

VisezEau® (ReachforWater): a project to learn how to increase drinking of tap water and reduce drinking of bottled and sugary drinks among primary school children, with the aim of encouraging healthy weight and protecting the environment

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Registration date 31/01/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Consumption of beverages (drinks) contribute to the quality of a person's diet. It has been suggested that the rise in obesity is partly due to people drinking less water and more sugar-containing beverages (SCBs). One in four children in Québec and one in five in Canada are overweight or obese. This is a big public health issue given that childhood excess weight tends to last into adulthood and that many health problems are associated with having too much excess weight. Moreover, drinking non-bottled beverages can help protect the environment. Unlike SCBs, non-bottled water is poorly promoted, but it is a human right, is the best drink for quenching thirst and hydration and, when substituted for SCBs, can prevent overweight and obesity.

The ReachforWater (VisezEau®) project has been designed to promote drinking of good-quality non-bottled tap water and to reduce drinking of bottled water and SCBs among children. This 3-year study intervention aims to test how well ReachforWater (VisezEau®) works in preventing overweight among children aged 5-12 years attending Québec (Canada) primary schools. In children, this study will measure changes in water and SCB consumption, as well as their body measurements. As children can encourage behavioural changes in adults, our study will also measure changes in water and SCB consumption among parents. In summary, ReachforWater (VisezEau®) has the potential to improved child health and environmental protection.

Who can participate?

All children in 1st to 4th grade (aged 6-10 years) of the participating schools at the start of the intervention and their parents or guardians

What does the study involve?

This project is designed to influence school culture in order to make it fun and easy to drink tap water. New decorated fountains dispensing filtered cooled water will be installed in ReachforWater (VisezEau®) schools. All children and school staff will receive high-quality and visually appealing reusable personal water bottles to fill at the new fountains. In addition, a smaller reusable water bottle for lunch boxes will be provided to children in order to replace bottled beverages (water and SCBs). Many enjoyable learning activities about the benefits of drinking non-bottled tap water will take place in class and at childcare services. Kids will also learn about the negative impacts of bottled beverages (plastic and sugar). Some of these activities will carry over to students' homes. Effects of this project on children and their parents from ReachforWater schools will be compared to those from schools that are not yet involved in the project.

What are the possible benefits and risks of participating?

Participants might drink more tap water and less sugary drinks, which might benefit their health. There are no risks associated with participating.

All measurements are non-invasive. All participating schools groups will eventually receive the intervention. Children will not see any personal data while measurements are taken or at any other time.

Where is the study run from?

The ReachforWater (VisezEau®) project will be run from the CHU of Québec - Laval University Research Centre (Canada) and will take place in a total of 35 schools from 3 different Québec school boards (Canada).

When is the study starting and how long is it expected to run for?

May 2019 to June 2022

Who is funding the study?

The Québec Government (Canada)

Who is the main contact?

Michel Lucas, michel.lucas.1@ulaval.ca

Study website

<https://reachforwater.org/>

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

18-SP-00268-01

Study information

Scientific Title

The VisezEau® (ReachforWater) intervention trial in primary school: shifting towards normalization of non-bottled tap water consumption for preventing excess weight gain and for environmental protection

Acronym

VisezEau® (ReachforWater)

Study objectives

Excessive weight gain among Québec children aged 6 to 12 years can be reduced by drinking more water and less sugar-containing beverages.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/06/2019, Comité d'Éthique de la Recherche du CHU de Québec - Université Laval [CHU de Québec - Université Laval research ethics committee] (10, rue de l'Espinay Édifice D, 7^e étage Québec, Québec, G1L 3L5 Canada; +1 418 525 4444 ext 52715; ethiquedelarecherche@chudequebec.ca), ref: 2017-3505

Study design

Stepped-wedge cluster-randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Overweight (including obesity)

Interventions

The intervention is a multi-level (school and home) theory-based intervention to be deployed according to the randomized trial design. The intervention is designed to improve the beverage consumption profile of participating children as a means of improving their body composition.

Operational objectives of the intervention:

1. To normalize (develop the reflex of) drinking non-bottled water at school, as well as at home by:

1.1. Improving access to non-bottled water at school

1.2. Improving the pleasure of drinking non-bottled water

1.3. Increasing awareness of the health benefits associated with drinking non-bottled water

1.4 Creating a social environment supportive of developing the reflex of drinking non-bottled water

2. To reduce the consumption of sugar-containing beverages (SCB)

2.1. At school: Enable and promote the replacement of fruit juice (e.g. TetraPak) by tapwater in the children's lunch box

- 2.2. Outside the home and schools: develop critical thinking and provide tools enabling the consumption of water as the first choice for hydration during key activities (e.g. for sports; for hot weather) for children and parents
- 2.3. Raising awareness and preparing children to apply epicurean sensibilities in the context of SCB consumption (i.e. when, how much, which occasion; how to say no) and provide alternatives and an education to taste and flavours
- 2.4. Raise awareness on the effects of sugar from ultra-transformed products in liquid format on the body
- 2.5. Raise awareness on how social justice and environmental justice are impaired by ultra-transformed products in liquid format.

