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The School Opening in the Age of Pandemic (SOAP) Study: A Cluster-Randomised Re-Introduction of School Activities in Norway

Study protocol

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Revision chronology

Version	Amendment
30.04.2020	Original version (submitted for ethical review)
04.05.2020	Added ICRCTN registration number

World Health Organization Trial Registration Data Set

Data category	
Primary registry and trial identifying number	ISRCTN 44152751
Date of registration in primary registry	04.05.2020
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Source(s) of monetary or material support	-
Primary sponsor	Norwegian Institute of Public Health
Secondary sponsor(s)	-
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Public title	SOAP (School Opening in the Age of the Pandemic)
Scientific title	The School Opening in the Age of Pandemic (SOAP) Study: A Cluster-Randomised Re-Introduction of School Activities in Norway
Countries of recruitment	Norway
Health condition(s) or problem(s) studied	COVID-19
Intervention(s)	Partial school closure vs. open schools
Key inclusion and exclusion criteria	Municipalities in Norway (schools, staff, pupils and general population)
Study type	Cluster randomised trial
Date of first enrolment	To be decided
Target sample size	5 400 000 (population of Norway); approx. 5000 tested adults from households of persons born 2004–2009
Recruitment status	Recruitment has not started
Primary outcome(s)	Proportion of tests positive for COVID-19 among tested adults (aged 25–65) who live in the same household as children born 2004–2009
Key secondary outcomes	• Proportion of tests positive for COVID-19, among tested born 2004–2009 • Proportion tests positive for COVID-19, among tested grandparents and great grandparents of children born 2004–2009

Data category	
	• Proportion of severe COVID-19 (hospitalisation or death), among all grandparents and great grandparents of children born 2004–2009 • Own data collection of psychological and behavior outcomes based on a short questionnaire • Measure of movements and activity based on anonymised teledata • Measure of social-distancing (contacts) from the infection-tracing "Smitteapp" • 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. • Hours worked among adult household members of persons born 2004–2009 during intervention period.

Abstract

The effect of school closure to prevent the spread of SARS-CoV-2 is uncertain, while many negative consequences are evident. The trade-off between the benefits and harms of school closures is nearly impossible to make without knowing the likely impact on disease incidence. The Norwegian government announced on March 12th that all schools were to be closed. 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).

Background

Systematic reviews have found that school closures may have a mitigating effect during influenza epidemics, based on observational studies and modelling exercises (1, 2). Yet school closures also cause considerable harm and have unintended consequences both for the students involved, and for their parents, families, and the society (3). Thus, its effect on spread of infection and on the dynamics of an epidemic need to be weighed against the harms of closing schools. Although 90% of the world's student population is affected by temporary school closures due to the COVID-19 outbreak (4), there is a paucity of prospective trials to assess the benefits and harms of keeping schools closed.

Well-designed studies conducted during an epidemic can provide crucial evidence to inform decisions during outbreaks and for future epidemics. The best methodology to assess the benefits and harms of interventions is by randomisation of exposed individuals or clusters to the options at hand, with meticulous follow-up of both groups. Historically, few if any randomised controlled trials of the effectiveness of social distancing measures have taken place, despite such measures being key components of the public health response during epidemics. A Cochrane Collaboration systematic review in 2011 found no studies of the effect of social distancing during an epidemic (5), and a recent update found that the situation had not changed much over the last decade: "We were disappointed to find only one trial on person distancing which is currently the core of the global containment strategy. This points to the difficulty and lack of interest in carrying out such studies" (6). Thus, there is substantial uncertainty with regard to the effect of school closure or opening for epidemics in general, and for the current COVID-19 pandemic in particular.

Children may play a lesser role in the spread of SARS-CoV-2, than of influenza-viruses; fewer children than adults are registered COVID-19-postive, a smaller proportion of tests on children are positive with COVID-19 than with seasonal influenza, and no outbreaks or clustering of cases among school children have been reported (7, 8). Also, children seem to be more mildly affected by the disease than adults, and may thus be less infectious (9). However, children may still carry the virus without symptoms, and they may contribute to virus spread (10).

Norwegian authorities decided at an early stage in the epidemic (March 12th 2020) to close all schools (11), as have most other countries. Some countries, e.g. neighbouring Sweden and Iceland, have decided against closing schools (12).

