Is Carbon Dioxide Content Under Nose-Mouth Covering in Children Without Potential Risks? A Measurement Study in Healthy Children

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Harald Walach (1,2,3), Ronald Weikl (4), Stefan Hockertz (5), Andreas Diemer (6), Helmut Traindl (7), Anna Kappes (8), Juliane Prentice

1 Poznan University of the Medical Sciences, Pediatric Clinic, Poznan, Polen

2 Witten/Herdecke University, Dept. of Psychology, Witten, Deutschland

3 Change Health Science Institute, Berlin, Deutschland

4 Kinderarztpraxis, Passau, Deutschland

5 tpi consult, Bollschweil, Deutschland

6 Allgemeinmedizin, Gernsbach, Deutschland

7 Traindl-consult, Wien, Österreich

8 Anna Kappes, Müllheim, Deutschland

9 Juliane Prentice,

Address for Correspondence:

Prof. Harald Walach

Schönwalder Str. 17

D – 13347 Berlin

+49 30 467 97 436

harald.walach@uni-wh.de

Abstract

Children and parents report problems when wearing nose-mouth covering (face masks, NMC). Little is known how much carbon dioxide is accumulating under such masks, or, rather, how well gas exchange works. First results from other groups point to the fact that carbon dioxide accumulates and might reach dimensions that are beyond safety norms. If this should be substantiated, especially in children, there would have to be a new weighing of health and safety concerns in children and protection against infection. This is dwhy we want to conduct a controlled measurement study in children.

40-50 healthy children volunteers will be measured by a specialist engineer with their parents present and under supervision of medical and psychotherapeutic personnel. The protocol will last approximateley 25 minutes per child, about 15 minutes with NMC and 10 minutes without. Another 15 minutes will be taken for additional measurements (breathing, temperature, blood oxygenation). All measurements are completely non-invasive. We will measure oxygen and carbon-dioxide content of breathed air and blood oxygenation, as well as facial temperature after wearing a mask. By comparing oxygen and carbon dioxide content with two different types of masks and without any we can see, whether the carbon dioxide content is above norm values under NMC.

Background

Since the WHO has alarmed the world to the SARS-CoV2 pandemic in March 2020 most governments try to stop the spread of the novel corona virus. The governments of Germany and Austria, and possibly in other countries as well, have begun to make the wearing of nose and mouth covering (NMC), or face masks, compulsory even for children going to school. The evidence base for such a procedure to prevent infection is mixed at best. Two recent systematic reviews reach the conclusion that wearing face masks does not prevent infections by influenza virus, which is very similar to SARS-CoV2 [1,7]. Ines Kappstein, a well known German hygiene specialist, pointed out that there are only very few data that support the wearing of NMC in general contexts, and practically none for children [8]. Perhaps wearing NMC is popular, because in Hong Kong and Taiwan it was possible to stem the infection rapidly and here 98% of the population was wearing NMCs in public [9]. A review of non-randomized studies concludes that a small benefit cannot be excluded [10]. However, the first pragmatic randomized study comparing the suggestion to wear NMC in public with no recommendation found that the effect is small and not significant [11]: of 6.000 participants 42 or 1.8% were infected in the experimental group, and 53 or 2.1% in the control group. When comparing those that actually did wear the masks the effect was even smaller. Positive effects of prevention of infection are likely small.

Against this background of a small protective benefit the question whether NMC increases carbon dioxide in breathed air substantially is getting more important. The first large scale German survey in parents and children, the Co-Ki-study of the University Witten/Herdecke using data of 25.930 children has shown that children report side effects to a high percentage [4]: 68% of parents report that their children have problems. Most frequently they report irritation, tension and stress (60% of parents), headaches (53%), difficulties

concentrating (50%), fatigue and sleepiness (30%). It is possible that a high content of carbon dioxide in breathed air might be the reason.

