Official Title of the study

Cities for Better Health

Childhood Obesity Prevention Initiative in JAPAN

NCT number: NCT06855563

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[LATEST VERSION AS OF 9 Sep 2026]

Context

The Cities for Better Health Childhood Obesity Prevention Initiative (CBH COPI) is a multi-country DAS based on primary data collection in accordance with Disease Area Studies (DAS) Standard. CBH COPI is a global study including an initial six countries of Australia, Brazil, Canada, Japan, South Africa, and Spain.

A Global Study Protocol is prepared by the Global Implementing Partner (the Behavioural Insights Team and Delivery Associates), reviewed by the CBH COPI Study Group (LKKS, CFBQ, JSDP), endorsed by the Lead Study Manager (JHVT) and approved by the Line of Business Head in Obesity Health Equity (JJWL). The Global Study Protocol is further registered at ClinicalTrials.Gov (NCT06855563).

A Local Study Protocol for Japan is intended to follow the overarching principles and methodological framework for country-level studies provided by the Global Study Protocol. This is to ensure that country-level studies are conducted to a high standard and in a consistent manner so that meaningful global-level meta-analyses can be conducted. The Local Study Protocol in Japan is based on a template that references the Global Protocol and follows DAS SOP 0359335 and is intended to be used externally and submitted to ethics committees and other relevant external bodies.

The local study protocol in Japan was developed by Chiba University in collaboration with the Behavioural Insights Team, with input from Novo Nordisk affiliates in Japan (YON) and local stakeholders, reviewed and approved by the Principal Investigator (JHVT), and endorsed by the Head of the Obesity Health Equity Project (JJWL).

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1 List of Abbreviations

BIT	Behavioural Insights Team
BMI	Body Mass Index
CBH	Cities for Better Health
COPI	Childhood Obesity Prevention Initiative
DA	Delivery Associates, Inc.
DALY	Disability Adjusted Life Year
DAS	Disease Area Studies
DiD	Difference-in-Differences Analysis
DQQ	Diet Quality Questionnaire
GDR	Global Dietary Recommendations
GIP	Global Implementation Partners
HRQoL	Health-Related Quality of Life
JHSD	Junior High School District
MLMC	Multi-Level Multi-Component
MVPA	Moderate to Vigorous Physical Activity
NN	Novo Nordisk A/S
OHE	Obesity Health Equity
QALY	Quality-adjusted life year
RCTs	Randomised controlled trials
SOPs	Standard Operating Procedures
SSB	Sugar-sweetened beverages
ToC	Theory of Change
WHO	World Health Organization

2 Disease Area Study

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3 Study Information

Title	Cities for Better Health Childhood Obesity Prevention Initiative (CBH COPI)
Universal Trial Number	NCT06855563
Protocol version number	V2.0
Last updated	9 Sep 2026
Research questions and objectives	RQs and objectives • Primary research objective: estimate the impact of intervention package on average BMI of the target population of children • Secondary research objective: estimate the impact of intervention package on average health-related quality of life of the target population of children • Exploratory research objectives: estimate the impact of intervention package on behaviours related to physical activity and diet for the target population of children; model the long-term effects on quality-adjusted and disability-adjusted life years, and the incidence of non-communicable conditions; examine cost-effectiveness
Country of study	Japan

4 Abstract/Synopsis

CBH COPI Overview

- The Cities for Better Health Childhood Obesity Prevention Initiative (CBH COPI) is a multi-country 3-year prevention and intervention project targeting childhood obesity through dietary and physical activity interventions in communities facing challenging conditions in urban areas. One-third of overweight and obese children and teenagers live in urban areas (estimated based on UNICEF (2022) and WHO (2024)). This initiative seeks to develop, implement, and evaluate evidence-based interventions tailored to each urban community in difficult situations (challenging conditions defined differently in Japan) in an initial set of countries (Australia, Brazil, Canada, Japan, South Africa, and Spain). If successful, this model is expected to be expanded within each country and to other countries and regions. To support this initiative, Novo Nordisk A/S (NN) is working with a consortium of Delivery Associates (DA) and the Behavioural Insights Team (BIT) as the Global Implementation Partner (GIP), driving the project's implementation in each of the countries.
- As part of CBH COPI, (i) the development and delivery of the intervention package will be monitored, and (ii) a monitoring and evaluation strategy will be devised and implemented to estimate the impact of CBH COPI on children's diet, physical activity, health-related quality of life, and weight.
- Each country will develop and implement locally adapted monitoring and evaluation surveys (summarized in the Local Study Protocols), in accordance with the strategies outlined in the Global Study Protocol and the requirements of the global framework to the extent possible. The results from each country-level study will be aggregated for a global analysis to estimate the program-level impact of CBH COPI.

Intervention Requirements

[The intervention package has not yet been finalised and remains subject to change.]

CBH COPI in Chiba City is an evidence-based, multi-level intervention project targeting children, with a primary focus on their surrounding environments. The interventions currently being planned are as follows:

Intervention sites	**Intervention description**
Elementary schools	In consultation with each elementary school, initiatives related to physical activity and diet will be implemented within the scope of the national curriculum guidelines. ・Super Hopscotch: Install foot-shaped signs and other markings on outdoor surfaces between the entrance/exit and school gates, as well as in the gymnasium—areas children frequent during daily school life. Place guides nearby explaining how to play and indicating difficulty levels, creating a safe and enjoyable play space. ・Playground Equipment Completion Card: Place numbered stickers on each piece of playground equipment, matching them to numbers on the completion card. Calendar-style Playground Equipment Completion Cards are distributed to children, who check off the numbers of the equipment they played on each day. ・ Bug & Find Journal: Distribute sketchbook-style “Bug & Find Journals” to children. They sketch insects or flowers found that day. Award stickers (Silver, Gold, Diamond) based on the number of sketches completed. Additionally, place a “Bug & Find Map” in the classroom where children place stickers marking their discovery locations. ・Outreach Lesson *Target schools: 2 of the 11 eligible schools *Participants: All students in Grade 5 and above *Activity: A lesson on the importance of having a well-balanced diet. During the lesson, students from the participating schools will create POPs (small promotional cards or signs placed next to products).
Parks	In consultation with Chiba City, an environment that naturally encourages healthy choices will be fostered through modifications to city-managed facilities and awareness campaigns. • Standing long jump: Mark a measurable distance for standing long jump on the pavement to create a fun and challenging environment.

	• Slalom (line walking/running): Draw lines using shapes such as triangles, circles, and squares to create a path where children can walk or run along the line. • Footprint maze: Children follow colored lines and shapes drawn on the ground to reach a goal, combining visual cues with physical movement. • One-leg walking (balance walking): Place footprints on a curb about 10–20 cm wide, allowing children to move forward by alternating one leg along the footprints. • Stair climbing: Display multiplication tables, English words, or phrases on the risers or sides of stairs to encourage children to climb them. • 25 m run: Mark a 25-meter distance on the pavement to create a fun running environment. • Hopscotch 1 (numbers/patterns): Draw numbers and shapes (e.g., diamonds) on the pavement so children can combine one-leg and two-leg jumps. • Hopscotch 2 (footprints): Place footprints in multiple directions at short intervals so children can move by jumping with both feet. • Target throwing: Children throw balls or frisbees toward the center of a target and compete for points.
Ambassador Program	In partnership with supermarkets in the junior high school districts where the target elementary schools are located, initiatives will be implemented to encourage healthy choices. • • Implement a Kids Ambassador Program ➢ Target: Approximately 22 students in total (2 students from each of the 11 target schools) ➢ Recruitment: Open to all 4th and 5th grade students ➢ Implementation and dissemination process: ➢ Ambassadors learn, experience, and share through a 3-day program ➢ The organizing team compiles the activities (e.g., creating videos and posters) ➢ Share within the school (poster displays, video screenings, presentations by ambassadors, etc.)
Home	In consultation with each elementary school or community partner, support will be provided to foster healthy habits within each household. • Provide tools to manage lifestyle habits, including the habit-forming app "Min-Challe," which allows anonymous teams of up to five users with a shared goal to report their daily achievements to each other by sharing photos (https://minchalle.com/).
Chiba University Academy	- Target participants: Students from the intervention schools and the Chiba University Elementary School. - Three lectures are planned. - A Ken-Ken-Pa (hopscotch) course will be installed at the affiliated elementary school, or a simplified mat version will be used for hands-on activities. - An experiential booth will allow participants to experience the intervention components, with the aim of increasing the intensity and engagement of the intervention.

CBH COPI Milestones

CBH COPI launched in March 2024 as a three-year (2025-2028) project with six initial participating countries (Australia, Brazil, Canada, Japan, South Africa, and Spain):

- The mobilization phase (including the development of interventions and field research protocols) was implemented from April 2024 to March 2025.
- Baseline data collection is expected to be complete by September 2025, to be followed as soon as possible by intervention implementation.
- The first follow-up data collection is expected to be complete by September 2026, with dissemination of study results (i.e. submission to peer-reviewed journals) by March 2027.
- The second follow-up data collection is expected to be complete by September 2027, with dissemination of results (i.e. submission to peer-reviewed journals) in March 2028.

Local Study Protocol Overview

Background

In recent years, childhood obesity has become a serious global health issue. According to the World Health Organization (WHO), more than 379 million children and adolescents were reported to be obese in 2022 (WHO, 2022)[1], with obesity rates among 5- to 19-year-olds increasing by 5% each year. Overweight and obesity contribute to approximately 2.3% of the global disability-adjusted life years (DALYs) (WHO, 2024)[2] and increase the risk of serious health issues such as cardiovascular disease and type 2 diabetes.

In Japan, childhood obesity is also an important health issue. The final evaluation of the "Healthy Future City Chiba Plan" (Planning Period: FY2013–FY2023) formulated by Chiba City found no improvement in the indicators for children with tendencies toward obesity. Specifically, in Chiba City, the percentage of fifth-grade elementary school children with a moderate to severe tendency toward obesity increased from 4.3% to 6.7% for boys and 3.0% to 3.6% for girls between FY2011 and FY2021. However, since this evaluation is based on a baseline and post comparison, it is entirely

[1] WHO. (2022). *World Obesity Day 2022 – Accelerating action to stop obesity*. https://www.who.int/news/item/04-03-2022-world-obesity-day-2022-accelerating-action-to-stop-obesity

[2] WHO. (2024). *Indicator Metadata Registry Details*. https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3420

possible that the "Healthy Future City Chiba Plan" helped to mitigate obesity rates (in other words, without this initiative, the obesity rates might have increased even further). These data suggest the continuing importance of local childhood obesity prevention measures.

To address this issue, including in Japan, Novo Nordisk Pharma Ltd. is promoting the Cities for Better Health Childhood Obesity Prevention Initiative (CBH COPI) project, which carries out a package of multi-level interventions based on a common framework tailored to the regional characteristics of six countries: Australia, Brazil, Canada, Japan, South Africa, and Spain. In Japan, in October 2024, Chiba City, Chiba University, and Novo Nordisk Pharma Ltd. signed a "Partnership Agreement on Obesity and Obesity Prevention" and agreed to implement CBH COPI in Chiba City. Interventions based on the CBH COPI methodology will be implemented in Chiba City in collaboration with its Smart City Promotion Division, and the results will be integrated with data from five other countries for a comprehensive global analysis. This integrated analysis of multinational data is expected to generate evidence that will contribute to a global childhood obesity control strategy through community-based solutions.

Research Objectives and Key Indicators

The objective of the CBH COPI Japan is to develop, implement, and evaluate the effectiveness of a preventive intervention package to promote healthy eating, physical activity, health-related quality of life, and reduction of overweight and obesity rates among children aged 6-12 in Chiba City, Japan.

- The primary study objective is to estimate the impact of the CBH COPI intervention package on the average BMI of children in the target population in Japan at 1-year and 2-year follow-up. The corresponding primary outcome is BMI-z (adjusted for age and gender).
- The secondary research objective is to estimate the impact of the CBH COPI intervention package on the average health-related quality of life (HRQoL) of children in the target population in Japan at 1-year and 2-year follow-up. HRQoL will be proxied by the total score from the KIDSCREEN-10.
- Exploratory research objectives include estimating the impact of the CBH COPI intervention package on the physical activity and dietary behaviors of children in the target population in Japan at follow-up times of one year and two years. These behaviors are associated with the likelihood of living with overweight/obesity. Physical activity outcomes will be measured using the Core Indicators and Measures of Youth Health – Physical Activity & Sedentary Behaviour Module questionnaire. Diet outcomes

will be measured using the Diet Quality Questionnaire (DQQ) (children aged 6-9 will receive a simplified version).

- In addition, University of Oxford will model the impact of CBH COPI on quality-adjusted life years (QALYs) and health care savings, disability-adjusted life years (DALYs), and risk of noncommunicable diseases such as cardiovascular disease (CVD) and type 2 diabetes (T2D) in Japan. A cost-effectiveness analysis may also be conducted.

Study Design

There are 107 public elementary schools across 56 Junior High School Districts (JHSDs), all located within the six wards of Chiba City. In this study, interventions are implemented at the JHSD level. We selected 22 JHSDs - 20 based on an initial power calculation (detailed in the 'Power and sample' part of this abstract), with an additional 2 to account for potential attrition/drop-out - based on the presence of key intervention points including supermarkets, parks, and/or after-school programmes. These 22 JHSDs will be randomly assigned to intervention and control groups (11 each), with randomisation stratified by ward to ensure balanced geographical coverage across groups. Data will be collected from one elementary school within each JHSD/cluster (i.e. one school per cluster) through online surveys (Microsoft Forms). The target is to obtain at least 100 valid responses per school, defined as surveys with signed consent forms and all required fields completed. To maximise statistical power, we will continue recruiting participants until we reach the cap of 150 responses per school before the expected survey closure on [Baseline: 14th July - 30th Sept 2025; 1-year follow up: 13th July - 30th Sept 2026; 2-year follow up: 12th July - 30th Sept 2027]. Recruitment will primarily involve printed flyers distributed to children at schools and if possible Suguru, a school broadcasting app, and sending follow-up reminders to encourage participation both in paper and Suguru. We are currently estimating a 30% response rate per school. Based on school enrolment numbers in the 2025/2026 academic year, this means 4 schools/JHSDs across 3 wards may fall short of the 100 response target.

If the total sample falls short of the minimum target of 2,200 valid responses (100 per cluster across 22 clusters), we may raise the cap in schools that have already reached 150 to help meet the overall sample target and maximise statistical power. Furthermore, where available, administrative school records will be used as the primary source for height and weight data to calculate BMI z-scores. This will allow us to observe BMI z-scores of all students; however, survey responses are still required to measure the secondary and exploratory outcomes (HRQoL, physical activity and diet measures), as well as covariates.

Data Sources

- All data will be collected through a single online survey (MS Forms) completed by children with the support of their parents or caregivers. This includes the primary outcome (BMI-z adjusted for age and gender), secondary outcome (HRQoL), exploratory outcomes (measures related to physical activity and diet), demographics, and additional indicators (e.g. household income). For the BMI-z measure, parents will be asked to input their child's height and weight using official school health records sent home after annual check-ups. If these records are not available, parents will be guided to measure height and weight themselves following instructions provided within the survey.

Power and Sample

- Our goal is to achieve at least 100 valid responses per cluster, with a maximum of 150 responses per cluster due to incentive constraints. This aligns with the original power calculation, which was based on detecting a Cohen's d of 0.15 using 20 clusters, each with 100 observations, and assuming 80% power. To account for potential attrition - particularly in the control group - two additional clusters were added, increasing the total to 22 clusters, whilst keeping the target of 100 observations per cluster. This reduced the minimum detectable effect size (MDES) to 0.144.

  As the study progressed, an additional power calculation was conducted to simulate key aspects of this study more accurately including:

  - Stratified randomisation by ward
  - Actual student enrolment numbers per school/JHSD (for the 2025/2026 academic year)
  - A refined recruitment/data collection procedure to allow for the 30% expected response rate
  - A cap of 150 survey responses per school due to budgeted incentives

  Under these updated assumptions, the MDES was further reduced to approximately Cohen's d = 0.140. This reflects the expected sensitivity of the study if roughly 30% of children in each cluster (capped at 150) respond. Despite this update, our recruitment goal remains

unchanged: we aim to achieve at least 100 valid responses and will continue recruiting up to the 150 response cap to maximise power.

- The target population for this study is children aged 6 to 12 years old in Japan, which corresponds to the full range of Japan elementary school grades (grade 1 through grade 6). Although the initial target age range was defined by the global study as 6-13, the scope was narrowed to focus solely on elementary school students. This avoids the need to involve secondary school students. A minimum of 2,200 children (with at least 100 valid responses per cluster) will be sampled from the selected 22 JHSDs in Chiba City with elementary schools as the data collection sites.

Analysis

Country-level analyses will be conducted using individual-level repeated cross-sectional data. The primary analysis will use ANCOVA regression models, complemented by baseline descriptive analysis, subgroup analyses, and sensitivity analysis where appropriate. To support pooled estimates in the global-level meta analyses, we will also run difference-in-differences (DiD) models. These estimates will not be used for country-level inference but will serve as inputs for the global meta-analysis. Where participant responses can be linked across years, longitudinal analysis will be conducted as well. However, this is not the primary focus of the study due to uncertainty around attrition in the longitudinal sample.

Publications

Findings will be submitted for publication in peer-reviewed international journals by December 2027. Potential targets include the International Journal of Public Health, BMC Public Health, and Public Health Nutrition. The Japan team will produce publications with the findings from the study in Japan. The publications that are currently planned are:

- **Local Study Protocol Development Paper (Led by Chiba University):** This paper will reflect the content of the Theory of Change (ToC) of the intervention program, with submission targeted for Q1 2026. Specifically, it will include details about the program's development, monitoring and evaluation, key components of the framework, and results from baseline data collection.

- **Local Study Impact Evaluation Paper (Led by Chiba University):** This paper will focus on the impact evaluation of CBH COPI in Japan at the 1-year and/or 2-year follow-ups, with submission targeted for Q4 2027.

There will also be separate publications for global findings that capture the overall impact of the programme. To ensure this goes ahead, we will pre-register this study on the ClinicalTrials.gov in advance before the enrollment of the first participant (i.e. allocation, data collection).

