

FIT FIRST 20: a special school-based physical education program targeted to fourth- and fifth-grade students

Submission date 23/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/10/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In Denmark, less than one-third of 11- to 15-year-old children are sufficiently physically active. Physically inactive children are more likely to gain excessive weight, be inactive later in life, and develop chronic diseases. Therefore, this study aims to improve the physical fitness and well-being of children with an evidence-based physical education program.

Who can participate?

10-12-year-old children enrolled in a school in Denmark

What does the study involve?

Student participants will receive a special physical education program based on FIT FIRST principles if their schools are randomly assigned to receive the program. In the remaining schools, student participants will attend physical education classes, as previously established by the school. All students will respond to a questionnaire and carry out physical tests during a school day at school start, at the end of the school year, and 1 year after the project.

What are the possible benefits and risks of participating?

The potential benefits are improved physical fitness and well-being after the FIT FIRST program is implemented. No side effects are expected.

Where is the study run from?

University of Southern Denmark (Denmark)

When is the study starting and how long is it expected to run for? (what are the overall start and end dates?)

January 2019 to July 2026

Who is funding the study?

Novo Nordisk Foundation (Denmark)

Who is the main contact?

Peter Krustrup, pkrustrup@health.sdu.dk

Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Fund application number: 0077612

Study information

Scientific Title

The effects of FIT FIRST 20 on physical fitness, well-being, and sports-club participation in 10-13-year-olds

Acronym

FIT FIRST

Study objectives

A school-based physical activity intervention will improve psychosocial well-being and physical fitness and increase sports club participation among school-aged children and youth (4th to 5th grade, 10-12 years).

Ethics approval required

Ethics approval not required

Ethics approval(s)

Conforming to current legislation, the project was submitted to The Regional Scientific Ethical Committees for Southern Denmark. The committee decided that the project was exempt from the obligation to notify. Notification of this decision was forwarded via email on 01/05/2023.

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Well-being and physical fitness

Interventions

Participating schools are randomly assigned to the intervention group, the intervention and booster group, or the control group. The method of randomisation is stratified. The first and second strata include the schools recruited in the first and second recruitment rounds, respectively. As recruitment continues until summer 2024, new strata will be formed at a later stage.

The intervention and intervention-and-booster schools will implement three weekly 40-minute FIT FIRST lessons during one school year. Intervention-and-booster schools will also receive an 8-week FIT FIRST 20 booster program half-school year after the FIT FIRST program is implemented. A booster is a strategy that is implemented after the end of an intervention to amplify its effects in the long term. It often applies the same principles of the original intervention within a shorter period, but more intensively. The control group will be offered the opportunity to implement the intervention 1 year later. Baseline measurements are conducted at the beginning of a school year, followed by post-intervention assessments at the end of the school year as well as 1 year after the end of the intervention for all participating schools.

Intervention Type

Behavioural

Primary outcome measure

All outcomes are measured at baseline as well as 1 year and 2 years after intervention start:

1. Physical fitness measured through the following physical tests: Yo-Yo IR1 Children's test, the standing long jump test, arrow-agility test, balance test, the handgrip strength test, resting heart rate, blood pressure measurement, and InBody 230 bioimpedance measurements of body mass, lean mass, and fat percentage,
2. Well-being, measured using KIDSCREEN-27
3. Overall self-worth, measured using the Physical Self-Inventory (PSI-S)
4. Motivation to movement, measured using the perceived locus of causality questionnaire and the psychological need states in sport questionnaire

Secondary outcome measures

Sports club participation. Data are collected through a questionnaire. Questions include "which sports do you practice in your spare time?" and "how many times a week do you practice sports in your spare time?". Measured at baseline as well as 1 year and 2 years after intervention start.

Overall study start date

01/01/2019

Completion date

01/07/2026

Eligibility

Key inclusion criteria

1. Student enrolled in a school in Denmark
2. Student attending 4th, 5th or 6th grade during the research project period

Participant type(s)

Learner/student

Age group

Child

Lower age limit

10 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

Currently (October 2023), the researchers consider two scenarios for recruitment. Scenario 1 involves an effect size $d=.15$ and an estimated sample size of 1776. Scenario 2 involves an effect size $d=.20$ and an estimated sample size of 1085. The total number of schools will vary between 20 and 25 depending on the chosen scenario.

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/04/2023

Date of final enrolment

31/08/2024

Locations**Countries of recruitment**

Denmark

Study participating centre**University of Southern Denmark**

Department of Sports Science and Clinical Biomechanics (ISSCB)

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Sponsor information**Organisation**

University of Southern Denmark

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Sponsor type
University/education

Website
https://www.sdu.dk/en/om_sdu/institutter_centre/iob_idraet_og_biomekanik

ROR
<https://ror.org/03yrrjy16>

Funder(s)

Funder type
Charity

Funder Name
Novo Nordisk Fonden

Alternative Name(s)
Novo Nordisk Foundation, Novo Nordic Foundation, NNF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/07/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available by requesting them from Peter Krstrup, Professor of Sport and Health Sciences at the University of Southern Denmark (e-mail: pkrstrup@health.sdu.dk). All data will be available after the end of the

research project and indefinitely. Data is anonymized and there will be no restrictions in analyses or access criteria.

IPD sharing plan summary

Available on request