The normal content of carbon dioxide in breathed air in the open is about 0.04 volume % (i.e. 400 parts per million/ppm). 0.2 vol% or 2.000 ppm are acceptable for closed rooms according to the German federal environmental office. This is at the same time the cut off for children and pregnant women, which is considered safe. Maximum concentration at the working place for healthy adults during 8 hours of work and 40 hours per week is considered 0.5 vol% or 5.000 ppm.

To the best of our knowledge there are no solid peer-reviewed data on carbon dioxide concentration in breathed air under NMC, especially for children. Ing. Dr. Traindl, coauthor of this study, has made some pilot measurements in 3 persons and found 3-5% CO_2 in breathed air under NMC (30.000 – 50.000 ppm). One of these volunteers was a child, and here CO_2-concentrations were steadily measured at 3,4-5% (34.000-50.000 ppm) [12]. A team from South-Tyrol conducted measurements in November 2020 in 24 volunteers using different types of NMC and clarified discrepancies to a study that had been conducted by the official government of the autonomic region in Bolzano [13]. Those results reported by Ing. Oberrauch are considerably higher than those reported by the government. This is obviously due to the fact, that the governmental working group of the region of Bolzano had subtracted the environmentally measured carbon dioxide values from measures, which led to an artificially lowered result. The data of the South Tyrolian study [13] regarding different types of NMC are reported in Table 1,

Table 1 – Results of the study by the Group of Oberrauch in South Tyrol and those of the official governmental study

	Oberrauch	Province of Bolzano
No mask	3.143 ppm (2.000-5.000)	590 ppm (50-2.250)
FFP2-N95	11.000 ppm (7.000-15.000)	3.850 ppm (1.220-8.080)
cloth	11.500 ppm (5.000-24.000)	4.590 ppm (1.480-10.280)
Surgical mask	7.292 ppm (5.000-13.000)	3.350 ppm (950-5.320)

It is obvious that the results found in 24 volunteers and the official data diverge widely, with the data by Oberrauch and his group being beyond acceptable values [13]. Should these results be replicated in children this would have to lead to immediate discussions with official decision makers.

This is the reason why we want to measure in a well-controlled, experimental study in volunteer children carbon dioxide and oxygen content in breathed air with and without different types of NMC to find out whether raised values are found under different conditions.

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Method

Target Group

Participants will be children in school age, whose parents have shown interest in the study. The children will be healthy, free from infections or neurological diseases, have no psychological disorders that would produce problems during 15 minutes of wearing a face mask and have no medically indicated exception from the compulsory NMC order.

Participation is strictly on a volunteer basis and no remuneration is presented. As a gratification parents will receive privileged information about the results before publication.

Children will be accompanied at all times by their parents, should they so wish. Older children beyond age 14 can also come on their own if they wish. In all cases the informed consent of their parents will have to be given. An informed consent and information leaflet for children will also explain that they can always withdraw without giving any reason

Aims

We want to measure in a short-term experimental protocol how the CO_2/O_2-concentration in breathed air under NMC and in the facial area without NMC will develop. We also want to measure the CO_2/O_2-concentration in inhaled and exhaled air without NMC.

Simultaneously, we will measure blood oxygenation, heart rate and breathing frequency to figure out, which physiological consequences the wearing of NMC will have. We will compare different materials – FFP2 masks and surgical masks – and thereby estimate the porousness of different materials. Data like the ambient air, age, size, breathing frequency of the children, volume of the masks will be documented.

We will measure the following data:

- Age, gender, size and weight of children.
- Type of NMC normally worn.
- CO_2/O_2-concentration in facial vicinity without NMC. The mix of inhaled and exhaled air will be considered
- CO_2/O_2-concentration in the volume of different types of masks while wearing them (surgical mask and FFP2) and in the inhaled and exhaled air
- Pressure minima and maxima in near-facial areas before and during the measurement, i.e. with and without MNC
- Breathing frequency before, during and after wearing of NMC
- Blood oxygenation before, during and after wearing of NMC
- Pulse frequency before, during and after wearing of NMC
- Thorax widening with and without NMC
- Facial surface temperature before, during and after wearing of NMC
- Volume of the different types of NMC
- Air diffusion of children's normally worn masks in comparison with certified masks
- Air parameters in the measurement room (temperature, humidity, CO_2 content at the beginning and at the end of the measurements

Measurement Protocol:

All measurements are non-invasive, using probes that are attached to the face of the child; thus, they will neither enter the nose nor the mouth. Blood oxygenation and temperature will be measured non-invasively using optical means and infra-red measurements (see table 2).

