

INFORMATION SHEET AND INFORMED CONSENT FORM

Official Study Title

Physical Activity and Fitness in Pediatric Inflammatory Bowel Disease (PAFIT-IBD)

Clinical Trials Identifier

NCT Number: NCT07484620

Document Type

Information Sheet and Informed Consent Form

Document Date

10 March 2026

Study Sponsor / Responsible Organization

Universidad Rey Juan Carlos (URJC)
Madrid, Spain

Collaborating Institution

Hospital Infantil Universitario Niño Jesús
Madrid, Spain

Study Description

This document contains the **Information Sheet and Informed Consent Form** for the study titled “*Physical Activity and Fitness in Pediatric Inflammatory Bowel Disease (PAFIT-IBD)*”, a prospective single-arm interventional study evaluating the effects of a structured physical activity intervention on physical activity, physical fitness, inflammation, and clinical outcomes in children and adolescents with inflammatory bowel disease.

Important Note

This document was prepared for submission to **ClinicalTrials.gov** in accordance with the requirements of the **Protocol Registration and Results System (PRS)**. Uploaded documents may be posted publicly on the ClinicalTrials.gov website after PRS review.

This document does **not contain any personally identifiable information about study participants**.

Introduction

You are invited to allow your child to participate in a research study conducted in a hospital setting. Before deciding whether to participate, it is important that you understand why the study is being carried out and what participation will involve.

Please read the following information carefully and do not hesitate to ask any questions.

Study Objective

The aim of this study is to analyze how physical activity, physical fitness, and other lifestyle-related factors are associated with inflammation, clinical outcomes, and quality of life in children and adolescents with inflammatory bowel disease.

Procedures

The physical exercise program will last approximately **12 weeks**, with a frequency of **two sessions per week at the hospital and one optional home-based session**.

Each session will last approximately **45 to 60 minutes**, depending on the child's age and clinical condition.

The total estimated number of **in-person sessions will be 24**, with the possibility of including shorter optional guided home sessions.

Participation will include:

- Assessment of **physical activity using an accelerometer**
- Simple **physical fitness tests** adapted to the participant's age and health status
- **Questionnaires** about health, quality of life, fatigue, cognition, and lifestyle habits
- Collection of **routine clinical laboratory samples** according to clinical practice guidelines. No additional laboratory samples beyond those required for usual clinical care will be collected.

All questionnaires and forms will be completed electronically using **Microsoft Forms**.

The estimated time required to complete the questionnaires is **approximately 20–30 minutes per assessment**. There will be **one assessment at the beginning and one at the end of the study**, distributed across several forms that may be completed flexibly and at different times if necessary.

Exercise Program Summary

PHYSICAL EXERCISE PROGRAM

Summary for families

Duration of the program

- 12 weeks

Frequency

- 2 sessions per week at the hospital
- 1 session per week at home

Duration of each session

- 45–60 minutes

Aerobic exercise

- Brisk walking
- Progressive running
- Active group games

Strength exercises

- Simple bodyweight exercises
- Adapted to age and physical fitness level

Safety and supervision

- Activities adapted to each child
- Gradual progression
- Supervision by qualified professionals

Where are the sessions held?

- Hospital facilities
- Retiro Park (located opposite the hospital) for some outdoor sessions
- Outdoor group activities under supervision

Risks and Benefits

The risks associated with the study are **minimal** and comparable to those of regular physical activity and daily travel.

All tests and activities will be adapted to the participant's clinical condition.

During exercise sessions, **mild muscle discomfort or temporary fatigue** may occur.

In addition, some aerobic exercise sessions will take place in **Retiro Park**, located across from the hospital. The main additional risk involves walking from the hospital to the park.

This movement will always be done **in groups, accompanied by research staff, and using pedestrian crossings and regulated intersections** to minimize risk.

In case of **adverse weather conditions or other circumstances that could compromise safety**, outdoor sessions will be canceled or adapted.

No direct benefit can be guaranteed; however, the information obtained may contribute to improving the management of the disease in the future.

Voluntary Participation

Participation is **completely voluntary**.

You may withdraw your consent at any time without affecting the usual medical care provided to your child.

Confidentiality and Data Protection

Personal data will be processed in accordance with applicable data protection regulations, particularly:

- **Regulation (EU) 2016/679 of the European Parliament and of the Council (General Data Protection Regulation, GDPR)**
- **Spanish Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD)**

All data will be treated **confidentially and pseudonymized** in accordance with these regulations.

No personal identifiers will be collected within the study forms.

Pseudonymization means that the data collected in the study will **not be directly associated with the child's name or identifying information**.

Each participant will be assigned a **study code**, and researchers will work only with this code rather than personal identifiers.

If contact information is required for logistical reasons, it will be collected through a **separate form**.

Data that could identify participants (such as name or phone number) will be stored in a **separate database**, used only for organizational purposes and **not for scientific analysis**.

For any questions regarding personal data protection, you may contact the **Data Protection Officer of Hospital Infantil Universitario Niño Jesús**:

pdatos.hnjs@salud.madrid.org

Consent

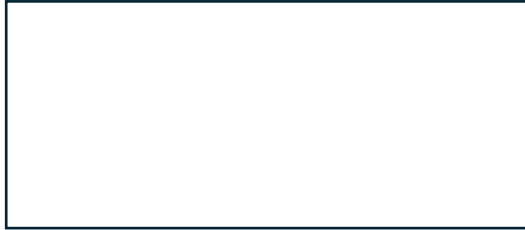
I declare that:

- I have read and understood the information provided above.
- I have had the opportunity to ask questions.
- I understand that participation is voluntary.
- I understand that I may withdraw this consent at any time without affecting my child's usual medical care.

Please select one option:

- ☐ **I voluntarily ACCEPT my child's participation in this study**
- ☐ **I DO NOT ACCEPT my child's participation in this study**

Parent / Legal Guardian Signature:



Parent / Legal Guardian Signature:



Principal Investigator Signature:

