

# Effectiveness and transferability of a school-based intervention to improve healthy and sustainable food choices by schoolchildren

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| <b>Submission date</b><br>11/03/2024   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>29/05/2024 | <b>Overall study status</b><br>Ongoing            | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>29/05/2024       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

At least 40% of cancers are related to behavioural choices or environmental factors that can be modified. Therefore, prevention, by focusing particularly on diet, is a priority in the fight against cancer. It is now acknowledged that consumers' behaviours are largely influenced by marketing, advertising, and external pressure (e.g. peers, family, social environment), as stressed also by a 2017 INSERM collective expert report. Eating behaviour also is very strongly influenced by the food choice motivations (e.g. the importance of choosing products that are good for my health, good for the environment). These motivations are influenced by environmental factors (e.g. marketing and media, food accessibility and availability, social factors (e.g. culture, parental and peer influence), and also individual factors (e.g. self-efficacy, perceived social norms, knowledge). In addition, factors influencing diet-related motivations do not have the same meaning and weight depending on the consumers' age. A review of the literature on interventions to change young people's diet showed that school is an ideal place to promote healthy eating behaviours. Therefore, it is relevant to design educational tools/interventions adapted to adolescents in order to develop their capacity to choose foods in a conscious and informed way for a sustainable diet.

The primary objective of the study is to evaluate the effectiveness of Epidaure Market to promote more sustainable food choices among children in the second and third year of junior secondary school in France (age range: 12-14 years). The secondary objectives are 1) to evaluate the intervention effects on the feeling of self-efficacy, perceived social norms, knowledge about sustainable food, and marketing techniques and how they influence their choices; 2) to assess the intervention acceptability, feasibility, and transferability. To build the intervention and to optimally influence the targeted variables, we followed the work by Carey & al, (2019) based on behaviour change techniques (BCT).

### Who can participate?

5th and 4th grade students aged 12 to 14 years, in the Montpellier and Dijon academies.

What does the study involve?

by young people through educational sessions based on the use of an application that simulate a virtual supermarket. This intervention takes place in a school environment and was co-developed by health researchers, French National Education teachers, and prevention actors, in order to promote its acceptability by teachers and its accessibility to all students.

What are the possible benefits and risks of participating?

There is no known risk in taking part in the procedure. Adolescents benefit by acquiring new knowledge about balanced and responsible eating.

Where is the study run from?

Université Paul-Valéry Montpellier (France)

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

May 2022 to December 2026.

Who is funding the study?

Institut National Du Cancer (France)

Who is the main contact?

Florence Cousson-Gélie, [florence.cousson-gelie@univ-montp3.fr](mailto:florence.cousson-gelie@univ-montp3.fr)

## Contact information

### Type(s)

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### Type(s)

Public, Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

GANT INCa 2022-201

## Study information

### Scientific Title

Epidaure Market - Effectiveness and transferability of a school-based intervention to improve healthy and sustainable food choices by schoolchildren: protocol of a randomized controlled trial and qualitative study.

### Study objectives

We assume this intervention will: impact their food choices to move towards more sustainability (health, ecology & ethic); improve self-efficacy to choose product; impact attitude and social perception for sustainable food; increase skills and knowledge on nutrition, marketing strategies and environmental impact of food.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 06/05/2022, CER UPVM - Université Paul Valéry - Montpellier III (France) (Route de Mende, Montpellier, 34090, France; +33 4 67 14 20 00; contact.comite-d-ethique@univ-montp3.fr), ref: IRB00013307- 2022-14

### Study design

Interventional cluster randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Other, Prevention, Efficacy

## **Health condition(s) or problem(s) studied**

Prevention on healthy and sustainable food choices among 5th and 4th graders (age range: 12 - 14 years).

## **Interventions**

Epidaure Market is a virtual supermarket. The visual display with the different aisles, gondola heads, promotional offers, micro-announcements, and the atmosphere have been designed to recall the actual experience of shopping in a supermarket and to subject the user to the current marketing methods. Users make their purchases on a screen (computer or tablet with or without touch screen) by moving around the aisles of the virtual supermarket. A cash receipt may be printed at the end of the game session to analyze the purchase choices.

