotion interventions early in life may induce long-lasting healthy behaviors that could help to curb the cardiovascular disease epidemic. (J Am Coll Cardiol 2022;79:283-298) © 2022 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

R esearch on cardiovascular disease (CVD) prevention has been a global priority in recent decades,<sup>1,2</sup> and interest has increased further during the coronavirus disease-2019 pandemic, which has exposed unexpected cardiovascular vulnerabilities.<sup>3</sup> CVD is strongly associated with unhealthy habits such as a nutritionally poor diet, sedentary

lifestyle, and smoking,<sup>4</sup> and these unhealthy habits are alarmingly prevalent among children and adolescents.<sup>5,6</sup> Studies have reported a relationship between low cardiovascular health in childhood and poor cardiometabolic outcomes in adulthood<sup>7</sup>; it therefore seems reasonable to initiate healthy lifestyle education as early in life as possible.<sup>5</sup> The school



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#### ABBREVIATIONS AND ACRONYMS

BH = body and heart BMI = body mass index

CVD = cardiovascular disease KAH = knowledge, attitudes, and habits PA = physical activity SES = socioeconomic status environment has great potential as an intervention setting because children spend so much of their time there.<sup>2,8</sup> However, more research is needed to define which specific intervention characteristics and strategies contribute to the effectiveness of schoolbased interventions for health promotion and obesity prevention.<sup>9,10</sup>

The SI! Program (Salud Integral-Comprehensive Health) is a multilevel and multicomponent school-based program for

the promotion of cardiovascular health, aimed at achieving lasting lifestyle changes in children from preschool age.<sup>11-14</sup> The SI! Program for preschoolers has been assessed by using cluster-randomized trials in 3 countries with different socioeconomic contexts: Colombia,<sup>15</sup> Spain,<sup>12,16</sup> and the United States.<sup>17,18</sup> Schools were randomized to receive the SI! Program for 4 months or to the control group, and a structured survey was conducted at baseline and at the end of the intervention to assess changes in KAH (knowledge, attitudes, and habits) toward a healthy lifestyle. These studies included >3,800 children from 50 schools, their parents/caregivers, and teachers. Children in the intervention group reported a significantly larger increase in KAH scores after the implementation of a 4-month health promotion program compared with those in the control group.<sup>15-17</sup> However, until now, the SI! Program has not consistently shown a sustained improvement in relevant cardiovascular health metrics across the life span of a child beginning at 3 to 5 years of age.<sup>15-17,19</sup> In the absence of definitive evidence to determine best practices, we can, in the interim, value and continue to apply the evidence we have.<sup>20</sup>

The current review describes lessons learned from the implementation of the SI! Program for 10 years in the context of Rogers' Implementation Science  $Model^{21,22}$  adapted to health promotion: 1) dissemination (conveying information about the existence of a health promotion program to potentially interested parties); 2) adoption (explicit decision by a local unit or organization to try the program); 3) implementation (executing the health intervention effectively when it is put in place); 4) evaluation (assessing how well the health promotion program achieved its intended goals); and 5) institutionalization (the local unit or organization incorporates the intervention/ program into its continuing practices). Table 1 outlines the main stages of the implementation science framework adapted to school-based health promotion

#### HIGHLIGHTS

- Health promotion from early childhood is a global priority and can be delivered effectively to preschool-aged children.
- Lasting lifestyle changes can be promoted by health promotion strategies initiated in early childhood through locally coordinated and communitysupported science-based multidimensional and multilevel programs.
- Further research is needed to clarify the factors such as socioeconomic status that influence child health and effectiveness of intervention.

programs and the specific actions conducted as part of the SI! Program.

#### DISSEMINATION

Dissemination is an active approach to spreading evidence-based interventions to a target audience via determined channels by using planned strategies.<sup>23</sup> The school environment has great potential for effectively disseminating health promotion strategies. The literature of implementation science suggests that evidence-based interventions should be appropriately disseminated, to the right audiences, and implemented at the right time.<sup>24</sup> There are noted time points in a child's trajectory when improvements can be made to enhance long-term cardiovascular health status. A recent study of 51,505 children found that almost 90% of those who were obese at 3 years of age were overweight or obese in adolescence, and the most rapid weight gain occurred between 2 and 6 years of age among obese adolescents.<sup>25</sup> Another study conducted in 62,565 children found that overweight at 7 years of age was associated with increased risk of adult type 2 diabetes only if it continued until puberty or later ages.<sup>26</sup> Consequently, children's health during the preschool years in particular is a key determinant of obesity later in life. Compared with 3- to 4.5-year-olds, children aged 4.5 to 6 years display a model of attention much closer to that of adults.<sup>27</sup> This suggests that 4 to 5 years of age is the most favorable time to start a school-based intervention focused on healthy habits. To reach this audience, it is necessary to distill theory and evidence and translate this knowledge into user-

Implementation Framework Stages <sup>a</sup>	Example Actions From the SI! Program
I: Dissemination	Dissemination strategy relies on the most effective methodologies for generating significant learning in children
1. Intervention components	The SI! Program breaks down cardiovascular health into 4 interrelated components: diet, physical activity, emotion management, and body and heart.
2. Intervention design	A multidisciplinary team of experts facilitating successful assimilation of diverse methodologies designs the activities and resources.
3. Intervention strategy	The intervention includes the classroom, teachers, families, and school environment so children are more effectively involved.
II: Adoption	The local and/or regional educational administrative agencies authorized the program to be included in their schoo system and helped to obtain the initial acceptance of the school community.
III: Implementation	The SI! Program includes diverse activities led by specifically trained teachers.
<ol> <li>Initial considerations regarding the host setting</li> </ol>	The intervention and the assessment strategies are tailored to the local population and the corresponding environment to increase the likelihood of behavioral change.
2. Structure for implementation	The introduction of a school team coordinator within the school staff helps teachers and school leaders to ensur an effective implementation and allows for cascade training of teachers unable to attend the training sessions
3. Ongoing support strategies	In the SI! Program, a local program coordinator (a nonschool staff layperson) supports the school community, th school team coordinator (school staff), and the teachers.
4. Improving future applications	Improving strategies aim to increase adherence; for example, repetition of simple messages for children and families, constant support and motivation for teachers, and simple recommendations for a healthy school environment.
IV: Evaluation	The effectiveness of the program was evaluated through randomized controlled trials in 3 countries with differen socioeconomic contexts: Colombia, Spain, and the United States.
V: Institutionalization	The SI! Program is expanding to >250 schools in Spain and to >40 schools in the 5 boroughs of New York City

friendly resources<sup>22</sup> using the expertise of a multidisciplinary team and formative qualitative research to test appeal and comprehension of messaging to maximize uptake and impact (Key Element #1 of the Central Illustration).

**INTERVENTION COMPONENTS.** A systematic review of childhood obesity prevention programs showed higher significant effects on body mass index (BMI) with interventions that involve multiple components.<sup>28</sup> However, most preschool interventions have targeted only physical activity (PA) and/or diet components alone.<sup>9,29-34</sup> The SI! Program has a multifaceted and cross-sectional vision that breaks down cardiovascular health into 4 interrelated components that interact and add up (Figure 1; Key Element #2 of Central Illustration). Through the components diet and PA, children learn how a well-balanced diet and an active life are directly connected to a healthy heart. The most innovative component, emotions management, seeks to instill protective behavioral mechanisms against substance abuse (mainly smoking) and other health behaviors such as dietary decisions later in life by working on self-awareness, self-esteem, decision-making, listening, and communication skills. This component is fundamental to improving healthy lifestyles in children.<sup>5,35,36</sup> Finally, the body and heart (BH) component helps the children to understand how the human body works and how it is affected by behavior and lifestyle (and therefore by the 3 other

components). Appropriate goals for preschool children in each component are presented in Table 2.

Furthermore, health educational programs that are multidimensional, offering a comprehensive view of health as a function of lifestyle and body, may encourage the adoption and ownership of a health curriculum by children.

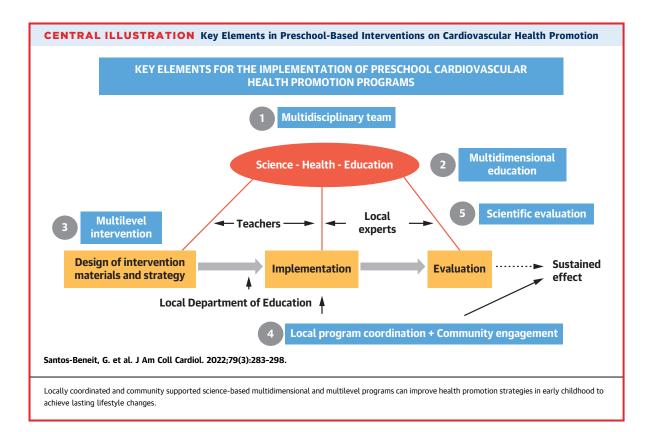
**INTERVENTION DESIGN.** The multifaceted nature of CVD requires complex interventions targeting several behaviors and/or levels of influence.33,37 A successful school-based health intervention program will therefore benefit from a core team comprising specialists from several fields related to education and health. Likewise, the intervention strategy needs to be logistically feasible and effective from the educational point of view. Combining the scientific evidence with optimal teaching strategies requires synergy between experts in each domain to ensure that the message reaches the target population in the most effective way. To support the considerable complexity of stages and processes that this implies, multimethod approaches may be required.<sup>38</sup> Based on these premises, the SI! Program activities and materials were designed by a multidisciplinary team of experts (nutrition, PA and sport sciences, education, and psychology) facilitating successful assimilation of methodologies from different fields proven to be the most effective at generating significant learning.<sup>15,39-45</sup>

The program aims to generate positive habits and attitudes related to body self-care and health-related

presidente

Provectos en colaboración Año 2022

286 Santos-Beneit *et al* Lessons Learned From Preschool Health Promotion JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298



matters.<sup>12</sup> These positive attitudes are generated through knowledge acquisition,  $^{\rm 15}$  motivation, and content reinforcement by using animated characters, which help to make abstract concepts concrete and provide the children with a role model. Furthermore, to accommodate the symbolic thinking typical of this age group,<sup>46</sup> the SI! Program featured a heart-shaped mascot named Cardio who complies with all the recommended healthy behaviors. The program also uses Sesame Street characters such as Dr. Ruster, a Muppet doctor based on one of the authors (V.F.), who introduces and conveys most messages and activities (Supplemental Figure 1). The design of the materials can help to hold the attention not only of the children but also of teachers and families. Other materials include video segments with a "view and do" approach for use in classrooms and printed materials made to fit the distribution strategy in school settings; these include a colorful storybook, an interactive board game on healthy behaviors, flash cards on emotions management, family activities, and a teacher's guide.<sup>11</sup>

Learning is most effective when the activities are related to direct experimentation,<sup>47,48</sup> artistic

expression, play,<sup>49</sup> viewing videos,<sup>50</sup> reading stories,<sup>51</sup> and group activities.<sup>47,48</sup> In summary, a multidisciplinary team is essential for ensuring a more complex tailoring of the program from curricular messaging to implementation.

**INTERVENTION STRATEGY.** The SI! Program includes 4 levels of intervention: classroom, teachers, families, and the school environment (Figure 1; Key Element #3 of Central Illustration). According to Cognitive Social Theory, the environment has a fundamental influence on the learning process and behavior change,52 and children are engaged more effectively if the intervention includes their immediate surroundings.75 The SI! Program primarily follows a teacher-delivery model used in other prior interventions in preschool.31,32,53-54 Teachers are crucial to the success of school-based interventions, especially those involving preschool-aged children. The trusting relationship developed between children and teachers allows the message to be received with greater attention and credibility than if it came from external personnel.<sup>36</sup> In addition, family members are young children's primary social context, providing

JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298

experiences and access to food and PA through which children begin to acquire healthy or unhealthy lifestyles.<sup>55-61</sup> To facilitate participation of family members, the SI! Program includes simple and accessible activities (Supplemental Figure 2). Lastly, the school environment can have a significant effect on the success of school-based interventions<sup>38,62</sup> by fostering a community of health, and thus it may be appropriate that the intervention program includes recommendations for the whole school environment. In the SI! Program, a healthy school environment is promoted through simple messages on posters or flyers distributed throughout the school (Figure 2).

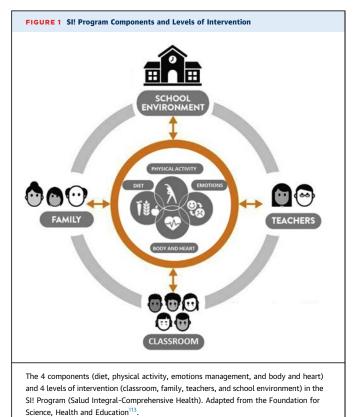
In summary, a multilevel approach targeting not only children but also their families, teachers, and the school environment is likely needed for the success of a school-based health promotion program.

#### ADOPTION

Adoption is the decision of an organization or a community to commit to and initiate an evidencebased intervention.<sup>23</sup> Establishing a close relationship with stakeholders and building trust in the community are essential for generating support for school-based health promotion interventions.<sup>63</sup> This requires working partners and leaders who have a long-standing relationship with and deep commitment to their local community. The SI! Program obtained the support of the local and/or regional educational administrative bodies. The corresponding education administrations authorized the program to be included in their school system and curriculum, and then helped to identify eligible schools for the implementation and to obtain the initial acceptance of the school community. The eligible schools were invited to participate in a 1-day meeting during which the fundamentals of the SI! Program were presented. To formally volunteer to participate in the health promotion program, a designated staff person in a leadership role (eg, director/principal, site director, education director) submitted an application/approval letter on behalf of the school. In summary, the support of corresponding educational administrative entities is crucial to successfully introducing a health promotion program into the school system.

#### IMPLEMENTATION

The implementation process of the SI! Program in the context of external literature is described in the following sections by using a meta-framework called the Quality Implementation Framework<sup>22</sup> comprising the following 4 phases: 1) initial considerations



regarding the host setting; 2) creating a structure for implementation; 3) ongoing structure once imple-

implementation; 3) ongoing structure once implementation begins; and 4) improving future applications. Each stage includes critical steps in the implementation process. When coordinated with specific step-related actions, this tiered design can allow for effective implementation of health education programs.

PHASE I: INITIAL CONSIDERATIONS REGARDING THE HOST SETTING. Assessment strategies. Interventions can be tailored to the study population and the local environment to increase the likelihood of behavioral change. As an effective qualitative analysis tool, focus groups conducted in a pilot phase of the study before initiation of the health program ensure that the intervention is adapted to the needs and cultural preferences of the targeted community.<sup>64</sup> Accordingly, it might be necessary to include local health and educational advisors to adjust both the educational strategies and the assessment tools to the socioeconomic and cultural context of each setting. This strategy may help the research team to adapt the

Corazones sanos. Publicaciones. Proyectos en colaboración 288 Santos-Beneit *et al* Lessons Learned From Preschool Health Promotion

Component	Goals
Diet	Acquiring knowledge of different food groups (eg, fruit, vegetables, cereals, greens) and their beneficial properties
	Understanding the importance of a balanced diet (different colors and varied foods)
	Learning the different foods recommended for each daily meal
	Learning food portion sizes and the difference between hungry and full
	Awakening taste and curiosity about different types of cuisine and trying new foods
Physical activity	Understanding the relationship between the energy we get from healthy foods and movement (physical activity)
	Understanding the function of the muscles and bones through physical activity
	Developing gross motor skills
	Developing coordination through dance and play, and learning how to get the body moving
	Acquiring healthy routines and habits around physical activity
motions management	Identifying, representing, and naming the basic emotions that human beings commonly experience
	Understanding and expressing how emotions make us feel and what they feel like
	Exploring the causes of different emotions and how they differ from person to person
	Knowing strategies to manage and self-regulate emotions such as breathing and painting, with the guide of an adult
	Knowing the external and internal body parts and working on body function
Body and heart	Caring for the body and heart
	Learning about the heart, its function in the body, its movement, and the relationship between movement and the hea
	Understanding the senses, their functions, and how the senses give us information about our environment

whole approach of the intervention to each country. The specific issues considered in the SI! Program were local and cultural health beliefs or practices related to food, facilities, and daily time allocated for PA in school; children's transportation methods to school (eg, walking, public transportation); meals provided in school; popular songs or stories; local everyday rituals; and their celebrations in schools (eg, birthdays).