Time per child:
Ca. 30 minutes for air measurements and 15 minutes for additional measurements.

1. Sociodemographic data of the child:
   Age, gender, height, weight

2. Description of the NMC normally worn

3. Measurement and documentation of ambient air:
   - CO_2-cncentration (ppm)
   - Temperature
   - Humidity

   Apparatus: PCE-CMM 10 (producer: PCE)
   - CO_2: rage 400ppm – 5.000ppm, steps 1ppm
   - Humidity: 0 – 99%
   - Temperature -10,0 °C – 50,0 °C, steps 0,1 °C

4. Temperature measurement (touch free) in facial area
   Measurement with IR-camera

   Apparatus: IR-camera: testo 868 (producer: Testo GmbH)
   - IR-resolution 160 x 120 Pixel
   - range: - 30 °C - + 100 °C, precision: + 2 °C, + 2% of measured value

   IR-temperature measurement testo 830 (producer: Testo GmbH)
   - Range: - 30 °C - + 400 °C, precision: + 1,5 °C, + 1,5% of measured value
   - resolution: 0,1 °C

5. CO_2/O_2-measurement in facial air with and without NMC

Measurement point is between mouth and nose; measurement hose is fixed using a textile adhesive band that is adapted to the head size.

A small part of the breathing air will be taken by an integrated pump

(flow 0,1 l/Min.). The distance of the suction point from the face is about 0.5 cm.

Measurement of CO_2 and O_2 with gas measurement device. Documentation by display recording online on a laptop using data-tracing and saving of snapshots. Docuemtation intervals 15 seconds (written records) and 30 seconds (data-tracing).

Further measurements:

- Pressure measurement under MNC: measurement point between mouth and nose (analogous to CO_2/O_2-mesurements)
- An additional thin hose in parallel to the one for air content will allow the connection with a low pressure manometer, which can measure pressure when breathing.
- O_2-saturation in blood with finger-pulse oximeter
- The finger-pulse oximeter will be attached to one finger of the child and the blood oxygenation measured before, during and after CO_2/O_2-measurements.
- Measurement of breathing frequency

Gas measurement apparatus: G100 (manufacturer: Geotech)
CO_2: Range: 0 – 20 Vol.%, precision + 1 %
O_2: Range: 0 – 100 Vol.%, Precision + 1 %

Low pressure manonmeter: G1107 (Manufacturer: GHM Messtechnik)
20,00 hPa - +20,0 hPa, Precision 0,01 hPa (= 1 Pa)

Finger-pulse oximeter: GT-300C203 (Manufacturer: Geratherm)
SpO_2: Range: 70% - 99 %, resolution 1 %
Pulse frequency: Range 30 bpm – 235 bpm, resoluation: 1 bpm

Breathing frequency: manually by counting.

Measuremnt in sequence:
- no MNC
- surgical mask
- FFP2 mask
- no MNC

The first and last measurements (no MNC) are considered baseline, the two measurements with different MNCs are considered experimental and will be randomized. Randomization is stratified by age (below 12 and above 11 years).

