Pool testing as a Strategy for Avoidance of SARS-CoV-2 Outbreaks in Schools (STACAMA): Protocol for a Feasibility Study

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Abstract

Background: School closures are a widely implemented strategy for limiting infection spread in the current SARS-CoV-2 pandemic. The negative impact on children and young people is increasingly apparent, however.

Objective: We aim to evaluate the feasibility of an infection monitoring program in schools to enable targeted quarantining to replace school closures.

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Results: We will quantitatively and qualitatively evaluate the logistics and the acceptability of the program.

Conclusions: This study should inform the design of infection surveillance programs in schools based on gargle samples and a pool testing strategy, enabling identification of any aspects requiring adaptation before large scale implementation. Our focus on each step in the logistics and on the reported experience of families should enable a robust assessment of the feasibility of such an approach.

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Abstract

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Keywords: SARS-CoV-2; schools; pool testing; gargle test; test strategy; monitoring; surveillance

Introduction

Background

The pandemic declared in March 2020 by the World Health Organization, due to the spread of the new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted in unforeseen challenges to education systems around the world. Although school closures have been a widely implemented measure to limit viral transmission, closing educational establishments has resulted in a plethora of adverse consequences, many of which had not been considered at the outset, for the current generation of children

and young people. In addition to the negative impact on educational attainment, a myriad of further repercussions is coming to light, including detrimental effects on general health, social development, and mental well-being [1–4]. Wider-ranging sequelae have included failure to detect cases of child abuse [5–8], as well as obesity [9], and also undernourishment among children usually reliant on school lunches [10] . The impact has been greatest on children in socially disadvantaged circumstances [11,12], especially children of primary school age [13]. School closures can also play an important role in health care planning, when essential clinical staff have children of school age [14]. When emergency care cannot be provided or is unsuitable due to the child belonging to a risk group, grandparents may be called upon to take on a care role [15], despite strong evidence that older ages groups are at greater risk of severe illness from COVID-19 (coronavirus 2019 disease) [16–18]. Although it was apparent from the early stages of the pandemic that children can be affected by SARS-CoV-2 [19], it is now also well-established that children tend to have milder acute symptoms [20,21], and younger children have lower SARS-CoV-2 infection and transmission rates than adults [22–27]. Against this backdrop, the development of concepts to enable safe re-opening of schools is imperative, not only during the current pandemic but also to avoid a repeat of widespread school closures in the future. Indeed, with the rising number of infections in the current pandemic resulting from new mutations of SARS-CoV-2 with a higher transmission rate, we are already potentially facing the next wave in the current pandemic.

Despite the protective measures implemented in schools on re-opening in the summer of 2020 following the first lockdown, including the wearing of face masks to cover nose and mouth, regular handwashing, and social distancing, the infection incidence rose, and further school closures ensued in many countries. Regular testing of the population for infection with SARS-CoV-2 was proposed early in the pandemic [28,29], and surveillance programs with contact-tracing and quarantining have been recommended as a potential strategy to enable schools to re-open [26,30–32].

Until now, we are aware of two studies successfully implementing a regular surveillance program for the monitoring of SARS-CoV-2 infections in schools, both of which involve performance of swabs by medical staff for polymerase chain reaction (PCR) testing [33,34]. Despite massive expansion of testing capacities, however, regular testing and provision of rapid results for all school children would place a substantial logistical burden on schools. Here we present a study protocol for the evaluation of the feasibility of an efficient SARS-CoV-2 testing strategy based on pool testing in two model schools in Magdeburg, Germany (STACAMA: STudie zur Ausbruchsvermeidung von CoronA an MAgdeburger Schulen [Study of Corona Outbreak Avoidance in Magdeburg Schools]). We aim to assess both the practical implementation of the testing procedure as well as its acceptance among pupils and their parents/guardians in a primary and a secondary school. The evaluation of the test procedure will be performed in close collaboration with the Regensburg University Children's Hospital of East Bavaria, St. Hedwig, where a similar concept is being applied in a choir-based boarding school (STACADO: STudie zur Ausbruchsvermeidung von CoronA bei den Domspatzen [Study of Corona Outbreak Avoidance in the Cathedral Choir School]), the Regensburger Domspatzen.

