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Personalized Exercise Coaching to Improve Quality of Life in Pediatric IBD

- *FIT4IBDKids*

Study protocol

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STUDY PROTOCOL

Title

Personalized Exercise Coaching to Improve Quality of Life in Pediatric IBD: FIT4IBDKids

Abstract

Introduction: Crohn's disease and ulcerative colitis are the most common forms of pediatric inflammatory bowel disease (IBD), which is increasingly diagnosed in children and adolescents. Beyond gastrointestinal symptoms such as abdominal pain, diarrhea, and rectal bleeding, many pediatric patients experience persistent fatigue, reduced physical activity, and impaired quality of life. Current care still lacks structured exercise recommendations. Given the well-established physical and psychological benefits of physical activity, this study investigates whether tailored exercise can reduce fatigue, improve quality of life, and ease gastrointestinal symptoms in children with IBD.

Methods and analysis: This prospective controlled trial aims to include 70 children with IBD aged 6-18 years, divided into two groups based on baseline physical activity levels. Participants will complete a 24-week tailored exercise program, adjunctive to standard treatment, monitored using a Health Smartwatch. Primary outcomes are fatigue, quality of life, disease activity, and cardiorespiratory fitness, assessed via validated questionnaires and VO_2max testing. Secondary outcomes include muscle strength, aerobic capacity, heart rate variability, body-mass index, and intestinal inflammation measured by fecal calprotectin, ultrasound, and mucin analysis.

Ethics and dissemination: This study received ethical approval from the Ethics Committee at the University Hospital of Antwerp and the University of Antwerp and adheres to the Declaration of Helsinki. Written informed consent will be obtained from parents and participants. Exercise programs will be tailored to individual capacity, and adverse events will be monitored; participants may withdraw at any time. Results will consist of anonymized datasets, deposited in a secure repository to support transparency and reproducibility.

Key messages

What is already known on this topic: Pediatric IBD patients are troubled with reduced exercise capacity, reduced physical activity and greater fatigue compared to healthy peers. Previous studies suggest that physical activity may improve cardiorespiratory fitness and enhance psychological well-being in pediatric patients with IBD.

What this study adds: This study provides novel insights into the benefits of structured physical activity, individual coaching and its potential role in multimodal management. Furthermore, the trial adds the effect of a durable exercise programme on fatigue and quality of life (QOL) in pediatric IBD patients.

How this study might affect research, practice or policy: The findings could support the integration of structured exercise and coaching programs into routine care for pediatric IBD, providing a non-pharmacological approach to reduce fatigue and improve quality of life. Results may guide clinicians on safe and effective exercise prescriptions tailored to disease severity and baseline activity levels.

Key words: Inflammatory bowel disease (IBD), Children, Physical exercise, Fatigue, Quality of Life, Adolescent

Introduction

Inflammatory bowel diseases (IBD) are chronic inflammatory gastrointestinal disorders, most commonly represented by Crohn's disease (CD) and Ulcerative colitis (UC).(1-2) Approximately, the disorders affect 100 to 200 per 100 000 children in the United States, with an ever-more rising incidence of 10 pediatric patients per 100 000 peers.(1, 3-4) Most frequently, the onset of IBD appears before the age of 35, often in adolescence and young adulthood.(3) IBD results from the interaction between patients' microbiome, a genetic predisposition and environmental factors. These influences converge and lead to a dysregulated mucosal immune response against the commensal intestinal microbiota of the host.(5-6) Several studies have investigated genetic risk factors in pediatric patients, further supporting the association between a higher burden of common risk variants and rarer variants with high penetrance, and early-onset IBD.(7-8) Yet, the contribution of environmental influences at young age cannot be disregarded, as lifestyle factors are associated with a predisposition to IBD. Inadequate representation of gut taxa, dysbiosis and an overall restriction in the diversity of intestinal bacterial species may interfere with gut homeostasis, generate tissue dysfunction, and promote inflammation.(7,9) Implicated risk factors include a lack of exposure to breast milk, fatty diet, early exposure to antibiotics and Cesarean section.(10-12) Although symptoms of IBD vary, patients usually complain of abdominal pain, diarrhea, rectal bleeding, extreme fatigue and weight loss.(2) The development of gastrointestinal symptoms at any point in time, with recurrent and remitting course, implies reduced quality of life, substantial morbidity, high medical costs and significantly lower physical activity levels.(1) Therefore, in pediatric IBD patients, a reduced exercise capacity is being observed compared to healthy peers.