„Block 1“ - „5a.“ Baseline before MNC measurements

5a1. CO_2/O_2-Measurements of breathed air. Measurement in facial area without MNC (Baseline 1), inhaled and exhaled air combined
Duration: 2 (max. 3) minutes

5a2. CO_2/O_2-Measurements of breathed air. in facial area without MNC (Baseline 1a), only inhaled air
Duration: 2 (max. 3) minutes

5a3. Measurement of thorax excursion without MNC
3-5 measurements, written documentation

5a4. Surface temperature: Measurement (without touchin) in facial area
Measurement with IR camera

„Block 2 and 3“ - „5b. and 5c“ Experimental measurement 1 & 2 with surgical or FFP2 mask in randomized sequence

5b1 CO_2/O_2-measurements of air with MNC. Measurement in close facial area with experimental mask inhaled and exhaled air combined
Measurement/documentation.
Duration: 2 (max. 3) minutes

5b2 CO_2/O_2-measurements of breathed air. Measurement in close facial area with experimental mask
Measurement/documentation of inhaled air.

Duration: 2 (max. 3) minutes

5b3 CO_2/O_2-measurements of exhaled air. Measurement in close facial area with experimental mask
Measurement/documentation of exhaled air

Duration: 2 (max. 3) minutes

5b4 Measurement of thorax excursion with experimental mask
3-5 measurements, written documentaiton

5b5. Measurement of surface temperature (touch free) of facial area
Measurement using IR-camera

„Block 4“ - „5d.“ Baseline after experimental measurements same as 5a

All measurements are documented in writing during the experiment.

At the end the CO_2/O_2-values and the time trace will be documented via data-tracing of the values displayed at the laptop. Sampling frequency: every 5 to 15 seconds.

6. Interval, no MNC
duration: 5 minutes, free time

6a: Measurement of the breathability of the everyday MNC worn normally by the child during the interval by experimentators

Apparatus: Own construction in line with norm EN 14683 (medical face masks, testing procedure), which is an air-passing measurement of the material using a negative pressure manometer. The mask is tightened over a measurement hose and air is sucked into the hose continuously with a volume of 100 l/hour. Depending on the breathability of the material there will be a steady state low-pressure in the hose. Continuous measurement of the steady-state low pressure with a fine manometer.

Apparatus: GDH 200-07 (Manufacturer: GHM Messtechnik)

Range 0,00 – 19,99 hPa, resolution: 0,01 hPa (= 1 Pa)

We will calibrate the system with certified masks (surgical and FFP1/2) which will allow to test the breathability of the material in comparison with the certified products.

Documentation: written documentation

6b: Measurement of the breatability of the certified surgical mask during the interval by experimentator, apparatus like 6a.

7. Measurements after 5 minutes rest for child without MNC
   - O_2-saturation in blood using finger-pulse oximeter

   Apparatus: point 5

8. Measurement and documentation of ambient air parameters:
   - CO_2-concentration (ppm)
   - temperaturre
   - humidity

Rooms will be ventilated after each measurement unit.

Protocol

First, measurements of ambient air parameters without MNC with child present will be taken (3 minutes, baseline 1). Afterwards, measurements of conditions with masks (5x3 Minutes) will be performed. Measurements of breathed air without masks will be taken with child present (3 Minutes, Baseline 2). After 5 minutes interval a post-measurement of temperature und breathed air with child present will be taken without MNC.

Table 2 – Protocol Summary

Baseline 1 Measurement without MNC	Measurements with MNC1 & 2 randomized	Baseline 2 Measurement without MNC	Interval, parallel measurements	Post measurement
2x3 Minutes	5x3 Minutes	2x3 Minutes	5 Min.	3 Minutes
Room: CO_2-concentration (ppm) temperature humidity *Child*: temperature	*Child*: CO_2-concentration (ppm) in breathed air close to face Breathing frequency Blood	*Child*: Temperature CO_2-concentration (ppm) in breathed air close to face Breathing frequency Blood	*Child*: Interval *Additional mesaurements by experimentator.*: Breathability of masks	*Room*: CO_2-concentration (ppm) temperature humidity *Child*: temperature CO_2-concentration

CO_2-concentration (ppm) in breated air close to face Documentation soc-dem. data	oxygenation	oxygenation		(ppm) in breated air close to face Breathing frequency & volume

Controls and Quality Assurance

Blinding is considered unnecessary, as the measurements are objective. Measurements will be conducted exclusively with calibrated and producer-certified apparatuses. The measuring engineer has ample experience in using the apparatuses and has conducted a pilot study. Data will be documented immediately after measurements either by written documentation or data capture via the instruments used (data tracing, screen snap shots).