5 Key Milestones

Table 1. Key milestones

	Milestone	**Timing**
1	**Kick-off phase** *Onboarding of affiliates and the GIP*	By June 2024
2	**Mobilisation phase** ● *Identification & onboarding of local academic partners* ● *Define scope of study* ● *Develop interventions* ● *Develop and refine global/local study protocols* ● *Obtain ethical and data collection approvals from relevant bodies*	By March 2025
3	**Baseline and start of data collection** ● *Baseline data will be collected (month 0)* ● *Monitor intervention implementation*	14th July to **30th Sept 2025**
4	**1st follow-up: data collection** ● *Follow-up data will be collected (month 10-12)*	13th July to 30th Sept 2026
5	**1st follow-up: dissemination of study results** ● *Findings from baseline and 1st follow-up will be reported at global level (including analysis of pooled data from the six countries), and at local level (including analysis of local data)*	By March 2027
6	**2nd follow-up: end of data collection** ● *Follow-up data will be collected (month 20-24)*	Expected by August 2027
7	**2nd follow-up: dissemination of study results** ● *Findings from 2nd follow-up will be reported at global level (including analysis of pooled data from the six countries), and at local level (including analysis of local data)* ● *Review programme results* ● *Scale as appropriate*	By March 2028

6 Rationale and Background

Childhood obesity has become a serious global health issue. According to the World Health Organization (WHO), over 379 million children and adolescents were reported to be obese in 2022, and the obesity rate among 5- to 19-year-olds has been increasing by 5% annually. Overweight and obesity account for around 2.3% of global disability-adjusted life years (DALYs) and significantly raise the risk of conditions such as cardiovascular disease and type 2 diabetes. Research shows that community-level, evidence-based prevention strategies can reduce the risk of childhood obesity (Russel et al., 2023[3]; Ananthapavan et al., 2017[4]). Even small reductions in body mass index (BMI), when applied at scale, can lead to meaningful decreases in long-term health risks (e.g. cardiovascular diseases (CVD) and type 2 diabetes (T2D)) (Russel et al., 2023; Ananthapavan et al., 2017).

In Japan, childhood obesity remains a pressing concern. The final evaluation of Chiba City's "Healthy Future City Plan" (2013–2023) showed no improvement in obesity rates. Among 5th-grade students, the obesity rate rose from 4.3% to 6.7% for boys and from 3.0% to 3.6% for girls between FY2011 and FY2021 — indicating a worsening trend and the need for targeted local interventions. To address this global issue, Novo Nordisk Pharma Ltd. launched the *Cities for Better Health: Childhood Obesity Prevention Initiative (CBH COPI)*, applying a shared intervention framework tailored to six countries: Australia, Brazil, Canada, Japan, South Africa, and Spain.

In Japan, Chiba City, Chiba University, and Novo Nordisk Pharma Ltd. signed a "Partnership Agreement on Obesity and Obesity Prevention" in October 2024 to implement CBH COPI locally. The Chiba initiative will follow the CBH COPI framework, with results integrated into a broader international analysis. This global collaboration aims to build robust evidence for effective childhood obesity prevention strategies worldwide.

[3] Russell, S. J., Mytton, O. T., & Viner, R. M. (2023). Estimating the effects of preventive and weight-management interventions on the prevalence of childhood obesity in England: A modelling study. *The Lancet Public Health*, *8*(11), e878–e888. https://doi.org/10.1016/S2468-2667(23)00216-5

[4] Ananthapavan, J., Sacks, G., Brown, V., Moodie, M., Nguyen, T. M. P., Barendreg, J., Veerman, J. L., Herrera, A. M. M., Lal, A., Peeters, A., & Carter, R. (2018). *Assessing cost-effectiveness of obesity prevention policies in Australia* (Australia) [Report]. Deakin University. https://apo.org.au/node/210491

Theory of Change

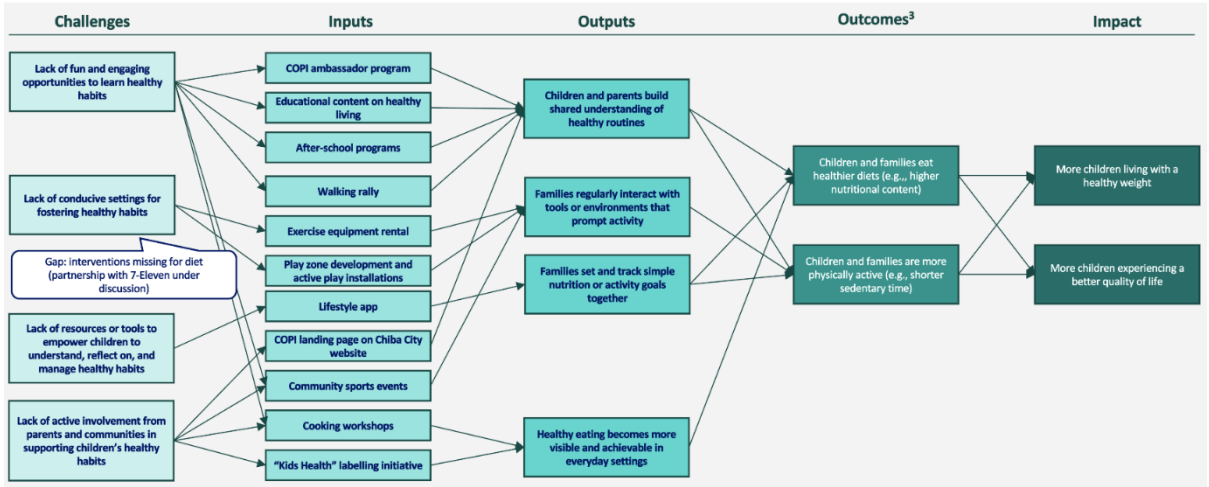
[This Theory of Change has not yet been finalised and remains subject to change.]

Evidence-informed global and local theories of change (ToC) has been outlined to comprehensively describe what is in scope for the project objectives, including how and why a desired change at short, medium, and long-term is expected (see illustration below). These were developed with reference to the theoretical COM-B Model for Behaviour Change identifying capability (C), opportunity (O) and motivation (M) as three key factors to changing behaviour (B).

Figure 1. Global Theory of Change (ToC)



Figure 2. Local Theory of Change (ToC) for Japan



7 Research Questions and Objectives

The purpose of this project is to develop, implement, and evaluate the effectiveness of a package of prevention interventions among children aged 6-12 years living in Chiba City, Japan. The CBH COPI intervention packages are intended to promote healthy eating, physical activity, a positive health-related quality of life, and a reduction in rates of living with overweight or obesity. The Japan team aims to implement a multi-level approach focusing on the environment around the children such as family, schools, parks and supermarkets.

Global-level requirements for the intervention packages are:

- They must be multi-level (i.e. targeting at least two of individual, external and structural environments).
- They must be multi-component (i.e. targeting both healthy diet and physical activity, with individual interventions targeting diet and/or physical activity)
- They must be co-created by the communities in which interventions are implemented (inter-sectorial partners such as universities, local government etc.)
- They must be health equity oriented in terms of both access and improvement (i.e. interventions are implemented with and in disadvantaged communities, targeting multiple levels).

7.1 Primary Objective

The primary research objective of this study is to estimate the impact of the CBH COPI intervention packages on the average BMI of 6-12 years old children in Japan, at one-year and two-year follow-ups.

The intervention packages aim to reduce the average BMI of the target population by:

- (i) Reducing BMI for children living with overweight or obesity
- (ii) Maintaining BMI for children with a normal weight status (between –2 standard deviations and 1 standard deviation of the normal weight BMI z-score for their sex and age, following the WHO definition)
- (iii) Reducing the proportion of children living with overweight or obesity

7.2 Secondary Objective

The secondary objective is to estimate the impact of the CBH COPI intervention package on the average health-related quality of life (HRQoL) of children in the study population in Japan, with follow-up at 1 year and 2 years.

7.3 Exploratory Objectives

Exploratory objectives include estimating the impact of the CBH COPI intervention package on the physical activity and dietary behaviors of children in the study population in Japan, with follow-up at 1 year and 2 years. Additionally, the study aims to model the long-term effects of the CBH COPI intervention package on quality-adjusted life years (QALYs), disability-adjusted life years (DALYs), and the incidence of non-communicable diseases in Japan. This will be conducted as part of the global study.

8 Research Methods

8.1 Study Design

There are 107 public elementary schools across 56 JHSDs, all located within six wards in Chiba City. Based on the initial power calculations, the target effect size (Cohen's d = 0.15) can be detected with 80% power using 20 JHSDs. However, to guard against potential attrition during the study, 2 more JHSDs were recruited, bringing the total to 22. By default, data will be collected from these 22 JHSDs. In this study, the intervention package will be implemented at the JHSD level, meaning that the allocation to intervention and control will also occur at the JHSD level, which serves as the unit of clustering in the analysis. Throughout this protocol, the terms 'JHSD' and 'cluster' are used interchangeably.

8.1.1 Selection Procedure for the 22 Clusters (JHSDs)

A total of 22 clusters in Chiba City were shortlisted based on the criteria below:

- They contained schools that were willing to participate in the programme

- They contained supermarkets suitable for retail-based interventions (a criteria that was later relaxed)
- They contained district or neighbourhood parks large enough to support community-based activities
- The quality and connectivity of green spaces, parks, and recreational infrastructure was assessed to be conducive to intervention delivery
- One school per cluster was selected for data collection. Schools with larger student enrolment numbers and existing after-school programmes were prioritised.

8.1.2 Allocation Method

The allocation method is a clustered RCT, stratified by ward: within each ward, JHSDs will be randomly allocated to intervention and control groups.

1. **Stratification by ward:**

The 22 clusters (JHSDs) will be randomly allocated to the intervention and control groups with stratification by ward. Stratification by ward serves three functions: 1) ensures balanced geographical coverage between intervention and control groups; 2) enhances equity (i.e. ensures the intervention reaches a diverse set of communities) and; 3) enhances balance on potential baseline differences in health indicators (e.g. BMI) and sociodemographic attributes.

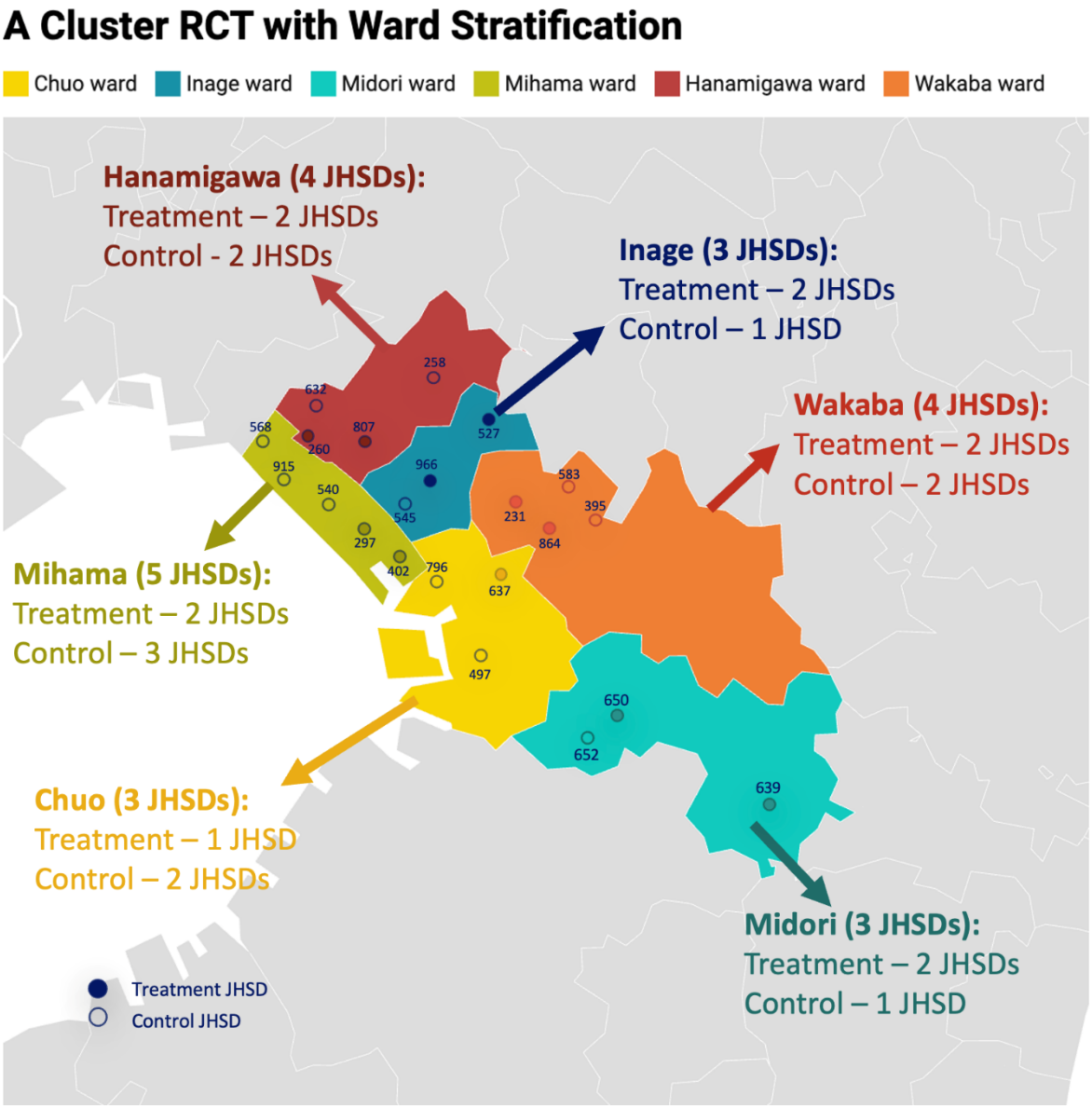
Random allocation was chosen to strengthen causal inference. Within each ward, clusters will be randomly allocated to intervention and control with the following rule:

- Wards with an even number of clusters will be allocated on a 50:50 ratio to intervention and control
- Wards with an odd number of clusters will choose one option randomly:
    - *(n*+1) intervention + n* control*
    - *n* intervention + (n*+1) control*

Where n* is the (number of clusters - 1)/2.

This process will yield 11 intervention and 11 control clusters.

Figure 3. Randomisation visualisation



Note: This cluster RCT shows the final allocation of JHSDs to intervention and control groups, with schools serving as the point of data collection, using current student enrolment figures from the 2025/2026 academic year.

2. Balancing the number of students:

Whilst stratification helps to achieve a balanced mix of clusters from more and less populated wards, this study will also calculate the relative imbalance in student enrolment between intervention and control groups to ensure that the two groups are roughly equal in student numbers. This is done using the formula: relative imbalance = (larger group size ÷ smaller group size) - 1. For example, if the

intervention group has 1,100 students and the control group has 1,000, the imbalance is (1,100/1,000) - 1 = 0.1, or 10%. If the calculated relative imbalance exceeds 10%, the randomisation is discarded and repeated. This process continues until the relative imbalance is 10% or less. 10% was judged to be a threshold small enough to conclude that groups are fairly balanced without being overly restrictive.

The following steps will be taken to perform the allocation in R:

1. Generate all possible randomisation patterns assigning the 22 JHSDs into 11 intervention and 11 control groups, following the ward-based stratification described above.
2. Calculate the total number of students assigned to the intervention and control groups for each randomisation pattern.
3. Exclude randomisation patterns where the relative imbalance between intervention and control groups exceeds 10%.
4. Randomly select one pattern from the filtered pool, and verify that the selected pattern meets all criteria.

Final allocation is found in Annex 1.

8.2 Participants and Consent

This study aims to assess the impact of the intervention package on its target population: children aged 6–12 in Japan. Chiba was selected as the study site due to its suitability for school-based interventions. The primary survey participants will be children aged 6 to 12 years (Grades 1–6) enrolled in public elementary schools across the selected 22 JHSDs. As of May 2025, all 22 schools have been successfully recruited. Parents or guardians must provide informed consent for their child's participation by completing a digital consent form embedded at the beginning of the survey.

8.2.1 Inclusion Criteria

- The child and parent who can read Japanese
- The child attends a participating school
- The child is aged 6–12 years at the time of consent (inclusive).
- The parent or guardian has completed the required consent form.

8.2.2 Exclusion Criteria

- Consent form is incomplete or missing.
- The child refuses to participate or their guardian withdraws consent at any point, as outlined in the informed consent process.

8.2.3 Withdrawal Criteria

Withdrawal from the study occurs in the context of participation in data collection and measurement. Criteria for discontinuation of participation in the study are as follows:

- Parental request: At any point during the study, a parent or guardian may request that the child be withdrawn from the research data collection process. This decision need not be justified and will be honored immediately. Parents/guardians are encouraged to discuss the reasons for withdrawal with the research team to address any concerns that may apply to other participants.
- Child's request: If a child requests to withdraw from the research data collection, the child's request will be honored.

The withdrawal procedure is as follows:

- If a parent wishes to withdraw their data, they must contact CU and provide their email address along with other identifiable information (i.e. child's school, sex, birth month/year) to allow CU to locate the corresponding survey response. CU will then remove the data from the dataset and issue a confirmation email, including a PDF document verifying the data deletion, in accordance with CU Ethics Committee requirements. Any concerns expressed by the child that led to the discussion of withdrawal should be documented and addressed accordingly. However, in Japan, surveys are completed at home, and there is little likelihood of parents contacting Chiba University unless they actively choose to do so.

- **Data Handling:**

  Before data analysis, individual-level data will be anonymised by removing email addresses and replacing school names with school IDs to ensure that researchers cannot identify individuals. Once anonymisation is complete, individuals cannot be identified, and data points cannot be removed, even upon parental request. At CU, anonymisation will not take

place until all three waves of data collection are complete — baseline (2025), first follow-up (2026), and second follow-up (2027) — with anonymisation scheduled for [October 2027].

For baseline data

On the other hand, a copied version of the CU dataset, held by GIP, will be anonymised at each data point, with baseline anonymisation scheduled for November 2025. For baseline data, data points can be removed from both CU's and GIP's datasets upon parental request until November 2025. After this point, removal of baseline data will only be possible from CU's dataset (until CU anonymise data in 2027).

For 1-year follow up data

a copied version of the CU dataset, held by GIP, will be anonymised at each data point, with baseline anonymisation scheduled for November 2026. For 1-year follow up data, data points can be removed from both CU's and GIP's datasets upon parental request until November 2026. After this point, removal of baseline data will only be possible from CU's dataset (until CU anonymise data in 2027).

