

Hi Five - a school-based intervention to reduce infections and improve hygiene and well-being among school children

Submission date 13/12/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Illness is the most common reason for school absence. 86 percent of all Danish children have been absent from school because of illness during a school year. Two thirds of children's illnesses are caused by infection. Hand washing with soap and water is the most important hygiene measure in preventing the spread of infection. The aim of this study is to find out whether hygiene education and extra cleaning can improve hand hygiene and reduce the spread of infections in Danish schools.

Who can participate?

Danish boys and girls enrolled in the participating schools.

What does the study involve?

43 schools were randomly allocated into one of three groups. 15 schools carried on as normal, 14 schools received hand hygiene educational materials and encouraged daily hand washing before lunch, and 14 schools received hand hygiene education, encouraged daily hand washing before lunch, and increased the cleaning of the school toilets during the school day.

What are the possible benefits and risks of participating?

The possible benefits of participating for the pupils and teachers are fewer sick days due to infections and better well-being. There are no known risks to participants.

Where is the study run from?

National Institute of Public Health, University of Southern Denmark.

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

The study started in September 2011 and will run until June 2013.

Who is funding the study?

Tryg Foundation (TrygFonden), Denmark.

Who is the main contact?

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Study website

<http://www.interventionsforskning.dk/hifive>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Hi Five - a cluster-randomized controlled trial to reduce infections and improve hygiene and well-being among 6-15 year olds in Denmark

Acronym

Hi Five

Study objectives

An educational and cleaning intervention in Danish schools can improve hand hygiene and reduce the prevalence of infections by 20% among children in intervention schools compared to control schools, and positively influence the children's wellbeing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Danish Data Protection Agency, 01/10/2011, ref: 2011-54-1240

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

Only available in Danish. The information includes information material to parents, teachers and schools. Please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Hand hygiene, hand washing, infectious illness

Interventions

The Hi Five intervention consists of three components:

1. Educational materials (5/6 lessons) tailored to three age groups: 0.-3. grade, 4.-6. grade and 7.-9. grade.

Subjects: 1. Introduction to microbes, 2. Spread of infections, 3. How to wash hands most effectively? 4. School toilets.

2. Daily hand washing before lunch

3. Extra cleaning of school toilets during the school day

Hi Five schools were randomized into either control or one of two intervention groups. 15 schools had no intervention (control), 14 schools had education and daily hand washing before lunch and 14 schools had education, daily hand washing before lunch and extra cleaning of school toilets (in the school year 2012- 2013).

All pupils at the 28 intervention schools received the education course during the fall 2012.

Baseline data was collected December 2011 to April 2012. Follow-up data will be collected in December 2012 to April 2013. The effect of the intervention is measured on one class at each grade level at each school.

Intervention Type

Behavioural

Primary outcome measure

1. Frequency of absence episodes and the number of days absent due to infectious illness among pupils measured over five months (Dec. to April) at baseline and follow-up (SMS data from parents SMS registers of illness and infection).
2. Frequency of absence episodes from school last week due to infectious illness (data from pupils self-reported questionnaires).

Frequency of absence episodes and the number of days absent due to illness and infection will be analyzed at individual-, class- and school-level.

Secondary outcome measures

1. Parents absence from work due to the pupils infectious illness (SMS registration)
2. Pupils hand washing behavior (before lunch, after toilet visit, use of soap etc.) (data from pupils' self-reported questionnaires)
3. Pupils' use of the school toilets (data from pupils' self-reported questionnaires)
4. Toilet facilities and cleaning standard of the schools toilets (bacteria samples, observations and photographs of/from the school toilets)
5. Pupils' well-being (data from pupils' self-reported questionnaires)
6. Pupils' norms of and attitudes towards hand washing (data from pupils' self-reported questionnaires)
7. Pupils' knowledge of bacteria and spread of infectious illness (data from pupils' self-reported questionnaires)
8. Frequency of teacher's absence episodes and the number of days due to infectious illness measured over five months at baseline and follow-up (from SMS registration by teachers of own illness and infection)
9. Health economic evaluation (parent, child, teacher, school information)

Analyses in the project will have a special focus on subgroup analyses especially age, gender and socioeconomic position

Overall study start date

01/09/2011

Completion date

30/06/2013

Eligibility

Key inclusion criteria

All pupils at participating schools enrolled in grade 0.-8

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

7,527 pupils (4,940 in the intervention group, 2,714 in the control group) at 28 intervention schools and 15 control schools from 20 municipalities cross nationally

Key exclusion criteria

1. Schools not run by municipalities (private schools)
2. Schools for children with special needs

Date of first enrolment

01/09/2011

Date of final enrolment

30/06/2013

Locations**Countries of recruitment**

Denmark

Study participating centre

Øster Farimagsgade 5A

Copenhagen

Denmark

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Sponsor information**Organisation**

Tryg Foundation (TrygFonden) (Denmark)

Sponsor details

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Sponsor type

Government

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<https://ror.org/02rcazp29>

Funder(s)

Funder type

Government

Funder Name

Tryg Foundation (TrygFonden) (Denmark)

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?
Other publications	process evaluation	01/06/2015	17/12/2020	Yes	No
Results article	results	01/03/2015	17/12/2020	Yes	No