Lately, significant advances have been seen in the multimodal care of children with IBD. Given the expansion of therapeutic options, physicians' goals have shifted from solely symptom control to improving QoL, reducing fatigue and mucosal healing with consequent reduction of bowel damage.(5) This could be a promising approach: considering pediatric IBD patients show higher rates of fatigue, impaired QoL, difficulties in social functioning and GI manifestations.(13-14) Nonetheless, physical activity is known to be associated with many physiological and psychological health benefits across the lifespan. Assessing this adjunctive lifestyle intervention, scientific trials reported less fatigue (PedsQoL-MFS), an improved QoL (IMPACT-III), an increased exercise capacity and a decrease in IBD disease activity.(15-17)

However, the lack of standardized physical exercise programmes adjunctive to medical treatment guidelines implies a critical gap in literature. Currently, the state of the art standard of care only includes immunosuppressives, dietary advice and psychological counseling.(2, 18-19) With a growing population of pediatric patients facing IBD, we need to gain a better understanding of new approaches in effective, multimodal therapies. The aim of this study is to assess the effectiveness of physical exercise on reducing fatigue, improving QoL and intestinal manifestations in children with IBD. The information provided in the present study may be

useful for the multimodal management of children with IBD in whom fatigue, lower QoL and GI manifestations are an important burden.

Research Objective

The primary objective of this research is to gain novel insights into the potential of physical activity in reducing fatigue, improving QoL and GI manifestations in children with IBD. **Table 1** shows the research objective according to the PECO framework. The study design will be composed of two parallel groups to investigate the role of physical activity: on the one hand patients with higher exercise habits, on the other hand children with lower exercise habits. To this end, the two groups of pediatric IBD patients will undergo a 24 weeks exercise programme, adjunctive to their current treatment, quantified by a Health Smartwatch (Garmin Inc.). The primary outcomes will then be characterized by the PedsQoL-MFS, IMPACT-III, PCDAI and PUCAI questionnaires, as well as VO2-max quantification.

Table 1. Research objective within the PECO framework

Population:	Children diagnosed with IBD (ESPGHAN Guidelines), aged between 6 and 18 years old
Intervention:	An adjunctive 24 weeks exercise programme to current treatment, quantified by Health Smartwatch
Comparison:	Outcomes after adjunctive exercise programme to current treatment
Outcome	Fatigue, QoL and GI manifestations

The proposed research will confirm or refute current hypotheses about physical training suggesting an improvement in quality of life (QoL), fatigue and bowel symptoms in children with IBD. Furthermore, investigating the effectiveness on secondary outcomes including muscle strength and aerobic capacity will be a new contribution to current knowledge.

Methods

Study Design

This study is designed as a prospective single-center controlled trial. In consonance with a comprehensive baseline assessment, children with IBD will be allocated into two groups. The protocol adheres to the SPIRIT

(Standard Protocol Items: Recommendations for Interventional Trials) Statement: a minimum set of recommendations for reporting the protocol of a randomized trial. This study was registered with project ID 7893 and EDGE number 004446. **Figure 1** shows the flowchart of study design.