Soon after the decision in Norway to close schools, questions arose about when to reopen them (13). Given that there is no conclusive evidence on benefits and harms of school closures, the decision on when or how to reopen schools is difficult. After a month (on April 7th) the Norwegian government announced that kindergartens and day care centres would reopen on April 20th, and schools would reopen for grades 1 to 4 on April 27th. Some parents oppose this decision, claiming that it is unsafe to reopen now. Although no explicit criteria have been set for deciding on whether or when to reopen schools for grades 5 and above, or any threshold to steer by for closing again if the pandemic resurges, the understanding seems to be that these decisions will be guided by changes in COVID-19 incidence.

Given the unpredictability of the epidemic curve, an increase in COVID-19 incidence may have several causes and is therefore a poor indicator of the impact of the reopening of nurseries and schools. A randomised re-introduction of normal school activities is the only way to know whether full reopening of schools is the better option in handling the COVID-19 epidemic in Norway.

We therefore propose to randomize Norwegian schools (alternatively municipalities) to reopen fully (grades 1 – 10) or keep only partially open (grades 1–4). The primary aim of the trial is to estimate the relative effect of keeping schools partially closed versus reopening schools on the incidence of COVID-19-disease. Our hypothesis is that the effect is not substantial. We will also compare possible harms on pupils (e.g. scores in national performance tests) and adults (e.g. income).

This protocol can also be applied if the government considers reopening for other age groups than 5-10 grade, e.g. only 5- 7 grade or upper secondary school. Similarly, if reverting to closed schools is being considered.

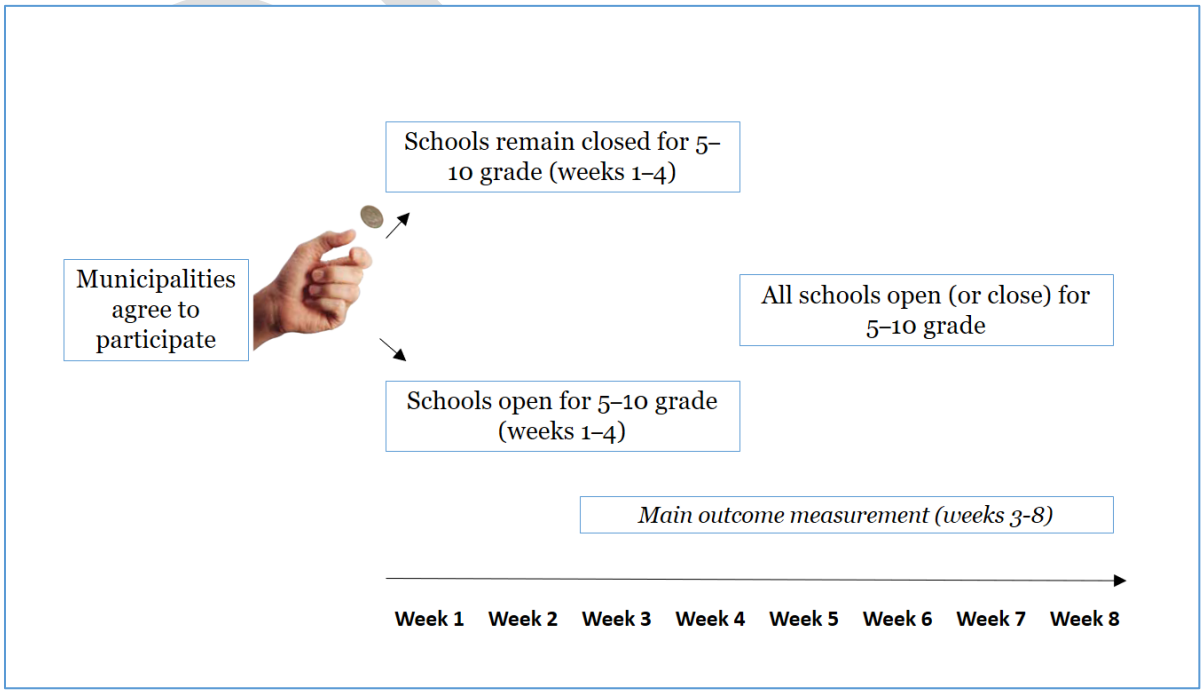
Methods

The nature of the intervention and the outcomes of interest, render it difficult to randomise individual students. We will therefore randomise clusters of children at the school level.

If, for technical, political or legal reasons randomisation is only feasible at the municipal level, we will do that.

We propose to invite all 356 municipalities (385 municipalities and city districts) in Norway to take part in the study, and to agree to randomise their schools to remain closed for 5–10 grade or fully reopen. We envisage an intervention period of 4–5 weeks.