Decisions about adaptation. An important characteristic of implementation science is using malleable designs that allow for changes and modifications to achieve the best and most impactful results.<sup>65</sup> Flexibility within the implementation design is crucial to adapt to key variables such as the starting age for the health promotion program. According to the teachers involved in the SI! Program, the first year of preschool is unlikely to be the most appropriate for an intervention. In this period, the class group is being formed, and it takes time for relationships between the children and the teacher to become fully settled. It is likely more efficient to implement the intervention when the group has already acquired a series of daily routines because it is easier to incorporate new content and activities into a familiar schedule. Despite this, the choice of starting age for a comprehensive school health intervention is also determined by the structure of educational stages in each country.

The SI! Program objectives within each component are addressed in a very direct and simple way so they

can be easily adapted to different socioeconomic settings or coexist with health promotion strategies at the local level. This is important to avoid an inequitable administration of the intervention that may lead to further enhancing the existing divide in childhood obesity.<sup>66</sup> For example, goal #1 in **Table 2**, "Acquiring knowledge of different food groups (eg, fruit, vegetables, cereals, greens) and their beneficial properties," can be approached by using examples of accessible food and can coexist with any school or community food program. Moreover, the SI! Program materials can be distributed via hard copy in a teacher kit portable file box or digitally accessed, thus building flexibility into the intervention delivery.

Capacity-building strategies. Teachers have a fundamental role in transmitting knowledge and shaping children's behavior during learning.<sup>67</sup> A school-based program encouraging behavior change goes beyond standard preservice teacher education, and specific training is therefore fundamental to helping teachers implement the intervention correctly, improve instructional practices in this area, and thus foster high fidelity.<sup>68</sup> Professional development opportunities, when properly designed, also serve as motivational mechanism and increase trust with the intervention developers. The SI! Program includes formal training to teachers in skills needed to promote healthy habits in children; this training also addresses teacher motivation and self-reflection on their own health to help teachers set an example of healthy living. The core concepts of such a teacherJACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298

training program are as follows: 1) the relationship between healthy habits acquisition from childhood and improved quality of life in adulthood; 2) the SI! Program teaching approach; and 3) the concept of whole health as the interrelation between a healthy diet, PA, emotional education, and the BH.<sup>69</sup> Teacher training also includes in-depth work on the course materials, analysis of teaching plans, and proposed measures to improve the school environment. The SI! Program teacher training may last from 10 to 50 hours depending on local requirements on formal professional development.

PHASE II: STRUCTURE FOR IMPLEMENTATION. Implementation teams. The introduction of a school team coordinator greatly helps teachers and staff leaders (eg, director/principal, site director, education director) to ensure effective implementation of the program. The school team coordinator can be a teacher or any other staff member and should be an active part of the faculty with an interest in health, good social and communication skills, and an empathetic manner. The presence of a school team coordinator can facilitate teacher training, as he or she can conduct "cascade training" ("train-the-trainers") of teachers unable to attend the training sessions. The school team coordinator can also act as a link between parents, teachers, and the school leadership to promote decision-making related to the school's health needs and participation in the annual Healthy Week. Ultimately, responsibility for conducting the program is shared proactively across the entire educational community.

Implementation plan. The SI! Program includes various types of activities with different learning goals that take between 5 and 50 minutes to complete (Table 3), totaling a minimum of 40 hours; they are distributed through teaching units of diet, PA, emotions management, and BH in a balanced way. The activities should be repeated whenever possible to instill deep-seated healthy attitudes and behaviors. To achieve a minimum daily practice of PA needed to improve children's health, 53,70-74 the SI! Program includes a 20-minute PA routine (eg, a choreography in video format to practice throughout the school year). Thus, with the complementary activities, the overall program exposure can increase up to 70 hours. The success of a health promotion program requires a minimum of 30 to 40 hours of exposure annually.<sup>53,75</sup>

The family activities are related to classroom activities, providing a direct link between home and school (Supplemental Figure 2). At least 6 family activities are distributed across the teaching units, covering the 4 SI! Program components as follows: 1

TABLE 3         Types of Activity for the Classroom									
	Teaching Goal								
Initiation	Introduce or activate knowledge								
Development	Acquisition of knowledge and skills								
Synthesis	Consolidate new learning and understand its usefulness in daily life								
Complementary (optional)	More in-depth exploration of corresponding content								
Family	Application at home of the acquired knowledge								
Adapted from Carral et al."									

activity for diet, 1 for PA, 3 for emotions management. and 1 for BH. These activities are divided into 2 parts: 1) a short explanation of the importance of the specific health-related topic; and 2) a component-related game or activity that the child is expected to undertake together with family members, to create daily routines.<sup>69</sup> Furthermore, schools participating in the SI! Program are provided with a document presenting 10 action recommendations for the school environment (Figure 2) and a poster with simple key health messages for families. The SI! Program's health awareness messages are further reinforced through an annual Healthy Week or a "Celebrating what we have learned" week, which fosters an inclusive, playful community atmosphere in which habits and concepts are better retained.36,76 Schools participating in the SI! Program are provided with a model itinerary for this special week, including content and activities designed to include all family members and encourage their full participation.

PHASE III: ONGOING SUPPORT STRATEGIES. The effectiveness of a health promotion program depends not only on the quality of the materials and curriculum offered to teachers and families but also on the follow-up and support provided by the program developers.<sup>40</sup> Teachers take on the role of intervention facilitator alongside their primary role as a teacher. A recent study of school-based interventions in adolescents found that a passionate, well-trained layperson can effectively change students' and teachers' practices.<sup>77,78</sup> Given the role model status of preschool teachers and their primary responsibility to teach the designated syllabus (as well as ancillary academic and administrative tasks), there is a risk that these responsibilities might undermine or conflict with the ethos of the intervention.<sup>79</sup>

In this context, the inclusion of a local program coordinator (a nonschool staff layperson) is a recommended strategy to support the school community, the school team coordinator (school staff), and the teachers (Figure 3; Key Element #4 of Central Illustration). This nonschool staff role can be

Proyectos en colaboración Año 2022

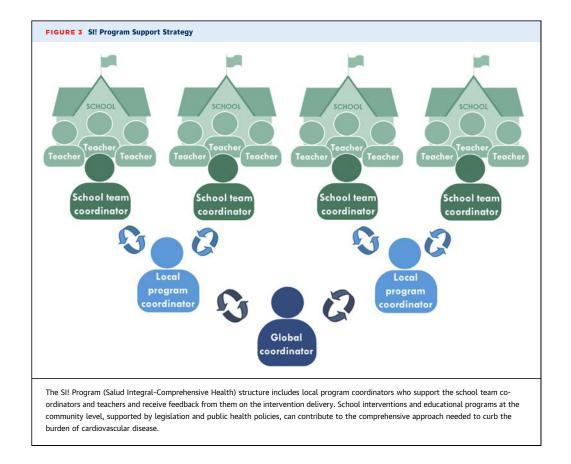
JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298



performed by any specifically trained person who has the skills to communicate with the various members of the educational community. The local program coordinator has 2 main tasks: 1) to ensure the quality of the intervention by monitoring its implementation; and 2) to secure and sustain the commitment of the teaching staff implementing the program (and therefore achieving optimal adherence to the program). The local program coordinator may receive training through a global coordination system, including guidelines for teacher support and implementation monitoring.

Informe Anual 2022 83

#### Santos-Beneit *et al* 291 Lessons Learned From Preschool Health Promotion



The local program coordinator's key contact point in the school is the school team coordinator. The creation of an standardized monitoring and feedback system for implementation allows the research team to evaluate intervention adherence and also to improve or adapt the strategy based on the school community's feedback.62 The local program coordinator, in communication with school-level actors, ensures effective coordination of teacher training, meetings (in-person or remotely), curriculum presentation, frequent motivational communication, and provision of information about recent publications related to cardiovascular health and findings from the global developer team's projects. Successful engagement of the educational community will mostly depend on whether people believe the issue is directly relevant to them, see evidence of progress, and have a sense that their actions can make a difference.79

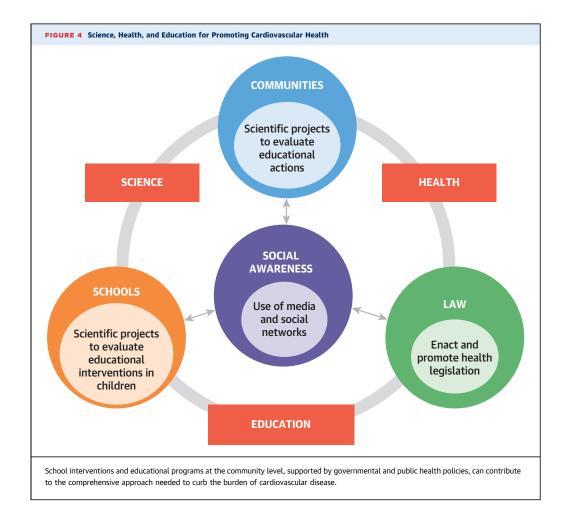
Teacher motivation is crucial for optimal implementation because highly motivated teachers are more engaged, and their motivation is linked to that of their students.<sup>80</sup> The local program coordinator will help to increase and sustain teacher motivation by providing mentorship and encouragement during check-ins, aside from simply providing technical assistance with the curriculum. This will provide the teachers with the opportunity to feel supported during check-ins throughout the school year. To assess how well different aspects of the SI! Program are being implemented, teachers are required to provide reports on the number of activities delivered to children and the families. This becomes a key aspect for process evaluation because accurate interpretation of outcomes depends on knowing what aspects of the intervention were delivered and how well they were conducted.<sup>62</sup>

**PHASE IV: IMPROVING FUTURE APPLICATIONS. Main challenges.** The involvement of families in health promotion interventions is challenging, and family socioeconomic status (SES) may play a crucial role in its success. Previous findings showed that children from families with low SES generally

Proyectos en colaboración Año 2022

292

Santos-Beneit *et al* Lessons Learned From Preschool Health Promotion JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298



respond less well to lifestyle interventions than those from families with higher SES.<sup>16,17,81</sup> Therefore, concern exists that such interventions could increase inequalities rather than reduce the gap. Nevertheless, the risk of increasing health disparities is generally lower for complex interventions acting on multiple targets and in multiple settings<sup>66</sup> such as the SI! Program. Because the SI! Program curriculum includes a minimum of 40 hours of exposure annually, it could be inequitably administered. However, because schools are required to implement a number of hours of health education as part of the standard curriculum, the SI! Program helps the participating schools meet local health education standards. Health education is a vital tool for improving health and lifestyle decisions; it is fair to acknowledge, however, that many structural factors, including food accessibility and affordability, exist and create health disparities that are difficult to target with education alone.

Obesity prevention strategies shown to be effective in lower SES participants often include communitybased strategies or policies aimed at structural changes to the environment, whereas interventions primarily based on directing information at individual behavior change tend to be ineffective in this group.<sup>82</sup> Based on these premises, and to facilitate family member participation, the SI! Program includes simple and accessible activities for the whole community. The key messaging for families focuses on simple recommendations that encourage widespread adoption by family members. Moreover, the integration of web applications may increase family engagement.<sup>83</sup>

Another valuable resource may be to provide schools with an extended document containing

JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298 293

healthy school recommendations encouraging school management teams to assess the school environment and identify any shortfalls related to health promotion. In addition, specific workshops or training for school staff and families may increase their awareness through education and personal feedback, which could improve adherence to these recommendations. A collaborative approach is recommended, in which families and school staff form a partnership in developing a plan for behavior change tailored to the needs of the local community.<sup>84</sup>

Regarding the curriculum, some content could be considered novel by teachers if the topic is not commonly taught in-depth within the regular curriculum. In this regard, some concepts may need to be reinforced. As an example, in the SI! Program, the emotions management unit has been revised based on teachers' feedback and reinforced with a guide on how to integrate the development of emotional competence through day-to-day classroom activities as well as at home. This guide supported teachers in creating emotionally reassuring environments, encouraging family involvement, and assessing students' progress toward desirable emotional management abilities. In addition, it is necessary to develop materials to address specific needs, such as activities for remote learning, or alternative resources that do not require the use of electronic or web-based materials if access to such technology is limited.

Improving adherence. Fidelity to the delivery protocols supporting evidence-based practice is a source of outcome variation.<sup>38</sup> In Spain, an intensive monitoring and teacher support system was established, and nearly 100% adherence was achieved, meaning that the health promotion curriculum was nearly completely delivered. However, in the SI! Program study in Harlem, a potential dose-response effect of the intervention was assessed. The differences in KAH scores between children receiving <50% of the program modules (low adherence) versus those receiving 50% to 75% (intermediate adherence) or >75% (high adherence) were analyzed. Compared with the low-adherence group, the high-adherence group showed a significantly larger change from baseline in overall KAH score.<sup>17</sup> A dose-response effect was also observed after delivering the SI! Program in community centers to children aged 9 to 13 years in Bogotá.<sup>19</sup> The impact of intervention adherence highlights the importance of strategies promoting intervention fidelity to achieve the highest benefits for the targeted population.<sup>62</sup> In this regard, and as mentioned previously, the SI! Program uses a coaching approach for teachers through a local program coordinator and a methodology based on up-to-date

findings. The intervention design allows for continuous improvement of materials through focus groups, annual feedback from teachers, and review of the scientific evidence. Furthermore, it includes some proven strategies to increase the adherence, such as repetition, constant support and motivation, and, most importantly, simple messages, as lower health literacy is associated with greater risk of nonadherence.<sup>84</sup>

#### EVALUATION

Before expanding a health promotion program, it may be appropriate to evaluate the effectiveness of the intervention while adhering to evidence-based practice (Key Element #5 of the **Central Illustration**). Randomized controlled trials are the reference standard for assessing relationships between intervention and outcomes.<sup>85</sup> Therefore, scientific evaluations through randomized controlled trials are one of the most reliable ways to test the efficacy of school-based interventions.

