STUDY PROTOCOL

Official Study Title

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

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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 **Study Protocol** 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**.

1. ABSTRACT

Pediatric inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, is a chronic condition associated with persistent intestinal inflammation, fatigue, reduced physical fitness, and impaired quality of life. Despite advances in treatment, many pediatric patients present functional limitations that are not systematically addressed in clinical practice.

The aim of this study is to evaluate the effect of **physical activity (PA)** and **physical fitness** on inflammation, clinical outcomes, and quality of life in children and adolescents with IBD.

This is a **hospital-based prospective single-arm interventional study** that includes a structured 12-week physical activity intervention and medium-term follow-up (6–12 months).

Participants will include children and adolescents aged **6–17 years** with a confirmed diagnosis of IBD in clinical remission or mild-to-moderate disease activity.

The intervention will consist of a **supervised physical activity program adapted to the participant's age and clinical condition**.

The **primary outcome** will be the change in physical fitness assessed using the **ALPHA fitness test battery**.

Secondary outcomes include:

- Objective inflammatory markers (fecal calprotectin, C-reactive protein)
- Disease activity indices
- Body composition
- Quality of life
- Fatigue
- Cognitive function
- Mental health
- Nutritional status

The study involves **minimal risk**, comparable to regular physical activity, and is expected to generate potential benefits for participants and valuable knowledge to improve the comprehensive management of pediatric IBD.

The project will be conducted in accordance with ethical and legal principles governing research involving minors.

2. BACKGROUND AND RATIONALE

Inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, is a chronic condition that frequently begins during childhood and adolescence.

In pediatric populations, IBD is associated not only with persistent intestinal inflammation but also with several extraintestinal manifestations, including:

- fatigue
- musculoskeletal pain

- growth delay
- mood disturbances
- reduced quality of life.

Several studies have shown that children and adolescents with IBD have **lower levels of physical activity and poorer physical fitness compared with healthy peers**.

Low cardiorespiratory and muscular fitness may contribute to:

- increased systemic inflammation
- poorer disease control
- greater symptom burden.

However, most existing studies are **cross-sectional**, rely on **self-reported physical activity**, and do not comprehensively assess physical fitness using objective testing.

Physical activity and physical fitness are **modifiable lifestyle factors** with low cost and potentially high clinical impact.

In the general pediatric population, better physical fitness is associated with:

- lower inflammation
- improved mental health
- better cognitive performance.

Nevertheless, in pediatric IBD there is a **clear lack of well-designed hospital-based studies** evaluating the combined relationship between:

- physical activity
- physical fitness
- objective inflammation
- clinically relevant outcomes.

This project proposes an **integrated hospital-based study** to evaluate the role of physical activity and physical fitness as prognostic factors for clinical evolution, inflammation, and quality of life in children and adolescents with IBD, as well as the impact of a structured physical activity intervention.

3. HYPOTHESES

Children and adolescents with IBD who present higher levels of physical activity and better physical fitness will show lower levels of objective inflammation and lower disease activity.

Better physical fitness will be associated with lower fatigue, improved quality of life, and better cognitive functioning.

Physical fitness will act as a **mediator** in the relationship between physical activity and clinical outcomes in pediatric IBD.

A structured physical activity intervention will improve physical fitness, reduce inflammation, and improve quality of life in children and adolescents with IBD.

4. OBJECTIVES

General Objective

To evaluate the association between physical activity, physical fitness, and clinical outcomes in children and adolescents with IBD, as well as the effect of a structured physical activity intervention.

Specific Objectives

- To describe levels of physical activity and physical fitness in children and adolescents with IBD.
- To analyze the association between physical activity and objective inflammatory markers.
- To analyze the relationship between physical fitness and disease activity, fatigue, and quality of life.
- To evaluate the association between physical fitness and cognitive and mental health variables.
- To analyze whether physical fitness mediates the relationship between physical activity and clinical outcomes.
- To evaluate the effect of a structured physical activity intervention on physical fitness, inflammation, and quality of life.
- To analyze the sustainability of these effects at medium-term follow-up (6–12 months).

5. STUDY DESIGN

Hospital-based prospective interventional study, single-arm, with baseline, post-intervention, and follow-up assessments.

Phase 1 – Observational phase

Cross-sectional and longitudinal evaluation of participants.

Phase 2 – Intervention phase

Prospective, non-randomized single-arm physical activity intervention.

Phase 3 – Follow-up phase

Medium-term follow-up (6–12 months) after baseline or intervention completion to evaluate clinical, inflammatory, and functional evolution.

Study Setting

Pediatric Gastroenterology clinics and functional areas of **Hospital Infantil Universitario Niño Jesús (Madrid, Spain)**, in collaboration with **Universidad Rey Juan Carlos (Madrid, Spain)**.