There will be two control measurements as a pre- and post-baseline. All apparatuses will be calibrated according to manufacturers' standards.

Measurements of breathed air under experimental masks (5b & 5c) will be randomized to exclude effects of sequences and randomization will be stratified by age of children (below and above age 10).

The experimental rooms will be ventilated sufficiently before the next child is measured. Hygiene rules will be followed according to regulations as log as they do not interfere with the measurement procedures. Personnel is tested to be free of SARS-CoV2.

The randomization will be conducted using randomizer.org. To sets of random numbers will be prepared, for children up to 11 years of age and beyond. A coin toss will decide whether even or odd numbers will mean first surgical or first FFP2 masks. As the request will be for equal numbers of 2 conditions, there is no blocking or sequencing effect that will consequently completely blind the randomization sequence. Cards will be prepared with the sequence written on them and put in opaque sealed envelopes with running sequential numbers written onto them. This will preclude any tampering with the randomization sequence.

Statistics – Power Analysis

Poweranalysis

There are no pilot data available, hence we will base our analysis on existing data. We assume that we will measure 3.000 ppm (or 0,3 vol%) CO_2 at baseline, i.e. a value which is slightly above current accepted norms, which is a conservative estimate. We assume further that good masks will produce values between 5.000 ppm and 12.000 ppm. The table of raw-data from [13] allows us to calculate as means for CO2-content of breathed air without masks 3.143 ppm, with surgical mask of 7.292 ppm and with cloth masks a value of 11.500 ppm, as well as a

standard deviation of 2.500 ppm for surgical masks, 5.300 ppm for cloth and 1.000 ppm for no masks.

This results in the following standardized mean differences (calculated with the larger SD for a conservative estimate):

Normal air vs. surgical masks: d = 1.6

Normal air vs. Cloth masks : d = 1.6

In order to secure such a strong effect with 90% power 7-9 children would be sufficient per comparison, i.e. 18 children. As we will also measure other parameters, such as breathing frequency and blood oxygenation, we will use a safety factor of 2, which will require about 40 complete data sets.

We will stratify children into age groups up to 11 and beyond and want to recruit approximately similar numbers into each stratum.

Handling of Missing Data:

We expect few missing data, as automated measurements and immediate minuting will reduce measurement glitches. Therefore, only complete data-sets will be taken into the analysis. Should a data-set be incomplete in respect to one variable (for instance temperature in one condition), then we will interpolate it with the mean for that group in this condition. A sensitivity analysis with a nearest neighbor algorithm will be calculated. The more conservative value will be used in all cases.

Statistical Analysis

The statistical analysis will utilize a linear model with a time-factor and type of mask as a grouping factor. This presupposes normal distribution, which will be checked visually and statistically (Shapiro-Wilk's test). Should normal distribution not be given, an appropriate model will be chosen, should log-transformation not result in normality.

As different cell-sizes might be present, a mixed model will be chosen. Age, gender, ambient carbon dioxide content will be used as covariates. Type of mask is a fixed factor, time is a random factor. For each dependent variable - CO_2-concentration, blood oxygenation, breathing frequency – we will calculate a separate model. Although the variables will be correlated the logic of the study requires separate estimates.

This inferential statistical analysis allows to judge, whether CO_2-content of inhaled air, blood oxygenation and breathing frequency are influenced by the wearing of MNC. It is silent about any clinical importance of the findings. Hence effect sizes as deviation of the empirical values from the norms published by the Federal Environmental Office will be calculated with the largest standard deviation as standardization factor. This means that a score of 1 sigma will be one standard deviation below or above the maximum norm score. Where such values are not available, they will be calculated as deviation from baseline without MNC.

Ethics

The study has been presented to and judged ethically sound by the ethics board of the University Witten/Herdecke. Recommendations have been incorporated into the present protocol.