Published trial results about preschool-based interventions could help to ensure the replicability of interventions in diverse settings and socioeconomic backgrounds.<sup>9,10,29,33,36,86,87</sup> There are several scientific challenges to measuring the efficacy of an intervention in the school setting. One of the main challenges, particularly for research on preschoolers, is the nature of the assessment tools. The methodology (individual vs group administration), and design (number and complexity of items) have to be adapted to the stages of maturation in children.<sup>15,40,88</sup> Preschool-aged children cannot yet read well, and thus questionnaires in the SI! Program included simple pictures to support both questions and answers and were administered individually by trained early child education professionals. Questions were adapted to the sociocultural context by using names and pictures of local foods, pictures of local playgrounds, and images reflecting local ethnic diversity. In the SI! Program, the overall questionnaire assessed children's KAH in relation to a healthy lifestyle. This metric is based on a progressive acquisition and retention of healthy habits in children according to the Trans-theoretical Model of Health Behavior Change, which includes 5 stages of behavior modification.44 The KAH score aggregates the "precontemplative" and "contemplative" stages as the acquisition of knowledge (K), the "preparation" phase as setting this knowledge into attitudes (A), and the final "action" and "maintenance" stages as the acquisition of the desired habit (H). This was translated into component-specific KAH scores plus an

Corazones sanos. Publicaciones. Proyectos propios

Proyectos en colaboración

#### 294 Santos-Beneit *et al* Lessons Learned From Preschool Health Promotion

JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298

overall score representing the intervention as a whole.<sup>89</sup> The KAH system has been shown to serve as a surrogate of improved lifestyle and therefore may be a successful measure of the ability of the intervention to instill these concepts and provide children with tools for self-promotion of health.<sup>36,90-95</sup> However, there is a lack of consistent evidence about the association between KAH scoring systems and health indicators such as BMI, waist circumference, or blood pressure. In the SI! Program trial in Spain, a positive trend in the intervention group both for KAH score and adiposity indicators was found<sup>16</sup>; in contrast, other studies showed no significant differences between the intervention and control groups in any of the anthropometric variables, even though several components of knowledge, attitudes, and behaviors score were significantly changed by the intervention.96

Questionnaires can carry a subjective component that may affect the results; however, individual administration by trained staff can help to standardize the process and minimize this problem. In contrast, direct measurements are an accurate and reliable source of information, and a combination of questionnaires and direct measurements allows for cross-validation. Data collection should be standardized and conducted by trained technical personnel such as nutritionists, nurses, and child assessors. Given the lack of consensus regarding BMI cutoffs, large-scale comparisons might be aided by using both local percentiles and growth charts from the World Health Organization or the U.S. Centers for Disease Control and Prevention.97 Some indicators of fat amount and distribution, such as skinfolds or circumferences, may add valuable information widely used in the pediatric setting.98 Other health indicators, such as a blood glucose or lipid profile, or accelerometers to assess PA have been included in other interventions in preschoolers and in the SI! Program for Secondary Schools trial.<sup>14,99-101</sup> Providing information and guidance to families based on their children's results was a great incentive for participation, especially in communities with low access to medical care such as the population of the study conducted in Harlem.

#### INSTITUTIONALIZATION

Transferring and sustaining effective programs in real-world settings is a complex, long-term process that requires effective strategies for dealing with the subsequent phases of program scale-up.<sup>62</sup> The

institutionalization stage takes place when the local unit or organization incorporates the health promotion program into its continuing practices.<sup>22</sup>

The SI! Program is expanding and thus far has been successfully implemented in >250 schools in Spain, reaching >30,000 children and providing training to an average of 170 teachers per school year. The corresponding local government's Education Departments have recognized the SI! Program training as part of teachers' certified training, which is a strong motivating factor for teachers and schools.

Implementation and evaluation of the SI! Program for >10 years have yielded several lessons and insights regarding the challenging task of promoting cardiovascular health in the school setting, starting with preschool-aged children. To promote the commitment of the educational community, the SI! Program team is providing feedback on the results through meetings and social- and/or mass media, forging a lasting connection with the community and creating a feeling of belonging.<sup>87</sup> This feedback includes the accumulated experience of the implementation and teachers' suggestions and comments.

The SI! Program is now expanding across the 5 boroughs of New York City through a new project called the CHSEI (Children's Health and Socioeconomic Implications) project. This study is putting in place all the accumulated experience acquired over the last 10 years to improve the development of materials, implementation strategy, and scientific evaluation. The diverse ethnic and socioeconomic backgrounds in New York City offer a unique opportunity to expand our health promotion program and to explore which socioeconomic factors, at both the family and borough level, may eventually affect children's health, how they are implicated in the intervention's effectiveness, and how they can be addressed to reduce the gap in health inequalities.

The sustainability of school-based interventions can be promoted by interventions at different strata, such as workplace health promotion programs,<sup>102,103</sup> active aging programs,<sup>104-107</sup> or more intense parallel health promotion programs specifically targeting parents/caregivers.<sup>108</sup> Although the maximum possible sustained public health benefit would come from implementing multiple interventions at all levels of the ecological model, the single interventions with the greatest impact on population health are those focusing on the physical and social environmental context and on socioeconomic and policy factors.<sup>109</sup> It is crucial to engage all potential JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298 295

partners as strategic collaborators to ensure that interventions address the full spectrum of CVD, from prevention and risk factor reduction to diagnosis and treatment.<sup>63,110</sup> Moreover, the collaboration of community health and government agencies is necessary to provide the public with a coherent message on health matters; for example, through advertising, food labeling, adaptation of local infrastructures to promote PA as healthy leisure, and price regulation of healthy foods.<sup>111</sup> All these strategies, added to school programs and legislative actions (Figure 4), can contribute to the comprehensive approach needed to curb the burden of CVD.<sup>112</sup>

Thus, community engagement (Key Element #4 of the **Central Illustration**) is crucial to introduce and maintain an effective sustained health promotion program in the school system.

#### CONCLUSIONS

Transferring effective programs into real-world settings is a complicated, long-term process that requires effective integration of implementation research. This review has presented key lessons learned from implementing the SI! Program for over a decade in different educational settings around the world. Some key elements in the promotion of cardiovascular health in the school setting have been identified: 1) multidisciplinary teams; 2) multidimensional educational programs; 3) multilevel interventions; 4) local program coordination and community engagement; and 5) scientific evaluation through randomized clinical trials.

A core challenge in global health is translating scientific evidence into educational and community practices. This challenge becomes more complex when it requires individual, organizational, and systemic behavior change. By matching rigorous scientific impact studies with implementation framework analysis, we can help bridge the divide between science and educational practice. ACKNOWLEDGMENTS The authors thank the SHE Foundation, intellectual owner of the SI! Program, and its collaborators. The authors also thank Sesame Workshop for providing supporting materials for the intervention and for their long-standing partnership, in particular Brenda Campos and Carolina Casas. The authors are indebted to the children, families, and teachers who participated in the projects in Colombia, Spain, and the United Sates, as well as to the local teams who collaborated in the studies. The authors especially thank Maribel Santana and Carles Vilarrubí. Simon Bartlett provided English editing.

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ADDRESS FOR CORRESPONDENCE: Dr Rodrigo Fernández-Jiménez, Centro Nacional de Investigaciones Cardiovasculares (CNIC), Calle Melchor Fernández Almagro, 3, 28029 Madrid, Spain. E-mail: rodrigo. fernandez@cnic.es. Twitter: @rodrigo\_fjez. OR Dr Valentin Fuster, The Zena and Michael A. Wiener Cardiovascular Institute Icahn School of Medicine at Mount Sinai, 1 Gustave L. Levy Place, New York, New York 10029, USA. E-mail: valentin.fuster@mountsinai.org.

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JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298

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298

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JACC VOL. 79, NO. 3, 2022 JANUARY 25, 2022:283-298

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**KEY WORDS** cardiovascular disease, child, health promotion, implementation science, lifestyle, prevention

**APPENDIX** For supplemental figures, please see the online version of this paper.

Real C et al. Magnetic resonance imaging reference values for cardiac morphology, function and tissue composition in adolescents. EClinicalMedicine 2023;57:101885.

## Articles

# Magnetic resonance imaging reference values for cardiac morphology, function and tissue composition in adolescents

Carlos Real,<sup>a,b</sup> Rocío Párraga,<sup>a,b</sup> Gonzalo Pizarro,<sup>a,c,d</sup> Inés García-Lunar,<sup>a,d,e</sup> Ernesto González-Calvo,<sup>a,b</sup> Jesús Martínez-Gómez,<sup>a</sup> Javier Sánchez-González,<sup>f</sup> Patricia Sampedro,<sup>a</sup> Irene Sanmamed,<sup>a</sup> Mercedes De Miguel,<sup>ag</sup> Amaya De Cos-Gandoy,<sup>ag</sup> Patricia Bodega,<sup>ag</sup> Borja Ibanez,<sup>a,d,h</sup> Gloria Santos-Beneit,<sup>g,i</sup> Valentin Fuster,<sup>a,i</sup> and Rodrigo Fernández-Jiménez<sup>a,b,d,\*</sup>

<sup>a</sup>Centro Nacional de Investigaciones Cardiovasculares, Madrid, Spain

<sup>b</sup>Department of Cardiology, Hospital Universitario Clínico San Carlos, Madrid, Spain

<sup>c</sup>Department of Cardiology, Hospital Ruber Juan Bravo Quironsalud UEM, Madrid, Spain

<sup>d</sup>CIBER de enfermedades cardiovasculares (CIBER-CV), Madrid, Spain

<sup>e</sup>Cardiology Department, University Hospital La Moraleja, Madrid, Spain

<sup>f</sup>Philips Healthcare Spain, Madrid, Spain

<sup>9</sup>Foundation for Science, Health and Education (SHE), Barcelona, Spain

<sup>h</sup>Department of Cardiology, Hospital Fundación Jiménez Díaz, Madrid, Spain

<sup>i</sup>The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, USA

#### Summary

Background Cardiovascular magnetic resonance (CMR) is a precise tool for the assessment of cardiac anatomy, function, and tissue composition. However, studies providing CMR reference values in adolescence are scarce. We aim to provide sex-specific CMR reference values for biventricular and atrial dimensions and function and myocardial relaxation times in this population.

Methods Adolescents aged 15–18 years with no known cardiovascular disease underwent a non-contrast 3-T CMR scan between March 2021 and October 2021. The imaging protocol included a cine steady-state free-precession sequence for the analysis of chamber size and function, as well as T2-GraSE and native MOLLI T1-mapping for the characterization of myocardial tissue.

Findings CMR scans were performed in 123 adolescents (mean age 16 ± 0.5 years, 52% girls). Mean left and right ventricular end-diastolic indexed volumes were higher in boys than in girls (91.7 ± 11.6 vs 78.1 ± 8.3 ml/m<sup>2</sup>, p < 0.001; and 101.3 ± 14.1 vs 84.1 ± 10.5 ml/m<sup>2</sup>, p < 0.001), as was the indexed left ventricular mass (48.5 ± 9.6 vs 36.6 ± 6.0 g/m<sup>2</sup>, p < 0.001). Left ventricular ejection fraction showed no significant difference by sex (62.2 ± 4.1 vs 62.8 ± 4.2%, p = 0.412), whereas right ventricular ejection fraction trended slightly lower in boys (55.4 ± 4.7 vs. 56.8 ± 4.4%, p = 0.085). Indexed atrial size and function parameters did not differ significantly between sexes. Global myocardial native T1 relaxation time was lower in boys than in girls (1215 ± 23 vs 1252 ± 28 ms, p < 0.001), whereas global myocardial T2 relaxation time did not differ by sex (44.4 ± 2.0 vs 44.1 ± 2.4 ms, p = 0.384). Sex-stratified comprehensive percentile tables are provided for most relevant cardiac parameters.

Interpretation This cross-sectional study provides overall and sex-stratified CMR reference values for cardiac dimensions and function, and myocardial tissue properties, in adolescents. This information is useful for clinical practice and may help in the differential diagnosis of cardiac diseases, such as cardiomyopathies and myocarditis, in this population.

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Keywords: Adolescent; Reference values; Magnetic resonance; Pediatrics; Ventricular function; Differential diagnosis



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<sup>\*</sup>Corresponding author. Centro Nacional de Investigaciones Cardiovasculares (CNIC). Calle Melchor Fernández Almagro, 3, 28029, Madrid, Spain. *E-mail address:* rodrigo.fernandez@cnic.es (R. Fernández-Jiménez).

#### Research in context

#### Evidence before this study

Cardiovascular magnetic resonance (CMR) is considered the most accurate non-invasive tool for assessing the morphology and function of the heart. Most studies assessing cardiac structure and function in healthy pediatric populations have used echocardiography. As the use of CMR expands, it is essential to have CMR reference values to define diseased and healthy cardiac states. However, studies providing CMR reference values in adolescence are scarce.

#### Added value of this study

CMR scans were performed in 123 adolescents (mean age 16 ± 0.5 years, 52% girls). Mean left and right ventricular enddiastolic indexed volumes were higher in boys than in girls (91.7 ± 11.6 vs 78.1 ± 8.3 ml/m<sup>2</sup>, p < 0.001; and 101.3 ± 14.1 vs 84.1 ± 10.5 ml/m<sup>2</sup>, p < 0.001), as was the indexed left ventricular mass (48.5 ± 9.6 vs 36.6 ± 6.0 g/m<sup>2</sup>, p < 0.001).

#### Introduction

Cardiovascular magnetic resonance (CMR) is increasingly used as an accurate, reproducible, and radiation-free non-invasive imaging tool for the clinical evaluation of the heart. CMR is established as the reference standard for assessing the dimensions and function of the right ventricle (RV) and the left ventricle (LV) in adult and pediatric populations.1,2 CMR is also considered the most accurate noninvasive tool for assessing the atrial chambers because of its superior spatial resolution and the excellent contrast it offers between the blood pool and myocardium.3 Moreover, CMR allows in-vivo myocardial tissue characterization with the use of mapping sequences that are able to quantify subtle changes in myocardial composition, such as edema or fibrosis, based on myocardial T1 and T2 relaxation time properties. These changes can appear in diseases that might affect children and adolescents, such as myocarditis4 and several cardiomyopathies.5

Due to considerations of simplicity and availability, most studies assessing cardiac structure and function in healthy pediatric populations have used echocardiography; however, as the use of CMR expands, it is essential to have CMR reference values to define diseased and healthy cardiac states. Previous studies have provided CMR reference values for biventricular volumes and function<sup>2,6-8</sup> and atrial size and function<sup>9</sup> in pediatric populations, but these studies covered a wide age range encompassing the whole of childhood and adolescence, with small sample sizes in each age subcategory. To our knowledge, no previous study has provided reference values for myocardial T1 and T2 mapping values in adolescence. The aim of the present study was to establish sex-specific CMR reference values for a battery Left ventricular ejection fraction showed no significant difference by sex ( $62.2 \pm 4.1 \text{ vs} 62.8 \pm 4.2\%$ , p = 0.412), whereas right ventricular ejection fraction trended slightly lower in boys ( $55.4 \pm 4.7 \text{ vs} .56.8 \pm 4.4\%$ , p = 0.085). Indexed atrial size and function parameters did not differ significantly between sexes. Global myocardial native T1 relaxation time was lower in boys than in girls ( $1215 \pm 23 \text{ vs} 1252 \pm 28 \text{ ms}$ , p < 0.001), whereas global myocardial T2 relaxation time did not differ by sex ( $44.4 \pm 2.0 \text{ vs} 44.1 \pm 2.4 \text{ ms}$ , p = 0.384).

#### Implications of all the available evidence

This study provides overall and sex-stratified CMR reference values and percentile tables for cardiac dimensions and function, and myocardial tissue properties, in adolescents. This information is useful for clinical practice and may help in the differential diagnosis of cardiac diseases, such as cardiomyopathies and myocarditis, in this population.

of relevant cardiac parameters in adolescents with no known cardiovascular disease.

