# Decreasing consumption of sugar-sweetened beverages and raising tap water consumption through Interventions based on nutrition and sustainability for kids: the DRINK study

Submission date	Recruitment status No longer recruiting	Prospectively registered	
25/05/2021		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
24/06/2021	Completed  Condition category	Results	
Last Edited		[] Individual participant data	
20/06/2025	Other	[X] Record updated in last year	

### Plain English summary of protocol

Background and study aims.

Regular sugar-sweetened beverage (SSB) consumption is at the top of the alarming dietary habits worldwide due to its well-established association with weight gain, obesity and dental caries in children. Although various environmental interventions, mainly focusing on nutritional and health components, have been implemented, the effectiveness of actions to reduce the consumption of sweetened beverage (SB) and the methods for evaluating them need to be improved. Furthermore, in a context of growing awareness of the need to rethink sustainable food systems, little is known about sustainability-focused interventions to positively address children's behavior including beverage consumption. The objective of this cluster randomized controlled trial is to evaluate the long-term effectiveness of nutrition- and sustainability-based interventions on the reduction in SB intake and on the increase in tap water consumption in primary grade children.

### Who can participate?

French-speaking Belgian primary schools will be randomized using a factorial plan, in four groups: one nutrition-based, one sustainability-based and one both-based intervention group along with one control without intervention. The estimated sample to include is of 48 schools for a total of 3.500 pupils followed-up over two years.

### What does the study involve?

The study will be conducted over two school years, with interventions implemented at the beginning of the year, i.e. October 2021 and 2022. Interventions will include an information meeting for the school staff, parents, and children, and conducted by dietitians; an encouragement to teachers to include "water breaks" using tap water during the school day; posters and flyers and provision of reusable cups and glass bottles. The distinction between intervention groups will be made through the nature of the information and documents given (nutrition based and/or sustainability based). Before (June 2021) and after each intervention period (June 2022 and 2023), children and schools will be evaluated through various

questionnaires and audit, respectively.

The main quantitative judgement criterion will be the change over time in mean SB consumption in the intervention group in comparison with the control group. The daily mean children's SB consumption will be estimated through an auto-administered 4-day diary, before and after each intervention period. The measurement error in beverage intake will be taken into account through an internal calibration study in a subset of 130 participants. Other nutrition-related behaviors and wellbeing, perception of environmental risks and related behaviors, and socioeconomic characteristics will be collected among children and their parents. A repeated audit will be carried out in all the selected schools in order to assess the process by which interventions are effective or not. Within the project, a qualitative work based on behavioral theories will be developed. It aims at identifying barriers and enablers in the transmission of health-related messages coming from the school environment to the children's caregivers. At last, the total cost of interventions will be monitored to support decision-makers who would like to generalize the interventions in schools under their authority.

What are the possible benefits and risks of participating?

For the schools included in an intervention group, pupils, parents and school staff will benefit from nutritional and/or environmental information, targeted information materials, and a continuous support through the provision of materials. By taking part in this study there are no risks of physical or psychological injury or harm.

Where is the study run from?

The DRINK study is being run by the School of Public Health of the Université libre de Bruxelles (Belgium)

When is the study starting and how long is it expected to run for? April 2021 to December 2023

Who is funding the study? Fonds de la Recherche Scientifique (FNRS) (Belgium)

Who is the main contact? Prof. Katia Castetbon, katia.castebon@ulb.be

## Contact information

## Type(s)

Public

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## Additional identifiers

### **EudraCT/CTIS** number

Nil known

### **IRAS** number

## ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

FNRS, Projet de recherche: T.0032.21 (Ref. e-space : 40003510)

## Study information

### Scientific Title

Cluster randomized controlled trial of nutrition- and sustainability-based interventions aimed at reducing the consumption of sweetened beverages and at increasing the consumption of tap water in primary school children in French-speaking Belgium

### Acronym

**DRINK** 

## Study objectives

Nutrition- and sustainability-based interventions towards primary-school children in French-speaking Belgium can be effective in the long term to reduce the consumption of sugar-sweetened beverages and increase the consumption of tap water.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 05/04/2021, Ethics Advisory Committee of the Faculty of Psychology and Education (Université libre de Bruxelles, Avenue Franklin D. Roosevelt 50, CP 135, 1050 Brussels, Belgium; no telephone number provided; Ethique.Psychologie@ulb.be), ref: 073/2021

## Study design

Interventional 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

Prevention of non-communicable diseases due to high consumption of sugar-sweetened beverages in primary-school children

#### **Interventions**

The French-speaking Belgian primary schools are randomized in four groups using a factorial plan: (i) control; (ii) nutrition-based intervention; (iii) sustainability-based intervention; and (iv) both.

Interventions consist in meetings for the parents of the pupils and the school staff, in an encouragement to teachers to plan water breaks during school days, and in the provision of posters, flyers, reusable cups and glass bottle, in all schools included in the intervention groups. The interventions take place on 2021-2022 and 2022-2023 school years.