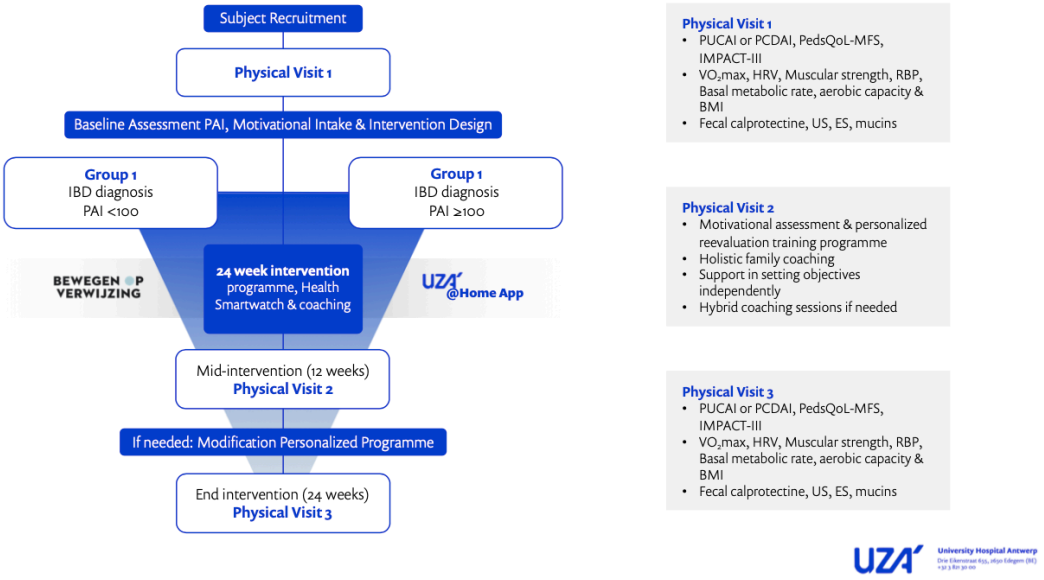
Study Population

Children with IBD will be allocated into two groups. The first group of this study will consist of children with higher exercise habits, in particular obtaining a weekly Personal Activity Intelligence (PAI) score ≥100 at baseline. Peers in the second group will reach PAI scores <100 at baseline. The personalized metric for physical activity tracking named PAI quantifies how much physical activity per week is needed to reduce the risk of premature mortality from non-communicable diseases. PAI and objectively measured cardiorespiratory fitness (as indicated by VO2peak) are positively associated in a graded fashion. Seventy pediatric patients will be included in this trial. Children were considered eligible for inclusion aged between six and 18 years old and diagnosed with IBD (Crohn's Disease or Ulcerative Colitis) according to the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Guidelines.

The following exclusion criteria are proposed:

1. Diabetes Mellitus (all types, according to the American Diabetes Association (ADA))
2. Malnutrition or Failure to Thrive, suspected or confirmed
3. Children with malignancy
4. Children with an acute phase of IBD disease activity
5. Children who are too fatigued to apply
6. Children < 120 cm, as VO2 max cannot be measured
7. Physical inability to perform a cardiopulmonary exercise test (CPET)
8. Participation in organized exercise training programs in a research setting
9. Medical contra-indications for exercise

FIGURE 1. **Flowchart of study design**



Sample Size Calculation

To ensure sufficient statistical 80% power for detecting significant differences in the outcomes, a sample size of 70 children with IBD has been determined. Each group will consist of 35 participants. Given the established graded and positive association between PAI and VO_2peak, this sample size is expected to allow detection of a moderate effect size with 80% power at a significance level of 0.05. The calculation accounts for variability in VO_2peak among pediatric IBD populations, and a margin has been included to accommodate potential attrition. Relevant covariates such as age, sex, and disease severity will be controlled for in the analysis to strengthen the internal validity of the study.

Intervention

The 24 week exercise programme, is designed by "Physical Activity on Prescription" (Bewegen Op Verwijzing). This multidisciplinary team develops personalized coaching programs designed to support physically inactive individuals in adopting a more active lifestyle. The intervention is characterized by professional guidance from a qualified and motivational coach, the development of a tailored physical activity plan, and continuous follow-up. The team will develop a holistic family-centered coaching trajectory for children aged six to 18 years. The intake session in which individualized physical activity goals are defined in collaboration with the child, encourages autonomy and active participation. Based on this initial assessment, a personalized coaching plan will be co-created with each child and their family, aiming to increase physical activity levels in a structured and supportive manner. The intervention will span a minimum duration of six months, in order to reduce the risk of drop-out and to promote long-term sustainability of behavioral change. All participants will participate in one supervised intake session with "Physical Activity on Prescription" (Bewegen Op Verwijzing) at baseline assessment. Furthermore, the online application **UZA@Home** provides digital support and guidance to patients

throughout their trajectory at the University Hospital of Antwerp (UZA). Its primary aim is to empower patients by equipping them with the necessary tools to actively engage in their treatment, while ensuring high-quality care as close to home as possible. Through the patient portal, individuals receive feedback on their intervention program and are able to consult appointments or access their medical records.