#### Methods

#### Study population

This study enrolled adolescents aged 15–18 years as part of the *Early ImaginG Markers of unhealthy lifestyles in Adolescents* (EnIGMA) project. For recruitment, the study took advantage of an already running clusterrandomized trial (NCT03504059) that includes 24 public secondary schools in Spain, encompassing 1326 adolescents<sup>10</sup>; a detailed analysis of their cardiovascular health status at enrollment can be found elsewhere.<sup>11</sup> For inclusion, adolescents needed to be enrolled in the cited trial and attend one of the 7 schools in the trial located in the Madrid region as of December 2020. Exclusion criteria were general contraindications for a CMR examination (pacemakers, cochlear implants, known claustrophobia, etc.), pregnancy, and evidence or history of cardiovascular disease.

All adolescents meeting the inclusion criteria were invited to participate through printed and email invitation letters sent to them and their parents or caregivers. Those who showed interest were invited to virtual meetings in which the study was presented and questions answered by investigators and clinicians leading the study. Invitees who verbally agreed to participate were scheduled to attend the imaging facilities at the *Centro Nacional de Investigaciones Cardiovasculares* (CNIC), where informed consent was signed and the CMR scan performed. The reporting of this study adheres to the *Strengthening The Reporting of Observational studies in Epidemiology* (STROBE) guideline for crosssectional studies.<sup>12</sup>

2

| 94

Proyectos en colaboración

#### Ethics statement

Written informed consent was obtained from all participants and at least one parent or caregiver. The study protocol was approved by the research ethics committee of the *Instituto de Salud Carlos III* in Madrid, under identifier CEI PI 63\_2020.

#### CMR acquisition protocol

CMR examinations were conducted between March-2021 and October-2021 using a Philips 3-T Elition X whole-body scanner (Philips Healthcare, Best, The Netherlands) equipped with a 28-element phased-array Torso-Cardiac coil. Body weight and height were measured immediately before the CMR examination. The cardiac imaging protocol included a standard segmented cine steady-state free-precession (SSFP) sequence to provide high-quality images for the assessment of cardiac chamber dimensions and function, as well as a mid-ventricular T2 gradient-spin-echo (T2-GraSE) mapping sequence<sup>13</sup> and a mid-ventricular 5 (3)3 modified look-locker inversion recovery (MOLLI) T1 mapping sequence for myocardial tissue characterization. Participant heart rate was recorded during SSFP CMR acquisition. The imaging protocol did not include administration of intravenous gadolinium contrast. Technical details of image acquisition are detailed in the Supplementary Appendix.

#### CMR analysis

Images were analyzed by experienced observers using a dedicated software program available at the CNIC imaging core lab (IntelliSpace Portal v12.1, Haifa, Israel). For the indexing of CMR values, body surface area (BSA) was determined with the Du Bois formula. Body mass index (BMI) was calculated as weight (kg) divided by height squared (m<sup>2</sup>). Age- and sex-adjusted BMI z-scores and percentiles were calculated based on Centers for Disease Control reference values.<sup>14</sup> According to these BMI percentiles, participants were categorized as being of normal weight (<P85), overweight (P85–P95), or obese (>P95).

## Cardiac cine imaging - ventricular volumes and function

LV endocardial and epicardial borders were manually traced in the end-diastolic phase, whereas only LV endocardial borders were traced in the end-systolic phase (Fig. 1). RV endocardial borders were manually traced in the end-diastolic and end-systolic phases (Fig. 1). Ventricular volume was calculated using the Simpson method. For the purpose of analysis, papillary muscles were included as part of the LV cavity volume. LV myocardial volume was calculated as the difference between the epicardial and endocardial volumes at the end-diastolic phase, and LV mass was computed as the myocardial volume multiplied by myocardial density (1.05 g/ml). The LV end-diastole and end-systole phases were visually defined based on short and long axis images (of the maximum and minimum volume, respectively), and the defined phases were assigned to both ventricles.

LV contours in the basal slices were included if > 50% of the cavity was bounded by myocardium. If myocardium with trabeculations was visible in basal slices, these were considered part of the RV rather than the right atrium or pulmonary artery. In uncertain cases, the identification of basal slices was facilitated by simultaneous visualization in long axis views. The LV and RV outflow tracts were considered part of the ventricles and were therefore included in the corresponding ventricular volume. The interventricular septum was included in the LV mass.

Strokes volumes (SV) were obtained as end-diastolic volume (EDV) – end-systolic volume (ESV). LV and RV ejection fraction (LVEF, RVEF) were computed as EF (%) = (EDV - ESV)/EDV. LVEDV, RVEDV, LVESV, RVESV, LVSV, RVSV, and LV mass were normalized to BSA.

#### Cardiac cine imaging - atrial size and function

For the left atrium (LÅ), volumes were measured using the biplane area–length method with 4-chamber (4Ch) and 2-chamber (2Ch) views,<sup>15</sup> whereas for the right atrium (RA) only area and length were reported because the RA could be assessed only in 4Ch view (Fig. 2).

The atrial endocardial border was manually traced to determine LA area with exclusion of the pulmonary veins, LA appendage (LAA), and mitral valve recess.<sup>16</sup> The anterior border of the LA was thus at the mitral annular plane, and the posterior border was at the pulmonary vein ostia. The RA endocardial border was manually traced with exclusion of the superior and inferior vena cava and the RA appendage. The anterior border of the RA was thus placed at the tricuspid annular plane.

Maximum LA volume (LAV) was obtained in the frame immediately before mitral valve opening, and minimum LAV was obtained in the frame immediately after mitral valve closure. LA pre-atrial contraction volume was obtained in the frame immediately before atrial contraction.

LAVs were calculated offline with statistical software using the area–length method (volume =  $[0.85 \times 2Ch$  area x 4Ch area]/length). Calculations were made with the shorter length between 2Ch and 4Ch views.

Atrial function was considered in three phases: reservoir (pulmonary venous return storage during LV contraction and isovolumetric relaxation), conduit (passive blood transfer into the LV), and pump (active contraction during the final diastolic phase). The following formulas were used for calculation of atrial function parameters:<sup>16</sup>

\*LA emptying fraction (LAEF) (reservoir function): [(LAVmax - LAVmin)/LAVmax] × 100. Articles

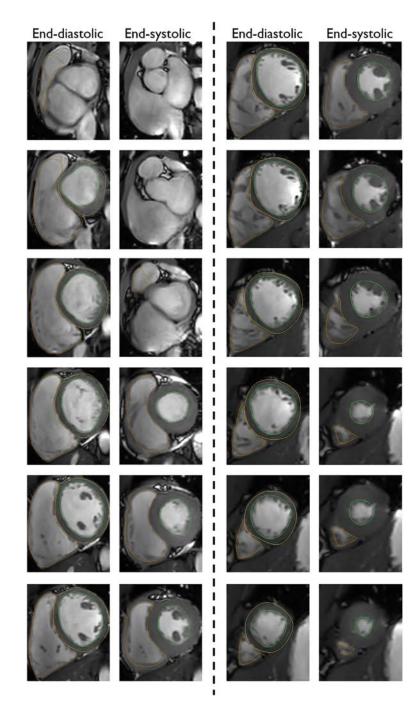


Fig. 1: Ventricular tracing in cardiovascular magnetic resonance cine sequences. Ventricular slices and tracing from base (top left) to apex (bottom right) of the same participant during the end-diastolic and end-systolic phases of the cardiac cycle.

4

www.thelancet.com Vol 57 March, 2023

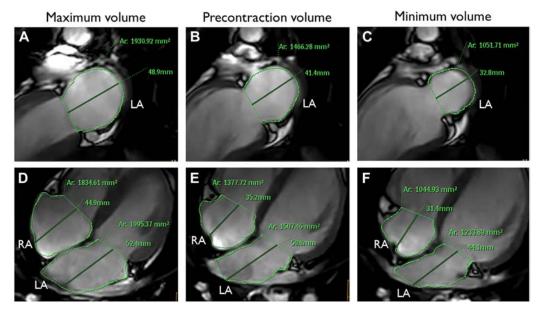


Fig. 2: Atrial tracing in cardiovascular magnetic resonance cine sequences. Representative 2-chamber (A, B, C) and 4-chamber (D, E, F) longaxis views. For the calculation of atrial function, the left atrium (LA) and right atrium (RA) were assessed in the maximum-volume, precontraction-volume, and minimum-volume phases.

\*LA passive emptying fraction (LAPEF) (conduit function): [(LAVmax - LAVprec)/LAVmax] × 100.

\*LA active emptying fraction (LAAEF) (pump function): [(LAVprec - LAVmin)/LAVprec] × 100.

#### Parametric myocardial mapping

The LV endocardial and epicardial borders were manually traced by an experienced observer, ensuring that no blood or epicardial fat was included in the region of interest (ROI). The myocardial ROI was automatically segmented according to the American Heart Association (AHA) segment model,<sup>17</sup> thus obtaining 6 segments in the mid-ventricular slice (Fig. 3).

Images were assessed for susceptibility effects and for cardiac or respiratory motion, and a motion correction tool was used when needed. The presence of artifacts despite motion correction led to the exclusion of the affected myocardial segment. For each participant, global averaged myocardial relaxation time was obtained as the area weighted mean value of all analyzable segments. If more than two segments were of poor quality, the whole corresponding mapping study was excluded from analysis. Global and septum values are reported, as recommended by the Society for Cardiovascular Magnetic Resonance (SCMR) for global assessment in both T1 and T2 mapping.<sup>18</sup>

#### Statistical analysis

Study data were collected and managed using the REDCap electronic data capture tool hosted at the CNIC. Normal distribution assumptions were verified with the use of box plots, normal probability plots and density function histograms; thus, normal distribution was the case for the majority of variables analyzed. Continuous variables are presented as means ± one standard deviation (SD), and categorical variables are presented as frequencies and percentages, unless otherwise specified. The Student t-test was used for between-sex comparisons of continuous variables, while the chi-square test was used for comparisons of categorical variables. For comparisons of continuous variables not following a normal distribution, analysis was supplemented with the use of the Wilcoxon (Mann-Whitney) test. Sexspecific percentiles were calculated using the weighted average method.

Intraobserver and interobserver agreement was assessed in 30 randomly selected participant studies and reanalyzed with the use of intraclass correlation coefficients (ICC) and Bland–Altman plots. ICC values and their 95% confidence intervals (CI) were calculated using the *icc* command for two-way random-effects model. Agreement was considered poor, moderate, good, or excellent for ICC <0.50, 0.50 to 0.75, 0.75 to 0.90, and >0.90, respectively. For Bland–Altman analysis, no significant systematic bias was assumed if the

## Articles

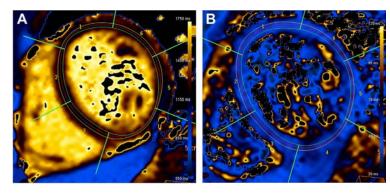


Fig. 3: Parametric mapping manual contouring. Representative T1 (A) and T2 (B) mapping assessed in a mid-ventricular slice from the same participant. The myocardium was divided into 6 segments according to the American Heart Association (AHA) segment model, indicated by the following numbers: 1 (mid anterior), 2 (mid anteroseptal), 3 (mid inferoseptal), 4 (mid inferior), 5 (mid inferolateral), and 6 (mid anterolateral).

95% confidence interval (CI) for the mean betweenmeasurement difference contained the value 0.

All statistical analyses were performed with Stata software package version 16 (StataCorp, College Station, Texas).

#### Role of the funding source

The funding sources had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. All authors confirm that they had full access to all the data in the study and accept responsibility to submit for publication.

#### Results

#### General characteristics

A total of 345 adolescents met the inclusion criteria and were invited to participate through printed and email invitation letters sent to them and their parents/ caregivers (Fig. 4). Approximately 43% of them responded to the invitation. Among 124 participants who finally gave written informed consent, one was unable to undergo the CMR examination due to claustrophobia. The analysis thus included 123 participants (overall response rate  $\sim$  36%), with a mean age of 16  $\pm$  0.5 years, of whom 52% were girls. 117 participants (95%) were born in Spain, while 5 (4%) were born in Latin America and 1 (1%) was born in Africa; within the 117 adolescents born in Spain, 26 (22%) had a migrant background (at least one parent/caregiver born outside Spain). General participant characteristics are listed in Table 1. Boys had higher weight, height, and body surface area (BSA) than girls, whereas there were no between-sex differences in mean BMI or inscan heart rate. Nevertheless, a higher percentage of girls were of normal weight according to categorized BMI percentiles.

#### Cardiac chamber dimensions and function

Descriptive summary statistics of the most important cine-imaging-derived clinical parameters are shown in Table 2. None of the imaging studies showed signs of significant structural heart disease. Boys had larger indexed biventricular volumes and LV mass (48.5 ± 9.6 vs 36.6  $\pm$  6.0 g/m², p < 0.001). LVEF was similar in both sexes (62.2  $\pm$  4.1 vs. 62.8  $\pm$  4.2%, p = 0.412), whereas RVEF trended higher in girls than in boys (56.8  $\pm$  4.4% vs. 55.4  $\pm$  4.7 vs, p = 0.085). Indexed LA volumes and RA area, as well as LA function measurements, were similar in boys and girls. Sex-stratified reference values for these CMR parameters, in the form of user-friendly clinically relevant percentiles, are provided in Table 3. Non-indexed ventricular parameters are included in Supplementary Table S1, and the remaining atrial parameters are provided in Supplementary Table S2. Intraobserver and interobserver agreement was good for most of the parameters analyzed (Supplementary Table S3 and S4 and Supplementary Figs. S1 and S2).

#### Non-invasive myocardial tissue characterization

A total of 4 T1-mapping studies and 5 T2-mapping studies were excluded in their entirety due to poor image quality in more than 2 mid-ventricular segments. In the remaining participants, 699 out of 714 segments (98%) were eligible for T1-mapping analysis, and 701 out of 708 segments (99%) were eligible for T2-mapping analysis. The majority of the excluded segments (78%) were located in the inferior/inferolateral wall and were mostly related to susceptibility artifacts.

Myocardial T1 relaxation times were higher in girls than in boys, both when measured as the mean of the global myocardial LV values ( $1252 \pm 28$  ms vs  $1215 \pm 23$  ms, p < 0.001) and when comparing only values in the septal segments ( $1261 \pm 31$  ms vs  $1220 \pm 26$  ms, p < 0.001) (Table 4). We found no between-sex differences in global T2 relaxation time;

www.thelancet.com Vol 57 March, 2023

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1 98

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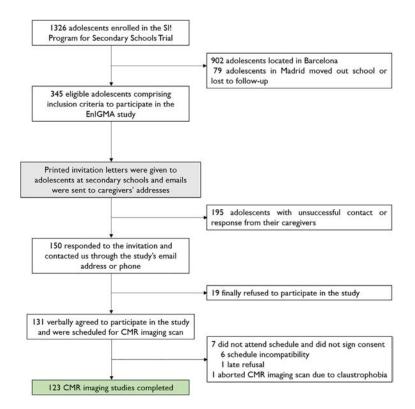


Fig. 4: Flow diagram of participants. CMR, cardiovascular magnetic resonance; EnIGMA, Early ImaGing Markers of unhealthy lifestyles in Adolescents.