6. PARTICIPANTS

Inclusion Criteria

- Age between **6 and 17 years**
- Confirmed diagnosis of **Crohn's disease or ulcerative colitis**
- Clinical remission or mild-to-moderate disease activity
- Follow-up at a pediatric gastroenterology outpatient clinic
- Written informed consent from a legal guardian

Exclusion Criteria

- Severe disease flare at enrollment
- Medical contraindication to physical exercise
- Major surgery in the previous 3 months
- Other severe chronic diseases limiting physical activity
- Cognitive or behavioral conditions preventing safe participation

Sample Size

The sample size was calculated considering the **change in cardiorespiratory fitness**, assessed using the **20-meter shuttle run test (20mSRT)**.

The intervention follows a **pre–post design**, where each participant serves as their own control.

Based on previous literature in pediatric chronic disease populations:

- Expected effect size: **Cohen's d = 0.5**
- Significance level: **α = 0.05**
- Statistical power: **80%**

The minimum required sample size is **34 participants**.

Considering expected drop-out rates of **15–30%**, the target sample size is approximately **100 participants**.

This sample size is considered realistic, ethically justified, and appropriate for the objectives of the study.

7. VARIABLES

7.1 Primary Variables

Physical Fitness

Assessed using the **ALPHA fitness test battery**, adapted for the hospital environment:

Cardiorespiratory fitness

- 20-meter shuttle run test

Muscular strength

- Handgrip strength
- Standing long jump

7.2 Secondary Variables

Physical Fitness

Speed and agility

- 4 × 10 m test

Physical Activity

Objectively measured using **accelerometry for 7 consecutive days**.

Main variables:

- Moderate-to-vigorous physical activity (MVPA, min/day)
- Total sedentary time
- Physical activity patterns

Subjective measures:

- PAQ-C (children)
- PAQ-A (adolescents)

Inflammation and disease activity

Inflammatory biomarkers:

- Fecal calprotectin
- C-reactive protein (CRP)

Disease activity indices:

- PCDAI (Crohn’s disease)
- PUCAI (ulcerative colitis)

Neurocognition and Mental Health

Attention and executive function

- BENCI computerized neuropsychological battery

Fatigue

- PedsQL Fatigue Module

ADHD symptoms

- ADHD Rating Scale

Anxiety and depression

- RCADS

Quality of Life and Daily Functioning

- IMPACT-III questionnaire (IBD-specific quality of life)
- Academic performance

Diet Quality

- KIDMED index

Body composition

- Lean body mass
- Body fat percentage
- BMI z-score

8. INTERVENTION

The intervention consists of a **structured physical activity program lasting approximately 12 weeks**, designed for children and adolescents with IBD.

The program includes **2–3 weekly sessions** combining:

- moderate-intensity aerobic exercise
- functional strength exercises.

Sessions will be adapted to each participant's **age, functional level, and clinical condition**.

Participants will serve as their own controls through **pre- and post-intervention comparisons**, as well as medium-term follow-up analyses.

Some aerobic sessions will be conducted in **Retiro Park**, located opposite the hospital.

Safety precautions include:

- group supervision by research staff

- use of pedestrian crossings
- cancellation or adaptation of outdoor sessions during adverse weather.

The intervention is considered **minimal risk**, comparable to usual physical activity.

9. STUDY TIMELINE

The study will last approximately **18 months**, starting in **January 2026**.

Phase 0 – Preparation and ethical approval (January 2026)

- Ethics committee approval
- Investigator team coordination
- Staff training
- Development of electronic forms
- Preparation of intervention materials

Phase 1 – Recruitment and baseline assessment (Feb–Mar 2026)

- Identification of eligible participants
- Informed consent and child assent
- Baseline assessments

Phase 2 – Physical activity intervention (Mar–Jun 2026)

- 12-week structured intervention
- Continuous monitoring of adherence and adverse events

Phase 3 – Post-intervention assessment (Jun–Jul 2026)

- Repeat baseline assessments
- Record clinical and functional changes

Phase 4 – Follow-up (Sep 2026 – Mar 2027)

- Reassessment at 6–12 months
- Monitoring clinical outcomes

Phase 5 – Data analysis and dissemination (Apr–Jun 2027)

- Statistical analysis
- Preparation of scientific manuscripts
- Communication of results

10. DISSEMINATION PLAN

Results will be disseminated through:

- peer-reviewed international journals
- national and international scientific conferences.

Approximately **five scientific manuscripts** are expected, addressing different objectives and phases of the study.

When possible, participating families will receive a **lay summary of the global study results**.

11. ETHICAL CONSIDERATIONS

The study involves **minimal risk**, comparable to regular physical activity.

Safety monitoring and adverse event reporting will be implemented.

The study will follow:

- **The Declaration of Helsinki**
- National regulations governing research involving minors.

Ethical approval will be requested from the **Research Ethics Committee of Hospital Infantil Universitario Niño Jesús (Madrid, Spain)**.

12. INFORMED CONSENT

Written informed consent will be obtained from the legal guardian and assent from the child when appropriate using electronic forms.

All questionnaires and forms will be administered through **Microsoft Forms within the institutional Microsoft 365 environment of Universidad Rey Juan Carlos**.

Participants will be identified using **pseudonymized study codes**, and identifiable information will be stored separately.

Data handling will comply with:

- **General Data Protection Regulation (EU 2016/679)**
- **Spanish Organic Law 3/2018 on Data Protection**.