This process and timeline will be clearly communicated to parents through the consent form provided at the start of the survey in Section 7 (4) "Data retention period" as below:

For baseline data*"If you wish to have your child's data deleted, it can be removed from both Chiba University's and BIT's datasets until November 2025. From November 2025 to September 2027, data can only be removed from Chiba University's dataset.*

For 1-year follow up data

"If you wish to have your child's data deleted, it can be removed from both Chiba University's and BIT's datasets until November 2026. From November 2026 to September 2027, data can only be removed from Chiba University's dataset.

From October 2027 onwards, the data will have been processed in a way that no individuals can be identified, and it will be used for analysis. At that point, data deletion will no longer be possible. Thank you for your understanding."

- Continued support: Withdrawal from the study does not affect the child's access to standard dietary or educational services or to elements of the intervention package.

8.3 Data Collection Procedure

[See Annex 3 for the latest data collection procedure updates]

Data collection will comprise four phases:

- **Phase 1:** During this phase, CU and NNPL will confirm data availability with each school - specifically, whether and when BMI-related data will be accessible to parents. They will also coordinate survey and reminder distribution methods (e.g. printed flyers, school broadcasting apps like Suguru), based on each school's preferences. Once agreed, CU will finalise the data collection timeline, including the survey open date and duration, as well as incentive distribution rules. CU will then prepare briefing materials (e.g. a video, slides) for schools. These will clearly outline the overall study, school's role in the study, key tasks and timelines, survey procedures, incentive rules, and reminder strategies. These materials will also include clear instructions for schools on how to support participant recruitment.

    - A school-specific survey link
    - A copy of the consent form and survey questionnaire
    - CU's contact details
    - Overall explanation of the study
    - A PDF flyer with a QR code

- **Phase 2:** In this phase, schools will distribute the printed flyers to parents via their children. Schools are asked to email CU/NNPL to confirm that flyer distribution has been completed. If no confirmation is received, CU/NNPL may send a follow-up email to request it. This phrase is expected to take at least a week.

- **Phase 3:** During this phase, parents will complete the survey. CU will conduct monitoring checks on a daily basis to determine whether the maximum threshold for responses has been reached (responses for 150 children per school). In the first or second week of data collection, CU will anonymise the data using the method outlined in Section 10.1 and will share the anonymised data with BIT through MS Teams SharePoint with access restrictions (i.e. restricted folder). This will be completed no later than the third week of data collection. BIT will then review the data and provide feedback to CU, including any necessary amendments to the survey.

In this phase, schools will also send reminders to parents using both printed flyers and Suguru. In parallel, CU will continue to respond to parent inquiries, including data deletion requests, via email or phone, and provide support with any questions received. CU will also compile a list of parent email addresses and send confirmation emails to those who have completed the survey, within three days of their response.

- **Phase 4:** During this final phase, the survey will be closed, and data will be cleaned. CU will conduct data analysis and share data after anonymisation. This is expected to be completed by November 2025(baseline data), November 2026(1-year follow up data), November 2027(2-year follow up data).

These phases are expected to be repeated for the follow-up data collection waves though specific details may be adjusted based on efficiency and feasibility. The following sections of the protocol detail how each of the key tasks above will be delivered.

8.3.1 Sampling

Data will be collected at three time points:

- Baseline (pre-intervention) data will be collected from July 2025
- One-year follow-up data will be collected from July 2026
- Two-year follow-up data will be collected (from [month TBC] 2027)

Baseline data collection will take place in both intervention and control groups before the intervention is implemented. Our primary sampling is a repeated cross-sectional approach, in which survey data are collected from a new group of children at each data collection point. A key limitation of this approach is that changes in outcomes over time could reflect differences in who was surveyed at each time point rather than the true impact of the intervention. To account for this, the primary statistical analysis will compare post-intervention outcomes between intervention and control groups whilst controlling for baseline measures at the cluster level. In cases where the same participants respond across multiple rounds, we will also conduct a longitudinal analysis, as described in Section 10.2.4; however, the main analysis will remain cross-sectional due to uncertainties around longitudinal attrition and its impact on statistical power.

8.3.2 Recruitment and Reminder System

[This section has been updated on 8th September 2026. See annex for the change]

This study aims to collect at least 100 valid responses per school (i.e. per cluster/JHSD), in line with the original power calculation assumptions. To maximise statistical power within the available incentive budget, recruitment will continue until the cap of 150 responses per school is reached. Participants will be recruited mainly through printed flyers. For the baseline data, as of June 2025, Chiba City has confirmed that they are able to send reminders using Suguru. For the 1-year follow up data, as of May 2026, Chiba City has confirmed that they are able to send reminders using Suguru.

Printed Flyers

The flyer design has been pre-approved by the ethics committee and includes the following:

- An explanation of the overall study
- A survey and a contact form QR codes as well as a survey URL (unique to each school)
- Estimated time to complete the survey
- Survey deadline
- Incentive details (amount and cap)
- CU contact information

For the baseline and 1-year follow up data, Flyers will be distributed to parents via their children on the official survey start dates of 14th July 2025 and 13 July 2026. Schools are required to notify CU via email once the initial flyer distribution is complete. To enable reminders, CU will send reminder flyers in the final week of August or the first week of September to schools that have not yet reached 110 responses. This timing avoids Japan's summer holiday period (18th July to 31st August 2025 or 2026), during which flyer distribution is not feasible. Moreover, whilst our goal is to obtain 100 valid responses, we anticipate that approximately 5–10% of responses may be invalid (e.g. invalid data points, missing values), particularly given that we allow self-measurement for parents without available data. Therefore, to secure 100 valid responses, we estimate that at least 110 responses will need to be collected to account for potential data loss due to data quality issues.

Suguru

Suguru is a school communication app commonly used in Japan to share school-related information. All 22 participating schools have confirmed their use of Suguru. For the baseline data, as of June, Chiba City has confirmed their ability to send reminders via Suguru. Reminders are expected to be sent on 18th August in 2025 for baseline data collection. If, by 22nd August 2025, response numbers remain insufficient, we may ask Chiba City (Smart City Promotion Division) on the 25th August 2025 whether an additional round of Suguru reminders can be sent—alongside the printed reminders scheduled for the first week of September to schools that have not yet reached 110 responses, as described above. For the 1-year follow up data, as of May 2026, Chiba City has confirmed its ability to send reminders via Suguru. The first and second Suguru reminders are planned for the first and third weeks of August 2026, respectively. In addition, printed reminder flyers will be sent in the final week of August or the first week of September to schools that have not yet reached 110 responses, as described above.

8.3.3 Survey Administration

[This section has been updated on 8th September 2026. See annex for the change]
Baseline survey data must be collected before intervention delivery begins in October 2025. Surveys will be administered online using Microsoft Forms and children will complete the survey with support from parents or caregivers for the following tasks:

1. Signing the consent form embedded in the survey
2. Clarifying question content if needed
3. Completing the parent/caregiver section of the questionnaire

It is essential that responses reflect the child's own views. To support this, the survey will begin with a prompt asking whether the child is/will be present during completion. If more than 20% of respondents indicate that the child was not present, a sensitivity analysis will be carried out to compare treatment/intervention effects using the full dataset and a dataset excluding those who responded without their child present. BMI data (i.e. height, weight) will be collected by asking parents to copy from the official school health data sent by their school either in paper or via email. In Chiba, annual school health check-ups are typically conducted between April and June.

As of June 2025, school data distribution schedules are as follows:

- 1 school: April 2025
- 5 schools: May 2025

- 5 schools: June 2025
- 11 schools: July 2025

As of June 2026, school data distribution schedules are as follows:

- 1 school: April 2026
- 5 schools: May 2026
- 5 schools: June 2026

11 schools: July 2026This means most schools are expected to have distributed the health data by the planned survey start dates of 14th July 2025 and 13th July 2026. However, there are two limitations:

- Some schools require parents to sign and return the distributed data, meaning not all parents may have access to the data even if it has been distributed.
- Parents from schools that distributed the data early (e.g. April) may have lost it by the time of the survey.

To account for this, the survey design will be adjusted to allow for two scenarios:

1. Parents copy height and weight from the distributed official school records, measured between April and June
2. Parents measure height and weight themselves at home

CU will provide a visual instruction to guide accurate height and weight measurement. The survey is expected to take approximately 20 minutes. Upon completion, the survey thanks participants for their time and notes that they will receive an Amazon gift voucher within a month or so, along with a confirmation email from CU.

8.3.4 Participant Compensation

[This section has been updated on 8th September 2026. See annex for the change]

Participants will receive an Amazon gift voucher worth 1,000 Japanese yen upon completing the survey. Due to the budget constraint, only the first 150 respondents will receive the voucher. To ensure participants are aware of this limit, the cap on incentives will be clearly communicated on the recruitment flyers and in the consent form embedded at the beginning of the online survey. If a parent completes the survey for multiple children, they will receive one voucher per submission. To confirm that multiple entries are for different children (e.g. siblings, twins) and not duplicates submitted solely

for additional vouchers, CU will manually review responses. Although MS Forms has a "one response per person" feature, it requires collecting names, which we aim to avoid. Therefore, manual review is currently the preferred approach. This process may take up to a month, after which CU will begin distributing the gift cards to the provided email addresses. To do this, CU will use the combination of variables below as a unique identifier for a child:

- Parent's email address
- Child's school (coded as 0–21 for the 22 participating schools, and as 22 for "other/unknown")
- Child's birth month and year
- Child's sex

To distinguish legitimate responses from parents of twins, triplets, or higher-order multiples from potential duplicates or disingenuous entries, the survey will include a prompt question: "*Do you have more than one child attending the same school?"* with possible response options of 1. "No"; 2. "Yes, but they are not twins, triplets or quadruplets"; 3. "Yes, and they are twins, triplets or quadruplets". Twins/triplets etc. who go to the same school will share the same values for all the variables above, and will only be treated as separate entries if this question is answered 3. "Yes, and they are twins, triplets or quadruplets". If answered 1 or 2, only the first complete entry will be kept in the analysis. However, both entries will still be eligible to receive the incentive regardless of inclusion in the dataset. This method of identifying children will also be used later for longitudinal analysis linking (more details in Section 10.2.4).

Invalid responses - such as incomplete, inconsistent, or clearly not legitimate responses - will be removed from the final dataset. In addition, whilst Chiba University do not anticipate a high number of responses from non-participating schools, a school selection question will be included in the survey as a dropdown menu as exclusion criteria. Participants who select the "other/unknown" option will be directed to the final thank-you page, and their response will not be included in the analysis. Regardless of data validity, and in line with the agreement with the CU ethics committee, Amazon gift vouchers will still be given to the first 150 complete responses per school to honour the incentive commitment approximately a month after the survey closure.

8.3.5 Survey Closure

[This section has been updated on 8th September 2026. See annex for the change]

A unified survey link will be used across all participating schools. The survey starts with a dropdown menu where participants select their school. The number of responses for each school will be monitored daily, and once a school reaches 150 responses, that school will be added to the exclusion criteria within the survey. This means that if a participant selects a school that has already reached the response cap, they will be automatically redirected to the final thank-you page and will not be able to proceed with the survey. For schools that do not meet this threshold, reminder messages will be sent as described above. The latest date that surveys will remain open is the end of September after which the survey will be closed to allow data cleaning and analysis to begin.

9. Output, Outcome and Impact Measures

At each data collection point—baseline, one-year follow-up (2026), and two-year follow-up (2027)—we will collect a set of indicators as listed below in the table. Some of these will be calculated using other data rather than gathered directly, for example our primary outcome BMI-z score (indicator #27) which will be calculated using the child's height, weight, age, and sex.

Additionally, outcomes #29-#32 will be estimated using the PRIME time model, an epidemiological tool developed by the University of Oxford. This model allows us to simulate how changes in average calorie intake or BMI may affect longer-term health outcomes, as described in Cobiac et al. (2023)[5].

All primary and secondary outcome indicators, and their associated analysis methods and results, will be disclosed on www.ClinicalTrials.gov.

Table 2. Output, outcome and impact indicators

[5] Cobiac, L. J., Law, C., & Scarborough, P. (2023). *PRIMEtime: An epidemiological model for informing diet and obesity policy* (p. 2022.05.18.22275284). medRxiv. https://doi.org/10.1101/2022.05.18.22275284

Indicator Type	#	Indicator	Time of Data Collection	Unit
Output *(Measures of the activities of the programme, such as products or services delivered)*	1	People reached	Quarterly	Number of people
	2	Children reached (0-18 years)	Quarterly	Number of people
	3	Target population reached (6-13 years)	Quarterly	Number of people
	4	Number of interventions commenced	Quarterly (reported annually)	Number of interventions
	5	Number of interventions active	Quarterly (reported annually)	Number of interventions
	6	Whether local governments have made a public commitment to CBH COPI (i.e. formal relationships)	One-off	Binary
	7	Whether relevant community stakeholders have been involved in intervention development and/or delivery	First at the end of intervention co-design stage, followed by annual reporting	Binary
Outcome *(Measures of short- or medium-term changes, which are needed to achieve the ultimate impact. Often focus on behavioural mechanisms)*	8	Moderate-to-vigorous physical activity (MVPA), minutes per day	At baseline, 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	Minutes per day
	9	Physical activity, minutes per day		Minutes per day
	10	Sedentary time (out-of-school recreational screen time), minutes per day		Minutes per day
	11	Energy expended through physical activity *(Calculated from physical activity responses)*		kcal per day
	12	Global Dietary Recommendations (GDR) Score		GDR score (0-18)
	13	Fruits and vegetables consumed		WHO-FV score (0-6)
	14	Sugar-sweetened beverages (SSBs) consumed		Number of mealtimes in which SSBs consumed (0-4) Proportion of children who consume any diet SSBs out of those who consume any SSBs (descriptive analysis)
	15	Added sugars consumed		WHO-sugar score (0-6)
	16	Saturated fat consumed		Transformed WHO-SatFat score (0-8)
	17	Fibre consumed		WHO-fibre score (0-10)
	18	All-5 food groups consumed		Number of all-5 food groups consumed

	19	Starchy staples consumed		Binary for consuming at least one starchy staple
	20	Dairy food consumed		Binary for consuming at least one dairy food
	21	Animal-sourced foods (ASFs) consumed		Binary for consuming at least one ASF
	22	Energy intake per day *(Calculated from diet questionnaire responses)*		kcal per day
	23	Carbohydrates consumed *(Calculated from diet questionnaire responses)*		g per day
	24	Protein consumed *(Calculated from diet questionnaire responses)*		g per day
	25	Fat (lipids) consumed *(Calculated from diet questionnaire responses)*		g per day
	26	Net calories *(Calculated from indicator #11 (sensitivity analysis) and #22)*		kcal per day
Impact *(Measures of long-term or broader changes, which reflect the ultimate goals of the programme)*	27	Body mass index z-score (BMI-z) adjusted for age and sex *(Calculated from height, weight, age in months and sex, or modelled based on indicator #26)*	At baseline, 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	z-score (using World Health Organisation Growth Reference)
	28	Health-related quality of life (HRQoL) - KIDSCREEN-10 index		0-100 scale
	29	Quality-adjusted life years (QALYs) *(Modelled based on indicator #27)*	At 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	Number of QALYs
	30	Disability-adjusted life years (DALYs) *(Modelled based on indicator #27)*		Number of DALYs
	31	Rate of cardiovascular disease (CVD) *(Modelled based on indicator #27)*		Cases per 100,000 target population
	32	Rate of type 2 diabetes (T2D) *(Modelled based on indicator #27)*		Cases per 100,000 target population
	33	Cost effectiveness metrics		In local currency and equivalised in common global currency
Demographics	34	Child's age	At baseline, 1st follow-up (10-12 months) and	Constructed from combining age in years and month of birth

	35	Child's sex	2nd follow-up (20-24 months)	1. Boy 2. Girl 3. Prefer not to say
	36	Child's ethnicity		Proxied by categorical (0-3) parental birth place: 0. 'Born in Japan'; 1. 'Mixed'; 2. 'Not born in Japan'; 3. 'Unknown' See Appendix 1 for the relevant survey question.
Others	37	Household income (compulsory)	At baseline, 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	Categorical (0-5) based on income quintiles: 0. income_Q0 (Less than 2 million yen) 1. income_Q1 (2–3.5 million yen) 2. income_Q2 (3.5–5.5 million yen) 3. income_Q3 (5.5–8 million yen) 4. income _Q4 (More than 8 million yen) 5. income_unknown (Unknown) See Appendix 1 for the relevant survey question.
	38	The name of child's school (exclusion criteria; compulsory)		Categorical (0-22): *0-21: correspond to each of the participating schools* *22: other* See Appendix 1 for the relevant survey question.
	39	(prompt) Whether the child was present whilst answering the survey	At baseline, 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	*"Are you answering the survey with your child?"* *1. Yes* *2. No*

				<u>Note</u> If more than 20% have answered 2. “No”, a sensitivity analysis will be carried out to compare treatment/intervention effects using the full dataset versus a dataset excluding those who answered ‘No’
	40	Whether the parent is answering for twins/triplets/other multiples	At baseline, 1st follow-up (10-12 months) and 2nd follow-up (20-24 months)	*Do you have more than one child attending the same school?*' *1. No;* *2. Yes, but they are not twins, triplets or quadruplets;* *3. Yes, and they are twins, triplets or quadruplets.* <u>Note</u> If this question is answered ‘*3. Yes, and they are twins, triplets or quadruplets*’, both entries will be kept for the analysis. If the response is ‘1’ or ‘2’, only the first complete response amongst duplicates will be kept."
	41	Whether parent has both height and weight data from school health check-up		Binary (0-1), calculated from two questions: *Q5: Do you have the results of your child’s height measurement taken at school?* *1. Yes* *2. No* *Q8: Do you have the results of your child’s weight measurement taken at school?* *1. Yes* *2. No*

				If parent answers '*Yes*' (option 1) for both questions Q5 and Q8, code this covariate as 1. Otherwise code as 0.

9.1 Primary Outcome Indicator: BMI-z

The primary outcome of interest for the global analysis is BMI z-score adjusted for age and sex (indicator #27). This is a standardisation of BMI using the WHO 2007 Growth Reference (available here).

9.2 Secondary Outcome Indicator: HRQoL

The secondary outcome of interest for the global analysis is health-related quality of life (HRQoL), which summarises quality of life via physical, mental and social health domains (indicator #28).