In general, the load incurred by children by the current protocol seems to be low compared to what they have to do in normal school practice. They are required to wear NMC for the duration of 15 minutes, where they are normally required to wear it for several hours per day. Children will have a benefit by knowing about their individual carbon dioxide load under NMC, which might allow them or their parents to file for exceptional circumstances. Apart from that we will generate important knowledge that can be used for political action. This additional knowledge is central, as currently political decisions are made without the respective evidence base.

Children can stop the measurement at any time and/or withdraw from the study without giving any reasons and without consent of their parents.

Protocol, Publication

The protocol will be made publicly available and results published regardless of findings. As soon as possible results will be made available on a pre-print server and the manuscript submitted to peer review.

Sponsoring

This is an investigator initiated study. There is no external sponsoring, and all members of the study team work free of charge. MWFD e.V. is organizing this study and covering essential expenses only.

OSF Link:

https://osf.io/yh97a/?view_only=df003592db5c4bd1ab183dad8a71834f

References

1. Jefferson T, Jones M, Al Ansari LA, 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. 2020:2020.03.30.20047217. doi: 10.1101/2020.03.30.20047217.
2. Xiao J, Shiu EYC, Gao H, Wong JY, Fong MW, Ryu S, et al. Nonpharmaceutical measures for pandemic influenza in nonhealthcare settings - personal protective and environmental measures. Ermergin Infectious Diseases. 2020;26(5):967-75. doi: 10.3201/eid2605.190994.
3. Kappstein I. Mund-Nasen-Schutz in der Öffentlichkeit: Keine Hinweise für eine Wirksamkeit. Krankenhaushygiene up2date. 2020;15(03):279-97. doi: 10.1055/a-1174-6591.
4. Cowling BJ, Ali ST, Ng TWY, Tsang TK, Li JCM, Fong MW, et al. Impact assessment of non-pharmaceutical interventions against coronavirus disease 2019 and influenza in Hong Kong: an observational study. The Lancet Public Health. 2020. doi: 10.1016/S2468-2667(20)30090-6.
5. Schrappe M, Francois-Kettner H, Gruhl M, Hart DJ, Knieps F, Manow P, et al. Thesenpapier 4.0: Die Pandemie durch SARS-CoV-2/Covid-19 - der Übergang zur chronischen Phase - Verbesserung der Outcomes in Sicht - Stabile Kontrolle: Würde und Humanität wahren - Diskursverengung vermeiden: Corona nicht politisieren. Köln: www.matthias.schrappe.com, 2020.
6. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, von Buchwald C, Todsen T, Norsk JB, et al. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers. Annals of Internal Medicine. 2020. doi: 10.7326/M20-6817.
7. Schwarz S, Jenetzky E, Krafft H, Maurer T, Martin D. Corona children studies "Co-Ki": First results of a Germany-wide registry on mouth and nose covering (mask) in children. Research Square Preprint. 2021. doi: 10.21203/rs.3.rs-124394/v1.
8. Traindl H. Kohlendioxid-Measurements der Luft unter MNS-Masken [Carbon dioxide measurement of air under standard mouth-nose protection masks]. Vienna: Traindl-consult, 2020 Contract No.: Project Number 303. https://www.afa-zone.at/?smd_process_download=1&download_id=2672
9. Oberrauch B, Adami M, Gutweniger U, Galli E, Dellasega V, Müller H, et al. Ist der Gebrauch von Mund-Nasen-Bedeckungen in der Gesamtbevölkerung eher schädlich als nützlich unter Berücksichtigung der CO_2 Konzentration? Luftqualität während des Tragens von Mund-Nasen-Bedeckungen mit Mini-Review [Does the use of a mask covering mouth and nose confer benefit or harm on the population: Air quality while wearing a nose-mouth coverage and mini-review]. Bolzano: 2020. https://2020news.de/wp-content/uploads/2020/12/DT_Unabha%CC%88ngige-Studie_zur_Mund-Nasen-Bedeckung-1.pdf

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