

Frequent intense training in schools for teenagers

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| Submission date 04/06/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 04/07/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 10/09/2024 | Condition category Other | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

This study plans to evaluate the effects of a 10-week FIT FIRST Teen (FFT) intervention on blood pressure, physical fitness and body composition of Danish adolescents aged 12-15 years old. The 10-week FFT training is expected to have beneficial effects on resting heart rate for Danish 12-15-year-olds, calling for further development and long-term evaluation of the program.

Who can participate?

Danish pupils aged 12 to 17 years old in 6th to 9th grade from 15 municipal schools

What does the study involve?

Participants will be randomly allocated to an intervention group or a usual practice control group. The FFT group will complete three weekly 40-minute FFT sessions with modified, motivating, involving, high-intensity sports-based activities. Before and after the 10-week intervention, resting heart rate and blood pressure, body composition (InBody270), postural balance, standing long jump and performance on the Yo-Yo intermittent recovery level 1 children's test (YYIR1C) will be measured.

What are the possible benefits and risks of participating?

The possible benefits are a better health profile and there are no risks of participating.

Where is the study run from?

University of Southern Denmark

When is the study starting and how long is it expected to run for?

August 2021 to December 2022

Who is funding the study?

1. Ole Kirk's Foundation
2. Novo Nordisk Foundation

Who is the main contact?

Dr Malte Larsen, mnlarsen@health.sdu.dk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The physical health effects of frequent intense training in schools for teenagers

Acronym

FIT FIRST TEEN

Study objectives

Frequent intense training in schools for teenagers will improve their physical health status

Ethics approval required

Ethics approval not required

Ethics approval(s)

17/08/2021: The Scientific Ethics Committee 2 for Region Southern Denmark confirmed that the project is not subject to notification to the committee system, as the project does not fall within the definition of a health science research project; ref: 21/43086

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Prevention of lifestyle diseases

Interventions

Randomization will be performed on a school level by picking notes with school names from a bowl. Pupils will be randomly allocated to either the intervention group or a usual practice control group. The intervention uses a specific sports training concept (FIT FIRST), which the teachers in the school deliver 3 x 40 minutes per week for 10 weeks.

Intervention Type

Behavioural

Primary outcome measure

Cardiorespiratory fitness measured using the Yoyo test at baseline and after 10 weeks

Secondary outcome measures

The following secondary outcome measures will be assessed at baseline and after 10 weeks:

1. Body composition measured using bioimpedance (InBody 270)
2. Resting heart rate and blood pressure measured using the Oscillometric method
3. Balance measured using the stork balance test
4. Muscle strength measured using the standing long jump test

Overall study start date

01/08/2021

Completion date

30/12/2022

Eligibility

Key inclusion criteria

Pupils at the recruited schools in 6th to 9th grade

Participant type(s)

Learner/student

Age group

Child

Lower age limit

12 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

1200

Total final enrolment

1355

Key exclusion criteria

Not meeting the participant inclusion criteria

Date of first enrolment

01/08/2022

Date of final enrolment

20/12/2022

Locations**Countries of recruitment**

Denmark

Study participating centre

University of Southern Denmark

Campusvej 55

Odense

Denmark

5231

Sponsor information**Organisation**

University of Southern Denmark

Sponsor details

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Sponsor type

University/education

Website

<https://www.sdu.dk/en>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Ole Kirk's Fond

Alternative Name(s)

Ole Kirks Fond, Ole Kirk's Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Denmark

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 peer-reviewed journal

Intention to publish date

01/08/2024

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date