The KIDSCREEN-10 will be used to create the proxy measure for HRQoL. This was developed from the (27-item) KIDSCREEN-27 to measure general HRQoL in a single scale; specifically, it is a subset of the questions in KIDSCREEN-27. The main proxy will be the KIDSCREEN-10 index, which is comprised of five dimensions:

- Physical (2 items)
- Psychological (2 items)
- Autonomy and parent relations (3 items)
- Peers and social support (1 item)
- School environment (2 items)

Each item has 5 possible responses based on how strong the respondent is feeling or the frequency of doing / feeling things over the last week. The KIDSCREEN survey instruments were originally designed for ages 8-18 but have been used with children as young as 6 years old (for example, Ardelean et al.

(2022)[6] validated it for 6-year-olds in Romania, and the scoping review of Befus et al. (2023)[7] references ages 6-18).

The survey will be adapted for children aged 6-9 to aid their understanding by slightly changing the wording of certain questions and response options (more details are in Appendix 1). In addition, for all children, images will be added before the questions on each dimension (with the exception of school environment, which will be combined with peers and social support) to encourage engagement among respondents. The introduction to the survey will also be changed for all children to account for the fact that this is one of three survey measures that will be presented to children in a single questionnaire.

Responses to each question are coded from 1-5. The main indicator for HRQoL will be the KIDSCREEN-10 index – i.e. the total score across the first 10 questions (10-50) transformed linearly to a 0-100 scale. A higher score corresponds to a higher health-related quality of life. In addition, there is an 11th item in which the respondent self-assesses their general wellbeing (scored from 1-5) which will also be converted to a 0-100 and analysed as a separate outcome.

9.3 Exploratory Outcome Indicators

9.3.1 Physical Activity Outcomes

Physical activity outcomes will be elicited via survey instruments adapted from the *Core Indicators and Measures of Youth Health - Physical Activity & Sedentary Behavior Module questionnaire*. This questionnaire asks children how long they spent (i) doing moderate-to-vigorous physical activity (MVPA) and (ii) sitting in front of a screen (outside of school) in each of the last 7 days. A question on walking time will be added to calculate total physical activity time. This is consistent with other papers that have split physical activity into walking, moderate activity and vigorous activity (e.g. Brown et al. (2004)[8]). In this study, ages 10+ will be asked about the last 7 days and ages 6-9 will be asked about

[6] Ardelean, V. P., Andrei, V. L., Miuţa, C. C., Boros-Balint, I., Deak, G.-F., Molnar, A., Berki, T., Győri, F., Geantă, V. A., Dehelean, C. A., & Borcan, F. (2022). The KIDSCREEN-27 Quality of Life Measure for Romanian Children Aged 6: Reliability and Validity of the Romanian Version. *Healthcare*, *10*(7), 1198. https://doi.org/10.3390/healthcare10071198

[7] Befus, E.-G., Helseth, S., Mølland, E., Westergren, T., Fegran, L., & Haraldstad, K. (2023). Use of KIDSCREEN health-related quality of life instruments in the general population of children and adolescents: A scoping review. *Health and Quality of Life Outcomes*, *21*(1), 6. https://doi.org/10.1186/s12955-023-02088-z

[8] Brown, W., Bauman, A., Chey, T., Trost, S., & Mummery, K. (2004). Comparison of surveys used to measure physical activity. *Australian and New Zealand Journal of Public Health*, *28*(2), 128–134. https://doi.org/10.1111/j.1467-842x.2004.tb00925.x

the previous day. In addition, the survey will be simplified for ages 6-9 by using fewer time categories for the questions on walking and MVPA time. This is because younger children are less able to accurately estimate the time they spent doing certain activities for each day of the last week, and these two questions refer to some relatively narrow intervals (e.g. 1-14 minutes, 15-29 minutes).

9.3.2 Diet Outcomes

Diet outcomes will be measured with an edited version of the *Diet Quality Questionnaire (DQQ).* The unadjusted DQQ asks children whether they have eaten from each of 29 food groups in the previous day. The exact form of the survey will differ by country: for each food group, the idea is to list specific "sentinel" foods (popular foods that capture around 95% of people who consume any item in the food group) and then ask children whether they've eaten any of those foods in the last day.

Because the DQQ does not collect data on the quantity or frequency of consumption within each food group, it may produce inaccurate estimates of total energy intake in a few ways. Each food group (or sub-question if there are multiple questions per food group, which is very rare) is associated with a single kcal value, even though it contains several items. In addition, children may consume multiple items from a single food group, or the same item multiple times, during a single day. To attempt to combat the latter issue, the DQQ will be augmented by asking children to specify whether any of the foods in each list was eaten for each "meal" (breakfast, lunch, dinner and snacks) or not at all. In addition, example images (appropriate for Japanese food culture) will be provided under each list of foods to aid understanding.

Children will also be asked a follow-up question about whether they had any diet SSBs (e.g. zero sugar). Due to limitations in MS Forms, this will be asked to all children, not just those who said they consumed any SSBs. The proportion of children who consumed any diet SSBs (out of the children who consumed any SSBs at all) will be analysed descriptively by country. In reporting, it will be noted that differences could emerge between the intervention and control groups (i) because the intervention affects the proportion of children who drink any diet SSBs and/or (ii) because the intervention affects the characteristics of children who decide to drink any SSBs.

For ages 10+, the "full" DQQ (i.e. the augmented version of the original DQQ) will be used. For ages 6-9, a simplified version of the DQQ will be used. This is adapted from Kruger et al. (2023)[9], who

[9] Kruger, H. S., Makore, P., van Zyl, T., Faber, M., Ware, L. J., Monyeki, M. A., & Kruger, R. (2024). Validation of a short food group questionnaire to determine intakes from healthy and unhealthy food groups in 5–9-year-old South African children. *Journal of Human Nutrition and Dietetics*, *37*(1), 234–245. https://doi.org/10.1111/jhn.13249

constructed and validated a short (parent-reported) 10-item survey in South Africa. The simplified DQQ reduces the number of food groups from 29 to 16; in addition, it provides simple descriptions for each of the new groups and some example images rather than a list of foods, and contains the extra question on diet SSBs described above. The creation of this simplified DQQ was prompted by initial, informal piloting in countries which suggested that younger children were not able to understand some of the foods in the full DQQ.

Note that it is not possible to construct some of the key outcome indicators (e.g. GDR score) from the simplified DQQ. For these outcomes, only responses to the full DQQ (from children aged 10+) will be used in the analysis. Furthermore, some indicators (e.g. energy intake) will be calculated in a different (potentially less sensitive) way for younger children. For these outcomes, the full sample should be used for the main analysis, which will be complemented by subgroup analysis by age (examining ages 6-9 and ages 10+ separately). Table 4 indicates which outcomes can be constructed for both the simplified and full DQQs, and which can only be constructed for the full DQQ.

For the full DQQ, Herforth et al. (2020)[10] suggest scores and related dichotomous indicators (i.e. binary indicators based on the score being above/below some cutoff) that are intended to measure the consumption of certain nutrients. The scores will be used as continuous outcomes in the main analyses to increase power, but the dichotomised indicators will be examined in a sensitivity analysis for interpretability. Some of the other outcomes (e.g. the all-5 score) have been taken from the Herforth (2023)'s DQQ indicator guide.

More details on exploratory outcomes are shown in Appendix 2.

9.4 Output Indicators and Assessment

Details on output indicators are shown in Appendix 3.

[10] Herforth, A. W., Wiesmann, D., Martínez-Steele, E., Andrade, G., & Monteiro, C. A. (2020). Introducing a Suite of Low-Burden Diet Quality Indicators That Reflect Healthy Diet Patterns at Population Level. *Current Developments in Nutrition*, *4*(12), nzaa168. https://doi.org/10.1093/cdn/nzaa168

9.5 PRIMEtime-Modelled Impacts and Cost Effectiveness Assessment

Indicators #29-#32 (in Table 2) will be analysed by the University of Oxford using the PRIMEtime model, with inputs provided by the GIP (for both local and global analyses).

The PRIMEtime model will be used to model the long-term health impact of the intervention package in each participating country. A closed-cohort analysis will be performed: effects will be estimated for those aged 6-13 at the time of intervention launch over their lifetimes. The PRIMEtime model will also be used to estimate the cost-effectiveness of CBH COPI by combining the estimated health impact with estimated intervention costs. The modelling will be performed for each country. All figures will be converted into 2024/25 prices in a common currency.

The effects on the PRIMEtime-modelled health impacts (indicators #29-#32) for each country will be estimated by feeding in the estimated effect on BMI-z (indicator #27) for all countries where BMI data are available into the PRIMEtime model. In countries where BMI data are not available, the estimated effect on net calories (indicator #26) will be fed in as the input. Where possible, the outputs of the PRIMEtime modelling will be aggregated across all countries to estimate the overall health impact of the programme. Sensitivity analyses will be considered to explore the impact of different approaches to aggregating findings across countries with heterogenous local designs (e.g. countries with/without available data for BMI-z).

The cost-effectiveness analysis will also explore if health benefits generated by the programme differ across socioeconomic groups (where the variable used to define socioeconomic status will be defined by country). For example, this could involve conducting distributional cost-effectiveness analysis (DCEA) (Asaria et al., 2015[11]).

10. Data Analysis

10.1 Data Analysis Approach

This study will use ANCOVA (analysis of covariance) regression models to assess the treatment/intervention effect, based on repeated cross-sectional data collected at baseline (2025)

[11] Asaria, M., Griffin, S., & Cookson, R. (2016). Distributional Cost-Effectiveness Analysis: A Tutorial. *Medical Decision Making*, *36*(1), 8–19. https://doi.org/10.1177/0272989X15583266

and at one-year and two-year follow-ups in 2026 and 2027 respectively. The model compares post intervention outcomes between intervention and control groups, controlling for baseline values at the cluster/JHSD level. This is important in a repeated cross sectional design where differences in outcomes over time could reflect changes in the composition of the sample rather than the true impact of the intervention package. The treatment/intervention effect is captured by the coefficient of the intervention group indicator.

A two-way fixed-effects model (i.e. a difference-in-differences approach) can better account for unobserved differences between groups - such as health attitudes or local policy context - which baseline outcomes alone may fail to capture. However, this approach will only be used to support estimates for global meta-analysis rather than for primary inference at the country level due to sample size constraints (reduced statistical power). Where participant responses can be linked across survey rounds, we will also conduct a longitudinal analysis with individual level and cluster level random effects. However, this is not a primary focus of this study due to uncertainty around longitudinal attrition across the three-year period, and no formal power calculations will be conducted. All regressions will report standard errors and p-values, using a default significance level of 10%.

10.2 Statistical Methods

10.2.1 Analysis for Primary Outcome Indicator: BMI-z

*BMI z-score is a standardised indicator of BMI (body mass index) that takes into account children's growth patterns, which vary with age and gender.

For all analyses, observations will be excluded if either (i) height-for-age z-score based on WHO 2007 growth reference is less than -5 or more than 4, or (ii) BMI-z is less than -4 or greater than 8. These are judged to be biologically implausible values (BIVs) based on U.S. Centers for Disease Control and Prevention (CDC) recommendations as updated in 2016. Note the CDC formula for calculating extreme z-scores is different from the WHO's, but the WHO does not recommend cutoffs for BIVs.

At baseline: descriptive analysis

At baseline, descriptive analysis will be performed on BMI-z, % of children living with overweight and % of children living with obesity. Specifically, the means for these outcomes will be presented for each combination of country and intervention group. In addition, results will be provided for each combination of intervention group and sex (male, female, prefer not to say), for each combination of intervention group and age band (6-7, 8-9, 10-11, 12 or over), and for each combination of

intervention group and socioeconomic status (categorised as quintile using local household affluence variable).

At each follow up: ANCOVA model

$$Y_{ic} = a + b \cdot Treat_c + c_1 BaselineY_c + c_2 MissngIndBaselineY_c + c_3 Xcompulsory_{ic} + e_{ic}$$

Here:

- - Y_{ic} is the outcome (measured at follow-up) for child *i* in cluster/age group *c*
- - $Treat_c$ is a binary variable for the child being in a intervention or a control cluster/JHSD
- - $BaselineY_c$ is the average outcome at baseline for the combination of cluster and age group represented by *c*, and age group is categorised as (6-7 years, 8-9 years, 10-11 years, 12 years or over). If no baseline data for the combination of cluster and age group as categorised above exists, set as –99.
- - $MissngIndBaselineY_c$ is a binary variable for baseline data being missing (instead of non-missing)
- - $Xcompulsory_{ic}$ is a vector of required characteristics for the child:
    - Sex (categorised as male, female, prefer not to say)
    - Age in years (categorised as 6, 7, 8, 9, 10, 11, 12 or over)
    - Ethnicity (categorised as both 'Japanese'; 'Mixed'; 'Non-Japanese'; 'Unknown')
    - Household income (categorised as less than 2 million yen, 2-3.5 million yen, 3.5-5.5 million yen, 5.5-8 million yen, more than 8 million yen, prefer not to answer)
    - Day of the week (categorical variable with up to 7 levels)
    - Whether parents have both height and weight data from school health check-up (binary variable equalling 1 for having both height and weight from school health check-up, and 0 if at least one of height and weight is not from school health check-up)
- e_{ic} is the error term

b is the coefficient of interest. Standard errors will be clustered at the cluster level (i.e. JHSD).

As sensitivity analysis, the outcome above will be replaced with (i) a binary variable for living with overweight (based on BMI for age-and-sex from WHO Growth Reference) and (ii) a binary variable for living with obesity (based on BMI for age-and-sex from WHO Growth Reference) as outcomes. For both outcomes, a logistic model will be used instead of a linear one.

Subgroup analysis will also be performed for the main BMI-z outcome by dividing the sample into subgroups for each characteristic and conducting separate regressions in each. Specifically, the following characteristics and subgroups will be used:

- **Age:** 6-9 years, 10+ years
- **Sex:** male, female (excluding those who chose 'prefer not to say')
- **Health equity:** Health equity will be defined based on household income variable (i.e. household affluence, see 'household income' in Table 2) using approximate income quintiles derived from Ministry of Health, Labour, and Welfare of Japan national data for 2024. For subgroup analysis, health equity will be classified as follows:
  - Below-median affluence: Categories 0 and 1 (i.e. less than 3.5 million yen)
  - At or above-median affluence: Categories 2, 3, and 4 (i.e. 3.5 million and above)
- **Ethnicity:** 'born in Japan', 'not born in Japan'. Using the child's ethnicity variable (0-3), category 0 will be classified as 'born in Japan' and categories 1-3 will be classified as 'not born in Japan'.

At each follow up: global analysis – two-way fixed-effects (TWFE) model

In addition, to support the global-level meta-analysis, a two-way fixed effects regression model should be estimated for each analysis (main outcome, sensitivity analysis, subgroup analysis) specified above. For linear models, this looks like:

$$Y_{it} = a + b_1 Treat_i + b_2 Post_t + b_3(Treat_i \cdot Post_t) + c_1 Xcompulsory_{it} + e_{it}$$

Here:

- Y_{it} is the outcome for child *i* at time *t* (where *t* indexes either baseline or the specific follow-up period)
- $Treat_i$ is a binary variable for whether the child being in an intervention cluster instead of a comparison cluster
- $Post_t$ is a binary variable for the period being a follow-up (instead of baseline)
- $Xcompulsory_{it}$ is a vector of required characteristics for the child (the same characteristics as in the ANCOVA model described above)
- e_{it} is the error term

b_3 is the coefficient of interest. Standard errors will be clustered at the cluster level (i.e. JHSD).

10.2.2. Analysis for Secondary Outcome Indicator: HRQoL

At baseline

At baseline, descriptive analysis will be performed on the KIDSCREEN-10 index, the child's self-assessment of their general wellbeing (11th item on the KIDSCREEN-10 survey) and the scores for each of the five scales being used (physical, psychological, autonomy and parent relations, peers and social support, school environment). These outcomes will all be linearly transformed to a 0-100 scale before analysis to aid interpretation.

Specifically, the means for these (scaled) outcomes will be presented for each combination of country and intervention group. In addition, results will be provided for each combination of intervention group and sex (male, female, prefer not to say), for each combination of intervention group and age band (6-7, 8-9, 10-11, 12 or over), and for each combination of intervention group and socioeconomic status (categorised as quintiles using local household affluence variable).

At each follow-up

The same model as the primary outcome analysis will be used, except BMI-z (and the baseline group-level BMI-z) will be replaced with the analogous indicators for HRQoL.

As sensitivity analysis, the following outcomes will be used instead: (i) KIDSCREEN-10 index, excluding the autonomy and parent relations questions (as these are expected to be less directly affected by the interventions), (ii) the child's self-assessment of their general wellbeing (11th item), (iii) the physical score, (iv) the psychological score, (v) the autonomy and parent relations score, (vi) the peers and social support score and (vii) the school environment score. These outcomes should all be linearly transformed to fit a 0-100 scale before analysis to aid interpretation.

Subgroup analysis will be performed by age, sex, household affluence and ethnicity using separate regressions as described for the primary outcome. Subgroup analysis will only be conducted for the KIDSCREEN-10 index, not the other outcomes used in the sensitivity analysis. Finally, a two-way fixed-effects model will be estimated for each analysis above (with the same type of regression and compulsory/optional characteristics).

10.2.3. Analysis for Required Exploratory Outcome Indicators: Physical Activity and Diet

At baseline

At baseline, descriptive analysis will be performed on each indicator. Specifically, the means for these outcomes will be presented for each combination of country and intervention group. In addition, results will be provided for each combination of intervention group and sex (male, female, prefer not to say), for each combination of intervention group and age band (6-7, 8-9, 10-11, 12 and over), and for each combination of intervention group and socioeconomic status (categorised as quintiles using local household affluence variable, plus missing if applicable). For certain diet outcomes which can only be calculated from the full DQQ, it will not be possible to provide results for the 6-7 and 8-9 age bands.

At each follow-up

The same model as the primary outcome analysis will be used, except BMI-z (and the baseline group-level BMI-z) will be replaced with analogous indicators for each indicator. Also, for the number of mealtimes in which SSBs were consumed (the first element of indicator #14), a quasibinomial model (with the proportion of mealtimes in which SSBs were consumed as the outcome variable in the regression and the number of mealtimes (i.e. 4) as the weight for each observation) will be used instead of a linear model. For the proportion of children who consumed any diet SSBs (the second element of indicator #14), a descriptive analysis will be performed, using just children who consumed any SSBs as the sample.