The design of the efficacy study is a cluster-controlled randomized trial to compare an intervention group (n=36 classes in which the intervention is carried out) and a control group (n=36 classes without intervention). These 72 second and third year junior secondary school classes are distributed as follows: 40 in Montpellier and 32 in Dijon. The population consists of students aged between 12 and 14 years.

For the proposed intervention, three educational sessions based on the videogame will be carried out at school, supplemented by information provided by junior secondary teachers during normal school hours. A pedagogical guide has been developed to support teachers; it also contains a range of various information materials for students. As the school programs are quite dense, the number of videogame sessions is small (n=3) to facilitate the project implementation in schools. Each videogame session targets the students' motivation of food choices, self-efficacy, and knowledge of balanced and responsible eating, while considering the influence of marketing. The sessions are designed around the BCTs, with the aim of influencing the motivations behind teenagers' food choices.

### **Session 1: Familiarization Session (50 minutes)**

During this session, students shop according to a scenario predefined by the teacher (shopping for a picnic and a snack; a list of pre-tested scenarios is available on the website), with a budget of 8 euros per person. Throughout the sessions, they will work in pairs. These purchases will then serve as a basis for comparison during subsequent sessions.

Pedagogical objectives involving BCTs 9.1 (credibility of sources: teacher leads in a school context) and 4.2 (Information on behavioural determinants and antecedents):

1. To learn how to read price information and to learn how to compare prices;
2. To learn how to read a product label, especially in relation to the product nutritional values and sustainability;
3. To understand the Nutri-Score meaning;
4. To introduce the concepts of processed and ultra-processed food, raw and fresh products;
5. To learn how to read information about additives;
6. To raise awareness of the product origin;
7. To understand the meaning of 'eating local';
8. To learn how to identify the main marketing techniques.

Session 2: Adaptability Session (110 minutes). This mobilizes the BCTs such as 4.1 (instructions for performing the behavior), 6.1 (behavior demonstration) or 5.1 (provide information on the health effects of the behavior)

1. Learning about the different components of sustainable food
2. Marketing techniques

3. Set up 2 groups (balanced diet, responsible diet) for shopping "good for health" or "good for the planet".
4. A product search task at home allows parents to be included in the intervention.

Session 3: Knowledge Enhancement Session (50 minutes). This mobilizes the BCTs such as 6.2 (social comparison) or 8.1 (practice and repeat the behavior)

1. Feedback on the in-house task
2. Last buying session and comparison with session 1

The feasibility and transferability of the intervention will be assessed using a mixed qualitative study (FIC model, Villeval et al. 2019; quantitative: Astaire grid, Cambon et al. 2013) with the various stakeholders (pupils, teachers, supervisory staff, parents). Data from the student questionnaires will be used to validate the information from the focus groups and individual semi-directive interviews, as well as the data collected in the ASTAIRE grid, which will include data to describe the population, environmental factors that could influence the effects of the intervention, implementation elements and means to support the transfer that contributes to adaptation to a new context.

A multi-component approach (intervention carried out in the school curriculum and by teachers) and its theoretical underpinning (DEVA method, Ajzen's TBP, BCTs) to guide intervention design enable behavior change. In presenting the protocol for this randomized controlled trial, we emphasize the importance of designing and implementing this trial on sound theoretical foundations related to health behavior change. Moreover, by combining the evaluation of a second territory, a transferability assessment of the intervention can be carried out with a view to future deployment.

This project will provide teachers with a "turnkey" intervention that meets school curricula, health needs, the development of psychosocial skills, public health issues and society's expectations in terms of food, sustainability and eco-citizenship.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Motivation to make food choices measured using a survey available on the "Epidaure market" website with specific access codes will be used to assess the various outcomes (primary and secondary) at 3 points in time: pre- and post-intervention surveys at 1 month and follow-up (4 to 6 months). The questionnaire used is based on that of Sautron et al (2015) but has been adapted for an adolescent population.