Testing strategy

We selected a test procedure involving pool testing of a gargle solution on the basis of its noninvasiveness, ease of implementation, and cost. Other test procedures, which may be used to identify SARS-CoV-2 infection, include taking a swab from the nose, throat, and/or mouth, saliva sampling, and serology. Although a deep nasal and throat swab has been deemed the gold standard in testing, it may be considered invasive, potentially finding low acceptance among asymptomatic children as a means of regular testing. Comparable sensitivity has, moreover, been demonstrated between deep nose and throat swabs and the use of saliva as a test material, both among symptomatic and asymptomatic individuals [35–37]. Cost-effectiveness is an important consideration for an ongoing program. Gargling a saline solution or filtered water for subsequent RNA testing can be carried out independently [38,39], saving the costs of support from clinical personnel with protective clothing [40]. Moreover, gargle tests have been established as providing an effective

approach to diagnosing respiratory infection among children [41], and they have been shown specifically to be effective in diagnosing SARS-CoV-2 infection [42]. The approach is particularly well-suited to a regular monitoring program, because gargle solution samples from several participants can be tested together in a so-called pool testing procedure [43], with lower costs than individual testing [44]. The possibility has been raised that pooling specimens could potentially result in a reduced sensitivity [44]. However, a modelling study evaluating various parameters involved in potential monitoring programmes, while taking account of the dynamics of the viral load over the course of SARS-CoV-2 infection, has suggested that the frequency of testing and rapidity of provision of test results have a greater impact on case detection than the sensitivity of the test used [45].

Aims

We aim to evaluate the implementation of a program to provide regular monitoring of SARS-CoV-2 infection occurrences among asymptomatic pupils, in order to avoid infection outbreaks and consequent school closures, based on a pool testing procedure of gargle samples. Central to the study are the evaluation of the logistics and the acceptability of the testing strategy. A further key consideration in the study design was the rapid communication of test results in accordance with national data protection standards.

Methods

Overview of Study Design

Asymptomatic pupils attending a primary and a secondary school in Magdeburg are being monitored for infection with SARS-CoV-2 over a study period of 16 weeks. Twice a week, five pupils are pseudorandomly selected from each class and invited to provide a gargle test sample for analysis in a pool test procedure, resulting in up to 8 pools from the primary school and 26 pools from the secondary school. A positive pool test will be followed immediately by testing of individual samples. After three weeks of testing, a questionnaire regarding reasons for choosing to participate or not, was distributed to all families, and the findings are currently under evaluation. Further questionnaires focusing on the acceptance of the test strategy are planned for halfway through and on completion of the study. In the case of lockdowns, the program will be, as is currently the case, temporarily suspended, then resumed when schools re-open.

Study population

Recruitment

Invitation to participate in the study took place through presentation of the study by a member of the study team (CMSR), the heads of the schools, and at the primary school, also by University Hospital management, at parent evenings at each school, which were attended by up to two elected parent representatives per class. A written summary of the information was provided to facilitate dissemination of an overview of the planned study invitation during separate parent evenings for each individual class with their class representatives. Subsequently, the full study information, as approved by the Local Ethics Commission, was distributed to all families, both in paper form and electronically, by email and through publication on the study website. The formal invitation encompassed the following study documents: study information sheet, data protection declaration, consent form, as well as a flyer explaining how to provide a sample through gargling the solution to be provided. The documents were made available in additional languages, through professional translation, as required. Following evaluation of the response rates, reminder letters were forwarded via the heads of the schools and parent representatives. Throughout the study period, a study website is maintained, and an email contact and a study telephone hotline (DW) are provided for any questions.

Inclusion/exclusion criteria

The study population includes pupils aged between 6 and 18 years (primary school: 6-10 years, 2 classes per

grade, 20-24 pupils per class; secondary school: 10-18 years, 4 classes per grade in grades 5-10, 22-30 pupils per class, grades 11 and 12: 93 and 96 pupils, with mixing groups according to course selection). Inclusion requires provision of written consent from the parents/guardian, as well as written consent from the pupil, depending on age.

School attendance was dependent on pupils being asymptomatic and having had no contact with persons confirmed to be infected with the SARS-CoV-2 virus in the preceding 14 days. Parents/guardians were required by the schools to provide weekly written confirmation of these statements before the school closures in December 2020.

