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FIVALIN (fitness, values and healthy lifestyles) project: a family-based intervention to prevent childhood obesity among low socioeconomic status school aged children in Barcelona, Spain

Submission date
22/06/2020

Recruitment status
No longer recruiting

Registration date
09/07/2020

Overall study status
Completed

Last Edited
31/07/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
The childhood obesity rates among the general population are alarmingly high and are even higher in socioeconomically deprived populations. In high-income countries, low socioeconomic position (SEP) is associated with a 16% higher risk of overweight and a 43% higher risk of obesity in children aged 0–15 years. A wide range of interventions has been implemented and tested to prevent obesity in children, but there is low evidence on the effects of interventions addressed to low socio-economic populations. For this reason, the aim of the FIVALIN study is to study the effects of obesity prevention and healthy lifestyle promotion intervention among vulnerable children (8-12 years old) and their families from community child centers.

Who can participate?
Family with children aged 8 to 12 years old who participate in community child centers

What does the study involve?
Sixty community child centres are allocated to an intervention group and a comparison group. The intervention group received 8-months healthy lifestyle promotion Intervention, while the control group received usual care provided in Community Child Centers (CCC) program plus two evaluation sessions (pre-evaluation and post-evaluation), and one family workshop at the middle of the project.
The intervention group actions involve children, adults and CCC educators. Children participate in 32 1-hour sport education sessions implemented by the CCC educators at each center. Adults and children participate in 8 2-hours family workshops implemented by Gasol Foundation staff. They also received 32 text messages plus 8 promotional videos in their smartphone and 4 packs of pedagogical material. CCC educators participate in 3 5-hours training during the project development, 6 follow-up online meetings and received an activity guide and a sport material box to promote healthy lifestyles and implement the sport educational sessions.

What are the possible benefits and risks of participating?
Regarding the benefits of participating in the study, the intervention group receive those incentives: pedagogical material, a T-shirt and a water bottle. The comparison group receive two incentives: a water bottle and a basketball. Participants family from the intervention group will also have benefits regarding the following points:
- Children are participating free of charge in sport educative sessions during the school year.
- Families are participating free of charge in family workshop that promote family cohesion, healthy role models and parenting practices.
A healthy lifestyles reinforcement or positive evolution and a positive weight status evolution is expected among the individuals that participate in the project activities.
No risks have been identified from the participation in this study.

Where is the study run from?
The Gazol Foundation (Spain)

When is the study starting and how long is it expected to run for?
September 2019 to September 2024

Who is funding the study?
NIKE Made To Play (USA)

Who is the main contact?
Dr Gómez Santos, sgomez@gasolfoundation.org

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The study protocol of the FIVALIN project: A family-based intervention to prevent childhood obesity among low socioeconomic status school aged children in Barcelona, Spain

Acronym
FIVALIN

Study objectives

The participation as a family in the intervention group of the FIVALIN project predicts a better evolution of children's weight status and healthy lifestyles - diet, physical activity, sleep and emotional wellbeing - in comparison with children from a family allocated in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/09/2019, CEIm Fundació Sant Joan de Déu (Medical Research Ethics Committee Sant Joan de Déu Foundation, Santa Rosa, 39-57 08950 Esplugues del Llobregat, Barcelona, Spain; +34 936 00 97 51; info@fsjd.org), ref: PIC-169-19

Study design
Interventional non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Childhood obesity, lifestyles, socioeconomic vulnerability, inequalities

Interventions
The study has three editions of 10 months each. It is conducted in community child centers (CCC) that vulnerable children attend during leisure time, normally afternoons after school time. The CCC are located in the city and metropolitan area of Barcelona (Spain). Per edition a total of 30 CCC are recruited and per each center a group of 18-20 socioeconomic vulnerable children (8-12 years old) and their families participate. Per each edition, a total of 15 CCC are allocated to the intervention group and 15 others to the comparison group. The recruitment is conducted by Gasol Foundation for convenience being the main criteria to allocate the CCC, their possibility to accomplish during each edition with the intervention commitments. The CCC that participate as a comparison group in one edition is invited to participate as intervention group the next project edition.
From the 30 CCC enrolled in each project edition a total of 540 children and 400 parents will be participating in the study, half of participants in the intervention group and in the comparison group. The present study aims to enroll, at the end of the three planned editions, 60 CCC, 1080 children and 800 parents. Some families will start their participation allocated in the comparison group and during the following edition will be allocated to the intervention group.
The intervention group received 8-month Healthy Lifestyle Intervention, while the comparison group received usual care provided in CCC program plus two evaluation sessions (pre-evaluation and post-evaluation), and a family workshop at the middle of the project which aim is to motivate their involvement to reduce possible missing cases on the evaluation.
The Healthy Lifestyle Intervention was designed based on an ecological perspective to prevent obesity among socioeconomically vulnerable children by promoting healthy lifestyles related on physical activity, healthy eating, sleep quality and duration and emotional wellbeing. The intervention comprised multi-level intervention strategies: child-level educational strategies, family strategies, and centre-level organizational strategies for obesity prevention and healthy lifestyles promotion among vulnerable children.

