The 'läuft.' trial - a school-based multicomponent program to establish a physically active lifestyle in adolescence

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
24/09/2013		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/10/2013	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
18/11/2019	Other			

Plain English summary of protocol

Background and study aims

Physical activity during childhood and adolescence is associated with substantial health benefits. However, only 22.7% of German adolescents are sufficiently physically active. Thus, the promotion of an active lifestyle in youth is an important aspect of public health. This study will evaluate the feasibility and effectiveness of the program in 8th grade students in Germany (Federal State of Schleswig-Holstein).

Who can participate?

Students of public schools between 13 and 15 years of age.

What does the study involve?

The Institute for Therapy and Health Research in cooperation with the Universities of Hamburg and Kiel developed the 'läuft.' program to improve physical activity in schoolchildren. Schools were randomly allocated to either the control group (treatment as usual) or the intervention group (lauft program). 'läuft.' is a school-based program that targets different levels: students, classes, schools and parents. The main components are two class competitions. On the one hand, each student receives a pedometer and documents his/her steps using an interactive user account on the 'läuft.' homepage. Classes achieving the highest step totals will be awarded. On the other hand, classes will be invited to implement and document physical activity-related school projects. The most creative and inventive ideas will also be awarded. Additionally, classes take part in educational lessons. Parents will receive information material about the benefits of physical activity and how they can support their children to engage in a physically active lifestyle. The headmaster and teaching staff of the participating schools will get information material with suggestions and encouragement to enhance physical activity in school. Information about students' physical activity-related attitudes and behavior will be assessed by questionnaires. In addition, physical fitness and parameters such as weight, height and blood pressure will be determined.

What are the possible benefits and risks of participating? Participating schools will be provided with intervention material (pedometers, information material and teaching material) and will receive incentives for their effort.

Where is the study run from?

About 100 secondary schools in the Federal State of Schleswig-Holstein in Germany.

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

The study will start in November 2013 and will run until July 2015. In November and December 2013 the recruitment of participants will be conducted. Assessments will be carried out by trained research staff at three times: before the start of the program (January/February 2014), immediately after the program (June/July 2014), and one year after the program (June/July 2015).

Who is funding the study? German Cancer Aid

Who is the main contact? Prof. Reiner Hanewinkel hanewinkel@ift-nord.de

Study website

http://www.laeuft.info

Contact information

Type(s)

Scientific

Contact name

Prof Reiner Hanewinkel

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The 'läuft.' trial - a cluster randomized-controlled study of a school-based multi-component program to establish a physically active lifestyle in adolescence

Study objectives

'läuft.' shows an effect on physical-activity related attitudes and behavior, sedentary behavior and cardiovascular risk factors (Body Mass Index, blood pressure, body composition and cardiovascular fitness).

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. The ethics committee of the German Psychological Society (DGPs), 18/10/2012
- 2. The Ministry of Education and Science of Schleswig-Holstein, 10/07/2013

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Establishing a physical active lifestyle and improve health and fitness in youth

Interventions

Intervention schools: implementation of the 'läuft.' program

Control schools: treatment as usual

Data collection in 3 waves Unit of allocation: schools

Intervention: The 'läuft.' targets four different levels:

1. Each student receives a pedometer and documents his/her steps over 12 weeks using an

interactive user account on the 'läuft.' homepage.

- 2. On class level there will be different competitions. The classes that achieve the most steps in selected weeks, the highest increases of steps and that develop the most inventive ideas to promote physical activity in school will be awarded. Besides, the intervention includes four educational lessons.
- 3. The headmaster and teaching staff of the participating schools will get information material with suggestions and encouragement to enhance physical activity in school. Participating teachers will be invited to an introductory seminar.
- 4. Parents will be involved with informational material about the program and will be invited to a parent-teacher conference about benefits of being physical active and how they can support their children to engage in a physical active lifestyle.

The intervention duration is 12 weeks. Before, immediately after and one year after the intervention assessments will be conducted in both groups.

Intervention Type

Behavioural

Primary outcome measure

Lifestyle behavior concerning physical activity and sedentary behavior, physical activity-related psychological and social constructs as well as cardiovascular fitness, Body Mass Index, blood pressure, body composition (fat mass) and waist circumference before, at the end and 12 months after the intervention.

Secondary outcome measures

Given impulses with regard to physical activity and activating strategies will be assessed qualitatively at the end of the intervention.

Overall study start date

01/11/2013

Completion date

31/07/2015

Eligibility

Key inclusion criteria

- 1. Students of public schools
- 2. Aged between 13 and 15 (8th grade), either sex

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

Sex

Both

Target number of participants

46 classes / 911 students

Total final enrolment

1020

Key exclusion criteria

- 1. Schools for disabled students
- 2. Missing parental consent

Date of first enrolment

01/11/2013

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

Germany

Study participating centre IFT-Nord Institute for Therapy and Health Research

Kiel Germany 24114

Sponsor information

Organisation

German Cancer Aid (Germany)

Sponsor details

Buschstr. 32 Bonn Germany 53115

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deutsche@krebshilfe.de

Sponsor type

Charity

Website

http://www.krebshilfe.de

ROR

https://ror.org/01wxdd722

Funder(s)

Funder type

Charity

Funder Name

German Cancer Aid (Germany) (ref: 110012)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/12/2013		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	1-year follow-up results	01/10/2018	18/11/2019	Yes	No