A minimum participation rate of 60% per year group was deemed necessary, because our aim is to assess the feasibility of a surveillance program based on pseudorandom sampling to monitor for SARS-CoV-2 infections in an asymptomatic cohort. A lower participation rate would change the program to a regular testing of the same individuals. The evaluation of the burden of more frequent testing would require a separate study. Pupils may be included at a later date, following study commencement, should they so choose, up until the end of the study period, potentially enabling further year groups to reach the 60% participation level required for testing to commence.

Leaving the study

Study participants can terminate their participation at any time, without providing reasons. If a participant leaves the study, the test results will be retained, in a completely anonymised form. Study personnel are not able to link the data with any individual person. All information is saved under a 16-digit code, which is known only to the participant, in the study app. Deletion of individual data is possible, but only if the participant discloses their 16-digit code.

Ethics and Consent

The study protocol was developed to meet the standards and gain approval from the Coordination Centre for Clinical Studies Magdeburg and the Data Protection Advisory Service of the University Hospital Magdeburg. The Local Ethics Committee of the Otto-von-Guericke-University Magdeburg has evaluated the STACAMA Study and agreed to its implementation (164/2). Participation in the study is voluntary. Participants are informed about the goals and content of the study, as well as over the data protection, and written, informed consent is a prerequisite for inclusion in the study.

Data Protection

The study will be carried out under strict adherence to data protection standards set out by the EU Data Protection Regulations (EU-Datenschutzgrundverordnung [DSGVO]) and the Federal Data Protection Act (Bundesdatenschutzgesetzes [BDSG]). All data are secured against unauthorized access and are stored on a secure server in Frankfurt, Germany, whose infrastructure is certified as being in accordance with the guidance set out under ISO 27001. All aspects of data transfer are encrypted, which is carried out in accordance with the recommendations set out under the AES-256 standard. The anonymized data may be provided to academic third parties for the analysis and evaluation of academic and medical hypotheses. The data will not be used for purposes outside the aims of the study, in particular not for commercial purposes. After the end of the study evaluation, the data will be deleted, at the latest on 31.12.2021.

Procedure

Hygiene measures

Before commencement of the study, each school head developed a hygiene policy suited to the relevant age groups and school facilities, in collaboration with the Dept. of Hygiene at the University Hospital Magdeburg and the study team (CMSR). At the beginning of the school year, an educational project week was provided at the primary school by members of the Depts. of Hygiene, Management, and Public Outreach at the

University Hospital Magdeburg and CMSR, in which the SARS-CoV-2 and the hygiene policy were introduced and explained using an interactive, age-relevant approach for each year group. At the secondary school, members of the Dept. of Hygiene held a series of presentations regarding hygiene and the limitation of the spread of SARS-CoV-2 for all pupils, for two consecutive year groups at a time to enable an age-appropriate delivery as well as compliance with social distancing requirements, with an opportunity to ask questions.

The hygiene policies at both schools involved strict separation of classes into separate cohorts. The wearing of masks covering the nose and mouth was required in the secondary school at all times, including when the pupils were outside. In the primary school, masks were also required, except during lessons and while on the playground outside. Classrooms were required to be aired for a minimum of 5 minutes at least once per lesson in the primary school and at least twice per 45-minute lesson in the secondary school. Hand hygiene was emphasized in both schools, and running water, soap, and disposable paper hand towels were provided in every classroom. Disinfectant dispensers were available at the school and cafeteria entrances at the secondary school, which could be operated with the forearm, and pupils were asked to bring disinfectant for personal use. School desks were rearranged to provide maximum distance between pupils. The school corridors in both schools were signposted to separate direction of walking, and a minimal distance of 1.5 m between individuals was emphasized. One-way systems were implemented in corridors and on staircases where possible. In the primary school only, sport lessons were carried out outside and with distancing measures, and singing was only permitted on an individual basis, with a minimal distance to others of 2 m. Sport and singing were not permitted at the secondary school, and school lunches were provided in small groups and no longer in a buffet format.

Testing

The surveillance program is performed as follows (Figure 1). On enrollment in the study, each pupil is given a test kit for provision of a sample, accompanied by an instruction leaflet, and an information sheet with a personal 16-digit participant code and instructions on how to use the study app, which is implemented on the qnome platform [46]. The study data are recorded and stored under this code. The assignment of the access codes to individual participants is not recorded and stored, so that it will not be possible to associate participant data with individuals.