Through randomisation, we will establish one *open schools group,* who will reopen (1–10 grade). The other group will be allocated to the *partial school closure group,* who will keep the schools partially closed (only open for 1–4 grade). 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).



We expect that our results will be used within Norway and other countries to inform decision-making during the current pandemic (e.g. in the anticipated 2nd and 3rd waves) and in future epidemics. Some of our outcomes will likely not be statistically powered to yield conclusive findings, but will contribute data to systematic reviews and meta-analyses and/or inform discussions about the internal and external validity of our main outcome. The effects of reopening or keeping schools partially closed are likely to depend on factors that influence disease transmission, which may vary during an outbreak. While randomisation should account for these factors within our trial, it may be difficult to generalize our results to other settings (e.g. at different points on the epidemic curve). We will therefore publish estimates of the basic and effective reproduction numbers (R_0 and R_e) along with the COVID-19 incidence rate, at the start of the trial.

Outcomes

To ensure feasibility, facilitate speed, and limit costs, we aim to base our outcome measures on routinely collected data, to the extent possible. Testing for COVID-19 takes place continuously and consistently across the country. All suspect cases have access to testing and laboratories use valid tests meeting quality assurance requirements. The Norwegian Institute of Public Health provides guidance that defines priority groups for testing. Adherence to these guidelines is likely to vary, but we expect that this variation is similar in the two groups.

Primary outcome

- Proportion of tests positive for COVID-19 among tested adults (aged 25–65) who live in the same household as children born 2004–2009. Data source: Norwegian Surveillance System for Communicable Diseases (MSIS)/laboratory results database, and Norwegian population registry. *[Alternatively, if necessary for technical, political or legal reasons, we will instead use test results from age group 39–51, as they have a 10 % probability of having children in 5–10 grade].*

  The outome will be measured from 2 weeks after schools are reopened, and until 4 weeks after the intervention period has ended. The study period ends either when all schools reopen, or when summer holidays begin. This applies to the main outcome, as well as the secondary outcomes related to COVID-19 (the first three on the list below).

Secondary outcomes

- Proportion of tests positive for COVID-19, among tested born 2004–2009. Data source: Aggregated data from MSIS/laboratory results database, and Norwegian population registry.

- Proportion tests positive for COVID-19, among tested grandparents and great grandparents of children born 2004–2009. Data source: Aggregated data from MSIS/laboratory results database, and Norwegian population registry.
- Proportion of severe COVID-19 (hospitalisation or death), among all grandparents and great grandparents of children born 2004–2009. Data source: Aggregated data from MSIS/laboratory results database, Norwegian Cause of Death Registry, and Norwegian population registry.
- *If we randomise municipalitites*: Incidence of test positive COVID-19 in whole population. Data source: Aggregated data from MSIS (municipality level), population size of municipalities from Statistics Norway.
- *If we randomise municipalitites:* Incidence of severe COVID-19 in whole population (hospitalisation or death). Data source: Aggregated data from MSIS (municipality level), Norwegian Cause of Death Registry, population size of municipalities from Statistics Norway.
- Own data collection of psychological and behavior outcomes based on a short questionnaire (with established items from existing surveys like UngData, WHO Health Behaviour in School Children (HBSC), National Student Survey (Elevundersøkelsen) and MoBa UNG) for 5–10 graders.
- Measure of movements and activity based on anonymised teledata from Telia and/or Telenor
- Measure of social-distancing (contacts) from the infection-tracing "Smitteapp"
- 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. Data source: Norwegian Education Database (NUDB).
- Hours worked among adult household members of persons born 2004–2009 during intervention period, using proportional sampling weights. Data source: the Norwegian labour force survey, Statistics Norway.

Managing risk of surveillance bias

A severe risk to the validity of this study is that testing behaviour may be affected by the intervention. Although testing of adults is less likely to be affected by school openings than testing of children, this will be closely monitored. If the difference in test prevalence between adult household members in the treatment and control groups during the first two weeks of the intervention, conditional of municipality, is larger than 10%, we believe that the share of positives in the two groups is no longer comparable. We assume that there will be little or no difference between the groups in spread of disease during the first two weeks. Hence, a difference in testing prevalence during this time period will likely reflect an intervention effect on testing per se, not linked to a difference in transmission which is unlikely to occur during the first two weeks.

In the event that we observe a 10% difference in proportions tested among adult household members between the two groups, the primary outcome and the first two secondary

outcomes become obsolete. We will then replace the window of measurement and study these outcomes only during the four weeks after the intervention period has ended. During that period, test frequency is not likely to be directly affected by whether schools have been reopened or not.