For sensitivity analysis, the alternative outcomes listed in Table 4 will be examined:

- Energy expended overall (during PA and non-PA time) - this will be fed into PRIMEtime for indicators #29-#32
- Other diet-related indicators as marked in Table 4 (using logistic models for these dichotomous / binary variables)

Subgroup analysis will be performed by age, sex, household affluence and ethnicity using separate regressions as described for the primary outcome. This will be done for each of the main measures in indicators #8-#26, but not the alternative outcomes marked in Table 2 as being for the sensitivity analysis. Finally, a two-way fixed-effects model will be estimated for each analysis above (with the same type of regression and compulsory/optional characteristics).

10.2.4 Longitudinal Analysis

Chiba University will also conduct a longitudinal analysis, which accounts for the fact that children will be measured at multiple different points.

Identifying Children

For each wave of data collection (baseline, 1-year follow-up, 2-year follow-up), we use the following variables to uniquely identify a child:

- Child's birth month and year (in YYYYMM format - note we do not have exact date of birth, only month and year)
- Child's sex (Male/Female)
- Child's elementary-school code
- Parent's email address

If multiple complete/valid responses at a given data collection point (baseline, first follow-up, second follow-up) have the same set of variables, these responses will all be removed for the longitudinal analysis. We anticipate that this will be a very small number of observations.

Analysis

To analyse the longitudinal data, random intercepts will be added for clusters and students:

$$Y_{ict} = a + b_1*Treat_c + b_2Post_t + b_3(Treat_c*Post_t) + c_1Xcompulsory_{ict} + v_c + u_i + e_{ict}$$

Here v_c is a school-level random effect and u_i is a student-level random effect. Standard errors will not be clustered.

This approach imposes two extra assumptions on the model (school-level random effects v_c and student-level random effects u_i are uncorrelated with the covariates) but makes estimates more efficient (i.e. lower standard errors) compared to using individual fixed effects or clustering standard errors at the child level.

11 Power Calculations

In this study, we aim to reach at least 100 valid observations per cluster, in line with the original power calculation assumptions. To maximise statistical power, we will recruit as many participants as possible within each cluster, up to a cap of 150 due to incentive constraints. This study was originally powered to detect a Cohen's d of 0.15 with 20 clusters and 100 observations per cluster, assuming 80% power. To account for potential attrition - particularly in the control group - two additional clusters were added, increasing the total to 22 clusters, while keeping the target of 100 observations per cluster. This lowered a minimum effect size (Cohen's d) of 0.144, which corresponds to:

- A 0.29 kg/m² change in BMI (SD = 2; Romon et al., 2009), and
- A 1.96 point change in HRQoL (SD = 13.65 on the KIDSCREEN-10 (see manual appendix A7_A), scaled to 0–100).

This estimate was based on:

- 22 clusters
- Target survey reach per cluster: 200
- Expected response rate: 50%
- Minimum observations per cluster: 100

As the study progressed, power calculations were refined to better reflect key aspects of the project, in particular:

1. Stratified randomisation by ward
2. Actual student enrollment numbers with a 150 participant cap per cluster

In the updated calculation, we incorporated the actual approach that will be used for selection - i.e. accounting for the fact that four wards have an odd number of clusters, only keeping allocations where the number of children in the intervention group is within 10% of the number of children in the control group. To model the sample size per cluster more realistically, we simulated the number of participants in each cluster using a binomial distribution with a response rate of 30%, and had a maximum of 150 participants per cluster to reflect the incentive cap. Cluster sizes exceeding this cap were set to 150 participants.

From this set up, we expect the minimum detectable effect size to be approximately 0.140 (Cohen's d) — equivalent to:

- 0.279 kg/m² in BMI
- 1.905 points on the HRQoL scale

This MDES shows a modest improvement in sensitivity compared to the original calculations although it would still be insufficient to detect smaller effects reported in some past studies, such as Cohen's d = 0.09 found in Allender et al. (2021)[12]. Nonetheless, the updated MDES is able to capture the range of effects observed in similar interventions like the EPODE programme in France, that achieved d = 0.35–0.39 with significant results (Romon et al., 2009[13]). As stated before, whilst the updated simulations reflect more realistic assumptions, our recruitment goal remains unchanged: we aim to reach at least 100 valid observations per cluster, in line with the original power calculation assumptions, and will recruit as many participants as possible until the 150 cap is reached within each cluster to maximise power.

Table 3. Japan power calculations - assumptions and results

Outcome	Primary outcome BMI-z score (adjusted for age and gender)	Secondary outcome HRQoL: KIDSCREEN-10 index
Number of groups	2 - intervention/ control	
Number of data collection points	2 - once before the intervention and once after the intervention (including two follow-ups, but each follow-up is analyzed separately).	
Power	80%	
Significance level	10% No correction for multiple comparisons (1 primary outcome, 1 secondary outcome)	
Percentage explained by post-intervention outcomes, pre-intervention outcomes (and other covariates)	50% (this has been adjusted downwards from the suggested value of ~0.8 from Allender et al. (2021) [WHO STOPS]). The individual-level autocorrelation is assumed to be quite high (for example, 0.8–0.9). If it is possible to control for individual-level data before the intervention, the proportion of explained variance would likely be higher (since R^2 = autocorrelation^2, using the above range for autocorrelation, R^2 would fall between 0.64 and 0.81). However, there is limited overlap between the pre- and post-intervention samples, and if children cannot be identified, the analysis must control for all children's pre-intervention outcomes at the area level, which would result in a decrease in predictive power.	

[12] Allender, S., Orellana, L., Crooks, N., Bolton, K. A., Fraser, P., Brown, A. D., Le, H., Lowe, J., de la Haye, K., Millar, L., Moodie, M., Swinburn, B., Bell, C., & Strugnell, C. (2021). Four-Year Behavioral, Health-Related Quality of Life, and BMI Outcomes from a Cluster Randomized Whole of Systems Trial of Prevention Strategies for Childhood Obesity. *Obesity (Silver Spring, Md.)*, *29*(6), 1022–1035. https://doi.org/10.1002/oby.23130

[13] Romon, M., Lommez, A., Tafflet, M., Basdevant, A., Oppert, J. M., Bresson, J. L., Ducimetière, P., Charles, M. A., & Borys, J. M. (2009). Downward trends in the prevalence of childhood overweight in the setting of 12-year school- and community-based programmes. *Public Health Nutrition*, *12*(10), 1735–1742. https://doi.org/10.1017/S1368980008004278

Regression approach	Cross-sectional model controlling for baseline as covariate (i.e. ANCOVA). This uses post-treatment/intervention outcomes on the left-hand side of the regression (i.e. as the outcome variable) and includes intervention-group dummy and pre-intervention/treatment outcomes at the cluster level (or whatever the lowest level available is) on the right-hand side as covariates. The coefficient on the intervention-group dummy is the treatment/intervention effect. A linear model is assumed.	
Number of clusters/JHSDs (with schools as a data collection point)	22 clusters (11 in intervention group, 11 in control group)	
intra-cluster correlation (ICC)	0.027 (This is based on the power calculation by Allender et al. (2021) and is based on the school-level ICC of BMI-z in children in Victoria, Australia, as reported by Strugnell et al. (2018)[14]).	
Number of children per elementary school (per data collection point)	If (student enrollment number in a given cluster * random response rate of 30%) > 150: 150, according to the incentive cap Else: 0.3 * student enrollment number	
Output: Standardized effect size (Cohen's d)	0.1396355	
Standard deviation (actual units)	2 kg/m^2 (based on Romon et al. (2009) [EPODE])	13.65 points on 0-100 scale (This is from manual appendix A7 A on the KIDSCREEN website. Specifically, it is the standard deviation for the KIDSCREEN-10 index (scaled to 0-100) found in the European norm data sample collected by the KIDSCREEN group.)
Output effect size (actual units)	0.279271 kg/m^2	1.906025 on a scale of 0-100

12. Data Management

12.1 Organisations involved in data collection & data analysis

Organisation	**Involved?**	**Roles**
Chiba University	Yes	Data collection & Data analysis
Chiba City	Yes	Distribution of survey link through digital Suguru reminders

[14] Strugnell, C., Orellana, L., Hayward, J., Millar, L., Swinburn, B., & Allender, S. (2018). Active (Opt-In) Consent Underestimates Mean BMI-z and the Prevalence of Overweight and Obesity Compared to Passive (Opt-Out) Consent. Evidence from the Healthy Together Victoria and Childhood Obesity Study. *International Journal of Environmental Research and Public Health*, *15*(4), 747. https://doi.org/10.3390/ijerph15040747

Participating schools	Yes	Distribution of printed flyers and printed reminder flyers and in some schools, digital Suguru reminder
BIT	Yes	Data analysis
The University of Oxford	Yes	Data analysis
NNPL	No	N/A
NNAS	Yes	Data analysis
DA	Yes	Collection of output data
Dera-e (operated by Cloud Inc.)	Yes	Distribution of Amazon vouchers

12.2 Data Transfer Paths

Data transfer paths as illustrated at Figure 4 below.

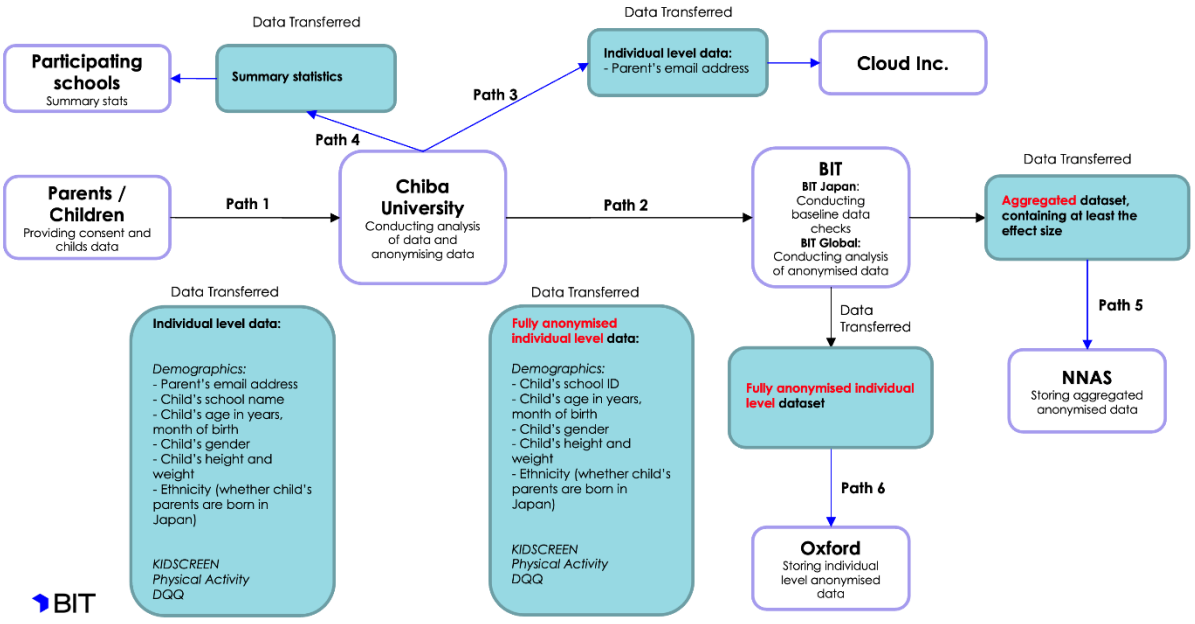


Figure 4: Data transfer paths

12.2.1. Path 1: From Parents/Children to Chiba University (CU)

In this data pathway, parent/guardian will provide information including their email addresses (for incentive distribution), the child's school name, the parents' place of birth (used as a proxy for ethnicity), and household income. Separately, information such as the child's age in years, month of birth, gender, height, weight, health-related quality of life (measured using KIDSCREEN), physical activity, and diet (measured using DQQ) will be collected directly from the child with supervision from the parent/guardian. These individual-level data will be gathered through an online survey conducted by CU via Microsoft Forms. Details of this process are explained to parents in advance in the Section 7 (1) "Information collected during the research period" of the informed consent form (click here for the original Japanese version of the consent form) as below:

"During the research period, we will collect email addresses for distributing compensation, place of birth, income, and health information such as the child's height and weight via parent/guardian. Additionally, from the child themselves, we will collect basic information such as birth month, age, and gender, as well as information about diet, physical activity, and general health. This information will be used to objectively evaluate the effectiveness of the research project."

This process has been reviewed and approved by the CU Ethics Committee, and moreover, CU will not use the collected data for further studies.

12.2.2. Path 2: From CU to BIT

In this data pathway, the individual-level data collected via Path 1 will be firstly fully anonymised and transferred to BIT through MS Forms SharePoint with restricted access. As CU will be constructing the longitudinal dataset for analysis, they will retain identifiable data in the original dataset until 2027. To enable BIT to receive an anonymised dataset at each data collection point (baseline in 2025, first follow-up in 2026, and second follow-up in 2027), CU will first create a separate copy of the dataset at each time point. CU will then apply the following anonymisation process to the copied dataset before sharing it with BIT:

Anonymisation Method

1. Remove parents' email addresses.
2. Replace school name with a school ID, for instance, 'Shinjuku school '= 0; ' Hanazono school' = 1.

Following this process, the anonymised dataset provided to BIT will include the following variables/indicators:

- Child's school ID
- Child's age in years
- Child's month of birth

- Child's gender
- Child's height and weight
- Ethnicity (proxied by whether child's parents were born in Japan)
- *HQoL via KIDSCREEN*
- *Physical Activity*
- *Diet via DQQ*

Ethical and legal basis for data received by BIT

The anonymisation process outlined above, including the removal of email addresses and replacement of school names with school IDs, has been reviewed and approved by the CU Ethics committee and therefore, data sharing with BIT has been confirmed to be legal and ethical (confirmed by CU via email).

The sharing of the anonymised dataset with BIT is covered under the existing contract between Chiba City, CU, and NNPL as shown in Appendix 5 (a full contract between CU, NNPL and Chiba City can be found here), and has been reviewed and approved by the CU Ethics Committee. Additionally, this is communicated to participants in the informed consent form under Section 7 (2): "Handling of personal information," as follows:

"Information obtained from the survey will have personally identifiable information (such as the name of the elementary school) removed, and will be managed with identification numbers assigned for research purposes to ensure individuals cannot be identified. Data that cannot identify individuals will be shared by Chiba University with BIT and Novo Nordisk A/S through secure systems. BIT will store the data on servers located in the United Kingdom, and Novo Nordisk A/S will store it on their Project Data Platform (PDP). Additionally, a summary of the research results will be shared with Novo Nordisk A/S. In all cases, no information that could identify your child will ever be shared."

12.2.3. Path 3: From CU to Cloud Co., Inc. (Incentive provider)

For each complete response (up to a maximum of 150 per school), participants will receive an Amazon voucher worth 1,000 yen (approximately £5) as compensation. The vouchers will be distributed via the Amazon gift card distribution service *Dera-e*. To enable this, participants' email addresses will be shared with Cloud Co., Inc., the company that operates *Dera-e*.

It is important to note that this data sharing arrangement had not previously been disclosed to GIP, communicated to participants through the consent form, or reviewed by the CU Ethics committee. Following the pre-launch meeting led by BIT on 11th July 2025, CU agreed to explicitly communicate this third-party data sharing in the consent form and added a following line in Section 7 (2) "Handling of personal information":

"*Email addresses will be used to distribute Amazon gift cards as compensation. The Amazon gift cards will be distributed through the Amazon gift card proxy service 'Dera-e' (*https://www.dera-e.jp/*). Therefore, email addresses will be shared with Cloud Co., Ltd/Inc. (*https://www.cloudsoft.co.jp*), the company that operates 'Dera-e'.*" *Email addresses will be used solely to distribute future survey requests for follow-up tracking. For the purpose of data linkage between the baseline and subsequent follow-up data, email addresses will be processed, but never analyzed directly. To ensure participant anonymity, we will convert the email addresses into pseudonymous research IDs (linkage codes) prior to conducting any data analysis.*

CU has informed the CU Ethics Committee of this revision to the consent form. Only after receiving approval, will CU share participant email addresses with Cloud Co., Inc. As of 16th July, the Ethics Committee's decision is still pending. For participants who completed the questionnaire prior to this consent form update between 8th July 2025 and 14th July, their email addresses have not been shared, nor will they be. In these cases, CU will distribute the Amazon vouchers directly. Cloud Co., Inc. is the only third party that will receive personally identifiable data collected in this study.

12.2.4. Path 4: From CU to Participating Schools

CU will share summary statistics with participating schools. These statistics will not contain any individual-level data. This has been communicated to participants in the consent form under Section 7 (2) "Handling of personal information" and has been reviewed and approved by the CU Ethics Committee:

"As reference material for developing school-level policies, survey data will be aggregated by school, and parts of the results will be provided to the headteachers of each school. However, no information that could identify individual respondents—such as who answered the survey—will be shared, so please rest assured."

12.2.5. Path 5: From BIT to NNAS

After BIT receive the anonymised copy of the individual-level data from CU, BIT will share aggregated data, containing at least the effect size with NNAS. This data sharing arrangement with NNAS is covered under the existing contract between Chiba City, CU, and NNPL as shown in Appendix 5 or

here. Additionally, this is communicated to participants in the informed consent form under Section 7 (2): "Handling of personal information," as follows:

"Information obtained from the survey will have personally identifiable information (such as the name of the elementary school) removed, and will be managed with identification numbers assigned for research purposes to ensure individuals cannot be identified. Data that cannot identify individuals will be shared by Chiba University with BIT and Novo Nordisk A/S through secure systems. BIT will store the data on servers located in the United Kingdom, and Novo Nordisk A/S will store it on their Project Data Platform (PDP). Additionally, a summary of the research results will be shared with Novo Nordisk A/S. In all cases, no information that could identify your child will ever be shared."

In addition, Novo Nordisk A/S will retain non-identifiable data for 10 years, or for the period required by local law, or as long as the data contributes to scientific purposes or improvements in product safety.

- **Storage Responsible Person**: Johan Lerbech Vinther
- **Storage Location**: Novo Nordisk Pharma Ltd. and Novo Nordisk A/S
- **Storage Period**: 10 years
- **Data Disposal Method**: The hard drive storing the data will be initialized and erased to ensure the data cannot be recovered.

12.2.6. Path 6: From BIT to the University of Oxford

To enable the PRIMEtime analysis, BIT will share fully anonymised individual-level data with Oxford University. As of July 2025, NNAS holds a Research Collaboration Contract with the University of Oxford, which formalises the use of data for the PRIMEtime analysis. Whilst BIT do not have a direct agreement with Oxford, this arrangement is referenced within Oxford's contract with NNAS.