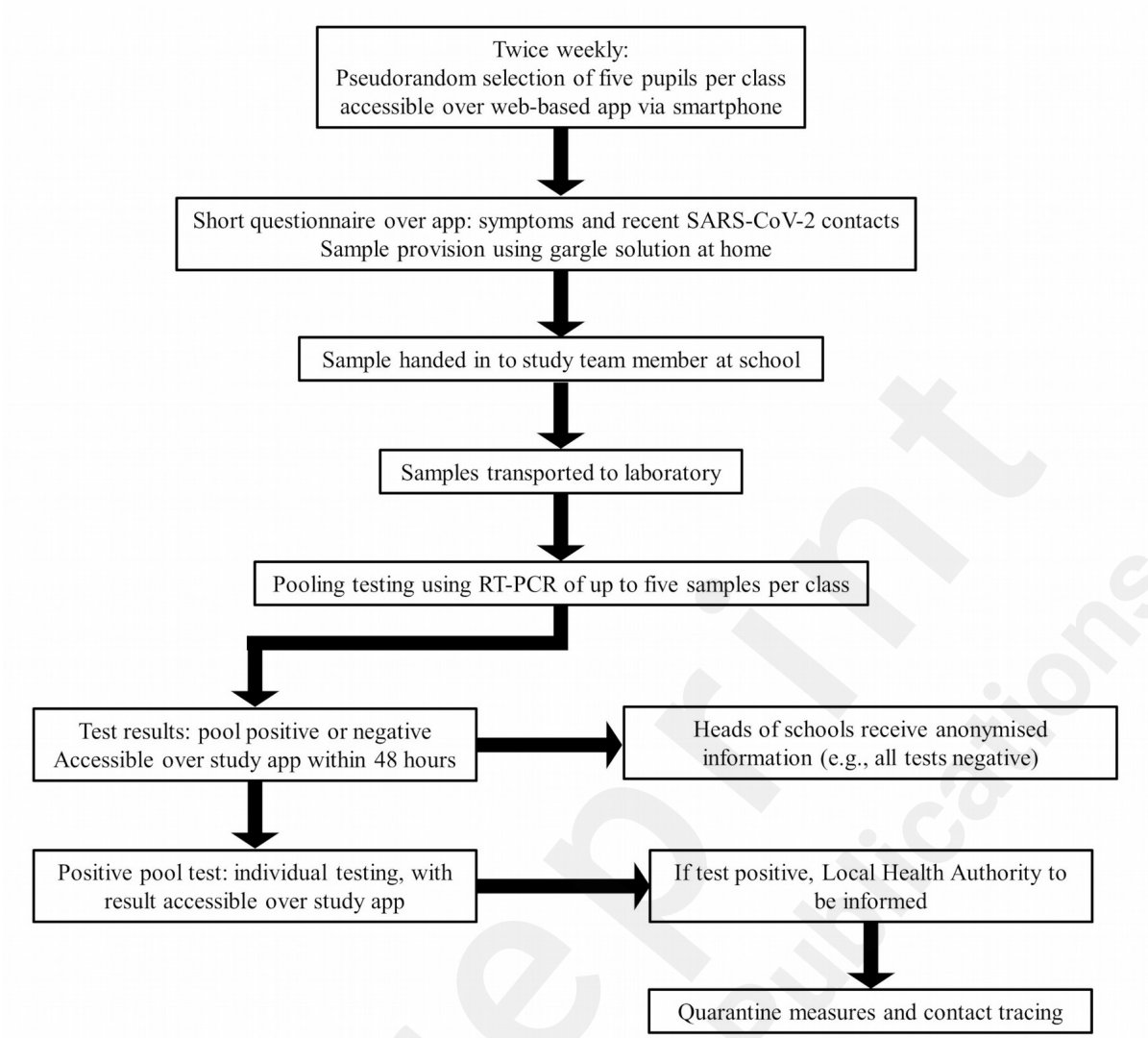

Figure 1. Monitoring procedure based on pool testing of gargle samples (RT-PCR = reverse transcription polymerase chain reaction).