	Overall	Boys	Girls	p-value
	N = 123 (100%)	n = 59 (48%)	n = 64 (52%)	
Age, years	16.0 (0.4)	16.1 (0.5)	16.0 (0.4)	0.384
Weight, kg	61.0 (10.5)	65.1 (10.1)	57.2 (9.4)	<0.001
Height, m	1.69 (0.09)	1.75 (0.07)	1.63 (0.06)	< 0.001
BMI, kg/m <sup>2</sup>	21.4 (3.2)	21.3 (2.9)	21.5 (3.5)	0.698
BMI z-score	0.09 (0.89)	0.04 (0.97)	0.13 (0.82)	0.586
Categorized BMI				0.005
Normal weight	107 (87.0%)	47 (79.7%)	60 (93.8%)	
Overweight	12 (9.8%)	11 (18.6%)	1 (1.6%)	
Obesity	4 (3.3%)	1 (1.7%)	3 (4.7%)	
Body surface area, m <sup>2</sup>	1.69 (0.16)	1.79 (0.15)	1.61 (0.12)	<0.001
Heart rate, bpm	69 (11)	68 (11)	69 (11)	0.663
Data are shown as mean (SD) for o	continuous variables and n (%) for categ	orical variables. P-values denote the	significance of between-sex differer	nces for continuous

variables analyzed by the Student t-test. The significance of sex-differences for categorical variables was tested by the chi-square test. BMI categories were defined according to age- and sex-adjusted body mass index percentiles (P) based on Centers for Disease Control reference values: normal weight (<P85), overweight (P85–P95), and obese (<P95). BMI, body mass index.

Table 1: Participant characteristics, overall and stratified by sex.

however, T2 relaxation time in the mid-ventricular septal segments was slightly higher in boys than in girls  $(45.6 \pm 2.8 \text{ ms vs } 44.0 \pm 2.7 \text{ ms}, p = 0.003)$  (Table 4).

Sex-stratified percentile values for parametric mapping parameters are provided in a user-friendly format for clinical use in Table 5. Intraobserver and interobserver

7

## Articles

	Overall	Boys	Girls	p-value
	N = 123 (100%)	n = 59 (48%)	n = 64 (52%)	
LVEDVi, ml/m <sup>2</sup>	84.6 (12.1)	91.7 (11.6)	78.1 (8.3)	<0.001
LVESVi, ml/m <sup>2</sup>	31.9 (6.4)	34.8 (6.6)	29.1 (4.8)	<0.001
iLVmass, g/m <sup>2</sup>	42.3 (9.9)	48.5 (9.6)	36.6 (6.0)	< 0.001
LVEF, %	62.5 (4.1)	62.2 (4.1)	62.8 (4.2)	0.412
LVSVi, ml/m <sup>2</sup>	52.8 (7.5)	56.6 (7.1)	49.0 (5.8)	< 0.001
RVEDVi, ml/m <sup>2</sup>	92.4 (15.0)	101.3 (14.1)	84.1 (10.5)	<0.001
RVESVi, ml/m <sup>2</sup>	40.8 (9.3)	45.4 (9.2)	36.6 (7.2)	<0.001
RVEF, %	56.2 (4.6)	55.4 (4.7)	56.8 (4.4)	0.085
RVSVi, ml/m <sup>2</sup>	51.6 (7.6)	55.9 (7.5)	47.6 (5.0)	<0.001
iLAVmax, ml/m <sup>2</sup>	37.8 (7.3)	39.1 (7.7)	36.7 (6.8)	0.070
iLAVprec, ml/m <sup>2</sup>	21.8 (5.9)	22.5 (6.3)	21.1 (5.4)	0.169
iLAVmin, ml/m <sup>2</sup>	14.3 (4.2)	14.7 (4.5)	14.0 (4.0)	0.325
LAEF, %	62.3 (7.8)	62.5 (8.3)	62.1 (7.4)	0.797
LAPEF, %	42.9 (8.3)	42.9 (9.0)	43.0 (7.7)	0.986
LAAEF, %	33.9 (10.0)	34.4 (9.9)	33.5 (10.3)	0.596
iRAAmax, cm <sup>2</sup> /m <sup>2</sup>	11.1 (1.5)	11.3 (1.6)	11.0 (1.4)	0.279

Indexed cardiac dimensions and function parameters are shown, overall and stratified by sex. Data are shown as mean (SD). p-values are derived from the analysis of between-sex differences by the Student t-test. For those continuous variables not following a normal distribution (i.e., RVEF), the p-value from the analysis of between-sex differences as analyzed by the Wilcoxon (Mann-Whitney) was 0.041. UVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; LVEF, left ventricular ejection fraction; LVSV, left ventricular stroke volume; RVEDV, right ventricular end-diastolic volume; RVESV, right ventricular end-systolic volume; RVEF, right ventricular ejection fraction; RVSV, right ventricular stroke volume; LAVmax, left atrial maximum volume; LAVprec, left atrial pre-contraction volume; LAVmin, left atrial minimum volume; LAEF, left atrial emptying fraction; LAPEF, left atrial passive emptying fraction; LAAEF, left atrial active emptying fraction; RAAmax, right atrial maximum area; i, indexed to body surface area.

Table 2: Biventricular and atrial cardiovascular magnetic resonance imaging values, overall and stratified by sex.

	BOYS							GIRLS						
	P3	P10	P25	P50	P75	P90	P97	P3	P10	P25	P50	P75	P90	P97
LVEDVi, ml/m <sup>2</sup>	74.3	76.6	82.2	90.3	99.9	108.0	117.7	61.2	67.6	72.7	78.5	82.7	88.2	97.2
LVESVi, ml/m <sup>2</sup>	24.3	27.3	28.7	34.1	39.5	43.2	49.5	19.6	22.4	25.7	29.6	32.3	35.8	38.7
iLVmass, g/m <sup>2</sup>	34.3	36.8	40.1	47.9	55.1	60.7	70.9	26.6	30.7	32.4	35.7	39.0	46.7	49.0
LVEF, %	53.6	56.8	59.8	61.7	65.6	67.9	69.7	54.7	56.3	60.0	62.6	66.4	68.6	70.6
LVSVi, ml/m <sup>2</sup>	46.2	49.5	52.4	54.8	61.7	66.0	74.6	40.0	41.4	45.1	48.5	51.6	57.4	63.3
RVEDVi, ml/m <sup>2</sup>	75.5	86.0	90.6	99.7	110.8	122.1	129.6	59.9	72.6	78.7	83.9	89.7	95.3	102.1
RVESVi, ml/m <sup>2</sup>	30.4	34.0	38.2	45.2	53.7	57.7	63.5	20.1	26.9	33.1	37.0	40.7	44.1	49.9
RVEF, %	47.5	49.2	51.3	55.4	58.2	62.7	65.7	48.1	51.2	53.7	57.1	58.8	62.9	66.4
RVSVi, ml/m <sup>2</sup>	42.2	46.9	50.2	55.8	60.5	67.7	72.0	36.7	40.6	44.6	47.6	50.5	54.8	58.1
iLAVmax, ml/m <sup>2</sup>	25.5	29.2	33.4	37.8	43.8	51.6	54.2	24.5	29.1	32.5	35.9	40.8	47.8	51.8
iLAVprec, ml/m <sup>2</sup>	10.7	12.7	18.2	22.4	26.9	31.0	34.8	12.9	14.0	16.4	20.8	25.1	27.5	35.7
iLAVmin, ml/m <sup>2</sup>	5.4	8.7	12.5	14.5	17.5	20.6	26.3	7.2	8.7	10.9	14.2	16.5	18.2	25.6
LAEF, %	43.7	52.5	57.7	63.0	68.0	71.1	82.0	44.9	51.6	56.6	63.5	67.6	70.8	76.0
LAPEF, %	25.1	32.2	36.5	42.2	48.7	56.3	61.4	29.6	32.6	37.0	42.2	48.2	54.0	57.0
LAAEF, %	11.3	22.4	29.0	34.4	40.6	47.3	55.5	12.3	16.8	27.3	33.6	40.2	45.9	52.8
iRAAmax, cm <sup>2</sup> /m <sup>2</sup>	8.2	9.2	10.2	11.2	12.1	13.5	15.5	7.9	8.9	9.8	11.1	12.1	12.9	13.6

Cardiovascular magnetic resonance cine imaging-derived reference values in adolescents for indexed cardiac dimensions and function parameters. LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-diastolic volume; LVESV, left ventricular end-diastolic volume; RVESV, right ventricular end-systolic volume; RVEF, left ventricular ejection fraction; LVSV, left ventricular stroke volume; LAVmax, left atrial maximum volume; LAVprec, left atrial pre-contraction volume; LAVmin, left atrial minimum volume; LAFF, left atrial emptying fraction; LAPEF, left atrial passive emptying fraction; LAAEF, left atrial active emptying fraction; RAAmax, right atrial maximum area; i, indexed to body surface area.

Table 3: Biventricular and atrial cardiovascular magnetic resonance cine imaging reference percentiles in adolescents.

www.thelancet.com Vol 57 March, 2023

	Overall	Boys	Girls	p-value
Native T1 relaxation time, ms	N = 119 (100%)	n = 58 (49%)	n = 61 (51%)	
Global	1234 (32)	1215 (23)	1252 (28)	< 0.001
Septal	1241 (35)	1220 (26)	1261 (31)	<0.001
T2 relaxation time, ms	N = 118 (100%)	n = 57 (48%)	n = 61 (52%)	
Global	44.2 (2.2)	44.4 (2.0)	44.1 (2.4)	0.384
Septal	44.8 (2.9)	45.6 (2.8)	44.0 (2.7)	0.003
The table shows global values (including all 6 derived from Student t-test of between-sex di values from the analysis of between-sex diffe	fferences. For those continuous varial	bles not following a normal distrib	ution (i.e., global and septal T2 rel	

Table 4: Myocardial native T1 and T2 relaxation time values, overall and stratified by sex.

	BOYS							GIRLS						
Native T1 relaxation time, ms	P3	P10	P25	P50	P75	P90	P97	P3	P10	P25	P50	P75	P90	P97
Global	1176	1189	1197	1214	1230	1250	1267	1206	1218	1233	1247	1270	1292	1309
Septal	1181	1190	1202	1215	1235	1257	1287	1209	1225	1238	1259	1280	1300	1342
T2 relaxation time, ms	P3	P10	P25	P50	P75	P90	P97	P3	P10	P25	P50	P75	P90	P97
Global	41.2	41.8	42.8	44.1	46.0	47.2	48.8	40.8	41.7	42.7	43.6	44.9	46.7	53.0
Septal	41.5	42.2	43.4	45.3	47.7	49.8	51.7	40.3	41.0	42.4	43.8	45.3	46.8	52.6
Septal 41.5 42.2 43.4 45.3 47.7 49.6 51.7 40.3 41.0 42.4 43.6 45.3 40.6 52.0 Cardiovascular magnetic resonance imaging-derived reference values in adolescents for myocardial native T1 and T2 relaxation time. The table shows global values (including all 6 mid-ventricular segments) and isolated septal values (including the 2 septal segments). P, percentile.														

agreement was good for the mapping parameters analyzed (Supplementary Table S5 and S6 and Supplementary Fig. S3).

#### Discussion

This study examined a battery of CMR imaging parameters obtained with a state-of-the-art 3-T CMR scanner from a sample of adolescents with no known cardiovascular disease. To our knowledge, this the first study focused on adolescents to provide CMRimaging-derived reference values for biventricular and atrial dimensions and function, as well as for myocardial tissue characterization parameters (Fig. 5). CMR imaging is central to the diagnosis of cardiac diseases that can appear in adolescent populations, such as cardiomyopathies and myocarditis.19 In this regard, recently updated Lake-Louis criteria highlight the importance of performing parametric mapping CMR sequences for the detection of myocardial inflammation<sup>4</sup> and the need for CMR reference values to distinguish between the diseased and healthy cardiac states. Furthermore, reference values in younger populations would help to fill the gap in knowledge about the normal physiologic changes from childhood to adulthood.

Our study was performed using a 3-T scanner, whereas reference values for cardiac chamber size and function reported in earlier studies of pediatric populations were mostly obtained with 1.5-T scanners.<sup>2,6-8</sup> The higher spatial and temporal resolution and shorter acquisition time with 3-T CMR may make it more suitable for the study of the relatively smaller hearts and higher heart rates of children and adolescents; however, a potential drawback is that 3-T CMR can be prone to susceptibility artifacts.<sup>20</sup> In the present study, very few cases were excluded because of poor image quality or other technical issues, supporting the feasibility of comprehensive high-quality 3-T CMR studies in adolescent populations.

Van der Ben et al.<sup>2</sup> reported reference values for biventricular volumes and function using pooled data from 3 studies of a total of 141 children and adolescents aged 0-18 years who were examined with a 1.5 T CMR scanner.<sup>6-8</sup> This population included 76 participants between the ages of 12 and 18 years (40 girls and 36 boys), which is the age range closest to that examined in our study. Their analysis revealed higher LV and RV volumes and higher LV mass in boys, in agreement with our findings. The study found no sex-related differences in LVEF or RVEF in this age range. Although we also found no sex-differences in LVEF, in our older adolescent population of 15-18-year-olds, we did find small differences in RVEF, which trended higher in girls than in boys. This between-sex difference is in line with findings in adults,<sup>21</sup> suggesting that differences in RVEF may become evident in the later stage of adolescence or young adulthood.

9

## Articles

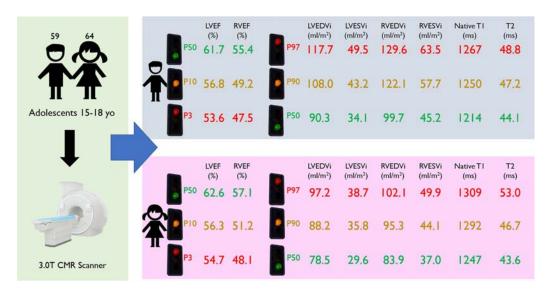


Fig. 5: Cardiovascular magnetic resonance reference values in adolescents. Cardiovascular magnetic resonance (CMR) parameters were obtained from 123 adolescents aged from 15 to 18 years in order to obtain reference values for this population. Median values are shown in green for all parameters displayed. For LVEF and RVEF, P10 and P3 values are shown in yellow and red, respectively. For LVEDVi, LVESVi, RVEDVi, RVESVi, native T1 and T2 mapping, P90 and P97 values are shown in yellow and red, respectively. CMR, cardiovascular magnetic resonance; LVEF, left ventricular ejection fraction; RVEF, right ventricular ejection fraction; LVEDVi, indexed left ventricular end-diastolic volume; RVESVi, indexed left ventricular end-systolic volume; RVEDVi, indexed right ventricular end

Compared with the *Van der Ben* et al. study in a mixed-age pediatric population,<sup>2</sup> we found higher overall values for all indexed volumetric ventricular parameters analyzed and slightly lower values for RVEF, LVEF, and LV mass. These differences may be due to the fact that, unlike *Van der Ben* et al.,<sup>2</sup> we excluded papillary muscles and trabecular tissue from the endocardial tracings. RV mass was not measured in our study because we considered that there was insufficient spatial resolution to trace the RV wall in our adolescent population. The difficulty of tracing the thinner RV wall is demonstrated by the modest interobserver agreement for RV mass measurements in the *Van der Ben* et al. study.<sup>2</sup>

Interestingly, our study showed slightly higher both non-indexed and indexed biventricular volumes as compared with adult population studies using similar analysis methods (papillary muscles included as part of the ventricle cavity volume).<sup>22</sup> Nevertheless, LV and RV volume values obtained are comparable to the ones showed for individuals aged 16–20 years old subgroup in a prior study.<sup>23</sup> This finding is in agreement with this study and others, showing that biventricular volumes are higher during late adolescence and young adulthood and decrease with advancing age in both genders.<sup>21,23-25</sup>

The atrium plays a critical role in modulating ventricular filling by functioning as a *reservoir* for venous return during ventricular systole, a *conduit* for venous return during early ventricular diastole, and a *booster pump* that completes ventricular filling during the enddiastolic phase.<sup>26</sup> We observed higher values of LA conduit (passive) function and lower values of LA booster (active) function than those reported in adult CMR studies.<sup>27,28</sup> These findings are consistent with pediatric echocardiography studies, which show conduit-function values peaking between the ages of 5 and 10 years, followed by a progressive decline into adolescence and adulthood, whereas the opposite pattern is observed for booster function.<sup>29</sup> Since atrial function is related to LV compliance, these age-related variations could serve as an early marker of physiological cardiac aging.

Diastolic dysfunction is a characteristic feature of different types of congenital or hereditary heart disease, such as tetralogy of Fallot and hypertrophic cardiomy-opathy.<sup>30</sup> Atrial size is related to diastolic dysfunction, whereas atrial function may be affected earlier and is a more sensitive parameter. In patients with congenital heart disease, atrial dysfunction initially affects reservoir and conduit function—triggering a compensatory increase in pump function—and thus eventually affects all three phases.<sup>31</sup> Because CMR provides better image quality and easier border tracking than echocardiography, it is a promising technique for the assessment of atrial function. However, very few studies have assessed

10

www.thelancet.com Vol 57 March, 2023

LA and RA volumes and function in healthy children. In one previous publication,<sup>9</sup> atrial volume was measured from short axis images using the Simpson method and included the LAA. Since atrial short axis images are frequently unavailable in routine acquisitions and the bi-plane area-length method in long axis view shows close agreement with the Simpson methods in short axis view,<sup>15</sup> we used 2-chamber and 4-chamber long-axis planes to measure atrial volumes and function. Moreover, the LAA is increasingly excluded from atrial measures,<sup>22</sup> and we therefore consider that our results could easily be applicable in daily clinical practice.

T1 and T2 mapping CMR techniques allow noninvasive myocardial tissue characterization based on quantifiable changes in magnetic tissue properties, i.e. myocardial relaxation time. Diseases that primarily affect the myocardium alter relaxation times, including myocarditis.<sup>4</sup> However, T1 and T2 relaxation times can also be affected by external factors, such as field strength and acquisition scheme.<sup>22</sup> In the present study, we used a MOLLI 5 (3)3 scheme for T1 mapping and a GraSE scheme for T2 mapping. These acquisition schemes are widely used because of their robustness and precision, and are recommended in clinical practice guidelines.<sup>5</sup>

Although there are no published mapping reference values in pediatric populations, a recent meta-analysis<sup>32</sup> revealed a mean myocardial native T1 relaxation time of 1122 ms (95% CI, 1100-1143 ms) in adults who underwent a CMR examination with a Philips 3-T scanner and a MOLLI acquisition scheme. The adolescents scanned in the present study with the same scanner vendor and field strength showed higher native T1 values (1234 ms ± 31.5 ms [mean ± standard deviation]). These differences need to be interpreted with caution, because T1 relaxation time can be significantly influenced by additional factors, such as changes to image acquisition schemes.33 Intriguingly, girls had slightly higher myocardial native T1 values than boys. This is in line with previous evidence from adults, which showed higher native T1 values in healthy women younger than 45 years.<sup>34</sup> The reason for these sex differences in native T1 relaxation times is unknown.

Reference T2 mapping values are based on relatively small studies, and therefore the effects of age and sex are even less well established.<sup>22</sup> Previous studies in healthy adults revealed an absence of between-sex differences in myocardial T2 values,<sup>35</sup> consistent with our finding of clinically irrelevant differences limited to the mid-ventricular septal segments. Nevertheless, studies done with the same vendor and similar acquisition schemes have reported different T2 values in healthy adult populations,<sup>35</sup> and absolute reference values should therefore be considered indicative.

This study reports reference values of CMR parameters based in a relatively large adolescent sample based in Spain and has some limitations. The impact of race/ ethnicity on CMR reference values could not be assessed and the geographical limitation of the sample could compromise external validity. A sensitivity analysis was conducted using mixed models and including school as random effect, and showed very similar results (Supplementary Table S7 and S8). Although the reference mapping values provided should be checked locally by each center, the reported normal ranges make an important contribution to the standardization in CMR imaging.

In conclusion, this study provides overall and sexstratified 3-T CMR reference values for cardiacchamber dimensions and function and myocardial tissue properties in adolescents. This information is useful for clinical practice and may help to distinguish between the diseased and healthy cardiac states and in the differential diagnosis of cardiac diseases, such as cardiomyopathies and myocarditis, in adolescent populations.

#### Contributors

RF-J, JS-G, BI and VF conceived the overall study and provided scientific support over the course of this work. CR and RP coordinated recruitment of participants, the consent process, and data collection for this study. MdM, AdC-G, PB and GS-B coordinated recruitment of schools and participants in the original trial and assisted the recruitment process for the present study. RF-I and JS-G designed the imaging protocol. PS and IS conducted imaging acquisitions. CR, RP, EG-C and RF-J supervised imaging acquisitions and performed initial quality assessment of images for analyses. GP and IG-L performed imaging analyses. CR and JM-G conducted statistical analyses. CR drafted the first version of the manuscript. CR, JM-G and RF-J directly accessed and verified the underlying data reported in the manuscript. All authors revised the manuscript critically for intellectual content and approved the published version.

#### Data sharing statement

The availability of data collected for the study to external researchers, including data dictionary and deidentified participant data, is restricted to related project proposals upon request to the corresponding author. Based on these premises, data will be available with publication after approval of the proposal and a signed data access/sharing agreement.

#### Declaration of interests

Javier Sánchez-González is a Philips Healthcare employee. Carlos Real is funded by the *Fundacion Interhospitalaria para la Investigación Cardiovascular*. The remaining authors declare no conflicts of interest.

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#### Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi. org/10.1016/j.eclinm.2023.101885.

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### **FULL RESEARCH PAPER**

Prevention in practice

## Sleep duration and its association with adiposity markers in adolescence: a cross-sectional and longitudinal study

Jesús Martínez-Gómez<sup>1</sup>, Juan Miguel Fernández-Alvira<sup>1</sup>, Amaya de Cos-Gandoy<sup>1,2</sup>, Patricia Bodega<sup>1,2</sup>, Mercedes de Miguel<sup>1,2</sup>, Anna Tresserra-Rimbau<sup>3,4</sup>, Emily P. Laveriano-Santos<sup>3,4</sup>, Vanesa Carral<sup>2</sup>, Isabel Carvajal<sup>2</sup>, Ramón Estruch () <sup>3,5</sup>, Rosa María Lamuela-Raventós<sup>3,4</sup>, Gloria Santos-Beneit<sup>2,6</sup>, Valentín Fuster () <sup>1,6</sup>, and Rodrigo Fernández-Jiménez () <sup>1,7,8</sup>\*

<sup>1</sup>Centro Nacional de Investigaciones Cardiovasculares (CNIC), 3 Melchor Fernández Almagro, Madrid 28029, Spain; <sup>2</sup>Foundation for Science, Health and Education (SHE), Barcelona, Spain; <sup>3</sup>Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN), Institute of Health Carlos III, Madrid, Spain; <sup>4</sup>Departament de Nutrició, Ciències de l'Alimentació i Gastronomia, Facultat de Farmàcia i Ciències de l'Alimentació, XIA, INSA, Universitat de Barcelona, Spain; <sup>5</sup>Department of Internal Medicine, Hospital Clínic, Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), University of Barcelona, Barcelona, Spain; <sup>6</sup>Department of Cardiology, The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, USA; <sup>7</sup>Department of Cardiology, Hospital Universitario Clínico San Carlos, s'n Profesor Martín Lagos, Madrid 28040, Spain; and <sup>8</sup>Centro de Investigación Biomédica en Red en Enfermedades CardioVasculares (CIBERCV), 3-5 Monforte de Lemos (Pabellón 11), Madrid 28029, Spain

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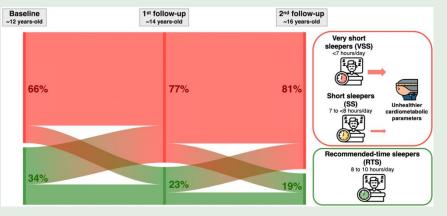
Aims	Large studies linking adolescents' objectively measured sleep duration and adiposity markers are lacking. We characterized sleep duration and its cross-sectional and longitudinal associations with adiposity markers in adolescence.
Methods and results	Seven-day accelerometry was performed in a cohort of adolescents enrolled in the SI! Program for Secondary Schools trial in Spain at approximately ages 12 (1216 adolescents, 49.6% girls), 14 (1026 adolescents, 51.3% girls), and 16 (872 adolescents, 51.7% girls) years. Participants were classified as very short sleepers (VSS; $<7$ h), short sleepers (SS; 7– $<8$ h), or recommended-time sleepers (RTS; 8–10 h). Adjusted associations between sleep duration and adiposity markers were analysed using generalized linear and Poisson models. At ~12 years, 33.7% of adolescents met sleep recommendations, and this percentage decreased with advancing age (22.6% at ~14 and 18.7% at ~16 years). Compared with RTS, overweight/obesity prevalence ratios at ~12, 14, and 16 years among SS were 1.19 [95% confidence interval (CI): 1.09–1.30], 1.41 (95% CI: 1.34–1.48), and 0.99 (95% CI: 0.77–1.26) and among VSS were 1.30 (95% CI: 1.28–1.32), 1.93 (95% CI: 1.41–2.64), and 1.32 (95% CI: 1.26–1.37). Compared with adolescents who always met sleep recommendations, the prevalence of overweight/obesity was ~5 times higher in those never meeting recommendations or meeting them only once. Similar trends were observed for the waist-to-height ratio ( $P = 0.010$ ) and fat mass index ( $P = 0.024$ ).
Conclusion	Most adolescents did not meet sleep recommendations. Shorter sleep duration was independently associated with un- favourable adiposity markers, and such adverse impact was cumulative. Health promotion programmes should emphasize the importance of good sleep habits.
Lay summary	<ul> <li>This study used a wearable activity tracker to analyse sleep patterns and their association with adiposity markers in a large cohort of adolescents at ages 12, 14, and 16 years.</li> <li>At 12 years, only 34% of adolescents met sleep recommendations (eight or more hours of sleep per day), and this percentage decreased with advancing age (23% at 14 and 19% at 16 years). Adolescents sleeping &lt;8 h a day were more likely to present overweight, obesity, or other adverse adiposity markers than their peers with sufficient sleep.</li> </ul>

\* Corresponding author. Tel: (+34) 91 453 12 00 (Ext. 2022), Fax: (+34) 91 453 12 65, Email: rfernandez@cnic.es

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• The link between insufficient sleep and adverse adiposity markers was independent of energy intake and physical activity levels, indicating that sleep itself is important. Therefore, health promotion programmes for adolescents should emphasize the importance of good sleep habits.

#### **Graphical Abstract**



Sleep duration changes from ages 12 to 16 years. All individuals with available data for sleep duration and at least one anthropometric measure at all time points were considered (n = 781). Sleep duration between 8 and 10 h/day was considered meeting sleep recommendations, whereas <8 h of sleep duration was considered not meeting sleep recommendations. This figure has been designed using images from Flaticon.com.

Keywords Overweight • Schools • Accelerometry • Health promotion • Child

## Introduction

Sleep is an essential physiological process playing an important role in body homoeostasis, learning processes, effective productivity and concentration, and growth.<sup>1</sup> Sufficient sleep is therefore especially crucial in adolescence, when many biological and psychological changes occur.

Sleep requirements diminish with advancing age,<sup>2</sup> but in recent decades, overall sleep duration has declined across all ages.<sup>3–5</sup> Thus, the proportion of children and adolescents not meeting sleep recommendations is growing.<sup>3</sup> Moreover, insufficient sleep has been linked to overweight and obesity,<sup>6–9</sup> identified by the World Health Organization as a global problem due to its increasing worldwide prevalence in recent decades. Spain has one of the highest prevalence rates in Europe, with one out of three young adolescents being overweight or obese.<sup>10,11</sup>

Most previous studies used self-reported methods (questionnaires) and were cross-sectional.<sup>6,12,13</sup> There is therefore a need for large studies characterizing and linking objectively measured sleep duration and adiposity markers over time in adolescence.

The main aims of the present study were as follows: (i) to determine sleep duration and its sociodemographic correlates at three time points using objective sleep assessments in a large cohort of adolescents in Spain with a mean age of 12.5 years at cohort entry and (ii) to examine the cross-sectional and longitudinal associations between sleep duration and a panel of adiposity markers during adolescence.

### **Methods**

#### Study design and population

This study used longitudinal data collected as part of the SI! (*Salud Integral*-Comprehensive Health) Program for Secondary Schools trial in Spain, which enrolled 24 secondary schools (7 in the Madrid region and

17 in the Barcelona region). This trial was launched in 2017 and finalized in 2021 and was designed as a cluster-randomized controlled intervention to test the impact of a comprehensive lifestyle programme on the cardio-vascular health (CVH) of adolescents in Spain, enrolling a total of 1326 ado-lescents with a mean [standard deviation (SD)] age at recruitment of 12.5 (0.4) years. Assessments of the same set of adolescents were scheduled during the school season at baseline (October 2017–February 2018), first follow-up (February 2019–May 2019), and second (final) follow-up (January 2021–June 2021). Additional details of the study design and data collection procedures are described elsewhere.<sup>14</sup> The present study included all adolescents with data available for sleep and at least one an thropometric measure at any time point.

The study is registered at ClinicalTrials.gov number NCT03504059 and was approved by the Committee for Ethical Research (CEI) of the *Instituto de Salud Carlos III* in Madrid (CEI PI 35\_2016), by the CEI of the *Fundació* Unió Catalana d'Hospitals in Barcelona (CEI 16/41), and by the University of Barcelona Bioethics Committee (IRB00003099). The reporting of the results of this trial adheres to the Strengthening The Reporting of OBservational studies in Epidemiology (STROBE) guideline for cross-sectional and cohort studies. The checklist can be found in Supplementary material online, *Table* S1.

#### Consent

Data were collected and handled according to Spanish Law 15/1999 on the Protection of Personal Data, ensuring the confidentiality of all participant data. Parents and caregivers provided written informed consent at the beginning of the study.

#### Assessment of quantity of sleep

Sleep was assessed with an accelerometer (Actigraph wGT3X-BT) placed on the participant's non-dominant wrist for seven consecutive days, 24 h a day. Records were considered valid if they provided data from at least four consecutive or non-consecutive days of wear time with a maximum of 960 min of sleep per 24 h. Valid records for 6 or 7 days were available in 96.7, 92.5, and 92.2% of individuals at baseline, first follow-up, and second follow-up, respectively.

Sleep duration was determined using Cole–Kripke cutoff points<sup>15,16</sup> and was first analysed as a continuous variable. Sleep duration was then subdivided into three categories based on sleep recommendations in adolescence. A mean sleep duration of 8–10 h per day was considered ideal, and participants within this range were considered the reference sleep duration group [recommended-time sleepers (RTS)].<sup>2</sup> The remaining groups included participants with very short sleep duration [<7 h/day, very short sleepers (VSS)] and short sleep duration [7–<8 h/day, short sleepers (SS)]. Participants who slept >10 h/day (n = 8 at baseline, n = 13 at first follow-up, and n = 9 at second follow-up) were excluded from the analysis.

### Adiposity parameters

All participants were instructed to fast overnight before measurements. Trained nutritionists measured participants' body weight and fat mass (OMRON BF511 body composition scale), height (Seca 213 stadiometer), and waist circumference (WC) (Holtain non-elastic tape). Body mass index (BMI) was calculated as body weight divided by height squared (kg/m<sup>2</sup>). Fat mass index (FMI) was calculated by dividing body fat mass by height squared (kg/m<sup>2</sup>). Waist-to-height ratio (WHtR) was calculated by dividing WC by height. Age- and sex-adjusted z-scores were calculated using validated cut-off points from the Centers for Disease Control (CDC) standards for BMI<sup>17</sup> and from the Third National Health and Nutrition Examination Survey (NHANES III) for WHtR.<sup>18</sup> The FMI-specific z-scores were calculated based on our sample. The participants' age range was 11–14 at baseline, 13–16 at first follow-up, and 15–18 at second follow-up. Due to the low number of participants in some age groups, for the calculation of age-specific FMI z-scores, some participants were combined in the same age group as follows: those aged 13 and 14 years at baseline (n = 119 and n = 17) were combined in the 13-year age group; those aged 14, 15, and 16 years (n =392, n = 33, and n = 2) at first follow-up were combined in the 14-year age group; and those aged 16, 17, and 18 years (n = 325, n = 23, and n =2) at second follow-up were combined in the 16-year age group. Normal weight, overweight, and obesity were defined as <85th, 85–<95th, and  $\geq$ 95th percentiles derived from the validated CDC cutoff points for BMI.<sup>17</sup>

#### Covariates

Moderate-to-vigorous physical activity (MVPA) was estimated with an Actigraph wGT3X-BT accelerometer for seven consecutive days. Records were considered valid if they provided data from a minimum of four consecutive or non-consecutive days, with at least 600 min per day of wear time. The MVPA was calculated according to specific cutoff points for adolescence.<sup>19</sup> Smoking status was determined with a standard questionnaire.<sup>20</sup> Information about total energy intake was obtained with an updated version of a validated 157-item semi-quantitative food frequency questionnaire (FFQ).<sup>21</sup> Sexual maturity status according to Tanner and Whitehouse<sup>22</sup> (from I to V) was self-reported by participants with the support of pictograms.

Families (parents/caregivers) completed a survey with questions related to sociodemographic information (educational level, household income, and migrant status). Parental educational level was categorized according to the International Standard Classification of Education (ISCED) as low (no studies, primary studies, or secondary studies; 0–3 ISCED score), intermediate (post-secondary non-tertiary education or short-cycle tertiary education; 4–5 ISCED score), or high (university studies; 6–8 ISCED score).<sup>23</sup> If more than one parental/caregiver educational level was reported, the higher was used for analysis. Self-reported household income was collected and classified as low (below the average), average, or high (above the average), according to the most recently published Spanish household income data.<sup>24</sup> Finally, a migrant background was assumed if at least one parent/caregiver was born outside Spain. The analysis considered the aforementioned information collected at any succeeding follow-up, the analysis considered the earliest reported information. Procedures for data collection are described in more detail elsewhere.<sup>14</sup>

#### Statistical analysis

For descriptive data, continuous variables are presented as mean and SD, and categorical variables are presented as frequencies and percentages.

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Statistical differences between identified sleep duration groups were determined by the  $\chi^2$  test with the Cochran–Mantel–Haenszel extension test for variables with ordered categories and by one-way analysis of variance (ANOVA) for continuous variables.

Cross-sectional associations between sleep duration groups and BMI, WHtR, and FMI z-scores at different time points were studied with multilevel linear mixed-effects models that account for the hierarchical clusterrandomized design. Similarly, associations between sleep duration groups and overweight/obesity prevalence were modelled with generalized models using a Poisson distribution with a log link and robust error variance. In unadjusted models, the region (Madrid or Barcelona) and schools within each region were handled as random effects. In adjusted models, fixed effects were the sleep duration group, randomization group, parental educational level, migrant background, MVPA, smoking and sexual maturity status, and total energy intake at each time point, while the region (Madrid or Barcelona) and schools within each region were handled as random effects. Associations between sleep duration and anthropometric measurements were also analysed using sleep duration as a continuous variable, instead of a categorical variable.

For the study of longitudinal associations between sleep time patterns across adolescence and adiposity outcomes at second (final) follow-up, four sleep groups were constructed based on adherence to sleep recommendations at the three time points evaluated: always following sleep recommendations, following sleep recommendations at only one time point, and never following sleep recommendations. The regression modelling strategies used were the same as those described above. Post-estimation testing of the linear hypothesis across sleep recommendation categories over time was performed using coefficients of orthogonal polynomials. In a separate analysis, the mean of the three sleep time measurements for each individual was obtained to consider sleep time as a continuous variable. To study the very short sleep duration (<7 h/day), short sleep duration (7-<8 h/day), and recommended sleep duration (8-10 h/day) during adolescence.

Interaction models and marginal effect plots were also fitted to identify possible by-sex heterogeneity in the associations between sleep duration and adiposity markers. Since no consistent significant interaction was detected, no by-sex stratification was conducted, and girls and boys were analysed together in the models. Missing values (if any) were not imputed. Sensitivity analyses were performed of cross-sectional associations including the 781 individuals with valid data at all time points evaluated, as well as multilevel models including the family identifier as an additional random effect to account for siblings enrolled in the study. Statistical significance was set at a-value < 0.05. All statistical analyses were conducted using Stata version 17 (StataCorp, College Station, TX, USA).

### Results

## Cross-sectional sleep duration patterns and associations

This analysis included 1216 adolescents (603 girls, 49.6%) enrolled in the SI! Program for Secondary Schools trial in Spain with a median age of 12.5 (25th percentile, 12.2; 75th percentile, 12.7) years at baseline; 1026 participants (526 girls, 51.3%) at first follow-up (median follow-up of 16 months from baseline); and 872 (451 girls, 51.7%) at second follow-up (median follow-up of 40 months from baseline). The mean (SD) accelerometer wear time was 22.5 (0.9), 22.5 (0.9), and 22.7 (1.0) hours per day at baseline, first follow-up, respectively.

At ~12 years of age, only 33.7% of adolescents met sleep recommendations (8–10 h/day), and this percentage decreased with advancing age (22.6 and 18.7% at ~14 and ~16 years of age, respectively). No associations were found at baseline with household income or parental educational level, but boys and individuals from families with a migrant background tended to sleep less (*Table 1*). Overall, adolescents who met sleep recommendations showed healthier ranges of adiposity markers, particularly at ~12 and ~14 years of age (*Table 2*).

Every sleep hour decrease per day was associated with an adjusted increment in the BMI z-score of 0.11 [95% confidence interval (CI):

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Proyectos en colaboración

#### Table 1 Baseline characteristics, overall and by sleep duration group

	Baseline				
	Overall	Not following	sleep rec.	Following sleep rec.	P-value
		VSS (<7 h)	SS (7–<8 h)	RTS (8–10 h)	
Number of participants, <i>n</i> (%)	1216 (100)	239 (19.7)	567 (46.6)	410 (33.7)	
Age in years, mean (SD)	12.5 (0.4)	12.6 (0.5)	12.5 (0.4)	12.5 (0.4)	0.106
Girls, n (%)	603 (49.6)	98 (41.0)	286 (50.4)	219 (53.4)	0.004
Household income, n (%)					
Low	396 (33.0)	79 (33.8)	180 (32.0)	137 (34.0)	0.726
Average	374 (31.2)	78 (33.3)	177 (31.4)	119 (29.5)	
High	430 (35.8)	77 (32.9)	206 (36.6)	147 (36.5)	
Parental education, n (%)					
Low	219 (18.2)	37 (15.7)	98 (17.4)	84 (20.8)	0.999
Intermediate	496 (41.2)	116 (49.4)	226 (40.1)	154 (38.0)	
High	488 (40.6)	82 (34.9)	239 (42.5)	167 (41.2)	
Migrant background, n (%)	383 (31.9)	92 (39.3)	181 (32.3)	110 (27.1)	0.001
Smoking status, n (%)					
Never tried tobacco products	1124 (92.5)	219 (91.6)	526 (92.8)	379 (92.7)	
Tried but non-smokers	66 (5.4)	14 (5.9)	28 (4.9)	24 (5.8)	0.485
Smokers	25 (2.1)	6 (2.5)	13 (2.3)	6 (1.5)	
MVPA in min/day, mean (SD)	74.6 (23.3)	79.1 (25.0)	75.7 (22.2)	70.4 (23.2)	<0.001
Total energy intake in kcal/day, mean (SD)	2535 (595)	2489 (588)	2550 (627)	2541 (555)	0.530

Values are mean (SD) or n (%). P-values are derived from ANOVA for continuous variables and the  $\chi^2$  test with Cochran–Mantel–Haenszel extension for ordered categorical variables. Sleep groups are ordered according to sleep duration.

rec., recommendations; RTS, recommended-time sleepers; SS, short sleepers; VSS, very short sleepers; SD, standard deviation; MVPA, moderate-to-vigorous physical activity.

0.03–0.19] at baseline, 0.12 (95% CI: 0.04–0.19) at first follow-up, and 0.05 (95% CI: -0.02-0.12) at second follow-up; an increment in the WHtR z-score of 0.12 (95% CI: 0.04–0.19) at baseline, 0.11 (95% CI: 0.05–0.18) at first follow-up, and 0.08 (95% CI: 0.02–0.14) at second follow-up; and an increment in the FMI z-score of 0.07 (95% CI: -0.01-0.15) at baseline, 0.13 (95% CI: 0.06-0.21) at first follow-up, and 0.06 (95% CI: -0.01-0.15) at baseline, 0.13 (95% CI: 0.06-0.21) at first follow-up, and 0.06 (95% CI: -0.02-0.13) at second follow-up. Similar trends were obtained after categorizing sleep time, with the VSS group (<7 h/day) showing the most adverse associations and the highest overweight/obesity prevalence at the three time points assessed (see Supplementary material online, *Figure S1* for unadjusted models and *Figure 1* for adjusted models). Similar results were obtained when restricting the analysis to individuals with valid sleep records for 6 or 7 days per assessment (see Supplementary material online, *Figure S2*).

## Longitudinal sleep duration patterns and associations

The analysis considered all individuals with available sleep time data and at least one anthropometric measure at the three time points assessed (n = 781). Most adolescents not meeting sleep recommendations at 12 and 14 years of age remained in the same condition at 16 years of age (n = 381 adolescents, 48.8%). In all, 31.6% (n = 247) and 14.9% (n = 116) of individuals met sleep recommendations at only one or two time points, respectively. Only 4.7% (n = 37) of participants met sleep recommendations at all time points.

Meeting sleep recommendations at all time points assessed during adolescence was associated with the healthiest adiposity outcomes at  $\sim$ 16 years of age, whereas individuals who never met sleep recommendations showed the most adverse associations, with a dose–response effect (see Supplementary material online, *Table* S2 for unadjusted

models and *Table 3* for adjusted models). Similar results were obtained when restricting the analysis to individuals with valid sleep records for 6 or 7 days in all assessments (see Supplementary material online, *Table S3*).

Average sleep hours were calculated across adolescence for each individual. A reduction of 1 h in sleep per day during adolescence was associated with a higher prevalence ratio (PR) of overweight/obesity (1.47; 95% Cl: 1.45–1.49) and increases in the BMI z-score (0.19; 95% Cl: 0.08–0.30), the WHtR z-score (0.22; 95% Cl: 0.12–0.32), and the FMI z-score (0.17; 95% Cl: 0.05–0.29) at the age of 16. Similar results were obtained for the analysis of mean sleep hours in the RTS, SS, and VSS categories, with the VSS category showing the most adverse associations (see Supplementary material online, *Figures S3* and S4).

### Discussion

This longitudinal study of a large adolescent cohort in Spain aged ~12 years at cohort entry generated a number of key findings: (i) at ~12 years of age, only 33.7% of adolescents met sleep recommendations (8–10 h/day sleep); (ii) this percentage decreased with advancing age (22.6 and 18.7% at ~14 and ~16 years of age, respectively); (iii) 48.8% of adolescents did not meet sleep recommendations at any of the three time points evaluated during adolescence, and only 4.7% always met the recommendations; (iv) boys and individuals from families with a migrant background tended to sleep less; and (v) sleep duration was independently and inversely associated with adiposity markers (prevalence of overweight/obesity, BMI, WHtR, and FMI z-scores), with the most adverse associations found in the VSS group, particularly at ~12 and ~14 years of age (Graphical Abstract). This is one of the first studies to determine sleep duration objectively during adolescence and

Obese, n (%)

WHtR, mean (SD)

Overweight, n (%)

WHtR z-score, mean (SD)

	Overall	Not following	sleep rec.	Following sleep rec.	P-value
		VSS (<7 h)	SS (7–<8 h)	RTS (8–10 h)	
Baseline					
Number of participants, n (%)	1216 (100)	239 (19.7)	567 (46.6)	410 (33.7)	
Adiposity markers					
BMI in kg/m², mean (SD)	20.1 (3.7)	20.8 (4.1)	20.3 (3.7)	19.5 (3.4)	< 0.001
BMI z-score, mean (SD)	0.35 (1.03)	0.53 (0.98)	0.40 (1.00)	0.16 (1.07)	<0.001
Categorized BMI z-score					
Normal weight, n (%)	887 (73.1)	159 (66.8)	406 (71.7)	322 (78.5)	< 0.001
Overweight, $n$ (%)	213 (17.5)	47 (19.7)	102 (18.0)	64 (15.6)	
Obese, n (%)	114 (9.4)	32 (13.5)	58 (10.3)	24 (5.9)	
WHtR, mean (SD)	0.46 (0.06)	0.48 (0.07)	0.46 (0.06)	0.45 (0.06)	<0.001
WHtR z-score, mean (SD)	0.03 (0.94)	0.23 (0.93)	0.04 (0.95)	-0.10 (0.91)	< 0.001
FMI in kg/m <sup>2</sup> , mean (SD)	4.9 (2.6)	5.2 (2.9)	5.0 (2.6)	4.6 (2.5)	0.009
FMI z-score, mean (SD)	-0.01 (0.98)	0.10 (1.06)	0.03 (0.98)	-0.14 (0.93)	0.005
First follow-up					
Number of participants, n (%)	1026 (100)	305 (29.7)	489 (47.7)	232 (22.6)	
Adiposity markers					
BMI in kg/m², mean (SD)	21.1 (3.7)	21.7 (3.9)	20.9 (3.7)	20.6 (3.3)	0.001
BMI z-score, mean (SD)	0.37 (0.93)	0.54 (0.93)	0.31 (0.96)	0.28 (0.85)	0.001
Categorized BMI z-score					
Normal weight, n (%)	776 (75.9)	210 (69.1)	376 (77.4)	190 (81.9)	0.001
Overweight, n (%)	162 (15.9)	59 (19.4)	75 (15.4)	28 (12.1)	
Obese, n (%)	84 (8.2)	35 (11.5)	35 (7.2)	14 (6.0)	
WHtR, mean (SD)	0.46 (0.06)	0.47 (0.06)	0.46 (0.06)	0.45 (0.05)	<0.001
WHtR z-score, mean (SD)	0.03 (0.81)	0.19 (0.85)	-0.01 (0.80)	-0.08 (0.75)	<0.001
FMI in kg/m <sup>2</sup> , mean (SD)	5.2 (2.7)	5.5 (2.8)	5.1 (2.7)	4.8 (2.5)	0.008
FMI z-score, mean (SD)	-0.01 (0.99)	0.17 (1.04)	-0.05 (1.00)	-0.16 (0.88)	<0.001
Second follow-up					
Number of participants, n (%)	872 (100)	344 (39.4)	365 (41.9)	163 (18.7)	
Adiposity markers					
BMI in kg/m², mean (SD)	22.1 (3.8)	22.6 (4.0)	21.7 (3.6)	22.0 (3.5)	0.007
BMI z-score, mean (SD)	0.30 (0.94)	0.43 (0.93)	0.19 (0.95)	0.28 (0.91)	0.003
Categorized BMI z-score					
Normal weight, n (%)	685 (78.6)	255 (74.1)	300 (82.2)	130 (79.8)	0.034