At present, the contract between Chiba City, CU, and NNPL does not explicitly mention data sharing between BIT and Oxford. However, both Chiba City and NNPL legal team have since confirmed via email that no contractual amendments are required for this purpose. Moreover, during a CU meeting held by BIT on 1 August, CU agreed to explicitly name the University of Oxford in the consent form. CU have since updated the CU Ethics Committee accordingly. BIT and CU have jointly agreed that no data will be shared by CU until the CU Ethics Committee approves this change and parents have been informed via the updated consent form.

Table 4 below shows the summary of the ethical and legal basis for data received by all the relevant stakeholders.

Table 4. Summary table for ethical and legal basis

	Type of data received?	Who will provide the data?	Is this process covered by the informed consent form?	Have CU ethics seen and approved this process?	Is this process consistent with the LSP and the data flows?
CU	Individual level data	Parents/children via the survey	Yes	Yes	Yes
BIT	Anonymised individual level data	CU via MS Teams with restricted access	Yes	Yes, and anonymisation method also approved	Yes
Cloud Inc (incentive provider)	Individual level data (email addresses only)	CU (for parents after consent form update only)	Yes	Yes	Yes
Participating schools	Summary statistics	CU	Yes	Yes	Yes
NNAS	Aggregated data	BIT	Yes	Still pending	Yes
University of Oxford	Anonymised individual level data	BIT	Yes	Yes	Yes

Chiba University will be responsible for collecting and storing individual-level data and program output data. The primary data will be stored on a cloud server (Microsoft Teams), external HDD for backup. After the data cleaning and anonymization process mentioned below, the data will be transferred to GIP (BIT) by default through MS Teams SharePoint with access restrictions by Chiba University for global analysis. BIT will store this data on its own data platform (hosted by Google with servers in the UK). The aggregated data (effect size and confidence intervals) will then be uploaded to a project data platform (PDP) hosted by Novo Nordisk, which will be used for global data storage. Anonymized data will be shared with GIP at the individual level at baseline and each follow-up point. The minimum requirements for data anonymization when shared at the individual level are as follows:

- Remove email addresses and replace school names with anonymised IDs while maintaining the nested structure. To do so, the analyst will remove the column for email addresses and create a key linking each school name to a unique number from 1 to 22.

- All other data should remain in the dataset unchanged.

13 Quality Control

13.1 Data Quality Control

To ensure data quality and integrity, a joint codebook including data cleaning (removal of unnecessary data and missing data completion) and harmonization rules (rules to ensure consistency among all data items in all six countries) will be distributed by the BIT global team to Chiba University in Japan. The Chiba University study group will organize and manage their data according to the same standards based on the contents of the distributed joint codebook, aiming to ensure data quality and completeness/integrity (consistent data with few missing or errors). Data cleaning and quality control will be carried out by Chiba University. Raw and cleaned data, along with any cleaning scripts, will be provided to the BIT global team for global analysis.

13.2 Monitoring Procedure

During the intervention period, monitoring should be conducted to ensure that the protocol is being followed. The following is a list of main dates and activities that will be carried out during the intervention period to monitor the implementation of the intervention.

The country team from BIT and the Japanese research team will hold quarterly operational meetings to review progress and discuss any research-related challenges. These meetings will serve as a platform for interdisciplinary dialogue between researchers, academic partners, and local stakeholders to facilitate decision-making and quality assurance with a collaborative approach. The following individuals will attend these meetings:

- COPI Lead Study Manager (JHVT, Novo Nordisk Headquarters)
- BIT Project Lead
- NN Project Lead: Risa yamamoto
- BIT Research Lead
- Chiba University Research Team: Gemmei Iizuka, Ling Ling

Meeting content will focus on monitoring the progress of the intervention program, mitigating risks in the conduct of the study, discussing participant consent procedures, data management, and data collection procedures, and reviewing deviations from the research protocol. Any irregularities

identified during these reviews will be communicated to the GIP. Deviations from the protocol will be documented, immediately addressed, and corrective actions documented.

13.3 Important Documents

Prior to the start of the study (before recruiting begins), the following documents will be prepared and finalized as part of the Global Study Group.

- Agreement between Novo Nordisk Japan and Chiba University for joint research, and an agreement with Chiba City.
- Chiba University's Ethical Review Approval Notification
    - Local Study Protocol
    - Informed consent
    - Participant Information Sheet and other written information provided to participants
    - Participant Registration Procedures
    - Copies of (Ethics Committee approved) participant information/informed consent/other written information
    - Formal agreement with Chiba City involved in the study, including organizations involved in recruitment or data collection

13.4 Retention of Research Report Documents

GIP and Chiba University agree to archive documents related to the study for 5 years after the final report or the first public release of the research (whichever is later). GIP and Chiba University must not discard any documents without prior approval from Novo Nordisk. Novo Nordisk will store the research documents according to company procedures and, if required by national regulations for long-term retention, in compliance with those regulations. GIP and Chiba University will also meet data retention requirements.

14 Limitations of the Research Methods

- **Spillover effects:** Because the intervention and control groups are within the same city, there is a possibility of spillovers from the former to the latter, which would bias the estimated effect of the interventions towards 0.
- **Representativeness of sample:** To mitigate selection bias and to make the sample as representative as possible, we collect data from schools from different JHSDs across all six wards in Chiba City. Randomisation will also be stratified by ward to ensure balance between intervention and control groups and reduce the risk of ward-level confounding.
- **Precision of physical activity outcomes for younger children:** The physical activity measures for younger children (ages 6-7) have been simplified, as younger children are asked about what they did yesterday rather than the last 7 days, and provided with only 3 categories for time spent (none, less than 1 hour, 1 hour or more). This means physical activity outcomes will be more noisy for these children and statistical power will be lower due to the reduced number of categories. However, this is preferable to presenting younger children with a questionnaire they will struggle to fill in accurately.
- **Precision of energy intake / expended:** The energy intake and energy expended outcomes are based on self-reported data with additional assumptions and are therefore noisier. However, alternative options for measuring these outcomes (e.g. replacing the DQQ with full Food Frequency Questionnaire, using accelerometers instead of a survey measure) would substantially increase the cost of data collection and reporting burden on participants.
- **Statistical power at the country level:** Under the assumptions in the power calculations, the minimum detectable effect size represents a moderate effect. The intervention packages may have smaller effects on this on the sample if, for example, the elements are spread too thinly or take longer than expected to fully implement. In addition, if the assumptions in the power calculations are inaccurate (e.g. inaccurate response rate estimate, sample size change), statistical power could be smaller than expected. The global-level analyses can detect effects half the size as the country-level analyses under the assumptions.

15 Protection of Participants

15.1 Risks and Monitoring

Whilst data collection is not expected to pose any specific burdens to participants, two potential risks and their corresponding mitigation strategies have been identified and are outlined below.

Potential risks and mitigation strategies:

	LEVEL OF RISK Rate from 1-5 how serious the risk is and how likely it is to occur (higher scores indicate a higher level of risk)		
ETHICAL RISK	SERIOUSNESS	LIKELIHOOD	MITIGATION
Psychological impact: The data collection process may affect children and adolescents, particularly concerning weight and height measurements. This could increase feelings of vulnerability or insecurity about their bodies, potentially leading to issues such as low self-esteem or social pressure.	2	1	The data collection and communication strategy has been carefully designed to minimise this risk. A number of measures are in place to mitigate potential impacts, including: ● Use of sensitive and inclusive language throughout the survey ● Providing access to psychological support if needed ● Clear communication in the consent form (embedded at the start of the survey) that height and weight data will be collected
Privacy and data protection risks: As the research involves personal health data (including BMI, dietary patterns, and physical activity levels) there is a risk of data breaches or misuse, which could compromise participant privacy and lead to stigmatisation or discrimination.	3	2	Strict data protection measures will be in place to prevent such risks, as well as strict contracts and agreements between parties on what is required when handling and sharing data. Anonymisation follows the method described in Section 10.1.1.

15.2 Informed Consent Form for Research Participants

Obtaining consent for the intervention:

The intervention in this study will be conducted as a community intervention and, in accordance with the guidelines of the International Ethical Guidelines for Health-related Research Involving Humans, consent will not be obtained from individual research subjects and the intervention will be widely disseminated to potential research subjects (children in Chiba City) for the following reasons:

- The intervention is a regional intervention targeting a wide range of children in a specific area of Chiba City, and it is impractical to identify individual research subjects.
- The risk of physical harm from the intervention is extremely low.
- The intervention package can be expected to provide certain benefits to the research subjects.

However, Chiba University's ethics review requires the “explanation and consent” process for research. To ensure ethically transparent research management, the signature of the decision-maker is necessary. Therefore, we will obtain the signature of the principal, who holds decision-making authority at the elementary school, on the explanation and consent form. Additionally, we will obtain electronic consent (via Microsoft Forms) from the principals of the participating schools.
Specifically, before proceeding to the Microsoft Forms response screen, a page is provided where the principal must review the written informed consent form. This page clearly displays an explanation of the intervention for the elementary school. After the principal reviews the written informed consent form, a “I Agree/I Do Not Agree” button is placed on the Microsoft Form to indicate consent. To obtain electronic consent, the principal's email address is required. However, the principal's email address will not be used for research purposes whatsoever.

Information for Chiba City residents:

Information Dissemination to Intervention Schools and Other Chiba City Residents
For intervention schools, information will be provided to students and parents through flyer distribution, school communication system (“Suguru”), and the Minchalle app. (See the table below: “Information Dissemination Methods for Intervention Schools”)

Location	Activity	Communication Method	Sample Message / Image Ideas
Parks	Park-based activities	– Flyers	**Sample message:** Your local park has become even more fun. Why not run, climb, and play freely in the newly improved park? Come and enjoy it with your friends and family. **Image ideas:** – Photos of newly installed park equipment – Children naturally playing (running, climbing, gathering)
Schools		Activity booklet	Vice Principal → Homeroom Teachers (Explanation) Homeroom Teachers → Students (Explanation and distribution of the activity booklet) Students → Parents (Notification)
Chiba University Academy	Flyers and related materials will be distributed.		As the details have not yet been finalized, this information will be updated once they are confirmed.
Ambassador Program	Flyers		

Through these efforts, we will ensure that local residents are informed about the interventions and have opportunities to ask questions about them.

The following information will be provided to Chiba City residents: “We will keep you informed about the progress and results of the study via our website. If you have any questions, please contact the research office at any time.

Website about this research study: https://forms.office.com/r/59pgF3Y5D4.”

Obtaining consent for the questionnaire survey:

Before proceeding to the online questionnaire, there is a page that parents/guardians must read through. This page includes a clear explanation of the research for parents. Parents indicate their consent before starting the survey. Only if the parent/guardian selects 'I agree' can they proceed to the next step (survey questions). If they select 'I do not agree', access to the survey is blocked.

15.3 Withdrawals and Data Handling

Regarding study dropouts, the data collected up to the point of withdrawal will be handled based on the prior consent of the participants and their guardians. Typically, parents will have the option to decide whether to retain the data for analysis purposes after withdrawal. That is, if parents permit data retention, the data up to the point of withdrawal can be used for analysis. Chiba University is responsible for deleting any data that is not to be retained after withdrawal.

The collected data will be anonymized, meaning it will not include any personal information. The data will be stored on an external hard drive with password protection. The external hard drive will be stored in a locked facility, and access will be restricted to authorized personnel only.

- **Storage Responsible Person**: Atsushi Nakagomi
- **Storage Location**: Center for Preventive Medical Sciences, Chiba University
- **Storage Period**: 10 years
- **Data Disposal Method**: The hard drive storing the data will be initialized and erased to ensure the data cannot be recovered.

For the global data analysis: BIT utilises a data storage solution provided by Google Drive on servers in the UK. The data is encrypted during transfer and storage, and only authorized staff who log in with two-factor authentication can access the data.

15.4 Institutional review boards/independent ethics committees, health authorities, and other relevant national agencies/organizations

This local study has obtained approval from the Chiba University Ethics Review Committee. The procedure is as follows:

First, the necessary documents, such as the Ethics Review Application and Research Implementation Permission Application, were downloaded from the official website of the university's

research support division (https://concl.m.chiba-u.jp/local/jimu/rinrishinsa/), and filled out. The list of documents required for the ethics review of this study includes the following:

1. Ethics Review Application
2. Research Implementation Permission Application
3. Study protocols
4. (Printed) instructions
5. Disclosure document
6. Research Members List
7. Research Organization Requirements Confirmation Form (Novo Nordisk Pharma)
8. Research implementation system
9. Self-Report on Conflicts of Interest
10. Information to be included in flyers when recruiting
11. Questionnaire

Next, the research group (Chiba University Preventive Medicine Center, Social Preventive Medicine Department) conducted an internal review of the prepared documents. After the internal pre-check, necessary revisions and additions were made. Finally, to meet the deadline for the Chiba University Ethics Review Committee meeting on 30th January 2025, the application documents were submitted by email to the Chiba University Inohana Research Support Division on 6th January 2025.

On 16th January 2025, the Inohana Research Support Division requested revisions. On 22nd January 2025, the research group resubmitted the revised documents. After resubmission, the documents were reviewed by the ethics review committee, and the evaluation was conducted from the perspective of opt-out concerning the intervention program. Approval was obtained on 1st May 2025 via email by the CU ethics committee as shown in Appendix 4.

15.5 Early Termination of Research Participation

In this study, if a statistically significant backfire (reverse) effect on either BMI-z (adjusted for gender and age) or HRQoL is observed at the first follow-up (at a 10% significance level), then Novo Nordisk, the Behavioural Insights Team (BIT), and Chiba University stakeholders will review the potential reasons for the reverse effect (e.g. the intervention method having the opposite effect, unexpected side effects). If necessary, early termination of the study may be considered.

16 Research Results Publications

Findings obtained through local studies will be submitted to peer-reviewed international journals for publication as conference presentations and academic papers by December 2027. Potential targets include the International Journal of Public Health, BMC Public Health, and Public Health Nutrition. Results will be anonymized and will not be published in such a way that individuals can be identified. In addition, efforts will be made to issue a press release promptly after the conference presentation or publication in an international academic journal and to make the information available on the web page of the Department of Social Preventive Medical Sciences, Center for Preventive Medical Sciences, Chiba University.

Local study publications and a tentative publication schedule have been agreed upon:

1. **Local Study Protocol Development Paper (Led by Chiba University)**
   This paper will reflect the content of the Theory of Change (TOC) of the intervention program. Specifically, it will include details about the program's development, monitoring and evaluation, key components of the framework, and results from baseline data collection. The start date for this paper is scheduled for July–mid-August 2025 (Q3), with submission targeted for January–mid-February 2026 (Q1).

2. **Local Study Impact Evaluation Paper (Led by Chiba University)**
   This paper will focus on the impact evaluation of CBH COPI and insights obtained from the 1-year and/or 2-year follow-up data. The start date for this paper is scheduled for Q2 2026, with submission targeted for Q4 2027.

Research Information Registration:

The findings from this local study will be pre-registered with the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA), through the National Library of Medicine (NLM), in the database ClinicalTrials.gov, which provides information about ongoing clinical trials and research.

Appendix

Appendix 1: Survey Questions

Consent

[Insert consent form]

Please read the explanation of this study carefully, and only select the 'I agree and will answer the questionnaire' button below if you, as the parent or guardian, consent to participate in the study yourself and also consent to your child's participation. By doing so, we will consider that both your consent to participate and your proxy consent for your child's participation have been obtained.

- I agree and will answer the questionnaire.
- I do not agree.

Introduction for parents – part 1:

Structure of this survey:

First, you will be asked to answer questions about yourself as the parent or guardian. After that, you will be asked to answer questions about your child (such as their health and daily habits). Please complete the questions about your child **together with them.**
If you have more than one child, please respond with information **about only one of them.**

What to prepare:
Please have your child's **body measurement results from this school year (2025)** ready, if available.
If you do not have access to the school measurements, please prepare a **measuring tape and a scale so you can measure your child's height and weight** at home.

Introduction for parents – part 2:
This part of the survey is for parents/guardians. We will ask you some questions about yourself, and some questions about the height and weight of your child.

Part 1: Demographics

[For parents]

Q1: Please select the name of your child's elementary school from below. (drop down menu)

22 schools plus “other/unknown” option

Q2: Please enter your email address.

Q3: (Confirmation) Please enter your email address once again.

Q4: Do you have more than one child attending the same school?

1. No
2. Yes, but they are not twins, triplets or quadruplets
3. Yes, and they are twins, triplets or quadruplets.

Q5: Do you have the results of your child’s height measurement taken at school?

1. Yes
2. No

Q6: (Only shown if Q5==”Yes”)

Please look at this photo and measure height at home.

1. Preparation: Confirm that the wall at the measurement location is vertical and the floor is level.

2. Removing shoes: Measure with bare feet or thin socks (Photo 1).

3. Adjusting posture: Touch the wall with four points: heels, buttocks, shoulder blades, and back of the head, and stand straight with the back extended (Photo 2).Lightly tuck the chin and look straight ahead.

4. Marking the top of the head: Place a ruler against the top of the head so that it is completely vertical to the wall (Photos 3 & 4). At the line where it touches the top of the head, mark the wall with a pencil or sticky note (Photo 4).

5. Measuring the distance from the floor to the mark: Use a tape measure or measuring stick to measure the vertical distance from the floor to the mark on the wall (Photos 5 & 6). Make sure the tape is extended vertically and not at an angle.

6. Reading and recording the value: Please read and record the height in centimetres to one decimal place.

[Note: There are no answer options for this "question".]

Q7: Please tell us your child's height. *(Unit: cm)*

To parents/guardians: Please enter numbers only, using half-width characters, and be as accurate as possible (to one decimal place, e.g. 130.4).

Q8: Do you have the results of your child's weight measurement taken at school?

1. Yes
2. No

Q9: (Only shown if Q8=="Yes")

Please look at this diagram and measure weight at home.

1. Preparation: Place the scale on a flat and stable floor (Photo 1). Adjust it so that the display is easy to read (Photo 2).

2. Removing shoes: Measure with bare feet or thin socks (Photo 3).

3. How to stand on the scale: Stand straight in the centre of the scale with both feet evenly aligned left and right (Photo 3).

Be careful that toes and heels do not stick out (Photo 4).

4. Maintaining posture: Keep your back straight and your gaze forward. Do not move on the scale and stay relaxed (Photo 5).

5. Reading the value: Once the reading stabilises, read the number shown on the scale. If using an analogue scale, correctly confirm the number indicated by the red needle.