Child strategies:
- 32 sport educational sessions for physical activity, healthy eating, sleep quality and duration and emotional wellbeing for 8 months, 8 sport session per healthy lifestyle subject. CCC implement those sessions.
Family strategies:
- 8 family workshops involving children and adults: two-evaluation sessions, a welcoming workshop, one workshop per each item (physical activity, healthy eating, sleep quality and duration and emotional wellbeing) will be developed and a closure workshop involving all participants families from all CCC in one day healthy event. Gasol Foundation staff implement those workshops in each CCC.
- 32 text messages.
- 8 promotion videos sent by text messaging.
- 4 packs of educative material.
Center strategies:
- 3 training workshops for two counselors of each CCC.
- Delivery of an activity guide and a sport material box to promote healthy lifestyles and implement the sport educational sessions.
- 6 follow-up online meetings.

Intervention Type
Behavioural

Primary outcome(s)
At baseline and 31 weeks: Body weight and height with the subjects wearing a t-shirt and light trousers and waist circumference elevating the t-shirt at the middle of their thorax. The measurements will be performed without shoes and using an electronic scale (SECA 899), to the nearest of 100 g, a portable SECA 217 stadiometer (to the nearest 1 mm), and a metric tape SECA 201 (to the nearest 1 mm). All measures are performed by trained field researchers.

Key secondary outcome(s))
At baseline and 31 weeks:
1. Children:
Self report:
1.1. Physical activity (PA) assessed by the child's Physical Activity Unified - 7 items Screener (PAU-7S)
1.2. The use of accelerometers is still not confirmed but in case that will be used, participants will wear the ActiGraph wGT3X-BT accelerometer for 9 days
1.3. Fitness condition: will be measured by International Fitness Scale (IFIS)
1.4. Health status: will be measured by one question of the self-perceived health status from the questionnaire EQ-5D-Y-5L

Report by parents:
1.5. Sedentary behavior: Will be measured by the Screen-time Sedentary Behavior Questionnaire (SSBQ)
1.6. Diet: Adherence to the Mediterranean diet will be recorded by the KIDMED index questionnaire
1.7. Sleep duration: The hours of sleep will be recorded by 4 questions from the Sleep Habits Survey for Adolescents (SHSA)
1.8. Sleep quality (of children) will be evaluated by the BEARS questionnaire
1.9. Emotional wellbeing: Will be measured by Strengths and Difficulties Questionnaire (SDQ)
1.10. Birthweight of children and if they received breastfeeding or not, measured by self-report

2. Parents:
Self report:
2.1. Gender; weight and height; birthday; country of origin; number of people in the household; smoking habit; educational level; work situation; general health status; annual income
2.2. Sleep duration: The hours of sleep will be recorded by 4 questions from the Sleep Habits Survey for Adolescents (SHSA)
2.3. PA level and sedentariness evaluated by the REGICOR Short PA Questionnaire
2.4. Diet quality will be evaluated by the short Diet Quality Screener
2.5. Self-perceived stress will be measured by the Perceived Stress Scale (PSS)
2.6. Environmental variables: home address

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Participate in a CCC
2. Participant family with children aged 8 to 12 years old
3. Have the informed consent signed positively by the parents/legal representatives

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
2575

Key exclusion criteria
Intellectual or physical characteristics that incapacitate their enrollment in the evaluation procedures

Date of first enrolment
01/10/2019

Date of final enrolment
01/03/2023

Locations

Countries of recruitment

Spain

Study participating centre
Casal dels Infants de la Mina
Rambla de la Mina, 32
Sant Adrià del Besos
Spain
08930

Study participating centre
Casal dels Infants del Raval
C/ Reina Amàlia, 22
Barcelona
Spain
08001

Study participating centre
Esplai la Florida
C/ Pedraforca, 29
2a Planta
l'Hospitalet de Llobregat
Spain
08905

Study participating centre
Fundació Pere Tarrés Montcada i Reixac
Avinguda Riera de Sant Cugat, 38
Montcada i Reixac
Spain
08110

Study participating centre
Fundació Pere Tarrés Can Sant Joan
C/ del Viver 0
Montcada i Reixac
Spain
08110

Study participating centre

Fundació Mans a les Mans
C/Foc, 100
Barcelona
Spain
08038

Study participating centre
Club Infantil i Juvenil Sant Feliu Sant Ildefons
C/ Emigrant, 25
baixos
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Spain
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Study participating centre
PES La Mina
Carrer Mar s/n
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Gasol Foundation

Funder(s)

Funder type
Industry

Funder Name
NIKE Made To Play

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
All dataset will be available for research organizations since the first edition of the project with no limit data. Interested organization should requested by contacting with Gasol Foundation Head of Programs:
- Name: Santiago Felipe Gómez Santos, PhD
- E-mail contact: contact@gasolfoundation.org or sgomez@gasolfoundatin.org
The research organitzation will be asked to inform of:
- Name and legal status of the organization
- Contact name and email
- Main objective of using the dataset
After review this information, if the main objective respect the ethical aspects and contribute on the mission of the Gasol Foundation, before sharing the dataset, the organization will sign a document that specify:
- Ethical use of the data
- The dataset analysis objective
- Commitment to share with the Gasol Foundation the type of analysis

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article		21/05/2021	24/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes