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PROTOCOL

SNaK+: A Survey of Na⁺ and K⁺ Intakes in New Zealand Children



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3. PROJECT FUNDING

Heart Foundation New Zealand Project Grant (Ref: 3719070). HE's salary is funded by a Heart Foundation of New Zealand Senior Research Fellowship (Ref: 3719071).

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6. REVISION CHRONOLOGY

Version:	Date:	Type of Amendment:
First draft version 1 (submitted to UAHPEC)	15 th October 2019	First draft
Draft version 1.1	11 th November 2019	Amendments made provided UAHPEC feedback.
Draft version 1.2	19 th November 2019	Addition of analysis of sodium and potassium by level of deprivation. Amendments also made regarding future urine storage and setup of Governance group.
Draft version 1.3	14 st January 2020	Addition of veggie meter pilot component.
Draft version 1.4	28 st January 2020	Additional changes made according to discussions from Advisory team meeting (held 20/01/20).
Draft 2	2 nd March 2020	Feedback from HDEC (outstanding ethical issues)
Draft 3	10 January 2022	Updated research team, timeline, school type, university logo, sample analysis location/process and delivery of science lesson
		Addition of Covid-19 precautions
		Removal of focus groups and parent/teacher follow-up interviews
		Removal of 24-hour diet recall

Not for Reproduction

Addition of child dietary habit
questions in the parent follow-
up survey

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8. OVERVIEW

8.1 TITLE

SNaK+: A Survey of Sodium (Na⁺) and Potassium (K⁺) Intakes in New Zealand Children.

8.2 INVESTIGATORS AND STUDY CENTRES

Dr Helen Eyles, School of Population Health, University of Auckland (study centre).

Dr Rachael McLean, Department of Preventive & Social Medicine, University of Otago.

8.3 STUDY PERIOD

March 2020 to Dec 2022.

8.4 AIMS AND OBJECTIVES

The main aims of the study are to:

1. Measure the sodium and potassium intakes and blood pressure of school children aged 8 to 13 years in New Zealand, with a focus on Maori and Pacific.

The secondary aim is to:

1. Investigate differences in sodium and potassium intakes, and blood pressure, by gender, ethnicity, household income, and by level of deprivation.

A pilot study will also be undertaken using the 'veggie meter' (optional to participants). The aims of this pilot are to:

1. If sufficient data are available, compare 'veggie meter' data with estimated carotenoid intake in a multi-ethnic group of New Zealand children.
2. Explore the potential prevalence of adequate fruit and vegetable intake in New Zealand children aged 8 to 13 years.
3. Examine the relationship between 'veggie scores' in children and 24-hour urinary potassium excretion.
4. Investigate differences in 'veggie scores' by age, gender, body size, ethnicity, household income, and level of deprivation.

8.5 STUDY DESIGN AND METHODOLOGY

A mixed methods study including a cross-sectional survey.

8.6 STUDY POPULATION

The main study population are children aged 8 to 13 years old (school years 3 to 8) attending an Auckland primary or intermediate school. Recruitment will initially focus on students in Years 7 and 8, and broaden to Year 3 and 6 as well as other regions such as Dunedin depending on recruitment success.

8.7 INCLUSION CRITERIA

- Child attends primary or intermediate school in New Zealand which has been selected and agreed to take part.
- Child is aged 8 to 13 years old (school years 3 to 8) and is a member of a class in which the teacher of a participating school has agreed to take part.
- Child has provided written informed assent.
- Parent/caregiver has provided written informed consent.
- Child is able to speak and understand English.

9. BACKGROUND

9.1 DIETARY SODIUM AND POTASSIUM AND THE BURDEN OF HIGH BLOOD PRESSURE AND CARDIOVASCULAR DISEASE

Diets high in sodium (most commonly found in food as salt) and low in potassium (found in fruits and vegetables) contribute >74,000,000 disability adjusted life years annually⁽¹⁾, mainly through their relationship with high blood pressure (BP) and increased risk of cardiovascular disease (CVD) later in life. In addition, excess dietary sodium is associated with an increased risk of stomach cancer and kidney disease^(2, 3), and new research suggests there may also be a direct link with obesity⁽⁴⁾.

New Zealand (NZ) adults have a mean daily intake of 3373mg of sodium (equivalent to 8.4g salt) per day⁽⁵⁾, well in excess of World Health Organization (WHO) guidelines (<2,000mg, or 5g of salt, per day)⁽⁶⁾. As preference for salty food begins early in life⁽⁷⁾, it is important to ensure that children are not exposed to high levels of salt in their diet. However, very little is known about the sodium intakes of NZ children – the latest Children’s Nutrition Survey is now 18 years old and did not report on sodium intake or BP⁽⁸⁾.

Additionally, there are no data on ethnic or income differences in sodium or potassium intakes in NZ, even though significant inequalities in heart health exist. One in four Pacific people have raised BP compared with one in five in other ethnic groups⁽⁹⁾, and on average, Pacific people experience high BP at younger ages than other ethnic groups, with some Pacific high school students in NZ exhibiting elevated BP compared to their non-Pacific counterparts⁽¹⁰⁾. A similar trend is also observed among Māori, where adults are 30% more likely to have high BP, 80% more likely to have ischaemic heart disease, and 111% more likely to suffer a stroke than non-Māori adults⁽¹¹⁾.

Nutritional practices in childhood are a significant precursor to eating patterns later in life^{(12, 13)(12, 13)(12, 13)(12, 13)(12, 13)(12, 13)(12, 13)(12, 13)}. Therefore, describing NZ children’s current sodium and potassium intakes, identifying the major food sources of these nutrients, and exploring the factors that influence children’s food choices, have important implications for public health.

9.2 ACCURATE MEASUREMENT OF DIETARY SODIUM AND POTASSIUM

Traditional dietary assessment methods such as diet recalls and records are not considered robust for measuring sodium and potassium intakes due to recall and social desirability bias, difficulty in accurately measuring salt added in cooking and at the table, and the need for brand specific food composition information⁽¹⁴⁾. However, the majority of sodium (90-95%) and potassium (80-85%) excreted by the body is lost in urine^(15, 16). Therefore, 24-hour urine collection is considered the gold standard measure⁽¹⁵⁾. Twenty-four hour urine collections have been used successfully to assess sodium and potassium intakes in large samples of children in the United Kingdom⁽¹⁷⁾, Europe⁽¹⁸⁾, and Australia⁽¹⁹⁾.

9.3 THE SALT IN KIDS PILOT STUDY

In 2017, a NZ pilot study measured sodium and potassium intakes in NZ children using 24-hour urinary sodium and potassium excretion⁽²⁰⁾. The pilot involved 19 children aged 8-11 years who provided a 24-hour urine sample. The overall results showed that median sodium intake was 2191mg/d, equivalent to approximately 5.6g of salt⁽²⁰⁾. This is higher than the guidelines for adult sodium intake prescribed by the WHO and also the Nutrient Reference Values (NRVs) for Australia and NZ - a maximum of 2000mg/d of sodium for children 9-13 years of age⁽²⁰⁻²³⁾.

Median potassium intake was reported as 1776mg/d, lower than the NRV recommended intake of at least 3000 mg/d and 2500 mg/d for boys and girls aged 9-13 years of age^(20, 21). The sodium to potassium molar ratio, what is often described as a better metric in the determination of BP in children, was 2.0, higher than the optimal ratio of one ^(20, 24-26).

Dietary recalls were also collected to identify major food sources of sodium and potassium for NZ children. Results show that the major sources for sodium were bread, pies and pastries, and bread and

pasta-based dishes⁽²⁰⁾. The main dietary sources for potassium were sauces and condiments, dairy products, and non-alcoholic beverages⁽²⁰⁾.

The pilot findings corroborate with a more recent 2019 study which measured sodium and potassium intakes in 82 NZ children aged 9-11 years. This study, comparing differences in methods for measuring sodium and potassium intakes, found 24-hour urinary sodium excretion to be 2119mg/d (5.4g salt) and 24-hour urinary potassium excretion to be 1414mg/d⁽²⁷⁾.

Both studies provide some indication of the current intakes and sources of sodium and potassium among NZ children. However, these study findings should be interpreted with caution due to their small sample size and their lack of information regarding potential differences in sodium and potassium intakes by ethnicity and income.

9.4 NEW ZEALAND'S COMMITMENT TO REDUCING POPULATION SODIUM INTAKE

In 2013, alongside several other countries, NZ made a commitment to the WHO to reduce population sodium intake by 30% towards 2,000 mg/day by 2025⁽²⁸⁾. However, to date, very little has been done to achieve this goal. Monitoring sodium and potassium intakes and determining the main food sources is the first logical step to inform the development of NZ guidelines and effective interventions and public health policies.

9.5 STUDY AIMS AND OBJECTIVES

The main aims of the study are to:

1. Measure the sodium and potassium intakes and blood pressure of school children aged 8 to 13 years in New Zealand, with a focus on Maori and Pacific.

The secondary aim is to:

1. Investigate differences in sodium and potassium intakes, and blood pressure by gender, ethnicity, household income, and level of deprivation.

The aims of the 'veggie meter' pilot (optional to participants) are to:

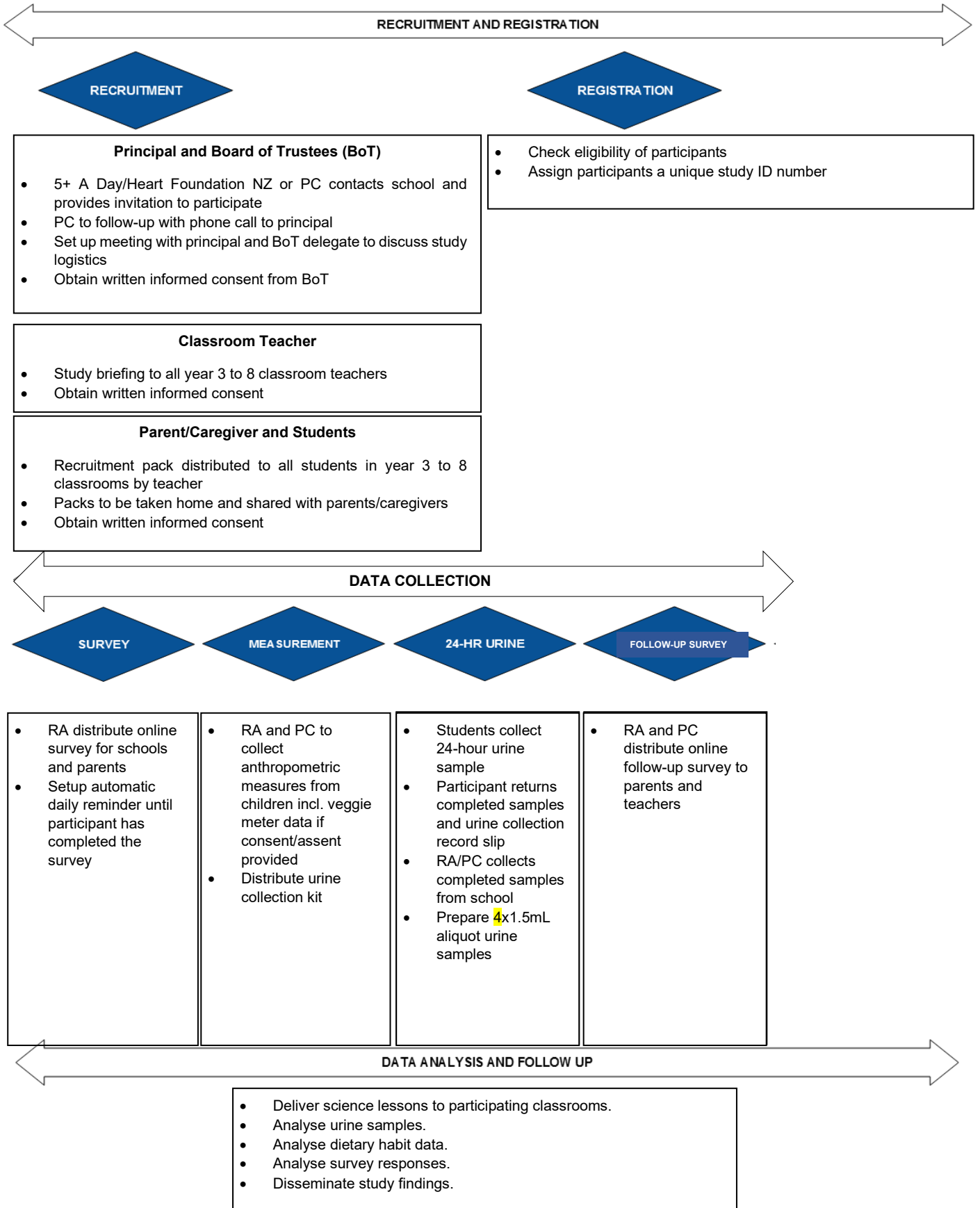
1. If sufficient data are available, compare 'veggie meter' data with estimated carotenoid intake in a multi-ethnic group of New Zealand children.
2. Explore the potential prevalence of adequate fruit and vegetable intake in New Zealand children aged 8 to 13 years.
3. Examine the relationship between 'veggie scores' in children and 24-hour urinary potassium excretion.
4. Investigate differences in 'veggie scores' by age, gender, body size, ethnicity, household income, and level of deprivation.

10. ROLES AND RESPONSIBILITIES

- Principal Investigator (PI)**
- Supervision and study oversight of all study procedures and documentation.

- Project Coordinator (PC)**
- Operational management of the study, including oversight of study procedures and documentation
 - Recruitment of schools
 - Informing principals and BoT about study protocols
 - Inform teachers and participating students about study protocols
 - Preparation of study equipment and documentation
 - Liaison with school principal, BoT and teachers around data collection
 - School survey
 - Lead data collection
 - Collect consent forms
 - Collect completed 24 hour urine samples, prepare aliquoted samples for laboratory analysis
 - Collect students' height, weight, waist and hip circumferences and blood pressure measurements
 - Collect veggie meter data if required
 - Administer follow-up parent/teacher surveys
 - Develop science lessons in conjunction with teacher advisor
 - Follow-up surveys with teachers/parents
 - Arrange Koha
- Research Assistant (RA)**
- Data collection in conjunction with the PC
 - Collect completed 24 hour urine samples, prepare aliquoted samples for laboratory analysis
 - Collect students' height, weight, waist and hip circumferences and blood pressure measurements
 - Collect veggie meter data if required
 - Collect dietary intake data
- Advisory Group**
- Development of current study design and implementation.
 - Continual engagement regarding study progress and decision making.
- Urine Samples for Future Research Governance group (includes advisory group + additional members)**
- Oversee management and access to urine samples intended for future research purposes.

11. STUDY PLAN SCHEMATIC



12. TIMELINE

Month and year	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May 20 to Oct 21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	
School terms															Term 2			Term 3		Term 4									
School holidays															25 April - 5 June		17 July - 22 Sept			9 Oct - 20 Dec									
Protocol	Completed	Completed	Completed	Completed	Completed	Completed																							
Prepare study documentation and briefing video		Completed	Completed	Completed	Completed	Completed																							
Prepare and submit Ethics application			Completed	Completed	Completed	Completed																							
Ethics received							Completed																						
Hire new staff for 2021 following project hold									Completed	Completed																			
Revise project due to pandemic and submit ethics amendment									Completed	Completed	Completed	Completed	Completed	Completed															
Ethics amendment approved															Completed														
School recruitment															Started - 1 school		4-5 schools			4-5 schools									
Project briefing session for teachers																													
Participant recruitment																													
Parent briefing																													
Data collection - 3 to 4 waves, 1 to 4 schools per term																													
Data cleaning																													
Data analysis																													
Write paper																													
Dissemination																													Ongoing

Term 1: Monday 31st January to Thursday 14th April
 Term 2: Thursday 2nd May to Friday 8th July
 Term 3: Monday 25th July to Friday 30th September
 Term 4: Monday 17th October to no later than Tuesday 20th December

2022 SCHOOL HOLIDAY DATES

Term 1: Saturday 16th April to Sunday 1st May
 Term 2: Saturday 9th July to Sunday 24th July
 Term 3: Saturday 1st October - Sunday 16th October
 Term 4: start by 20th December

13. STUDY DESIGN

A cross-sectional mixed methods study conducted in Auckland primary and intermediate schools.

