

Study of the level of physical activity, inactivity, and sleep patterns in children and adolescents in the Autonomous Community of the Basque Country (6–17 years old)

Submission date 15/03/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/03/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Physical inactivity and increased sedentary behavior are increasingly common problems and can lead to overweight, obesity, diabetes, heart disease, and decreased motor and cognitive capacity among children and adolescents. Establishing some healthy habits in childhood is essential for proper physical, motor, and cognitive development. The aim of this study is to describe the level of physical activity, sedentary behavior and sleep of children and adolescents in the Autonomous Community of the Basque Country.

Who can participate?

All children aged 6-17 enrolled in a school in the Basque Autonomous Community

What does the study involve?

Participants will be selected randomly based on gender, age, school, school location and socioeconomic status. They will have to wear an accelerometer for 7 full days and fill in a health habits diary.

What are the possible benefits and risks of participating?

The main benefit is to find out whether children and adolescents are sufficiently physically active on a daily basis, and assess their sedentary behavior and the relationship between these behaviors and sleep. This study has no risks as the participants will only have to wear an accelerometer and fill in a diary.

Where is the study run from?

The study is conducted from the Basque Autonomous Community and is carried out by the Basque Government, the University of Deusto and Mondragon Unibertzitatea, Mugikon and Athlon (Spain)

When is the study starting and how long is it expected to run for?
September 2020 to April 2022

Who is funding the study?
The Basque Government (Spain)

Who is the main contact?
Dr Aitor Coca Nuñez
aitor.coca@euneiz.com

Contact information

Type(s)
Scientific

Contact name
Dr Aitor Coca Nuñez

Contact details
Unibertsitate Etorb., 24
Bibao
Spain
48007
+34 (0)688749145
aitor.coca@euneiz.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PI2020011

Study information

Scientific Title
Study protocol on the level of physical activity, sedentary behavior, and sleep in the child and adolescent population in the Autonomous Community of the Basque Country (6–17 years old)

Acronym
MUGIKERTU

Study objectives

To describe the level of physical activity, sedentary behavior, or sleep of the child and adolescent population from 6 to 17 years old in the Basque Autonomous Country.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/10/2020, Euskadi Drug Research Ethics Committee (Basque Government Department of Health, CEIm-Departamento de Salud del Gobierno Vasco, C/ Donostia-San Sebastián, nº 1. Vitoria-Gasteiz 01010, Spain; +34 (0)945 01 92 96; +34 (0)945 01 56 34 ; +34 (0) 945 01 64 59; ceic.eaaa@euskadi.eus), ref: PI2020011

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Physical activity, sedentary behavior, sleep

Interventions

This study aims to recruit 1,111 representative random samples of children and adolescents from 6 to 17 years old from the Basque Autonomous Country. Participants must wear the ActiGraph WGT3X-BT accelerometer for a full 7 days and fill out a habit log of physical activity, sedentary behavior, and sleep routine. Participants will be randomly selected.

Intervention Type

Behavioural

Primary outcome measure

The level of physical activity, sedentary behavior, and sleep routine measured by ActiGraph WGT3X-BT accelerometers for 7 days.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2020

Completion date

15/04/2022

Eligibility

Key inclusion criteria

1. Belong to the student body of a participating school or institute
2. Have authorization to participate through a signed informed consent by the parents or legal guardians of the child or adolescent

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

1111

Total final enrolment

1150

Key exclusion criteria

Non-consent or refusal by the child or adolescent to complete the physical activity diary or to use the accelerometer, even with a signed informed consent by their parents or legal guardians

Date of first enrolment

01/11/2020

Date of final enrolment

30/10/2021

Locations

Countries of recruitment

Spain

Study participating centre

Universidad de Deusto

Unibertsitate Etorb., 24

Bilbao

Spain

48007

Study participating centre**Universidad de Mondragon**

Loramendi Kalea, 4, Edificio 6, Arrasate, Gipuzkoa
Mondragón
Spain
20500

Sponsor information

Organisation

Basque Government

Sponsor details

Donostia-San Sebastián kalea, 1
Vitoria-Gasteiz
Spain
01010
+34 (0)945018000
comisionjuridica@euskadi.eus

Sponsor type

Government

Website

<https://www.euskadi.net>

ROR

<https://ror.org/00pz2fp31>

Funder(s)

Funder type

Government

Funder Name

Eusko Jauriaritza

Alternative Name(s)

Gobierno Vasco, Basque Government

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Spain

Results and Publications

Publication and dissemination plan

1. Planned publication of the protocol
2. Planned publication of the results in a high-impact peer-reviewed journal

Intention to publish date

01/10/2022

Individual participant data (IPD) sharing plan

The datasets are stored in a private server that only researchers approved by the ethics committee have access to.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/06/2021	No	Yes
Protocol article	Protocol	11/03/2022	17/03/2023	Yes	No
Results article	outcome results	15/03/2023	17/03/2023	Yes	No
Results article	results with and without sports	06/01/2023	17/03/2023	Yes	No