6. Recording / Finishing: Write down the measurement in a notebook or app, and you are finished.

Q10: Please tell us your child's weight. (Unit: kg)

To parents/guardians: Please enter numbers only, using half-width characters, and be as accurate as possible (to one decimal place, e.g. 26.8).

Q11: What's your annual household income (including bonuses)?

1. Less than 2 million yen
2. 2–3.5 million yen
3. 3.5–5.5 million yen
4. 5.5–8 million yen
5. More than 8 million yen
6. Prefer not to say

Q12: Regarding your child's parents, were your child's parents born in Japan?

1. Both parents were born in Japan
2. Only one parent was born in Japan
3. Neither parent was born in Japan
4. I don't know

Q13: From this point onward, will you be completing the survey together with your child?

1. Yes
2. No

End message to parents:
This part of the survey is for **your child**. Please hand the device to your child and stay nearby to support them as they go through the questions. We'll be asking them a few questions about themselves and their health.

Introduction for children:
We are going to ask you some questions about yourself, then about what you did recently, and finally about what you ate yesterday. Please ask your parent or guardian if you are not sure about one of the questions.

[For children (ages 6-9 and ages 10-12)]

Q14: Are you a boy or a girl?

1. Boy
2. Girl
3. Prefer not to say

Q15: What month were you born?

[drop-down menu] January - December

Q16: How old are you?

1. 6 years old
2. 7 years old
3. 8 years old
4. 9 years old
5. 10 years old
6. 11 years old
7. 12 years old

Part 2: KIDSCREEN-10

Introduction to KIDSCREEN-10 (all ages):

First, we want to ask how you feel about your health, friends and school.

How to answer:

- Read each question.
- Think about how you have felt in the **last week** and then choose your answer.
- If you are not sure, give your best guess.

Remember:

- There are no right or wrong answers.
- If you do not want to answer a question, you can skip it.
- Please ask your parent or guardian if you are not sure about one of the questions."

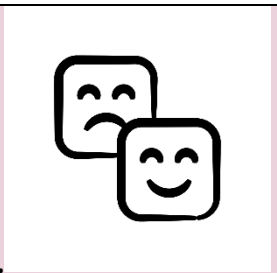
[For ages 6-9]

Thinking about the last week...



1. Have you physically felt fit and well?	not at all	a little	sometimes	a lot	all the time
2. Have you felt full of energy?	never	almost never	sometimes	almost always	always

[Page 2: Psychological scale]



Thinking about the last week...

3. Have you felt sad?	never	almost never	sometimes	almost always	always
4. Have you felt lonely?	never	almost never	sometimes	almost always	always

[Page 3: Autonomy and parent relations scale]



Thinking about the last week...

5. Have you had enough time for yourself?	never	almost never	sometimes	almost always	always
6. Have you been able to do the things that you want to do in your free time?	never	almost never	sometimes	almost always	always
7. Have your parent(s) treated you fairly?	never	almost never	sometimes	almost always	always

[Page 4: Peers and social support & school environment scales]



Thinking about the last week...					
8. Have you had fun with your friends?	never	almost never	sometimes	almost always	always
9. Have you got on well at school?	not at all	a little	sometimes	a lot	all the time
10. Have you been able to pay attention in class?	never	almost never	sometimes	almost always	always

[Page 5: Self-assessed general wellbeing]

11. In general, how would you say your health is?	poor	fair	good	very good	excellent

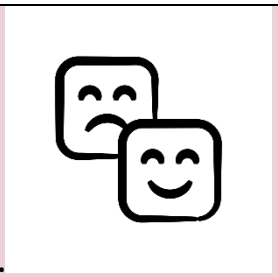
[For ages 10-12]

[Page 1: Physical scale]



Thinking about the last week...					
1. Have you physically felt fit and well?	not at all	slightly	moderately	very	extremely
2. Have you felt full of energy?	never	almost never	sometimes	almost always	always

[Page 2: Psychological scale]



Thinking about the last week...

3. Have you felt sad?	never	almost never	sometimes	almost always	always
4. Have you felt lonely?	never	almost never	sometimes	almost always	always

[Page 3: Autonomy and parent relations scale]



Thinking about the last week...

5. Have you had enough time for yourself?	never	almost never	sometimes	almost always	always
6. Have you been able to do the things that you want to do in your free time?	never	almost never	sometimes	almost always	always
7. Have your parent(s) treated you fairly?	never	almost never	sometimes	almost always	always

[Page 4: Peers and social support & school environment scales]



Thinking about the last week...

8. Have you had fun with your friends?	never	almost never	sometimes	almost always	always
9. Have you got on well at school?	not at all	slightly	moderately	very	extremely
10. Have you been able to pay attention?	never	almost never	sometimes	almost always	always

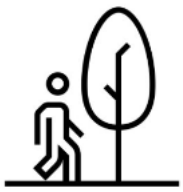
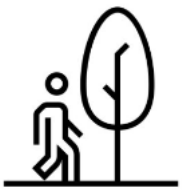
[Page 5: Self-assessed general wellbeing]

11. In general, how would you say your health is?	poor	fair	good	very good	excellent

Part 3: Physical Activity

Introduction to physical activity questions (ages 6-9):	**Introduction to physical activity questions (ages 10+):**
Next, please answer each question about what you did yesterday. If you don't understand a question, ask someone at home for help.	Next, please answer each question about what you did **in the last 7 days (from 7 days ago until yesterday).** If you don't understand a question, ask someone at home for help.

Questions on physical activity outcomes:

Question #	*Asking about previous day (default option for ages 6-9)*	*Asking about last 7 days (default option for ages 10+)*
1	 **How long did you spend walking yesterday?** Think about things like: ● Walking to school and back home from school ● Walking to and from the bus station ● Walking to and from the shops ● Walking around your local area or in the park If you are not sure, put your best guess. **1. How long did you spend walking yesterday?**	 1. For each of the **last 7 days (up to yesterday)**, mark how long you spent walking in the table below. This includes things like: ● Walking to and from school ● Walking to and from the bus or train station ● Walking to and from the shops ● Walking around your neighbourhood or in the park If you are not sure, put your best guess.

	[Response options: ● *Ages 6-9: none, less than 1 hour, 1 hour or more* ● *Ages 10+: none, 1 to 14 minutes, 15 to 29 minutes, 30 to 59 minutes, 1 to 2 hours, more than 2 hours]*	*Please choose one option for each day.* *[Present as radio, with days as a column on the left and answer options as a row along the top]* *[Response options:* ● *Ages 6-9: none, less than 1 hour, 1 hour or more* ● *Ages 10+: none, 1 to 14 minutes, 15 to 29 minutes, 30 to 59 minutes, 1 to 2 hours, more than 2 hours]*
2	**Physical activity is any activity that makes you <u>sweat</u> or be <u>out of breath</u>**. Some physical activities you may do are: **running, riding a bike, dancing, rollerblading, skateboarding, swimming, football, baseball, judo and karate.**  **How long did you spend doing physical activity <u>yesterday</u>?** Think about physical activity you did: ● During physical education class, if you had it ● During lunchtime ● After school ● In the evening ● In your spare time If you are not sure, put your best guess. **Do <u>not</u> count time you spent walking.** **2. How long did you spend doing <u>physical activity yesterday</u>?** Do not count time you spent walking. *[Response options:* ● *Ages 6-9: none, less than 1 hour, 1 hour or more* ● *Ages 10+: none, 1 to 14 minutes, 15 to 29 minutes, 30 to 59 minutes, 1 to 2 hours, more than 2 hours]*	**Physical activity is any activity that makes you <u>sweat</u> or be <u>out of breath</u>**. Some physical activities you may do are: **running, riding a bike, dancing, rollerblading, skateboarding, swimming, football, baseball, judo and karate.**  For each of the **<u>last 7 days (up to yesterday)</u>**, mark how long you spent doing **<u>physical activity</u>** in the table below. This includes physical activity you did: ● During physical education class, if you had it ● During lunchtime ● After school ● In the evening ● In your spare time If you are not sure, put your best guess. **Do <u>not</u> count time you spent walking.** *Please choose one option for each day.* *[Present as radio, with days as a column on the left and answer options as a row along the top]* *[Response options:* ● *Ages 6-9: none, less than 1 hour, 1 hour or more* ● *Ages 10+: none, 1 to 14 minutes, 15 to 29 minutes, 30 to 59 minutes, 1 to 2 hours, more than 2 hours]*

3	 **How long did you spend sitting or lying down looking at a smartphone, tablet, computer or TV <u>outside of school</u> <u>yesterday</u>?** Think about things like: ● Watching TV and films ● Playing video games ● Going on internet websites or apps like TikTok and YouTube ● Sending emails and text messages ● Talking to people over video ● Studying or doing homework using a computer If you are not sure, put your best guess. **3. How long did you spend sitting or lying down looking at a smartphone, tablet, computer or TV <u>outside of school</u> <u>yesterday</u>?** *[Response options (ages 6-9 and ages 10+): none, less than 1 hour, 1 to 2 hours, more than 2 hours but less than 5 hours, 5 hours or more]*	 3. For each of the **<u>last 7 days (up to yesterday)</u>**, mark how long **<u>outside of school</u>** you spent sitting or lying down looking at a smartphone, tablet, computer or TV screen in the table below. This includes things like: ● Watching TV and films ● Playing video games ● Going on internet websites or apps like TikTok and YouTube ● Sending text messages via LINE etc ● Talking to people over video ● Studying or doing homework using a computer If you are not sure, put your best guess. *Please choose one option for each day.* *[Present as radio, with days as a column on the left and answer options as a row along the top]* *[Response options (ages 6-9 and ages 10+): none, less than 1 hour, 1 to 2 hours, more than 2 hours but less than 5 hours, 5 hours or more]*

Part 4: DQQ

Introduction to DQQ (all ages):

Finally, we want to ask you about what you ate and drank yesterday.

Think about what you ate and drank for **breakfast**, **lunch**, **dinner** and as **snacks** yesterday.

How to answer:

- Look at each list of foods.
- If you ate a food from the list for breakfast, lunch, dinner or as a snack, select the box.
- **<u>If you did not eat anything from the list, select the box that says "I did not have this".</u>**
- Look at the pictures of food to help you.

[For ages 6-9]

[Note: Images of the relevant foods will be provided for each question.]

Yesterday, did you eat any...	**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
1. Fruits?					
2. Vegetables?					
3. Cereal, bread, rice, potatoes, pasta or noodles?					
4. Beans (e.g. edamame, natto)?					
5. Nuts (e.g. peanuts, almonds)?					
Yesterday, did you eat any...	**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
6. Eggs?					
7. Meat (chicken, pork, beef)?					
8. Fish?					
9. Cheese?					
Yesterday, did you eat or drink any...	**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
10. Milk or yogurt?					
Yesterday, did you drink any...	**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
11. Fruit juice?					
12. Cola, soda, sports drinks or energy drinks?*					
12*. Diet drinks (such as Diet Coke or Coke Zero)? [Note this question will be asked to all children due to limitations in functionality with MS Forms.]					
Yesterday, did you eat any...	**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
13. Cookies or cakes?					

14. Sweets, chocolate or ice cream?					
15. Potato chips?					
16. Fried foods like burgers, fried chicken or pizza, eaten at fast food places like McDonald's or at home?					

[For ages 10-12]

[Note: Images of the relevant foods will be provided for each question.]

Yesterday, did you eat any of the following foods?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
01 foods made from grains	Rice, onigiri, bread, udon, somen, ramen, or pasta?					
02 whole grains	Soba, brown rice, zakkoku, barley, barley bread, or corn?					
03 white roots/tubers	Potato, taro, sweet potato, yam, turnip, lotus root, or burdock root?					
04 legumes	Tofu, edamame, black soybeans, nattō, dried soybeans, kidney beans, or broad beans?					
Yesterday, did you eat any of the following vegetables?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
05 vitamin A-rich orange vegetables	Carrots, orange squash, or red bell pepper?					
06.1 dark green leafy vegetables	Spinach, bok choy, Japanese mustard spinach, Japanese mustard or nira?					
06.2 dark green leafy vegetables	Broccoli, chrysanthemum leaves, moroheiya, or Chinese cabbage?					
07.1 other vegetables	Tomatoes, lettuce, green pepper, cucumber, daikon radish, or seaweed?					
07.2 other vegetables	Eggplant, mushrooms, cabbage, okra, bitter melon, or zucchini?					
Yesterday, did you eat any of the following fruits?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
08 vitamin A-rich fruits	Persimmon, orange melon, mango, or loquat?					

09 citrus	Orange, mandarin, kumquat, or grapefruit?					
10.1 other fruits	Apple, banana, Japanese pear, peaches, cherries, strawberries, or grapes?					
10.2 other fruits	Melon, watermelon, kiwi, pineapple, or lychee?					
Yesterday, did you eat any of the following sweets?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
11 baked/grain-based sweets	Cakes, cookies, donuts, crepes, waffle cakes, red bean filled cakes, or daifuku mochi?					
12 other sweets	Candy, chocolates, ice cream, anmitsu, or pudding?					
Yesterday, did you eat any of the following foods of animal origin?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
13 eggs	Eggs?					
14 cheese	Cheese?					
15 yogurt	Yogurt?					
16 processed meats	Sausages, wiener, ham, Spam, or bacon?					
17 unprocessed red meat (ruminant)	Beef, sheep or venison?					
18 unprocessed red meat (non-ruminant)	Pork or wild boar?					
19 poultry	Chicken or duck?					
20 fish and seafood	Fish, dried fish, canned fish, or seafood?					
Yesterday, did you eat any of the following other foods?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
21 nuts and seeds	Japanese walnuts, peanuts, cashews, or almonds?					
22 packaged ultra-processed salty snacks	Potato chips or corn snacks?					

23 instant noodles	Instant noodles?					
24 deep fried foods	Agemono, deep fried chicken, deep fried potato and meat, deep fried meat, deep fried pork, tempura, deep fried prawns, or French fries?					
Yesterday, did you have any of the following beverages?		**Breakfast**	**Lunch**	**Dinner**	**Snack**	**I did not have this**
25 fluid milk	Milk?					
26 sweet tea/coffee/cocoa	Sweetened tea, sweetened coffee, Calpis, Yakult, flavored milk or soymilk, cocoa, or Frappuccino?					
27 fruit juice and fruit drinks	Fruit juice or fruit drinks?					
28 sugar-sweetened beverages (soft drinks, energy drinks, sports drinks)	Soft drinks such as Coca-Cola, Ramune soda, ginger ale, cider, Pocari sweat, or energy drinks?*					
28*	Diet drinks (such as Diet Coke or Coke Zero)? [Note this question will be asked to all children due to limitations in functionality with MS Forms.]					
29 fast food	McDonalds, Mos Burger, or KFC?					

Appendix 2: Exploratory Outcome Indicators Table

Table 4. Exploratory outcome indicators details			
Indicator Type	**#**	**Indicator**	**Details**
Physical activity outcomes	8	Moderate-to-vigorous physical activity (MVPA), minutes per day	This is defined (for children) as time spent in any activity that makes you sweat or be out of breath.
	9	Physical activity, minutes per day	This is calculated as MVPA time + walking time; a separate question is asked about each.
	10	Sedentary time, minutes per day	This is defined as screen time outside of school – non-screen sedentary time is less malleable and the activities that make up the malleable part of non-screen sedentary time (sitting

			and talking with friends) are hard to define. See Olds et al. (2010).
	11	Energy expended through physical activity per day	Energy expenditure can be estimated as kcal burned during MVPA time + kcal burned during PA (non-MVPA) time. Energy expenditure per minute will be calculated as: *Energy expenditure (kcal/min) = MET x BMR*. ● MET (metabolic equivalent) is assumed to be: o 5.5 for MVPA activities o 3.0 for PA (non-MVPA) activities o 1.2 for non-PA activities (used in sensitivity analysis / PRIMEtime modelling) ● BMR (base metabolic rate) is assumed to follow the Schofield equations below: o Boys aged 6-9: BMR = {[22.706 * weight (kg)] + 504.3}/1440 o Boys aged 10+: BMR = {[17.686* weight (kg)] + 658.2}/1440 o Girls aged 6-9: BMR = {[20.315 * weight (kg)] + 485.9}/1440 o Girls aged 10+: BMR = {[13.384 * weight (kg)] + 692.6}/1440 Values for MET and BMR are based on Butte et al. (2017). **Note it must be possible to link a child's physical activity data to their weight, age and sex for this calculation to be accurate, which requires all data to be captured in the same session/ set of surveys.** If it is not possible to collect data on weight, individual-level weight will be replaced with age-and-sex-specific medians from WHO country-specific growth curves (e.g. the WHO Growth Charts for Canada (2014)) or the global growth curves if country-specific curves do not exist.
Diet outcomes	12	Global Dietary Recommendations (GDR) Score	**Full DQQ only:** ● GDR score: calculated as 9 + GDR-Healthy – GDR-Limit (0-18) (see fact sheet from Technical Consultation on Measuring Health Diets (2021)) ● Sensitivity analysis: Dichotomous indicator: score >= 10 **Both full and simplified DQQs:** ● **Simplified GDR score: calculated as 6 + Simplified-GDR-Healthy – Simplified-GDR-Limit (0-12)
	13	Fruits and vegetables consumed	**Full DQQ only:** ● *WHO-FV score (0-6) ● Sensitivity analysis: Dichotomous indicator: score >= 3 **Both full and simplified DQQs:** ● Binary variable for consuming at least one fruit

			● Binary variable for consuming at least one vegetable
	14	Sugar-sweetened beverages (SSBs) consumed	**Both full and simplified DQQs:** ● Number of mealtimes in which SSBs consumed (0-4) ● Binary variable for consuming any SSBs ● Proportion of children who consume any diet SSBs out of those who consume any SSBs (descriptive analysis)
	15	Added sugars consumed	**Full DQQ:** ● *WHO-sugar score (0-6) ● Sensitivity analysis: Dichotomous indicator: score < 2 **Both full and simplified DQQs:** ● **Simplified WHO-sugar score (0-5) ● Binary variable for consuming at least one sweet food
	16	Saturated fat consumed	**Full DQQ:** ● *Calculated as 2 + WHO-SatFat (to transform range from [–2, 6] to [0, 8]) ● Sensitivity analysis: Dichotomous indicator: transformed score < 4 **Both full and simplified DQQs:** ● ***amount in g (calculated by summing the unweighted average across individual items' saturated fat values (in g) for all sub-question / mealtimes selected by the child) ● Binary variable for consuming at least one salty snack ● Binary variable for consuming at least one deep fried or fast food
	17	Fibre consumed	**Full DQQ:** ● *WHO-fibre score (0-10) ● Sensitivity analysis: Dichotomous indicator: score >= 4 **Both full and simplified DQQs:** ● ***amount in g (calculated by summing the unweighted average across individual items' fibre values (in g) for all sub-question / mealtimes selected by the child) ● Binary variable for consuming at least one legume
	18	All-5 food groups consumed	**Both full and simplified DQQs:** ● Number of all-5 recommended food groups consumed (0-5) ● Sensitivity analysis: all-5 score = 5
	19	Starchy staples consumed	**Both full and simplified DQQs:** ● Binary variable for consuming at least one starchy staple