There are several additional data sources that can be utilised to validate our primary and secondary outcomes, and for exploratory analyses:

- Proportion tested for COVID-19 among adults (aged 25–65) who live in the same household as children born 2004–2009, during the first two weeks of the trial. Data source: MSIS/laboratory results database, and Norwegian population registry.
- Survey data from the MoBa-cohort (Norwegian Mother, Father and Child Cohort Study): The data can identify the parents of persons born 2004–2009, and their responses to the COVID-19 survey that the full cohort receives per SMS every two weeks.
- Norwegian Syndromic Surveillance System (Sykdomspulsen): Here we can retrieve measures on the number of people contacting their doctor or an emergency out-of-hours clinic with respiratory tract symptoms and suspected COVID-19.
- Norwegian Institute of Public Health web-platform for self-report of COVID-19: Here we have self reported data from members of the public who post their symptoms.
- Prevalence data from random samples of MoBa-cohort: This will provide estimates of prevalence among parents of the school children, both for virus and antibodies.

Subgroup analyses

We will conduct subgroup analyses based on the incidence of COVID-19 cases at baseline (i.e. incidence of new cases in the 4 weeks preceding the trial). We will dichotomize municipalities in Norway by baseline incidence and compare the trial outcomes for the municipalities in the lower half, with the estimates for the upper half of COVID-19 baseline incidence. Further subgroup analyses will be made by school size, teacher-student ratio before intervention, 5– 7 grade vs. 8–10 grade (born 2007–2009 vs. 2004–2006), compliers vs. non-compliers in treatment group, gender, and by parents' education.

Statistical analyses

Analysis will be by intention to treat, i.e. we will include data from all schools, and analyse according to the group they were allocated.

We will estimate the relative risk of testing positive for COVID-19 in adults (25–65 years) residing with persons born 2004–2009 using a generalised linear model (log link function and binomial error distribution), adjusting for municipality which is used for stratification as a fixed effect and for the cluster design using random intercepts. If data are missing, we will consider using multiple imputation using chained equations (15, 16).

Power calculation

We base our power calculation on the following assumptions:

- 5% of all tests of adult household members of 5–10 graders are positive for SARS-CoV-2, in the *partial school closure group*.
- A substantial effect of partial school closure is a 40% relative reduction or more, i.e. in the *open schools group* more than 8.3 % of all tests of adult household members of 5–10 graders will be positive for SARS-CoV-2.
- Intracluster correlation coefficient (ICC) of 0.1 [Estimate is based on 1) ICCs from the Aberdeen University database of ICCs of implementation studies[1], where the average ICC for studies using outcome measures, not process measures, that were binary, was 0.04; 2) ICC from a cluster trial of physical interventions to reduce influenza incidence, which reported very small ICCs (17). It is difficult to estimate ICC in advance, but we believe our estimate is realistic].
- A nation-wide total of 5000 tests conducted on adult household member of 5–10 graders during the study period.

Based on these assumptions, we will need 934 randomised schools (alternatively 288 randomised municipalities) to be able to detect a statistically significant effect (significance level 5%, power 80%). With 2434 schools we are able to detect a relative risk reduction of 29% (5% vs. 7% test positive proportions). There are 2876 primary and lower secondary schools in Norway (GSI, 2020).

Ethical considerations

There are specific ethical aspects to consider for cluster-randomised trials, as outlined in *The Ottawa Statement on the ethical design and conduct of cluster-randomised trials* (18).
The key ethical dilemmas for our proposed trial are:

- Defining who the research participants are (teachers, pupils, parents and guardians, the population)
- Informed consent
- The role of "gate keepers" (headmasters, municipality councils, mayors, local medical officers)
- Assessing benefits and harms
- Protecting vulnerable participants

Defining who the research participants are (teachers, pupils, parents and guardians, the population)

It is realistic to assume that this trial will affect all inhabitants of Norway, either directly or indirectly. The intervention will affect staff and children in schools and the parents and

[1] https://www.abdn.ac.uk/hsru/what-we-do/tools/index.php#panel177

people residing with the pupils in both arms. If school closure has an effect on the spread of COVID-19, this could affect anyone in the community. The same goes for several of the other outcomes we propose to include. Consequently, all inhabitants in Norway can be regarded as research participants in this study.

There is usually substantial movement of people between Norway and other countries, particularly those with which Norway shares land borders (Sweden, Finland, and Russia). At the time of writing, however, Norway's borders are closed, so we do not consider those living outside Norway to be participants.