13.1 RECRUITMENT

We aim to recruit approximately 300 children aged 8-13 years from primary and intermediate schools in the Auckland region. All primary/intermediate schools in Auckland (~399 eligible schools) will be stratified by Ministry of Education decile ([2017 Ministry of Education School Directory](#)) and student ethnicity (Māori, Pacific, NZ European). Based on school and participant response rates of ~25% in our pilot, we estimate seven to nine schools will be required to recruit ~300 children (33 to 42 participants per school; n=1 dropout in our pilot). Selection will be made across the 10 school deciles; initially selection will include 2 schools each from quintiles 1 (decile1-2) and 2 (deciles 3-4), with one school selected from each of the remaining three quintiles (deciles 5-6; 7-8; and 9-10); in addition selection will focus on schools with a higher proportion of Māori and Pacific and relationships with existing organisations. Recruitment will also initially focus on students in Years 7 and 8, and broaden to Year 3 and 6 depending on recruitment success.

The recruitment of identified schools will be supported by two organisations, 5+ A Day and The Heart Foundation NZ. Where there is an existing relationship, these organisations will make the initial approach to school Principals and the Boards of Trustees, otherwise the approach will be made by the study PC. A RA or the PC will then follow up and arrange to meet with the school Principal and the Board of Trustees chair (or delegate) to discuss the study. Once a school has been recruited, the PC will work with the Principal and school staff to develop tailored recruitment processes for that school. Participating schools will be given the option of which term they wish to take part.

Study briefings will then be provided to teachers and informed consent sought. Participant information sheets and assent forms will be sent home with children for parents/caregivers. Online consent forms will be sent via a link in an email to principals, teachers and parents to obtain electronic consent. A video summarising study methods and participant procedures will be shown at briefings and made available to all participants.

13.1.1 Inclusion criteria

- Child is in year 3 to 8 and aged 8 to 13 years old.
- Parent/caregiver has provided written informed consent.
- Child has provided written informed assent.
- Able to speak and understand English.

13.2 DATA COLLECTION

The data collection methods are based on the successful NZ pilot⁽²⁰⁾, and a 2013 survey of sodium and potassium intakes in primary school children in Victoria, Australia⁽¹⁹⁾. The research team will follow the latest Covid-19 advice, precautions and guidelines provided by the [Ministry of Health](#), [Auckland University](#), and participating schools where relevant throughout the study.

13.2.1 Baseline Questionnaire:

13.2.1.1 Schools

Schools that agree to take part in the study will complete an online questionnaire to collect information on the physical location of the school with respect to other food sources, the school's current food policies, whether (or not) the school has a school garden, and whether the school receives any nutrition programmes such as milk for schools, free fruits and vegetables, and/or a school breakfast or lunch programme.

13.2.1.2 Parents/Caregivers:

Baseline information will also be collected from the parents/caregivers of children via an online survey (or hardcopy upon request). The information collected will include parent/caregiver and child

demographics, child dietary habits and discretionary salt use. Questions about child dietary habits will be based on those used by The Children's Nutrition Survey 2002 ⁽²⁹⁾ and the NZ Health Survey ⁽³⁰⁾ to allow us to compare our population with larger representative surveys. Demographic information to be collected will include household income, level of deprivation (via NZDep18), and child's ethnicity, age, gender, birth weight, existing medical conditions, and use of medications or dietary supplements.

Four questions on discretionary salt use will also be included, adapted from a study determining knowledge, attitudes and behaviours (KABs) related to dietary salt intake among Victorian adults⁽³¹⁾ i.e. 'Do you usually add salt during cooking?' 'Do you usually place a saltshaker on your table at mealtimes?' 'Does your child usually add salt to their meal at the table or in food preparation?' 'If you do add salt during cooking and at the table, what type of salt do you usually use: iodised/not iodised, table/rock/other salt? Information will also be collected on whether salt used is usually iodised. Participants will be able to select the most suitable response from the options: 'Yes, usually', 'Yes, sometimes', 'No', or 'Don't know'.

13.2.2 Twenty-four Hour Urine Collection

Measurement of children's intakes of sodium and potassium will be carried out by gold standard 24-hour urine collection and analysis. Children will be provided with a Urine Collection Kit and taken through a series of pictorial instructions and a video on how to collect 24-hours of urine. Written instructions and the video will also be provided to the child's parents/caregivers. Children can either begin their 24-hour urine collection at school or at home over the weekend, and will be provided tailored instructions, according to school or weekend day collection.

To commence the urine collection, children will be instructed to empty their bladder, discard this urine, record this time as the 24-hour urine collection start time, and begin collecting all urine voided during the next 24-hours. Children will be provided with a 2.5L wide mouth, rimmed polypropylene bottle for collection. A 500mL plastic handled jug will also be provided to assist with collection. If children elect to collect the urine on a school day, they will start their collection at school and the child will be given a second bottle to collect the remaining urine for the 24-hour period. Children electing to complete the collection on a weekend day will receive one bottle to bring back to school the following Monday. Parents/caregivers and children will be asked to report the hours of collection and any missed collections or spillages on a urine collection slip (included in the Urine Collection Kit); this slip will be returned with the 24-hour urine sample. Procedures at each school will be tailored, but all schools will be encouraged to provide a designated study bathroom for children to store collected urine during school hours.

All urine samples will be collected from the school and returned to the University of Auckland for temporary storage by the PC or RA. Each child's collected urine will be measured and prepared into a minimum of 2 x 1.5mL aliquots. Once all samples for all participants have been returned, aliquoted and frozen, the PC will notify the Auckland University laboratories to carry out the analysis on one aliquot for this study; the remaining aliquot will be stored at the University of Auckland Clinics as a backup. All remaining urine from these first two samples will be disposed of appropriately at the end of the study (flushing into toilet). Samples will be frozen at -4°C.

If participants provide consent, two additional 1.5mL aliquots of urine will be prepared and stored at the University of Auckland Clinics for use in future research measuring iodine and fluoride. It is intended that this future research will be undertaken in 2023. Storage and access to these additional urine samples for future research purposes will be managed by a Governance group¹. If urine for future research is not analysed before the end of 2023, additional informed consent will be sought from parents/caregivers and children prior to analysing these samples.

¹ The Governance group will consist of co-investigators, study advisors and independent Māori and Pacific ethics advisors who will manage storage and access to the remaining urine samples.

The molecular weights of sodium, sodium chloride and potassium will be used to convert laboratory mmol to mg (sodium and potassium intake)⁽¹⁶⁾. Completeness of samples will be assessed using urine volume, time of collection, and creatinine. Samples not exactly covering 24-hour will be normalised unless the participant has recorded missing more than one collection, volume <300mL, collection time <20 hours or >28 hours, and/or creatinine <0.1mmol/kg body weight⁽³²⁾.

Urine sent to the Auckland University laboratories will be analysed for urinary sodium and potassium using a Hitachi Cobas C311 analyser, using an Ion selective electrode. Urinary creatinine will be analysed on the Cobas C311 using a colorimetric assay based on the Jaffe method⁽³³⁾.

13.2.3 Anthropometry

Height, body weight, hip/waist circumference will be measured for all children participating in the study. Data will be recorded directly into an online form using REDCap software. In case of no/poor internet connection, data will be recorded on coded paper-based forms, which will be kept securely by the PC and RA. All anthropometric measures will be collected according to standard procedures published by the WHO⁽³⁴⁾ and wearing light clothing. Height will be measured, without shoes, to the nearest 0.1cm, using a calibrated stadiometer. Weight will be measured to the nearest 0.1kg using a calibrated portable electronic scale. Waist circumference will be measured using a standard measuring tape to the nearest 0.1cm. A minimum of two measurements will be taken. A third measurement will be taken if the second is not within 10mm of the first.

A mean will be used if only two measurements are taken; if three measurements are required, the median value will be used. Body mass index (BMI) centiles will be determined and age and gender adjusted BMI z-scores will be calculated. Children will be provided with their anthropometric measures on a paper slip to take home to their parents/caregivers. The WHO recommended standard units for the physical measurements included in this study, including their upper and lower limits for data entry purposes, are provided below⁽³⁴⁾:

Physical Measure	Unit	Minimum	Maximum
Blood pressure	Refer to paediatric guidelines ⁽³⁵⁾		
Height	cm	100	270
Weight	kg	20	350
Waist circumference	cm	30	200

13.2.4 Blood Pressure

Children's BP will be measured using an OMRON automatic BP monitor and using an appropriately sized cuff. Measurements will be taken from children in a seated position, after five minutes rest, with the child's right arm resting on a table at the level of the heart. Children will be asked to sit as still as possible and avoid coughing or talking. The average of three BP measures will be recorded for analysis.

13.2.4.1 Incidental findings:

13.2.4.1.1 Blood pressure:

We will be comparing children's BP readings against the screening table provided by the '*Clinical Practice Guidelines for Screening and Management of High Blood Pressure in Children and Adolescents*⁽³⁵⁾. Children with systolic BP and diastolic BP >90th percentile for their age, gender and height will be identified and their parents/caregivers will be informed of their child's BP via a phone call or email. Parents/caregivers will be strongly encouraged to raise this with their GP within the next 6 months (as outlined in Section 4.3.2 of the Clinical Practice Guideline) and repeat this measurement. A letter addressed to their GP will also be provided at this time.

The table provided by the '*Clinical Practice Guidelines for Screening and Management of High Blood Pressure in Children and Adolescents*⁽³⁵⁾ was designed to only identify children who need further evaluation of their BP. According to these guidelines, a diagnosis of hypertension or prehypertension

can only be confirmed if BP is elevated on three separate occasions (i.e. three GP clinic visits). As we are only measuring blood pressure on a single occasion, an elevated blood pressure reading may not be clinically significant. Nevertheless, we will continue to inform parents/caregivers of children, but direct contact with the child's GPs is not reasonable.

13.2.4.1.2 Increased sodium:

Parents/caregivers will also be notified after the study if their child is found to have high sodium results. We are only measuring sodium and potassium on one (24-hour) occasion. It is recommended that multiple 24-hour urine samples are needed for a more defined measure of how much sodium and potassium a child is consuming. A letter (with results) and the WHO sodium guidelines will be provided to parents/caregivers.

13.2.5 Veggie Meter Pilot

Participants will also be provided with the opportunity to take part in a pilot study aimed at exploring the prevalence of low fruit and vegetable intake in NZ children. If schools' consent, and child assent and parent/caregiver consent are provided, children will have their fruit and vegetable intake measured using the 'veggie meter' (Figure 1).

The veggie meter is a non-invasive method of measuring participants' levels of beta-carotene, a plant derived form of Vitamin A, through a fingertip reading device. The technology accurately and painlessly measures whether people are getting enough beta-carotene from plants to be considered healthy.

Three measures of skin colour will be undertaken and a score (low, medium or high), produced. Each measure takes 10 seconds and then the finger is removed for five seconds before placing over the light again.



13.2.6 Follow-up Surveys

Teachers and parents will each receive a link to a 5-10 minute follow-up online survey asking for feedback on the study experience. The parent survey includes additional questions regarding their child's dietary habits.

13.3 SAMPLE SIZE AND STATISTICAL ANALYSIS

Assuming a SD of 1,000mg from the from the NZ pilot study⁽²⁰⁾, 240 participants will give a two-sided 95% confidence interval with a margin of error of 127mg (i.e. 0.13 SD) on the estimated mean sodium intake (mg/day). Allowing for 20% incomplete urine samples, we aim to recruit 300 children. Descriptive statistics will be used to describe children's demographics, weight, height, BMI z-scores (BMI for age), blood pressure, sodium and potassium intakes and dietary sources of sodium and potassium.

Demographic information will be presented overall, and by gender, ethnicity, household income, and by level of deprivation (NZDep18). Continuous variables will be summarised as the mean, SD, median and range. Categorical variables will be summarised as frequencies and percentages. Based on estimated proportions of sub-groups in the final sample, differences in study outcomes between important subgroups will be tested using statistical tests appropriate for continuous and categorical variables respectively. Statistical tests will be two-sided at 5% significance level. Qualitative responses to surveys will be analysed using thematic analysis, and cultural aspects/barriers will be explored.

14. ETHICAL APPROVAL & CONSENT

14.1 ETHICAL APPROVAL

Ethical approval will be sought from the Health and Disability Ethics Committee (HDEC). All participants (Principals/Board of Trustees, teachers, children and parents/caregivers) will receive a Participant Information Sheet and a copy of their consent details prior to taking part in the study. All assent/consent form hard copies will be treated as confidential and stored securely at the University of Auckland for a period of ten years.

14.2 INFORMED CONSENT

Participation in the study is entirely voluntary. Written consent will be sought from the Principal of the school interested in participating in the study. Research staff will work with the principal and appropriate year level teachers to recruit children for the study. Written letters of invitation to participate in the study will be provided to students in year three to six to take home to their parents/caregivers. Children will be asked to discuss this with their parents at least one week (ideally two weeks) prior to recruitment. Information will also be sent home with school newsletters and advertised through other school media e.g. Facebook. A contact phone number will be provided for parents/caregivers to discuss any questions with the research team.

Written informed consent will be required from the parent/caregiver AND participating children (assent). Parents/caregivers will be advised that as children are under 16 years of age, they are able to refuse permission for their child to participate on the consent form. Children wishing to participate will be asked to provide assent/consent on the child participation information sheet and consent form. The use of stored urine samples for future research purposes and voluntary participation in the veggie meter pilot will be outlined in the Participant Information Sheet and Consent/Assent Forms. Urine stored for future research use will be managed by a Governance group. Parent/caregiver and child informed consent/assent will be attained prior to any future use of stored urine samples.

14.3 REIMBURSEMENT

To reimburse participants for their time, the school will be provided with a \$500 book or equipment voucher, and children will be given a \$20 gift voucher. Teachers will be offered a set of seven free interactive science lessons related to heart health and the study methods, which were developed with the support of an experienced teacher. If teachers choose to use these lessons, they will be asked to deliver the introductory lessons (which contain minimal information about salt and potassium intake but introduce the concept of heart health and blood pressure) before the research team collects the data. Other lessons directly related to sodium and potassium intake and making healthy food choices should be delivered once data collection is complete to ensure that the learnings do not affect child dietary behaviours. If needed, a researcher will be available to facilitate one of these lessons and/or provide equipment for the activities. Classrooms that take part in the Heart Healthy Celebration Lesson will be given an additional \$60 Koha towards food and ingredients. If they do not choose to use the lesson plans, teachers will deliver the recruitment packs and the school will choose a day and time for the research team to visit and collect data, which will be completed in a separate room during class time (i.e., each student will leave class for 15-minutes according to allocated time slots).

14.4 ANONYMITY AND CONFIDENTIALITY

Due to the nature of the collection methods, it will not be possible to anonymise data collected. Anthropometric, dietary, and blood pressure measurements will be collected from the study participants by the RA and PC. To protect the confidentiality of the participants, the PC will assign codes to each participant. The composition of participant codes will allow the PC and RA to link child data with their parent/caregiver information, school information, and classroom (teacher) data. Only the PC and RA will be able to decode these codes.

Identifying materials will be stored separately from coded outcome data and all data will be coded during data analysis. All data will be stored securely at the School of Population Health, University of Auckland

for a period of ten years after the youngest child turns sixteen. If additional urine samples have not been analysed at this time they will be disposed of appropriately, as for the disposal of surplus urine outlined in Section 14.2.2.

15. DISSEMINATION OF RESULTS

15.1 STUDY PARTICIPANTS

At the end of the study, participating schools will be offered a short, lay presentation on the findings of the research, either face-to-face and/or in video or infographic format. All participants will also receive a lay summary of findings via email or post in an infographic format. The public will also be informed via local media coverage.

15.2 ACADEMIC/ PROFESSIONAL COLLEAGUES AND OTHER STAKEHOLDERS

Academic publications will be sought in a high impact medical, cardiovascular, or nutrition journal and a presentation will be given at a national or international nutrition, public health, or cardiovascular conference. Reports will also be sent to key stakeholders including The Ministry of Health, The Heart Foundation of NZ, The Stroke Foundation, The Cancer Society, and Māori and Pacific health providers (e.g. Hāpai Te Hauora and Toi Tangata, Pacific Heartbeat).

16. OWNERSHIP OF DATA

Individual study data will remain the property of the individual participants. The School of Population Health, University of Auckland has the responsibility for storage, protection and retrieval of study data. Data will be stored securely for ten years, and after this time will be safely destroyed.

17. PUBLICATIONS

Efforts will be made to publish findings of this study.

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