Design: A three-step armed stepped wedge cluster randomised controlled trial (SWT) will test the efficacy of the VisezEau® (ReachforWater) Intervention implementation.

Duration: The duration of the Trial will be 34 months (i.e. 3 school years T1, T2 or T3, minus one summer period). The summer holiday periods will be void of intervention. Schools will be considered as trial clusters to avoid inter-classroom contamination. Schools will be allocated to groups receiving the intervention at the start of T1 (school year 2019-2020), T2 (school year 2020-2021) or T3 (school year 2021-2022).

Randomization: Using a randomization software number table, equal numbers of clusters (12 schools) will be selected for each of these three steps. The three School Boards involved in this trial have been selected for feasibility and external validity. Randomization will be forced to ensure that each School Board receives the intervention at a minimum of one school per year (request on behalf of School Boards).

Schools not receiving the Intervention will represent control clusters until they are randomly assigned to begin exposure to the intervention. With this design, each cluster will eventually receive the intervention. The same group of students will be followed over time. During T1, participants will be students from grades 1-4 (6-10 years old); T2 students in grades 2-5 (7-11 years old) and T3 students from grades 3-6 (8-12 years old).

Details of the VisezEau® (ReachforWater) intervention:

The VisezEau® (ReachforWater) Intervention design targets three levels:

1. Built environment: The installation of new water fountains providing cooled filtered water and the distribution of one high-quality appealing reusable personal water bottle to each student, as well as to all school personnel. In addition, a reusable smaller water bottle for lunch boxes will be provided to students in order to replace bottled and sugar-containing beverages.
2. Social environment and 3. Individual (child): The schools in the treatment arm will be given a standardized program. The main objectives of this program are to sensitize participants to the effects that increased drinking of tap water and decreased drinking of bottled and sugary drinks can have on health, the environment and society and provide exposure to knowledge transfer activities. The child, or individual targeted by the intervention, will be exposed through teachers, school administrators and daycare educators to a culture that promotes tap water consumption and discourages drinking of bottled and sugar-containing beverages. Moreover, several activities are designed to promote behavioural change at home. All educational components of the intervention will be based on the Education in Environment and Sustainable Development (EESD) in a critical pedagogy approach.

Social environment and individual activities:

1. A short video introducing the concept of the Intervention as well as a video about the importance of hydration will be presented in each classroom at the onset of the exposure
2. Comic book strips relaying core ideas and messages on water consumption, single use plastics,

- consumption of sugar containing beverages, evoking health, environmental and social justice issues will be distributed and read in classrooms
3. Teachers will have access to VisezEau® (ReachforWater) learning modules addressing hydration and health designed to contribute to the curriculum for physical education or science class
 4. An activity to develop taste and flavours education will be made available for use in childcare services during pedagogical days
 5. A documentary for children presenting the context of single use plastic environmental contamination and its effects on wildlife and human health will be viewed
 6. A library of books on various themes directly related to the specific objectives of the intervention will be brought to each school for the duration of the bioimpedance measurements.

Control (non-exposed schools):

Control groups will not receive any components of the intervention. A video will be made available for school personnel to explain the project and the implications for schools during their non-exposed condition. All the information that they require to participate in the study will be provided and all questions will be answered. A library of books on themes related to education in environment and sustainable development themes, but excluding water-specific themes, will be brought to each non-exposed school for the duration of the bioimpedance measurements.

A secured website (<http://reachforwater.org>) will be available throughout the intervention to support the program and will hold information and activity material.

Intervention Type

Behavioural

Primary outcome measure

1. Child's body weight measured by bioelectrical impedance analysis (InBody 770, GE Healthcare) by trained personnel, with participants wearing light clothing and no shoes, in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3
2. Child's height measured using a digital freestanding stadiometer (InBody BSM 170, GE Healthcare) by trained personnel in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3

These data will be used to calculate body-mass index (BMI), which in turn will be used to determine the prevalence of overweight and obesity. Overweight status will be determined by calculating BMI from the weight and height measurements according to International Obesity Task Force (IOTF) classification and Centers for Disease Control and Prevention (CDC) systems. BMI is defined as weight (kg) divided by height squared (m²).