	20	Dairy food consumed	**Both full and simplified DQQs:** ● Binary variable for consuming at least one dairy food
	21	Animal-sourced foods (ASFs) consumed	**Both full and simplified DQQs:** ● Binary variable for consuming at least one ASF
	22	Energy intake per day	**Both full and simplified DQQs:** ● Amount in kcal: ***This will be calculated by summing the unweighted average across individual items' kcal values for all sub-question / mealtimes selected by the child.
	23	Carbohydrates consumed	**Both full and simplified DQQs:** ● Amount in g: ***This will be calculated by summing the unweighted average across individual items' carbohydrate values (in g) for all sub-question / mealtimes selected by the child.
	24	Protein consumed	**Both full and simplified DQQs:** ● Amount in g: ***This will be calculated by summing the unweighted average across individual items' protein values (in g) for all sub-question / mealtimes selected by the child.
	25	Fat (lipids) consumed	**Both full and simplified DQQs:** ● Amount in g: ***This will be calculated by summing the unweighted average across individual items' fat values (in g) for all sub-question / mealtimes selected by the child.
Outcome calculated from PA and diet data	26	Net calories	This will be calculated as energy expended per day (indicator #11 sensitivity analysis, looking at both PA and non-PA time) minus energy intake per day (indicator #22).
PRIMEtime-modelled impacts	29	QALYs	These indicators will (for at least the main analysis) all use a closed-cohort simulation (i.e. estimating the effects of intervention on those aged 6-13 at the time of intervention launch over their lifetimes).
	30	DALYs	
	31	Rate of cardiovascular disease (CVD)	
	32	Rate of type 2 diabetes (T2D)	

**These indicators are the composite scores proposed by Herforth et al. (2020). See codebook or further details.*

***These indicators are slight alterations of the Herforth et al. (2020) scores which take into account the constraints of the simplified DQQ. See codebook for further details.*

****Individual items will be matched to food databases (selected at country level) and portion sizes will be converted from adults to children as appropriate to get kcal, carbohydrates, protein, fat, saturated fat and fibre information. For the full DQQ, the average will be calculated over the list of food items by country. For the simplified DQQ, the average will be calculated over the corresponding list of food items from that country's full DQQ.*

Appendix 3: Output Indicators

Table 5. Output indicators details			
#	**Indicator**	**Variable(s)**	**Details**
1	People reached	Highest intervention-level reach estimate (observed or estimated) of the initiative for relevant age group	***Local delivery lead/partner*** *responsible for collection of observed reach (e.g. individual-level interventions)* ***Local M&E partner*** *responsible for calculation of estimated reach (e.g. environment-focussed interventions)* **Observed reach:** This can be calculated through enumeration of participants or based on documentation (e.g. school records). **Estimated reach:** If an observed measure of reach cannot be formed, estimated reach should be calculated by first calculating the relevant target population based on the setting of the intervention, for example: ● School classes: size of class * number of classes ● School: size of school * number of schools ● Neighbourhood/city: size of relevant target population in neighbourhood/city Then multiply the size of the relevant target population by a factor F (0-1) based on local evaluation of the % of individuals reached within the setting to get estimated reach*.
2	Children reached (0-18 years)		
3	Target population reached (6-12 years)		
4	Number of interventions commenced	Number of interventions commenced each year Numbers will be reported both for the year and cumulatively	***Local delivery lead*** *responsible for collection (as part of intervention delivery metrics)* The GIP will define the number of interventions that commence in each country's intervention package within any given year and cumulatively from the start of the programme. This metric will be reported in total and also broken down by level (downstream, midstream, upstream) and target behaviour (physical activity, diet, both). Definitions for each intervention level are shown below: **- Downstream:** information and tools to support individuals in navigating unhealthy environments (e.g. introduce educational sessions on healthy eating and physical activity; provide parenting programmes that encourage healthy eating and/or physical activities;

			introduce food voucher programs to make healthy foods better value) **- Midstream:** small changes to the places in which children live to make the healthy choices the easy choice, but without entirely removing the risk factors for obesity (e.g. increase the relative proportion of healthy foods offered in school settings; position healthy foods more prominently in school cafeterias or supermarkets; introduce free, inclusive social recreation programmes, such as family sports leagues) **- Upstream:** structural changes to remove risk factors for obesity from the places in which children live (e.g. reformulate or swap items in school meals to make them healthier; provide healthy universal free school meals; introduce or renovate green space for physical activities)
5	Number of interventions active	Number of interventions active for each year	***Local delivery lead*** *responsible for collection (as part of intervention delivery metrics)* GIP will define the number of interventions that have been active in any given year (i.e. commenced and stopped OR commenced and continued OR continued from previous year). This metric will be reported in total and also broken down by level (downstream, midstream, upstream) and target behaviour (physical activity, diet, both).
6	Whether local governments have made a public commitment to CBH COPI (i.e. formal relationships)	Binary variable for whether there is an MOU (or equivalent formal agreement) with city stakeholders Sign date of the MOU (or equivalent formal agreement) should also be captured, as well as the stakeholders involved	***Local delivery lead*** *responsible for collection (as they build the M&E coalitions)* Public commitment refers to MOU or equivalent formal agreement exists with city stakeholders (e.g. mayor's office, local government)
7	Whether relevant community stakeholders have been involved in intervention development and/or delivery	Binary variable for whether there are relevant community stakeholders who have been involved in intervention development and/or delivery (at intervention package level rather than individual intervention) The types of stakeholders who have been involved (i.e. government, NGOs, private sector) should also be captured	***Local delivery lead*** *responsible for collection (as they lead/support intervention development and delivery)* Relevant community stakeholders are individuals or organisations who have either an active role to play in the delivery of an intervention or belong to/are associated with the target recipients of the intervention.

Appendix 4: Ethics Committee Approval

The original document is in Japanese and has been translated into English to meet ClinicalTrials.gov requirements.

Reception No.	M10825

April 30, 2025

Notification of Ethics Review Results

Principal Investigator
(Institution) Chiba University
(Affiliation) Department of Social Preventive Medical Sciences, Associate Professor
(Name) Atsushi Nakagomi

Chiba University Graduate School of Medicine
Chair, Ethics Review Committee
Hirotaro Iwase

We hereby notify you of the results of the review you requested, as described below.

Particulars

Research Title	Cities for Better Health Childhood Obesity Prevention Initiative
Items Reviewed (Review Documents)	■ Appropriateness of conducting the research (Application form / Research protocol, dated January 6, 2025) □ Appropriateness of continuing the research □ Changes to the research (□ Application for changes to the research, dated _____ / ____ / ____) □ Periodic report (Research progress report, dated _____ / ____ / ____) □ Other ( )
Review Type	■ Full committee review (Review date: April 25, 2025) □ Expedited review (Review completion date: _____ / ____ / ____)
Review Result	■ Approved □ Not approved □ Continued review □ Suspended (further explanation required to continue the research) □ Terminated (continuation of the research is not appropriate)
Reasons, etc. if other than "Approved"	
Comments	■ None □ Yes ( )
Remarks	

※ For multi-institutional collaborative research, approval also applies to the collaborating institutions designated for centralized review in Form 8, "Research Implementation Structure."

Reception No.	M10825

Committee Member List

Name	Affiliation	Sex	Member-ship Category	Attend-ance	Remarks
Hirotaro Iwase	Professor, Education And Research Center Of Legal Medicine, Chiba University	M	1	○	Chair
Yoshio Kobayashi	Professor, Department Of Cardiovascular Medicine Chiba University Graduate School Of Medicine	M	1	○	Vice Chair
Katsuhiko Asanuma	Professor, Department of Nephrology, Chiba University Graduate School of Medicine	M	1	○	
Motoko Y. Kimura	Professor, Department of Experimental Immunology, Chiba University Graduate School of Medicine	F	1	○	
Hideki Hanaoka	Professor, Chiba University Hospital Clinical Research Center	M	1	×	
Shinichi Okazumi	Director, Japan Community Healthcare Organization (Jcho) Chiba Hospital	M	1	／	
Sachie Yoshida	Project Assistant Professor, General Medical Education and Training Center, Chiba University Hospital	F	2	／	
Nobuyuki Okabayashi	Professor, Faculty of Law, Politics and Economics, Chiba University	M	2	○	
Higashijima Jin	Associate Professor, Graduate School of Global and Transdisciplinary Studies	F	2	○	
Hirou Nomura	Attorney At Law, HORI & PARTNERS	M	2	○	
Naoko Tsuchida	Director, Non-Profit Organization Sasaeau-Kai “Alpha”	F	3	○	
Minobu Shimazu	Project Assistant Professor,, Clinical Research Center, Chiba University Hospital	M	3	○	
Yuichi Machida	Section Chief, Research Promotion Division, Inohana Area Administration Department	M	4	／	

・Sex: M (male) / F (female)
・Membership Category: indicated by the following numbers
1 Experts in medicine or healthcare, or persons with knowledge of the natural sciences
2 Experts in ethics or law, or persons with knowledge of the humanities or social sciences
3 Persons able to express opinions from a general standpoint, including the perspective of research participants
4 Others deemed necessary by the committee
・Attendance: indicated by the following symbols
○ (Attended and not involved in the research under review)
－ (Attended but did not participate in deliberation or voting due to involvement in the research under review)

× (Absent)

Appendix 5: Contract confirming data sharing with BIT and NNAS

The original document is in Japanese and has been translated into English to meet ClinicalTrials.gov requirements.

Notwithstanding the provisions of this Article, Chiba University may provide personal information that it collects from participants under each Joint Research Agreement to The Behavioural Insights Team and Novo Nordisk A/S, as designated by Novo, to the extent necessary for the data analysis set forth in this Special Agreement. This is subject to the condition that Chiba University complies, and causes such recipients to comply, with the Act on the Protection of Personal Information (Act No. 57 of 2003) and all other applicable domestic and foreign laws, regulations, guidelines, and the like. However, the information provided by Chiba University shall not include any personal information provided to it by Chiba City.

Annexes

Record of Changes to Annexes

Date	Changes made	By Whom (e.g. BIT, CU, NNPL)
09.09.2026	Relevant to section 8.3.2 Recruitment and Reminder System to 8.3.5 Survey closure CU and BIT have jointly agreed to remove the 150-response incentive cap per cluster and continue data collection in clusters exceeding 150 responses, provided two conditions are met: • The overall response count does not surpass 3,300 (22 × 150) to remain within budget. • The same approach—omitting the per-cluster incentive cap—will be repeated next year.	Agreed via email by CU/BIT
22.06.2026	Intervention Requirements The implementation details for Elementary schools, Parks, Ambassador Program, Chiba University Academy have been finalized, so I updated the document accordingly.	CU
08.10.2025	Intervention Requirements The implementation details for Home and Community have been finalized, so I updated the document accordingly.	CU
18.07.2025	Added Annex 1 detailing the final randomisation allocation.	BIT
18.07.2025	Added Annex 2 outlining the accidental early data collection launch and its implication on data cleaning/analysis	BIT
28.07.2025	Added Annex 3 for recording any changes to the Data collection procedure, and any deviation from the original context.	BIT
28.07.2025	Added Annex 4. Consent Form Changes to keep track of all the changes made to the consent form.	BIT

Annex 1. Final Randomisation Allocation

On 3rd July 2025, CU submitted the pre-registration to ClinicalTrials.gov and received approval on 11th July 2025. Following this, CU conducted the stratified randomisation as described above. The final allocation is shown below: the treatment group includes 6,280 students, and the control group includes 6,381 students.

The relative imbalance between the groups: (6,381/6,280) - 1 ≈ 0.02, or approximately 2%, which is within the 10% threshold we defined earlier.

Schools (JHSDs)	Ward	Allocation	Enrolment #
Ohmori	Chuo	C	497
Shinjuku	Chuo	C	796
Miyako	Chuo	T	637
Kotehashi	Hanamigawa	C	258
Uenodai	Hanamigawa	C	632
Hanazono	Hanamigawa	T	807
Makuhariminami	Hanamigawa	T	260
Inagaoka	Inage	C	545
Konakadai	Inage	T	966
Sannoh	Inage	T	527
Kanazawa	Midori	C	652
Asumigaoka	Midori	T	639
Koyatsu	Midori	T	650
Makuharinishi	Mihama	C	568
Masagohigashi	Mihama	C	540
Utase	Mihama	C	915
Saiwaichodaisan	Mihama	T	402
Takasu	Mihama	T	297
Chishirodaiwakaba	Wakaba	C	395
Wakamatsu	Wakaba	C	583
Kitakaidsuka	Wakaba	T	864

Mitsuwadaikita	Wakaba	T	231
		Treatment	6,280
		Control	6,381
		Relative Imbalance	0.0160828

Annex 2. Early Data Collection Launch

During the Japan COPI data collection pre-launch meeting led by BIT on 11th July, it was noted that data collection had unintentionally begun on 8th July, prior to the previously agreed start date of 14th July. Between 8th July and 13th July (a day before the official data collection launch), approximately 140 responses have been collected from the following five schools.

School	**Responses received**	**Reason for early launch**
1. Kita-kaidsuka Elementary school	47	Was not aware that flyer distribution should happen on the 14th July
2. Shinjuku Elementary school	34	Was not aware that flyer distribution should happen on the 14th July
3. Koyatu Elementary school	33	The school health records were scheduled to be returned from parents on the 14th July, flyers were distributed to all students in advance.
4. Hanazono Elementary school	18	Was not aware that flyer distribution should happen on the 14th July
5. Miyako Elementary school	5	Was not aware that flyer distribution should happen on the 14th July

When the accidental launch occurred on 8th July, the questionnaire was still being finalised. Our quick data quality checks indicate that the data collected using the older versions of the questionnaire remains usable and does not present any significant issues that would compromise data quality. However, the following actions are required for this dataset:

- Identification and removal of test/dummy data points.
- For height and weight variables:
    - Any height values outside the range of 80–200 cm must be replaced with a missing value (do not remove the entire response).
    - Any weight values outside the range of 10–200 kg must also be replaced with a missing value (again, without removing the entire response).

Annex 3. Data Collection Procedure

Date	Section	Changes made	Rationale
21.07.2025	8.3.2 Recruitment and Reminder System	REMINDER SYSTEM • Distribute printed flyers again in After school programme; community centre • Follow up emails to parents who indicated they have more than one child	The response rates have remained low, and CU, NNPL and BIT have jointly agreed to explore alternatives.
28.07.2025	8.3 Data collection procedure **Phase 3**	Data sharing of the early cut data for quality check no longer goes ahead on the first or second week of data collection. Data sharing from BIT to Oxford will not proceed until: 1. NNPL confirms that no contractual amendments are required, and 2. Parents have been appropriately informed via an updated consent form.	As of 28 July 2025, BIT and NNPL are still working to enable data sharing from BIT to Oxford and to update the consent form to inform parents of this change. We have confirmed and communicated the following points to NNPL, who are currently consulting with their legal team: • Oxford has a research agreement with NNAS that includes a reference to BIT. • Oxford requires anonymised individual-level data for their PRIMEtime analysis.
28.07.2025	8.3.2 Recruitment and Reminder System **Printed flyers**	According to the protocol, schools were expected to notify CU via email once the initial flyer distribution was complete. This was not followed through. Instead, CU manually monitored incoming responses of the 22 schools, and only schools with zero responses four days after the data collection start date were followed up by NNPL via email or phone.	

04.08.2025	8.3.2 Recruitment and Reminder System **Printed flyers**	During the meetings, BIT and CU have explored following options to distribute flyers: 1. Distribute printed flyers at afterschool programmes; convenience stores; restaurants; summer festivals and other places where parents may gather. 2. [low possibility] Send printed flyers by post to households with children in the target age group within the relevant clusters. However, this would require the use of the Basic Resident Register to identify eligible households, which could take up to a month to prepare. Given our current timeline, this approach may not be viable at this stage.	Response rates have remained low. It is essential to release additional reminder flyers in particular in low-response clusters to ensure each cluster reaches 100 responses and the study remains sufficiently powered.
05.08.2025	8.3.2 Recruitment and Reminder System **Printed flyers**	Chiba City agreed and posted the flyer on the Chiba City staff websites.	

Annex 4. Consent Form Changes

Date	Changes made	Rationale
11.07.2025 during the Pre-launch meeting Part. 1	Added a line "*Email addresses will be used to distribute Amazon gift cards as compensation. The Amazon gift cards will be distributed through the Amazon gift card proxy service 'Dera-e' (*https://www.dera-e.jp/*). Therefore, email addresses will be shared with Cloud Co., Ltd/Inc. (*https://www.cloudsoft.co.jp*),*	During the Pre-launch meeting, BIT and CU jointly agreed that CU include this line in the consent form. We also agreed that for participants who completed the survey prior to this update, CU should distribute the Amazon vouchers directly, without involving a third party.

	the company that operates 'Dera-e'." To inform parents of personal data sharing with a third party.	
18.07.2025	Added 'NNAS' in data sharing, and distinguished between NNPL and NNAS in the ethics application.	To be transparent about the data sharing with NNAS
01.08.2025	CU and BIT jointly agreed to name the University of Oxford in the consent form. Decision from the CU ethics panel currently pending as of 4th August.	To be transparent about the data sharing with the University of Oxford

Annex 5. Sharing of early cut data & the data collected between 8th July and 14th July

In the follow-up pre-launch meeting led by BIT on the 18th July 2025, BIT and CU jointly agreed that data sharing including that of the early cut data should not go ahead until the consent form is updated to explicitly include data sharing with Oxford, and a follow-up message is sent to parents to inform them of this change, as explained in Section 12.2.6. In the BIT/ CU meeting on the 1st of August, CU agreed to name the University of Oxford in the consent form, and update the CU ethics panel. Once this is approved, and parents are informed via email, we will proceed with the data sharing of the early cut dataset.