Planned Measurement Methods

The primary outcomes of this trial include differences in cardiorespiratory fitness (CRF), as assessed by maximal oxygen uptake (VO_2max), in addition to patient-reported outcomes measured by the IMPACT-III, PedsQoL-MFS, and the disease activity indices PCDAI and PUCAI. Secondary outcomes encompass a range of physical health parameters, including heart rate variability (HRV), muscular strength, resting blood pressure, basal metabolic rate, aerobic capacity, and body mass index (BMI). Intramural inflammation will be quantified through fecal calprotectin levels. Furthermore, disease activity will be evaluated using intestinal ultrasonography, standard endoscopic procedures (no study specific procedures, only standard of care biopsies) and the analysis of gastrointestinal mucins. All measurements will be conducted during each physical follow-up visit at the hospital, which will occur at the beginning, mid-intervention (except for endoscopy) and after the 24 week intervention period.

Data Collection and Processing

All data will be collected prospectively in REDCap (Research Electronic Data Capture) during scheduled hospital visits at baseline, throughout the intervention period (one follow-up point), and at study completion. Physiological measurements, including VO_2max, heart rate variability (HRV), muscle strength, resting blood pressure, basal metabolic rate, aerobic capacity, and BMI, will be assessed using standardized protocols by trained healthcare professionals. Patient-reported outcomes will be obtained through validated questionnaires (IMPACT-III, PedsQoL-MFS, PCDAI, and PUCAI), administered electronically in the UZA@Home application. Stool samples for fecal calprotectin analysis will be collected according to standard clinical procedures, while intestinal inflammation and disease activity will be further evaluated via intestinal ultrasound, endoscopy, and mucin quantification. All data will be entered into a secure, password-protected electronic database compliant with GDPR and institutional data protection policies. Any discrepancies or missing values will be addressed according to a predefined data management plan. The four researchers adhere to the ‘Guide on Good Data Protection Practice in Research’ of the European University Institute (EUI). Technical appendix, statistical code, and dataset available from the Dryad repository.

Ethics

This study received ethical approval from the Ethics Committee at the University Hospital of Antwerp and the University of Antwerp (BUN B3002025000122) on October 20, 2025. Written informed consent will be obtained from parents and participants.

Results

All statistical analyses will be conducted using R (R Foundation for Statistical Computing, Vienna, Austria), with a two-sided significance threshold set at $p < 0.05$. Study findings will be reported in accordance with the CONSORT framework where applicable. Descriptive statistics will be used to summarize baseline characteristics and outcome measures, presented as means with standard deviations for normally distributed variables or medians with interquartile ranges for non-normally distributed variables. Data visualization, such as box plots and line graphs, will be included to illustrate key outcomes and temporal changes. All analyses will be transparently documented, and both statistically significant and non-significant findings will be presented to ensure balanced interpretation. The protocol fulfills all SPIRIT guidelines. Results will consist of anonymized datasets, deposited in a secure repository to support transparency and reproducibility.

Discussion

SWOT Analysis

Tailored exercise interventions in pediatric populations with chronic diseases are currently underrepresented in clinical research. This study will implement a 24-week individualized intervention program, developed by a multidisciplinary team based on each participant's baseline assessment. **Table 2** covers the most significant characteristics of our research within the SWOT framework.

Table 2. Research characteristics within the SWOT framework

Strengths:	Weaknesses:
• Hybrid intervention model enhancing patient engagement and long-term behavioral change	• No randomized cross over trial, yet other stratification models will be applied

• Assessment of both validated patient-reported outcome measures and objective, disease-specific clinical parameters	
Opportunities:	Threats:
• Motivational coaching and digital support could be reimbursed	• Often physical inability to perform a cardiopulmonary exercise test (CPET) • Compliance in chronic pediatric patients

Tailored exercise interventions in pediatric populations with chronic diseases are currently underrepresented in clinical research. This study will implement a 24-week individualized intervention program, developed by a multidisciplinary team based on each participant's baseline assessment. The intervention integrates the established "Physical Activity on Prescription" (*Bewegen op Verwijzing*) model, which is designed by professional guidance from a qualified and motivational coach, the development of a tailored physical activity plan, and continuous follow-up. All participants will receive digital support via the UZA@Home platform, which is integrated into the care trajectory at the University Hospital of Antwerp (UZA). This tool offers tailored feedback on the intervention and promotes treatment adherence. Together, these tools ensure a hybrid intervention model combining in-person and digital support, aiming to enhance patient engagement and long-term behavioral change. The impact of the intervention will be evaluated using both validated patient-reported outcome measures and objective, disease-specific clinical parameters.

Author contributions

MK and TS designed the protocol together and drafted this manuscript. EV critically revised the manuscript and approved the final version.

Conflicts of interest

No funding or conflicts of interest.

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