Secondary outcome measures

1. Water (total, non-bottled and bottled) and other beverage intake by children aged 6-12 years assessed using a 7-day beverage frequency journal. Intakes for different water and sugar-containing products will be recorded in usual portions (ml, cup) and will be reported in daily intakes (ml/day). Measurement frequency for beverage intakes will take place in Autumn T1 (prior to deployment of the Intervention), Spring T1, Autumn T2, Spring T2, Autumn T3 and Spring T3.
2. Dry lean mass assessed using bioimpedance in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3
3. Body fat mass assessed using bioimpedance in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3

4. Total body water assessed using bioimpedance in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3
5. Waist circumference (to enable calculation of waist:height ratio) assessed using bioimpedance in Autumn T1 (prior to deployment of Intervention) and Spring T1, T2 and T3
6. Direct measurements of the general water intake assessed using water distribution data provided directly by water meters installed at drinking water faucets and all fountains. The cumulative volume measured continuously will provide objective data on the baseline volume of water drawn in schools before the intervention and the volume of drinking water drawn over time during the intervention.
7. Learnings in terms of awareness, transformative learning, and critical consciousness assessed using the last box of a comic book strip, which will be completed by children after having read several comic strips created by the project. The children will complete their own story line with the objective of relaying their main takeaway(s) on the topic of the normalization of the consumption of non-bottled water. Measurement frequency will occur three times over the course of exposure (Spring T1, T2 and T3).
8. Beverage intake (non-bottled and other water and SCB intake (ml/day) of parents will be assessed with a 7-day beverage frequency journal. Intakes for different water and sugar-containing products will be recorded in usual portions (ml, cup) and will be reported in daily intakes (ml/day). Measurement frequency for beverage intakes will take place in Autumn T1 (prior to deployment of the Intervention), Spring T1, Autumn T2, Spring T2, Autumn T3 and Spring T3.
9. Population characteristics and prior child and parent diet patterns and data on children (Tanner puberty stage, physical and sedentary activities, consumption practices, food frequency, etc.) assessed via on-line questionnaire completed by parents. Moreover, the annual administration of the short-version of the questionnaire will assess changes over time, the effect of the Intervention by comparing the control and intervention groups, and take into account for covariate analyzes that will better reflect behaviors during the 3 years of the study.
10. An analysis of implementation will inform on conformity, coverage, intensity, and acceptance of deployment of each intervention component in schools exposed to the intervention. This evaluation focuses on both the elements and the processes. This includes the reporting by the VisezEau® (ReachforWater) team members throughout the study. Questionnaires will be completed throughout and at the end of each year by the management, teachers and other school personnel, namely daycare providers. These questionnaires enable us to document the implementation, the mindset of those involved and eventual actions intervening during the year. These intervening actions will also be reported in non-exposed schools. The implementation analysis will be used to determine how the results of the intervention could be correlated with the level of adoption or dissemination of one or several specific intervention components, to the heterogeneity in the execution or the theory of the Intervention itself.

Overall study start date

23/03/2018

Completion date

17/06/2022

Eligibility

Key inclusion criteria

1. All children in 1st to 4th grade (aged 6-10 years), i.e. children who will be primary students for the duration of treatment at T0/baseline
2. Children attending an eligible school that must meet the following criteria (at randomization):

- 2.1. Entity defined as a school by school board (legal institution)
- 2.2. Maximum one director per school
- 2.3. May comprise more than one building
- 2.4. The water distributed within the school is deemed potable
- 2.5. No major renovations or construction that would likely interfere with the study foreseen prior to June 2022
- 2.6. No new water fountains with bottle-filling nozzle installed prior to study
- 2.7. Complete schools, with grades 1 through 6
- 2.8. Governed by one the three French language School Boards selected by the research team based on geographical proximity to research headquarters, ease of initial communications to present the project, and willingness to participate

Participant type(s)

Other

Age group

Child

Lower age limit

6 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

Schools will be considered as trial cluster units and be allocated to groups receiving the Intervention at the start of either T1 (2019), T2 (2020) or T3 (2021). Equal numbers of clusters will be selected for each of the three steps (12 schools per step). Our sample size includes one extra cluster per step (11+1) allowing for withdrawal of schools. With a mean size of 100 children per school, 36 clusters correspond to 3,600 children from grades 1 to 4 at baseline (T0).

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

09/10/2018

Date of final enrolment

19/02/2019

Locations**Countries of recruitment**

Canada

Study participating centre

School Board of Portneuf

310, rue de l'Église
Donnacona
Canada
G3M 1Z8

Study participating centre**School Board of des Appalaches**

650, rue Lapierre
Thetford Mines
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Study participating centre**School Board of des Premières Seigneuries**

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Sponsor information

Organisation

Centre hospitalier de l'Université Laval

Sponsor details

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Sponsor type

University/education

Website

<http://www.chuq.qc.ca/fr/>

ROR

<https://ror.org/041v96n47>

Funder(s)

Funder type

Government

Funder Name

Ministère de la Santé et des Services Sociaux du Québec [Ministry of Health and Social Services of Québec]

Funder Name

Ministère de l'Environnement et de la Lutte contre les changements climatiques du Québec [Ministry of Sustainable Development, Environment, and Fight Against Climate Change of Quebec]

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

17/06/2023

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date