Pupils or their parents/guardians are asked to enter their 16-digit participant code into the study app each Sunday and Tuesday evening to ascertain whether they have been pseudorandomly selected through the study app to provide a gargle test sample for inclusion in the test pool for their class the following morning (Mondays and Wednesdays). On entering the code for the first time, participants are asked to complete a voluntary starting questionnaire, in which they are asked whether a member of the household is employed in health or social services. Before each test session, a further questionnaire is completed within the study app, in which participants are asked whether a family member or friend has tested positive for SARS-CoV-2 since the previous questionnaire and about relevant symptoms. An individual risk profile is then generated according to a point allocation system, and participants are selected for the next testing session through an algorithm with a weighting towards selection of participants at increased risk of infection.

The sample is produced independently at home in order to avoid the risk of spreading infection through gargling in the school. Participants are asked to provide a sample through deep throat gargling of 10 ml of 0.9 % NaCl solution. The procedure does not involve a health risk to participants. After gargling, the solution comes into a pot and the lid is screwed shut. A sample tube containing a vacuum is provided, which is applied to an opening in the lid of the pot. The gargle solution is then evacuated into the sealed sample tube. The sample tube has a bar code from the laboratory, which is scanned using a smartphone camera with the study app. The participant's 16-digit personal code is thus linked with the sample, which allows the

participant to access their test results subsequently using the app. The frequency with which a pupil is tested can also be determined via the code, without compromising anonymity. Participants are also requested to write their first and surname and class on the sample tube. This information is a legal requirement, as infection with SARS-CoV-2 is a notifiable disease. The processing laboratory is required to provide personal identification information to the Local Health Authority to enable quarantine measures to be applied and contact-tracing to be carried out. The school is subsequently legally required to provide the relevant individual contact information to the Local Health Authority. This procedure is in place independently from the study and is implemented when SARS-CoV-2 infection is confirmed in any person attending the school, regardless of where the testing was performed.

After transport to the laboratory by an independent contractor, the pooling of samples takes place in the laboratory on the basis of class attendance, because hygiene measures in place in both schools ensure that pupils in the same class form a consistent cohort. The pooled samples are tested using a PCR-based direct detection of SARS-CoV-2. In the case of a positive pool test, the samples involved in the pool procedure will be immediately tested individually and the results, as a yes/no response, assigned to the 16-digit access code and visible over the study app to the children and their parents/guardians within 48 hours. The pool testing procedure was developed by the participating commercial laboratory and is currently being registered for patenting. Internal evaluation procedures have thus far revealed no loss of sensitivity in comparison with single specimen measurements.

The measures to be implemented in the case of a positive finding were agreed in advance with the Local Health Authority responsible for imposing protective measures and contact tracing for notifiable diseases. The results from the previous two testing rounds will be additionally available, to enable early, rapid recognition of an outbreak. Pupils identified as contacts of a person infected with SARS-CoV-2 will be informed by the Local Health Authority. Whether the identification of a positive test for SARS-CoV-2 infection in a school results in quarantine measures for the entire class, course group, or similar, in addition to close contacts, lies at the discretion of the responsible Local Health Authority and is continually updated on the basis of local and national rates of infection. The recommendations of the Robert Koch Institute may be adapted to the local situation in accordance with the intended protection goals.

Questionnaires

To evaluate the acceptance of the test strategy among pupils and their families, a questionnaire was provided three weeks after study commencement, in paper and electronic formats, to the families of all pupils, which could be voluntarily and anonymously completed, regarding the reasons behind decisions over whether to participate. Halfway through and at the end of the 16 testing weeks, families will be asked about their experiences.

Data Analysis Plan

Endpoints

The study has two primary endpoints: the evaluation of the logistical implementation of the surveillance program and of its acceptance among participants and their families. The logistical implementation will be assessed according to the number of pool tests successfully performed per participating class. The stages in the procedure will be evaluated individually, including the following: 1) number of pre-test online questionnaires completed; 2) number of samples handed in at the schools; 3) arrival of samples at the laboratory within the recommended time frame for sample transportation; 4) analysis of pooled, and when a pool test is positive, individual samples; 5) provision of results accessible via the study app within 48 hours. The acceptance will be evaluated in four ways: 1) the participant quota as a whole, for each school, and for each year group; 2) participation of additional year groups over the study period; 3) the dropout rate from the study; 4) evaluation of the questionnaires.