Informed consent

In principle, all research participants need to give their informed consent. It is not feasible to ask for informed consent from all affected by school closure, and given the societal importance of the trial, we propose waiving this requirement for pupils, legal guardians and school staff. However, during the study period, parents and guardians should have the option to keep their children at home with home schooling if they choose to. We will secure informed consent from the participants of the questionnaire survey (persons born 2004–2009). Their legal guardians will receive information about the survey in advance, and be given the opportunity to decline their child's participation.

A legal issue question might be whether the schools can be expected to provide digital teaching to children that are held at home. Whether teachers can be asked to be exempt from coming to work is an issue between teachers and their employers.

The role of "gate keepers" (headmasters, municipality councils, mayors, local medical officers)

The trial would need political support from the national government to take place. It is not clear whether municipal authorities or schools should decide whether to participate, but local authorities are empowered to close schools that are viewed as risks to public health. National or local authorities may decide to exclude some municipalities, e.g. if the number of infected individuals in the community is judged too low to ethically justify keeping schools closed, or if the number of infected is considered too high to justify reopening.

It is clearly preferable if the trial is a collaborative effort where all take part to generate the needed evidence as efficiently as possible. Forcing municipalities and schools to take part is probably impractical and may be judged to be unethical. However, if many municipalities or schools do not take part, the findings will be weaker and less useful. We believe that having the central government strongly urging all municipalities and schools to participate is the best approach, while allowing municipality and school leaders, as well as parents and guardians, to opt out.

Assessing benefits and harms

Concerns have been raised about the negative consequences of the school closures, both in financial terms since parents and guardians are prevented from working, and the social, psychological, educational, and health impact on children (3, 19, 20). Although these negative effects are difficult to quantify, it is apparent they are substantial (3). Such negative effects are thought to be outweighed by the preventive effect school closure has on the spread of the SARS-CoV-2 virus. However, since this effect is also highly uncertain, balancing the benefits and harms is challenging. Currently, the government has decided that the benefits, in terms of reduced spread of disease, likely weighs more, and is therefore keeping older children (grades 5–10) out of school. Eventually, though, it will be impossible to say whether it is better to reopen schools fully or keep them partially closed. At that point – what clinical researchers refer to as "equipoise" – we believe a randomised trial will be the most ethically sound approach. An additional factor of potentially major importance, is that the findings from the trial would inform decisions in the anticipated new "waves" of the epidemic. For example, if the findings indicate that school closures have little or no impact on spread of the virus, closures can be avoided. This is an important potential benefit for the pupils, making it ethically defensible to expose half of them to the possible disadvantage of not being able to attend school physically for an additional few weeks.

Protecting vulnerable participants

There are vulnerable groups on both sides of the equation: some groups are likely to suffer more from not being able to attend schools, and some groups are more susceptible to being severely affected by COVID-19. Concerns about the wellbeing of children that are not able to leave their homes is an important reason that schools should be opened as soon as possible (20). Concerns about the spread of disease to vulnerable groups is an important reason for keeping schools closed. Our ability to monitor these groups during the conduct of the trial will be limited to the outcome measurements.

A clear prerequisite for conducting an ethical randomized controlled trial is that vulnerable participants are exempted from participation. When schools are closed, there needs to be provisions in place for children with an unsafe home environment to attend day care, and when parents and guardians need to work to fulfill critical tasks. These mechanisms are already in place in Norway. In cases when schools open, individuals in risk groups due to underlying health conditions need to be exempted from having to attend school.

Person data protection (GDPR)

We will prepare a formal data protection impact assessment (DPIA) and obtain approval from the Data Protection Officer at our institute for the measures we take to protect person data. We will publish non-person identifiable data to support dissemination in journals and official reports.

Funding

The need for external funding is limited, provided outcome measurements are based on routinely collected data. However, for some of the data collection, e.g. the planned survey to measure psychological outcomes, additional funding would be needed.

Internal funding depends on approval from Norwegian Institute of Public Health leadership to prioritise the study.

Authors' contributions

AF conceived of the study. All authors contributed to refinement of the study protocol and approved the final manuscript. *MF* and *CR* provided statistical expertise in clinical trial design.

Organisational structure and responsibilities

Principal Investigator and Research Physician

Atle Fretheim, Research Director, Norwegian Institute of Public Health, is responsible for

- Design and conduct of the trial
- Preparing the protocol and its revisions
- Organising steering committee meetings
- Publication of study reports

Trial Management Group

Members: Atle Fretheim, Martin Flatø, Pawel Stefanoff, Arnfinn Helleve, Michael Bretthauer, Anneke Steens, and Kjetil Telle.