The schools included in the control group have no specific intervention.

All the included schools are aware of the arm of inclusion, the intervention being open due to its content.

## Intervention Type

Behavioural

### Primary outcome measure

Daily mean sweetened beverage consumption estimated through a 4-day diary completed by children before the beginning of the interventions in Spring 2021, and at the end of each school year of intervention in Spring 2022 and 2023

## Secondary outcome measures

- 1. Potential interactions between nutrition- and sustainability-based information provided within the interventions; measured by the factorial plan at baseline, 12 and 24 months
- 2. Individual and family moderators in the intervention effectiveness; measured by autoadministrated questionnaires for children and parents at baseline, 12 and 24 months
- 3. School staff adherence to the set of interventions; measured with the identification of obstacles and facilitators in the implementation of the interventions through audits and qualitative interviews at baseline and 24 months
- 4. Total cost of the interventions; measures by monitoring of the project and audits of the schools at the end of the study

## Overall study start date

01/04/2021

### Completion date

21/12/2023

## Eligibility

### Key inclusion criteria

French-speaking regular primary schools in Wallonia and Brussels; pupils from 3rd to 5th grade at the time of the first assessment (Spring 2021)

### Participant type(s)

Healthy volunteer

### Age group

Child

#### Sex

Both

### Target number of participants

The estimated sample size needed is 48 schools (clusters), with 5,000 pupils included in the first and the 2nd year of evaluation, 3,500 at the 3rd evaluation. A total of 3,500 pupils are followed-up over the two years of the study. In each of the four groups of randomization, 12 schools and all their pupils in 3rd to 5th grades, are included.

### Key exclusion criteria

Pupils whose parents have refused them to fill the questionnaires and the 4-day diary (or who have refused themselves). To note, the intervention being set at cluster level, all pupils are exposed.

### Date of first enrolment

22/04/2021

### Date of final enrolment

21/10/2021

## Locations

### Countries of recruitment

Belgium

### Study participating centre Université libre de Bruxelles

Research Center in Epidemiology, Biostatistics and Clinical Research School of Public Health Route de Lennik 808, CP 598 Brussels Belgium 1070

## Sponsor information

## Organisation

Université Libre de Bruxelles

### Sponsor details

Avenue Franklin Roosevelt 50 Bruxelles Belgium 1050 +32 26503260 gestionfinanciere.recherche@ulb.be

### Sponsor type

University/education

### Website

http://www.ulb.ac.be/

### **ROR**

https://ror.org/01r9htc13

## Funder(s)

## Funder type

Government

### **Funder Name**

Fonds De La Recherche Scientifique - FNRS

### Alternative Name(s)

F.R.S. - FNRS, Fund for Scientific Research - FNRS, Belgian National Fund for Scientific Research, FNRS

### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Local government

### Location

Belgium

### **Funder Name**

Université Libre de Bruxelles

### Alternative Name(s)

**ULB** 

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Universities (academic only)

### Location

Belgium

## **Results and Publications**

### Publication and dissemination plan

Planned publications in high-impact peer-reviewed journals:

- Rationale and protocol development;
- Description of the test of the intervention tools;
- Results of the calibration study;
- Description of the schools', children's and families' characteristics at baseline and participation rates:
- Analyses to answer specific objectives regarding SB consumption;
- Intermediate evaluation at 1 year;
- Main final evaluation after 2 years;
- Qualitative assessments.

### Intention to publish date

21/12/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Name and email: Pr. Katia Castetbon, katia.castetbon@ulb.be

Type of data: individual de-indentified and raw data

Available from 2022 and for 10 years

Access criteria: data available only upon reasonable request by public research organizations in Belgium, subject to scientific relevance and an agreement signed between the organization and the Université libre de Bruxelles. This agreement will govern the conditions of use of these data in collaboration with the research team.

Consent from participants: given the nature of the data collected, the anonymous and confidential nature of the data collection, and the nature of the interventions conducted collectively at the school level, in an open-ended manner, and comparable to traditional school-based health promotion interventions, parents may refuse the participation of their child with a refusal form given along with an information letter. Moreover, participants (students, parents) may refuse to complete the proposed questionnaires. An internal calibration study is

additionnally conducted among 130 pupils (recruitment in progress), for whom an active consent by parents is collected.

Data anonymisation: The only re-identifiable data is the month and year of birth of the pupil, which are requested in the self-administered questionnaire, in order to perform analyses by age group. At the end of the collection, the link between the individual data and the name of the school will be removed, in order to make the database available to the research team completely anonymous. The telephone interviews for the 24-hour recalls required by the calibration substudy among 130 students requires a list of selected pupils in a few selected schools, with their first and last names and telephone number or e-mail adress. At the end of this collection phase, these identifiers will also be destroyed at the level of the research team and the dieticians who conducted the 24-hour recalls.

## IPD sharing plan summary

Available on request

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/09/2023	27/09/2023	Yes	No