ISRCTN44152751 https://doi.org/10.1186/ISRCTN44152751

School opening in Norway during the COVID-19 pandemic

Submission date
04/05/2020

Recruitment status
Suspended

Registration date
04/05/2020

Overall study status
Completed

Last Edited
07/09/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of March 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.

Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.

The Norwegian government announced on March 12th that all schools were to be closed as a measure to control the spread of the virus causing COVID-19. After a month of closures, the decision was made to reopen nurseries and schools for the youngest children (grades 1–4). The debate around reopening demonstrates the uncertainty around the consequences of school closures, and particularly concerns about the potential hazards of reopening. To aid evidence informed decision-making during the current and future epidemics, we propose to run a trial where we randomise schools (alternatively municipalities) in Norway to fully reopen (grades 1–10), or to remain partially open (grades 1–4). We will estimate the relative effect of keeping schools partially closed versus fully reopening schools on community transmission of the virus, and compare possible harms (e.g. scores in national performance tests).

Who can participate?
All primary schools in Norway.

What does the study involve?
Schools (alternatively municipalities) in Norway will be randomised to fully reopen (grades 1–10), or to remain partially open (grades 1–4) for four weeks.

What are the possible benefits and risks of participating?
Pupils and communities that are randomized to having schools that open up for levels 5-10, run the risk of increased viral transmission and incidence of COVID-19, while having the benefit of children being able to go to school. For pupils and communities randomized to having schools that remain closed for levels 5-10, the risks and benefits are the opposite. The main overall benefit for participating pupils is that the results from the trial may reduce the risk of unwarranted future schools closures during the COVID-19 pandemic. For adults and the community at large, the main benefit is improved knowledge about the impact of school closures as a measure to limit community transmission.

Where is the study run from?
Norwegian Institute of Public Health

When is the study starting and how long is it expected to run for?
May 2020 to September 2020

Who is funding the study?
Norwegian Institute of Public Health

Who is the main contact?
Prof. Atle Fretheim, atle.fretheim@fhi.no

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The School Opening in the Age of Pandemic (SOAP) study: a cluster-randomised re-introduction of school activities in Norway

Acronym
SOAP

Study objectives
Keeping schools closed for 5-10 grade does not have a substantial effect on the incidence of COVID-19, versus reopening schools for 5-10 grade.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 07/09/2020:
1. By 04/09/2020, the project had been rejected by Regional Ethics Committee South-East Norway, ref: 136575
2. Approval pending, National Ethical Board

Previous ethics approval:
Approval pending, The Regional Ethics Committee South-East Norway, ref: 136575

Study design
Interventional cluster-randomized study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) transmission in schools

Interventions
ARM 1-schools: Will remain closed for 5-10 level pupils.
ARM-2-schools: Will open for 5-10 level pupils.
The study period will last 4 weeks. The primary outcome measure will include data from 2 weeks after the commencement of the trial, and until 4 weeks after the trial period. We plan to randomise through a simple transparent process, e.g. a televised draw. We will do this by stratified randomisation, with separate draws of schools for each municipality. Hence, half of the schools in each municipality will be allocated to opening for all grades (1–10), and the other half to remaining closed for 5–10 grade (partial closure).

Intervention Type
Other

Primary outcome(s)

Positive COVID-19 among tested adults (aged 25–65) who live in the same household as children born 2004–2009 measured at 6 weeks, i.e. from 2 weeks after commencement of the trial, and 4 weeks after the intervention period

Key secondary outcome(s))
1. Positive COVID-19 among tested grandparents and great grandparents of children born 2004–2009 measured at 6 weeks, i.e. from 2 weeks after commencement of the trial, and 4 weeks after the intervention period
2. Severe COVID-19 (hospitalisation or death), among all grandparents and great grandparents of children born 2004–2009 measured at 6 weeks, i.e. from 2 weeks after commencement of the trial, and 4 weeks after the intervention period
3. Psychological and behavior outcomes based on a short questionnaire measured at
4. Movements and activity based on anonymised teledata measured after 4 weeks
5. Social-distancing (contacts) from the infection-tracing “Smitteapp” measured during the 4-week trial period
6. Scores in 8 and 9 grade national tests (nasjonale prøver), in the autumn of 2020, and grade point average for 10 grade, June 2020 and June 2021 measured in June 2020 and June 2021
7. Hours worked among adult household members of persons born 2004–2009 during the intervention period measured during the 4-week intervention period

Completion date
30/09/2020

Eligibility

Key inclusion criteria
All primary schools in Norway

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
None

Date of first enrolment
11/05/2020

Date of final enrolment
13/05/2020

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian Institute of Public Health
PO Box 222 Skoyen
Oslo
Norway
0213

Sponsor information

Organisation
Norwegian Institute of Public Health

ROR
https://ror.org/046nvst19

Funder(s)

Funder type
Government

Funder Name
Norwegian Institute of Public Health

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Norwegian Centre for Research Data, https://nsd.no/nsd/english/index.html). The dataset will include non-person identifiable data and be accessible at the time of publication or trial results, for anyone, and for all foreseeable future.

IPD sharing plan summary
Stored in repository