Study Protocol

Title:	Study of Child Health and Lifestyle during the COVID-19 pandemic
Acronym:	SCHL-COV
Funder:	JSPS KAKENHI Grant Number 21K10441 OYO Electric Co., Ltd.
IRB:	Research Ethics Committee of the Graduate School of Medicine, Chiba University
IRB Number:	3909
Protocol Version:	1.6
Protocol Date:	June 23, 2022
Principal Investigator:	Chisato Mori
Institution:	Department of Bioenvironmental Medicine, Graduate School of Medicine, Chiba University
Office Address:	1-8-1 Inohana, Chuo-ku, Chiba
Telephone:	+81-43-226-2015
Email:	cmori@faculty.chiba-u.jp
Correspondence:	Midori Yamamoto
Institution:	Center for Preventive Medical Sciences, Chiba University
Office Address:	1-33 Yayoi-cho, Inage-ku, Chiba
Telephone:	+81-43-290-3896
Email:	midoriy@faculty.chiba-u.jp

Abbreviations

BDHQ: Brief-type Self-administered Diet History Questionnaire
CAVI: Cardio Ankle Vascular Index
COVID-19: Coronavirus Disease 2019
K6: Kessler Psychological Distress Scale
SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2
QOL: Quality of Life

Table of Contents

1. Background Information

As a measure for the prevention of the spread of the new coronavirus disease (COVID-19) that broke out in Japan in January 2020, schools were temporarily closed and voluntary curfews were implemented in March 2020. This has resulted in a lack of exercise, changes in eating habits, and disrupted lifestyles. Additionally, concerns have arisen about increased stress and depression and decreased quality of life (QOL) due to changes in the home and learning environment and reduced social interaction. The Japan Pediatric Society has highlighted that the indirect health hazards, such as the physical and mental effects of school closures, are expected to outweigh the direct effects of COVID-19 on children. After the emergency declaration was lifted in May 2020, activities gradually resumed, including decentralized school attendance. However, concerns remain regarding the persistent physical and psychological effects of these measures on children. A lack of knowledge persists regarding the relationship between COVID-19 infection status and lifestyle in children, as well as the effects of lifestyle changes on their physical and mental health. This study employs a longitudinal survey of children to gain insights into these abovementioned issues.

2. Study Objectives

(1) Trends over time in COVID-19 infections among children and their relationship with lifestyle and background factors
Outcome measures: Seropositivity of SARS-CoV-2 antibodies

(2) Relationship between lifestyle changes and children's health status following temporary school closures and refraining from going out
Outcome measures: Body size, blood lipids, cardio-ankle vascular index (CAVI), bone mass/bone density, blood vitamin D (25(OH)D), depression, and quality of life.
Exposures: Energy and nutrient intake, eating habits and behavior, physical activity, sleep, electronic media use, and lessons learned

Significance of the Study: To contribute to health and hygiene in the community and school educational settings by providing insights that can aid in infection prevention and the maintenance of the mental and physical well-being of children.

3. Study Population

Participants: Elementary school students
Institution/location for data collection: A university-attached elementary school
Potential subjects/students: 630
Selection criteria: All students
Exclusion criteria: None

Because this study aims to assess children's health, it is essential that children be the participants.

4. Study Procedures

4.1. Observational Study Design

Prospective and retrospective

Longitudinal cohort studies

4.2. Methods

4.2.1 Participant Registration

The explanatory and consent documents for parents and assent documents for children are distributed and collected in elementary schools.

The registration of children is based on written parental consent and the child's written informed assent.

4.2.2 Observation, examination, survey and reporting items and schedule

(1) Background: Grade (years), date of birth, sex

(2) School records: height, weight, medical history, physical fitness, and health examinations (from the first grade of elementary school).

(3) Child’s Questionnaire (3rd grade and above; twice a year in the first year and once a year in the second and third years)

- Health-related quality of life (KIDSCREEN)
- Waking and sleeping times
- Screen time for electronic media and games other than study
- Outdoor activity time
- Dietary Questionnaire (BDHQ15y, completed with parent/guardian)

(4) Parents’ Questionnaire (twice a year for the first year and once a year for the second and third years)

- Basic information: Family structure, parental age, parental education, household income, parental employment status, financial status, and family environment.
- Pet ownership
- Stressful life events
- Depression and anxiety of mothers (K6)
- Children's school attendance, after-school childcare, and lessons
- Children's waking and sleeping times
- Children's screen time for electronic media and games other than learning
- Outdoor activity time
- Eating habits
- Children's stress reactions

- Timing of first menstruation in girls
- History of COVID-19 infection

(5) Physical activity measurement (wearing physical activity trackers for one week)

(6) Blood tests (8 ml collected)

- Anti-SARS-CoV-2 antibodies (IgG, IgM)
- Lipids
- Vitamin D (25(OH)D)

(7) Physical examinations

- Blood pressure
- Height, weight, and abdominal circumference
- Body fat percentage and muscle mass
- Bone mass/density
- CAVI (including heart rate, and upper and lower extremity blood pressure)

4.2.3 Research schedule

	1st year		2nd year	3rd year
	Initial	6 months		
Informed consent/assent	○			
Child's questionnaire (grade 3 and above)	○	○	○	○
Parent's questionnaire	○	○	○	○
Physical activity	○		○	○
Blood test Blood pressure Height/weight/abdominal circumference Bone mass/density CAVI	○		○	○
School records transcription Height, weight, medical history Physical fitness/health checkup	○		○	○

The survey continues after students reach middle school age.