Results

The recruitment of participants for the STACAMA study began when the 2020/21 school year commenced, and inclusion will continue to be possible until the end of the study period. In total, 52% of pupils and/or their parents/guardians had provided written consent to participation by the time testing began. The 60% participation rate required for testing commencement was reached in the third (62%), fourth (61%), and fifth (70%) grades at this time. The study started on 2 December, 2020 and was suspended after four testing rounds on 15 December, 2020 due to renewed school closures. During that time period, no pool tests were positive. Subsequent rounds of testing commenced on 8 March, when the schools reopened, and will continue until 16 study weeks have been completed in total. The 60% inclusion rate has now been met in additional classes, which will now be included: two classes in the sixth (66%) grade, one in the seventh (76%) grade, and two in the eighth (62%) grade. Participation has increased to 63% in the third grade and 73% in the fifth grade. Across all grades, participation is currently 54%. Study results will be published in peer-reviewed scientific journals on completion of data collection and analysis, with the manuscript reporting the evaluation of the first questionnaire data currently in preparation.

Discussion

This study will provide insights into the feasibility of a surveillance program in schools for the prevention of outbreaks of SARS-CoV-2 through regular gargle sampling and pool testing of randomly selected asymptomatic pupils. Such a program has the potential to enable schools to re-open safely, avoiding the far-reaching negative consequences of school closures. Through evaluating each stage of the proposed testing strategy, we expect to be able to establish which steps in the program can be successfully implemented, while identifying aspects that could require alternative solutions. The acceptability of such a program is paramount, if it is to be applied on a regular basis in all schools. The open questions in our questionnaire should allow us to gain an understanding of the impact of infection monitoring on pupils and their families. The use of gargle tests offers potential advantages over surveillance programs based on swab testing. Sample collection is noninvasive, safe, and can be performed independently at home, without a requirement for medical personnel and protective equipment or a risk of infection spread during sample preparation in schools. Furthermore, the samples can be readily used in a pool testing procedure. Pool testing offers a potentially efficient approach to monitoring infection in a low prevalence environment, which is an important consideration given finite laboratory capacity and the scale of testing required for all schools to be included.

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CMSR wrote the manuscript; CMSR, DW, and CA developed the study protocol for implementation in a

primary and a secondary school in Magdeburg, based on the protocol developed by MK for implementation in a boarding school in Regensburg; MK developed the participant selection algorithm; JN implemented the participant selection algorithm; CMSR was involved in school hygiene policy development, presentation of the study to parents in both schools, and contributed to the primary school hygiene project week; CMSR, DW, JN, MK, and CA critically revised the manuscript. The authors would like to thank the heads of both schools for their extensive engagement in the study planning; the Dept. of Hygiene at the University Hospital Magdeburg: Prof. Gernot Geginat and Dr. Lukas Bechmann, for their guidance in developing the school hygiene policies with the heads of the schools, Ms. Jessica Ziegler for presenting the hygiene policy to the parents at the secondary school, and Dr. Bechmann and Ms. Ziegler for presenting the hygiene policy to the children at the secondary school; the University Hospital Magdeburg: Prof. Hans-Jochen Heinze and Dr. Kerstin Stachel for assistance in obtaining funding for the study, as well as for their contribution to presenting the study to parents and engagement in the primary school hygiene project week, Dr. Antje Wiede and staff of the Coordination Centre for Clinical Studies and Dept. for Data Protection for extensive advice on participant anonymity, Dr. Stefan Feige and Ms. Ögelin Düzel for coordinating the primary school project week, Dr. Martina Beyrau, Dr. Mario Damerow, Mr. Stefan Reimann, and Dr. Saskia-Thérèse Schirmer for providing primary school project week sessions; colleagues at the Local Health Authority and State Dept. for Consumer Protection for informative discussions regarding quarantine measures; the pupils and their families for their participation; the school staff for their practical support in distributing and collecting study materials and providing facilities for the study team to accept samples from participants. The STACAMA study is funded through a grant from the Ministry for the Economy, Science, and Digitalization of the State of Saxony-Anhalt.

Conflicts of Interest

None declared.

Abbreviations

SARS-CoV-2: severe acute respiratory syndrome coronavirus 2
RT-PCR: reverse transcription polymerase chain reaction

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Supplementary Files

Figures

Monitoring procedure based on pool testing of gargle samples (RT-PCR = reverse transcription polymerase chain reaction).