### **Key secondary outcome(s)**

Measured before intervention (T0), 1 month after (T1) and follow-up 4 to 6 months (T2):

1. Assessment of social norms based on the theory of planned behavior (Ajzen et al, 1985)
2. Assessment of confidence in one's judgment to achieve a health outcome and confidence in one's ability to make healthy food choices (The Personal Efficacy Questionnaire for Eating Healthy Foods, Ravoniarison & Gollety, 2017).
3. Nutritional knowledge will be assessed using a product selection task (adapted from 'Opticourses' intervention by Darmon et al., 2020)

Measured after the intervention and will last until the end of the school year:

4. The feasibility, acceptability and transferability of the intervention will be assessed using a

qualitative study with the various stakeholders (focus groups with students, interviews with teachers, supervisory staff and parents). More specifically, transferability will be studied using the ASTAIRE grid and the FIC model.

-The ASTAIRE grid (Cambon et al. 2013) includes data to describe the population, environmental factors that could influence the effects of the intervention, implementation elements and means to support the transfer that contributes to adaptation to a new context.

-The FIC model has been detailed elsewhere (Villeval M et al. Implement Sci. 2019). Briefly, it has three main objectives: to improve the transferability of interventions, by distinguishing their transferable dimensions (key functions) from context-specific activities (forms); to deconstruct an intervention with the aim of describing it in detail, identifying its key functions, which could then potentially be transferred to other contexts; to better anticipate and analyze the effects of an intervention on social inequalities in health, thanks to this deconstruction.

A multi-stage qualitative methodology is used to achieve these objectives. For the FIC team, this involves taking part in project meetings, reading and analyzing documents produced as part of the intervention, and carrying out bibliographical research on the intervention's themes (e.g., the sociology of food), carry out focus groups or interviews (and transcribe them) with the project's actors (here, with teachers, members of the rectorats and researchers involved in the intervention) and, finally, develop key functions thanks to the literature review and the cross-referencing of data from all the materials.

This model will be adapted here to analyze the impact of interventions aimed at improving the (balanced and sustainable) food choices of secondary school pupils, in two French regions (Montpellier and Dijon), while documenting the conditions for its transferability to other regions and other publics (child profiles).

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

1. Middle school students aged 12 to 14 years
2. 5th and 4th grades
3. Whose parents have agreed to answer the questionnaires
4. Have the student's consent

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

12 years

### **Upper age limit**

14 years

### **Sex**

All

### **Key exclusion criteria**

1. Participants who refuse give informed consent
2. Parents of participants refusing informed consent

### **Date of first enrolment**

01/09/2022

### **Date of final enrolment**

30/06/2024

## **Locations**

### **Countries of recruitment**

France

### **Study participating centre**

**Université Paul Valéry - Montpellier 3**

Route de Mende

Montpellier

France

34090

### **Study participating centre**

**Université de Bourgogne**

Esplanade Erasme

Dijon

France

21000

## **Sponsor information**

### **Organisation**

Université Paul-Valéry Montpellier

### **ROR**

<https://ror.org/00qhdy563>

## **Funder(s)**

## Funder type

Research organisation

## Funder Name

Institut National Du Cancer

## Alternative Name(s)

The French National Cancer Institute, L'Institut national du cancer, INCa

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Research institutes and centers

## Location

France

# Results and Publications

## Individual participant data (IPD) sharing plan

Data not be freely accessible even after the study is completed. Part of the data may, however, be requested for specific research purposes, in order to reuse the protocols/methods/analyses implemented during the Epidaure Market project.

## IPD sharing plan summary

Available on request, Not expected to be made available

## Study outputs

| Output type                                   | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|--|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Information and consent letter children (in English) |              | 20/03/2024 | No             | Yes             |
| <a href="#">Participant information sheet</a> | Information and consent letter children (in French)  |              | 20/03/2024 | No             | Yes             |
| <a href="#">Participant information sheet</a> | Newsletter for students' parents (in English)        |              | 20/03/2024 | No             | Yes             |
| <a href="#">Participant information sheet</a> | Newsletter for students' parents (in French)         |              | 20/03/2024 | No             | Yes             |
| <a href="#">Study website</a>                 | Study website  | 11/11/2025   | 11/11/2025 | No             | Yes             |