Table 2	Adiposit	y markers a	t baseline a	and follow-ups,	overall and by	y sleep	duration g	roup
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FMI in kg/m<sup>2</sup>, mean (SD) 5.7 (3.0) 5.8 (3.0) 5.5 (3.0) 6.1 (2.9) FMI z-score, mean (SD) -0.01 (1.01) 0.10 (1.06) -0.10 (0.99) -0.01 (0.97)

45 (12.3)

20 (5.5)

0.45 (0.05)

-0.21 (0.80)

Values are mean (SD) or n (%). P-values are derived from ANOVA for continuous variables and the Cochran-Mantel-Haenszel test for ordered categorical variables. BMI, body mass index; FMI, fat mass index; rec., recommendations; RTS, recommended-time sleepers; SS, short sleepers; VSS, very short sleepers; WHtR, waist-to-height ratio.

56 (16.3)

33 (9.6)

0.47 (0.06)

0.05 (0.86)

to examine the association between this parameter and a panel of adiposity markers, both cross-sectionally and longitudinally.

124 (14.2)

63 (7.2)

0.46 (0.06)

-0.10 (0.83)

#### Sleep duration in adolescence

Two-thirds of our adolescent cohort slept < 8 h/day at 12 years of age, and this percentage increased with advancing age during adolescence. While this result is in line with previous studies, the percentage of

adolescents not meeting sleep recommendations in our cohort could be seen as surprisingly high. In Spain, the AVENA study (individuals from 13 to 18.5 years of age) found that ~20% of adolescents self-reported sleeping <8 h/day.<sup>25</sup> Similar results were reported in individuals aged from 12 to 15 years in the IDEFICS/I.Family study, which was conducted in eight European countries.<sup>26</sup> However, data collection for these studies was based on self-reported methods in the early part of this century (up to the early 2010s), and more recent studies in a

23 (14.1)

10 (6.1)

0.45 (0.05)

-0.16 (0.79)

5

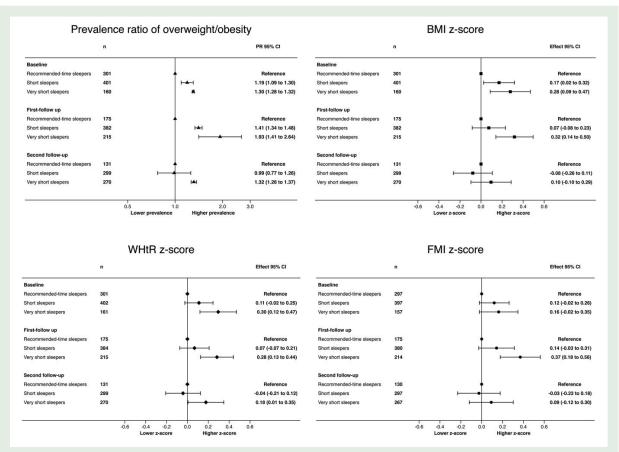
0.001

<0.001

0.173

0.026

#### J. Martínez-Gómez et al.



**Figure 1** Cross-sectional adjusted associations between sleep groups and adiposity markers across adolescence. Adjusted prevalence ratios and 95% confidence interval values were calculated with generalized models using a Poisson distribution with a log link and robust error variance and presented in a logarithmic scale. In these cases, fixed effects were the sleep group, randomization group, parental educational level, migrant background, moderate-to-vigorous physical activity, smoking and sexual maturity status, and total energy intake at each time point. The region (Madrid or Barcelona) and schools within each region were handled as random effects. Multilevel linear mixed models were used to determine the adjusted body mass index, waist-to-height ratio, and fat mass index z-score *B* coefficients and 95% confidence interval values, considering the same fixed and random effects as described above. BMI, body mass index; FMI, fat mass index; PR, prevalence ratio; RTS, recommended-time sleepers; SS, short sleepers; VSS, very short sleepers; WHtR, waist-to-height ratio; CI, confidence interval.

## Table 3 Adjusted associations between cumulative sleep recommendation groups across adolescence and adiposity markers at final follow-up

	Adiposity markers			
	Prevalence ratio Overweight/obesity	Continuous score		
		BMI z-score	WHtR z-score	FMI z-score
Number of participants, <i>n</i>	582	582	582	578
Always following sleep rec.	1 (reference)	0 (reference)	0 (reference)	0 (reference)
Following sleep rec. 2/3 time points	3.61 (1.14–11.38)	0.03 (-0.35-0.40)	0.27 (-0.05-0.60)	0.24 (-0.15-0.63
Following sleep rec. 1/3 time points	5.16 (1.39–19.24)	0.23 (-0.13-0.58)	0.32 (0.01–0.63)	0.35 (-0.02-0.72
Never following sleep rec.	5.82 (1.87–18.16)	0.27 (-0.08-0.63)	0.40 (0.09-0.71)	0.39 (0.03-0.76)
P-value for linear trends	0.002	0.064	0.010	0.024

Adjusted prevalence ratios and 95% confidence interval (CI) values were calculated with generalized models using a Poisson distribution with a log link and robust error variance. In these cases, fixed effects were the sleep recommendation group, randomization group, parental educational level, migrant background, moderate-to-vigorous physical activity, smoking and sexual maturity status, and total energy intake at baseline, whereas the region (Madrid or Barcelona) and schools within each region were handled as random effects. Multilevel linear mixed models were used to determine the adjusted BMI, WHtR, and FMI z-score  $\beta$  coefficients and 95% CI values considering the same fixed and random effects as described above. BMI, body mass index; FMI, fat mass index; rec., recommendations; WHtR, waist-to-height ratio.

sample from 24 European and North American countries have shown similar results to those we obtained, although the proportion of adolescents meeting sleep recommendations varies significantly across countries.<sup>3</sup> Sleep duration in adolescence could have decreased over the past 10 years for several reasons, including the more generalized use of electronic devices and pre-bedtime activities involving light exposure, trends that could not have been captured in previous studies.<sup>4</sup>

In line with these data, studies from locations across the world have shown a decrease in total sleep time with advancing age in adolescence.<sup>3–5</sup> Sleep loss during this stage of life is not completely driven by a reduction in physiological sleep requirements but can result from a convergence of influences, including biological (changes in sleep homoeostatic pressure and circadian timing systems), psychological (increased independence, such as bedtime autonomy, and academic pressure), and social engagement at late hours).<sup>27</sup> Our protocol consisted of the acquisition of data from wrist-worn devices, which have been shown to provide a more accurate estimate of sleep than hip-worn accelerometers, which usually overestimate sleep time due to poor wake detection.<sup>28</sup> Therefore, since questionnaire-based and hip-worn accelerometry results both tend to overestimate sleep time, our results might reflect a comparatively low but more accurate sleep estimate.

## Sociodemographic correlates of adolescent sleep duration

Most previous research has indicated that boys sleep less than girls,<sup>29–31</sup> in line with our finding that girls are likely to meet sleep recommendations than boys. This could be explained by several factors, such as a greater need for sleep in girls,<sup>32,33</sup> advanced puberty in girls compared with boys of the same age, or menstrual cycle phase and oral contraceptive intake, both of which interact with circadian rhythms.<sup>34</sup>

There is conflicting evidence for the influence of socioeconomic differences on adolescent sleep duration. While some studies have related shorter sleep duration to low socioeconomic and migrant backgrounds,<sup>35,36</sup> others have reported opposite associations.<sup>37</sup> In our study, only migrant background showed an association with shorter sleep duration. As there are cross-national variations in sleep time, cultural differences in bedtimes may contribute to the observed interethnic differences in sleep duration during adolescence.<sup>3</sup>

## Association of sleep duration with adiposity markers in adolescence

There is a well-established direct association between short sleep duration and adverse outcomes for all age groups, such as subclinical atherosclerosis,<sup>38</sup> cardiometabolic diseases,<sup>39–41</sup> and mortality<sup>42</sup> in adults and overweight/obesity in children and adolescents.<sup>6,7</sup> Our findings fit this pattern, and the strength and direction of the association between short sleep and overweight/obesity remained robust after adjustment for potential confounders and after categorizing sleep in the RTS, SS, and VSS groups. In addition to the traditional measures such as BMI, we also found similar associations for the adjosity markers FMI and WHtR. These adjosity markers have seldom been used and mostly in adults.<sup>43,44</sup> However, they are relevant because short sleep duration is directly associated not only with overweight/obesity but also with central obesity and percentage body fat mass, metrics that may provide a more accurate picture of some of the body composition changes that typically occur in adolescence.

The link between weight gain and shorter sleep duration can be explained by several factors.<sup>1,9</sup> Firstly, there is a likely contribution from biological processes, mostly related to hormonal and energy dysregulations. Sleep deprivation disrupts circadian rhythmicity and daily fluctuations in appetite hormones, resulting in higher levels of the appetite-stimulating ghrelin and low levels of the appetite-suppressing leptin.<sup>1,9</sup> Moreover, growth hormone is secreted mainly during sleep, and lower levels of this hormone are associated with increased risk of obesity.<sup>45</sup> Consequently, short sleep duration could activate the hedonic food pathway, resulting in some people choosing high-calorie and less healthy foods, especially carbohydrate-rich foods and sugar-sweetened beverages, and reducing their intake of fruit and vegetables.<sup>46,47</sup> Therefore, a reduction in sleep time could modify not only the composition and distribution of human food intake but also the amount, since time and opportunities to eat increase in parallel with the decrease in sleep duration.<sup>48</sup>

Sleep needs charge with age, and the impact of short sleep on adiposity markers may therefore evolve during the course of adolescence. This might explain why associations were stronger in early than in later adolescence (age 16 years). Another possibility is that the 8–10 h/day sleep recommendation could be excessive for adolescents aged 16 years. The US National Sleep Foundation recommendations<sup>2</sup> are based on observational studies and expert opinions and are still under debate.<sup>49,50</sup>

## Cumulative impact of insufficient sleep and clinical significance

The findings from the longitudinal data presented here are novel and suggest that the impact of short sleep duration on adverse adiposity markers is cumulative. For example, compared with adolescents who adhered to sleep duration recommendations throughout adolescence, those who met sleep recommendations at only one time point or at no time points had ~5 times higher prevalence of overweight/obesity.

Accumulated evidence demonstrates a clear relationship between sleep duration and health-related variables, including adiposity markers. The findings of the present study suggest that the link between insufficient sleep and adverse adiposity markers was independent of energy intake and physical activity levels, indicating that sleep itself is important and revealing the need to develop and test future intervention programmes aimed at promoting sleep in adolescents. However, obesity is a multifactorial condition, and sleep by itself may explain only a proportion of the variation in adiposity, and multicomponent interventions should therefore be taken into consideration. Appropriate sleep duration, healthy nutrition, and being physically active are three of the most important lifestyle components that together ensure good individual health and performance.<sup>48,51</sup> Although educational interventions can increase sleep duration, these interventions need to be considered in the context of the structural and home environment in which adolescents live and the broader public policy setting, since, for example, an early school start time has been identified as a key modifiable factor for inadequate sleep.<sup>52</sup>

#### Study limitations and strengths

There are some limitations that warrant consideration. Given the observational nature of the study, the possibility of residual confounding cannot be excluded. The schools and their participants were selected with a non-probabilistic sampling method. Moreover, as the schools were all located in the Madrid or Barcelona metropolitan areas, the population analysed might not be representative of the overall adolescent population in Spain. As in most behavioural assessments, sleep estimation may have been affected by a social desirability bias, potentially resulting in participants reporting healthier patterns on the days when they were wearing the accelerometer. To handle missing sleep data, we used pairwise and listwise deletion strategies in the analysis of crosssectional and longitudinal associations, respectively, and this might have affected the results. However, the results were consistent, and similar results were obtained in a sensitivity analysis of cross-sectional associations including the 781 individuals with valid data at all three time points as well as in models including the family identifier as an

Proyectos en colaboración additional random effect to account for siblings enrolled in the study (data not shown) and when restricting the analysis to individuals with valid sleep records for 6 or 7 days per assessment.

The major strength of our study is that it represents one of the largest samples of contemporaneous adolescents examined longitudinally for sleep duration and a diverse panel of adiposity markers to date in Europe with the use of objective assessment methods. This allowed us to study not only adolescent sleep duration but also its sociodemographic correlates and its association with distinct adiposity markers, something that could not be fully explored in previous studies.

### Conclusions

Most adolescents did not meet sleep recommendations during adolescence. Moreover, shorter sleep duration was associated with adverse adiposity markers, particularly at ages 12 and 14 years and when sleep duration was <7 h/day. The impact of short sleep duration on adverse adiposity markers was cumulative, and adolescents who did not meet sleep recommendations at any of the three time points showed the unhealthiest adiposity profiles. Health promotion programmes and public policies should emphasize the importance of good sleep habits to improve adolescents' health and well-being.

### Author contributions

V.F. conceived the overall SI! Program for Secondary Schools trial. J.M.-G., G.S.-B., A.d.C.-G., J.M.F.-A., A.T.-R., E.P.L.-S., P.B., M.d.M., R.E., and R.M.L.-R. co-ordinated the recruitment of schools and participants, consent process, and/or data collection. I.C., M.d.M., and V.C. coordinated the development and implementation of the intervention educational programme. J.M.-G. conducted statistical analyses and drafted the first version of the manuscript. J.M.-G. and A.d.C.-G. directly accessed and verified the underlying data reported in the manuscript. J.M.F.-A. and R.F.-J. provided scientific support over the course of this work. All authors revised the manuscript critically for intellectual content and approved the published version.

### Supplementary material

Supplementary material is available at European Journal of Preventive Cardiology.

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Conflict of interest: None declared.

#### Data availability

Data availability to external researchers is restricted to related project proposals upon request to the corresponding author. Based on these premises, deidentified participant data will be available with publication after approval of the proposal by the steering committee and a signed data sharing agreement.

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#### Sleep duration and its association with adiposity markers in adolescence

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9







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