4.2.4 Summary of Analysis

1) Outcome measures (children)

Seropositivity of anti-SARS-CoV-2

Body mass index (BMI)

Blood lipids

Blood vitamin D (25(OH)D)

Stress response and health-related QOL

(2) Analysis Methods

- Annual statistics for anti-SARS-CoV-2 seropositivity
- Multivariate analysis to explore lifestyle, diet-related, and family environment factors associated with outcome.

5. Study Period

1) Subject enrollment period: December 2020

2) Subject observation period: December 2020 – December 2023

3) Period of study implementation: December 2020 – June 2025

Continuation applications will be filed with the IRB for changes to the study plan. An annual report will be submitted annually.

6. Potential Benefits and Disadvantages

- Benefit: Parents will be given a brief report on their children's blood lipid levels, vitamin D levels, blood pressure, body composition, physical activity, and dietary questionnaires.
- Disadvantage: A volume of 8 ml of blood is drawn from the child per year.

7. Informed Consent

- Explanation and consent/assent documents approved by the IRB will be provided to children and their parents throughout elementary school.
  As the school assembly is restricted as a measure to prevent COVID-19 infection, sufficient explanation will be provided in the document only, and any questions will be handled through a telephone inquiry desk.
- Investigators obtain written voluntary consent from the surrogate (the child's parent) and written voluntary assent from the child.
  The investigators explain that the child's wishes should be respected during the decision-making process.

8. Addressing Clinical Adverse Events

As this is not an intervention study, no health hazards are assumed in principle and no special compensation will be provided.

A single blood draw of 8 ml from children is considered safe for health.

If a child feels unwell during blood collection, blood collection should be stopped immediately and appropriate action should be taken by the physician.

9. Protecting Personal Information

(1) Anonymization of samples/data and the possibility of linkage with personal information:
Samples and data collected from participating children or their parents will be collected along with the child's name. However, all samples and data will have their names removed after collection and will be assigned a personal identification number. The personal information and samples/data will be linked in a correspondence table.

(2) Scope of data handlers handling personal information
All data, including personal information, will be handled by the Data Manager of the Chiba University Center for Preventive Medicine.

(3) Handling of data after the withdrawal of consent.
Samples and data will be discarded after the withdrawal of consent, except for data that must be retained for publication of research results. Anonymized samples will be discarded after removing labels and contents. Documents and other materials will be shredded and incinerated, and information stored on external computer storage devices will be deleted. The personal information manager will erase the information stored on the external storage device of the computer.
For participants who have requested to discontinue cooperation, the samples and data collected up to that point will not be discarded and will be used for the research.

(4) Method for managing correspondence tables
Correspondences between personal information and identification numbers shall be stored on a computer that is not linked to another computer.
An external storage device that stores information must be maintained in a locked vault under strict control.

10. Research Funding

Operating expense grants, contracted research expenses, and Grants-in-Aid for scientific research expenses from the Ministry of Education, Culture, Sports, Science, and Technology.

11. Secondary Use of Samples and Information

Secondary use of the samples and information and their provision to other research institutions has not been planned.

12. Research Organization

Center for Preventive Medical Sciences, Chiba University
Department of Bioenvironmental Medicine, Graduate School of Medicine, Chiba University
Department of Clinical Medicine, Faculty of Education, Chiba University

Attached Elementary School of Faculty of Education, Chiba University
Faculty of Nutrition, Kagawa Nutrition University
OYO Electric Co., Ltd.
Fukuda Denshi Co., Ltd.

13. Storage of Records

(1) Storage of documents
Person responsible for storage: Chisato Mori
Storage location: Locked vaults in the data room at the Center for Preventive Medicine
Storage period: 10 years

(2) Sample Storage
Samples: Blood, plasma, serum
Person responsible for storage: Chisato Mori
Storage location: Locked biobank room at the Center for Preventive Medicine
Storage period: 10 years

14. Publication of Research Results

The results will be presented in academic papers and at conferences. Information that can identify individuals will not be included in the content of the presentation.

15. Financial Burdens or Payments for Study Population

There is no cost to participants.
There will be a cost for recharging the physical activity trackers.
No rewards will be given for participation in the study.