The Trial Management Group will

- Agree on final protocol
- Be responsible for the daily running of the study
- Review progress of study and if necessary agree on changes to the protocol

Trial Steering Committee

A Trial Management Committee will be established, that will give advice to the Principal Investigator and to the Trial Management Group.

Data Manager

- Maintenance of trial IT system and data entry
- Data verification

References

1. Jackson C, Vynnycky E, Hawker J, Olowokure B, Mangtani P. School closures and influenza: systematic review of epidemiological studies. BMJ Open. 2013;3(2).
2. Fong MW, Gao H, Wong JY, Xiao J, Shiu EYC, Ryu S, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings-Social Distancing Measures. Emerg Infect Dis. 2020;26(5).
3. Lempel H, Epstein JM, Hammond RA. Economic cost and health care workforce effects of school closures in the U.S. PLoS Curr. 2009;1:RRN1051.
4. COVID-19 Educational Disruption and Response: UNESCO; 2020 [Available from: https://en.unesco.org/covid19/educationresponse.
5. Jefferson T, Del Mar CB, Dooley L, Ferroni E, Al-Ansary LA, Bawazeer GA, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database Syst Rev. 2011(7):CD006207.
6. Jefferson T, Jones M, Al Ansari L, Bawazeer G, Beller E, Clark J, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis. medRxiv. 2020.
7. Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) — United States, February 12–March 16, 2020. CDC Morbidity and Mortality Weekly Report. 2020;69.
8. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19) — China, 2020. China CDC Weekly. 2020;2(8):10.
9. Liu Y, Yan LM, Wan L, Xiang TX, Le A, Liu JM, et al. Viral dynamics in mild and severe cases of COVID-19. Lancet Infect Dis. 2020.
10. Fretheim A. The role of children in the transmission of SARS-CoV-2-19 – a rapid review. Oslo: Norwegian Institute of Public Health; 2020 23.03.2020.
11. Helsedirektoratet har vedtatt omfattende tiltak for å hindre spredning av Covid-19: Helsedirektoratet; 2020 [Available from: https://www.helsedirektoratet.no/nyheter/helsedirektoratet-har-vedtatt-omfattende-tiltak-for-a-hindre-spredning-av-covid-19.
12. Olsson SV. Sverige: – Fortsatt ikke aktuelt å stenge skoler: NRK; 2020 [Available from: https://www.nrk.no/urix/sverige_-_-fortsatt-ikke-aktuelt-a-stenge-skoler-1.14946723.
13. Helljesen VO, S.V.; Omvik, O.R.; Fjeld, I.E. Høie vurderer gradvis åpning av skoler: NRK; 2020 [Available from: https://www.nrk.no/norge/bent-hoie-vurderer-gradvis-apning-av-skoler-1.14947893.
14. Ungdata is a cross-national data collection scheme, designed to conduct youth surveys at the municipal level in Norway: Oslo Metropolitan University; [Available from: http://www.ungdata.no/English.
15. van Buuren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. Stat Med. 1999;18(6):681-94.
16. Raghunathan T.W. LJM, Van Hoewyk J., Solenbeger P. A multivariate technique for multiply imputing missing values using a sequence of regression models. Survey Methodology. 2001; 27:11.
17. Aiello AE, Perez V, Coulborn RM, Davis BM, Uddin M, Monto AS. Facemasks, hand hygiene, and influenza among young adults: a randomized intervention trial. PLoS One. 2012;7(1):e29744.
18. Taljaard M, Weijer C, Grimshaw JM, Eccles MP, Ottawa Ethics of Cluster Randomised Trials Consensus G. The Ottawa Statement on the ethical design and conduct of cluster randomised trials: precis for researchers and research ethics committees. BMJ. 2013;346:f2838.
19. Gjellan MA, A. Sykehusene mangler barn med uforklarlige blåmerker og sår [Hospitals are missing children with unexplainable bruises and wounds]: NRK; 2020 [updated 30.03.2020. Available from: https://www.nrk.no/norge/sykehusene-mangler-barn-med-uforklarlige-blamerker-og-sar-1.14963483.

20. Muladal A. Coronatiltakene: Barnevernet får færre bekymringsmeldinge: VG; 2020 [Available from: https://www.vg.no/nyheter/innenriks/i/K3m3XG/coronatiltakene-barnevernet-faar-faerre-bekymringsmeldinger.