Does the 'Flavour School' sensory food education programme increase 4-7 year old primary school children's confidence and curiosity in tasting vegetables and fruit?

[X] Prospectively registered		
[X] Protocol		
Statistical analysis plan		
nt data		

Plain English summary of protocol

Background and study aims

Flavour School (https://www.flavourschool.org.uk/about-us) is a programme of sensory food education activities that has been developed for primary school children (aged 4-7). Children take part in fun sensory experiments and activities with healthy foods, learn to analyse flavours with their senses, and learn vocabulary and verbal skills to describe and share their eating experiences and opinions. It aims to build children's confidence and curiosity in exploring food (especially vegetables and fruit), and expand their food horizons, to support the development of healthy, happy relationships with food and eating. This study aims to assess the extent to which Flavour School causes children to become more curious and confident in exploring food.

If Flavour School sensory food education does significantly boost children's confidence and curiosity in exploring healthy food, then schools, teachers and policy makers can have confidence in a relatively cheap, accessible tool, which they can use to support children to develop of healthy, happy eating habits. Flavour School could equip children to be more open to developing a healthier and more varied diet, where this is provided to them. For example, children who are more familiar with vegetables and fruit, and more open to trying and tasting new foods may be more amenable to new, healthier school lunch menus - or to a healthy dinner cooked at home. Eating more fresh produce, especially vegetables, is a simple and effective way for people and populations to improve health outcomes, and eat a more ecologically sustainable diet.

Who can participate?

Schools based in London or Leeds with either 2 form entry, or alongside a class size and demographic-matched school can volunteer to participate in the study. Schools serving communities with high levels of deprivation are highly encouraged to participate. Pupils in the reception, year 1, and year 2 classes at these schools will be able to participate provided parental /guardian consent is given and there are no significant issues anticipated in their taking part, such as severe food allergies.

What does the study involve?

Flavour School is a programme of sensory food education activities for primary school children (aged 4-7). Children take part in fun sensory experiments and activities with healthy foods, learn to analyse flavours with their senses, and learn vocabulary and verbal skills to describe and share their eating experiences and opinions. It is delivered by usual class teachers as part of normal teaching hours, once-a-week over the course of one full school term (around 12 weeks). Teachers will be trained to use the Flavour School programme.

This study aims to assess the extent to which Flavour School causes children to become more curious and confident in exploring food. Using video recordings, we will closely observe children's engagement in a 'Flavour Explorers' activity devised for this study. We'll note how many foods they taste, rate their facial expressions (e.g. how much do they smile or frown), and observe how much they speak, and chat to each other, during the activity).

The researchers will measure each child's behaviour before doing Flavour School, and then again afterwards, to measure the change. If the programme is effective, the researchers expect to see that after doing Flavour School, children will be tasting more foods, visibly enjoying themselves more, and perhaps chatting more too, during the tasting activity.

To compare, an age-matched class (e.g. another Year 1 class) in the same school will do normal school teaching curriculum, without any Flavour School teaching. The researchers will look at whether the children in the classes who receive the Flavour School intervention become more curious and confident in exploring healthy foods, relative to the normal curriculum classes. This is to make sure that any changes really are a result of the Flavour School sensory food education programme.

What are the possible benefits and risks of participating? Benefits:

The Flavour School programme could facilitate the development of a healthy, varied diet, and higher consumption of vegetables and fruit. Children will learn about their senses and 'make friends' with fresh vegetables and fruit.

Risks:

Risks are not higher than for normal school activities.

To minimise allergy risks, common severe allergens will not be used (i.e. no nuts/seeds/lupins etc, no seafood). Schools hold allergy information for pupils. Foods to which a child present is allergic will not be used.

Children will be supervised by a responsible adult at all times to minimise choking risks. Adverse events: Any incidents will be logged in the Health and Safety documentation for the project and for the school. We do not anticipate incidents which would jeopardise the continuation of the project.

Where is the study run from?

The study will take place in 6-8 schools based in London or Leeds (UK)
The study is run from the School of Food Science and Nutrition, University of Leeds (UK)

When is the study starting and how long is it expected to run for? October 2019 to August 2022

Who is funding the study? Horizon 2020 Excellent Science - Marie Skłodowska-Curie Actions (Belgium) Who is the main contact? Dr Nicholas Wilkinson n.wilkinson1@leeds.ac.uk

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

799965

Study information

Scientific Title

Evaluation of the 'Flavour School' sensory food education programme: a cluster-randomised controlled trial in UK primary school children, aged 4-7 years, to determine changes in confidence and curiosity in tasting vegetables and fruit

Acronym

OASES

Study objectives

The Flavour School intervention will increase curiosity and confidence in tasting vegetables and fruits. 'Curiosity and confidence' will be operationalised by three types of behaviour during a tasting activity: willingness-to-taste (number of items tasted), non-verbal behavioural engagement (facial expression), verbal behavioural engagement (speaking/conversation during tasting activity)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/11/2019, Engineering and Physical Sciences joint Faculty Research Ethics Committee (EPS FREC), University of Leeds (Leeds, LS2 9JT; +44 (0)113 343 1642; MEECResearchEthics@leeds.ac.uk), ref: MEEC 18-048

Study design

Multi-centre cluster randomised control trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Quality of life

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

Children's eating behaviour, engagement in exploring healthy foods

Interventions

Participants will be students in one of the first three years of UK primary schools. Schools based in London or Leeds will be eligible to volunteer or self-select to participate. Some of these schools will have participated in the non-interventional pilot studies. These pilots addressed the assessment methods/tools that will be used in this study.

Cluster randomization is at the level of teaching classes, with matched controls within a school (e.g. at school X, we randomly assign Year 1 Class A to Intervention and Year 1 Class B to Control). Randomization will be to either the intervention or control arm of the study at a ratio of 1:1. There will be masking for outcomes assessors, but no masking for teacher and child participants, as the intervention is an experiential teaching programme and therefore cannot be masked.

The intervention arm receives the Flavour School sensory food education programme. This is a programme of once-a-week sensory food activities delivered over 12 weeks or 1 school term,

delivered by class teachers in normal school hours. Teacher training and resources are supplied by Flavour School.

The control arm receives no intervention and only the standard school teaching curriculum.

Participants in both arms of the study will be assessed in terms of their 'curiosity and confidence' in tasting vegetables and fruit at baseline/before the intervention group begins the programme and again at 12 weeks, once the intervention group complete the programme.

During the activity to assess 'curiosity and confidence' in tasting vegetables and fruit, children fill in a 'My Tasting Card', by drawing an emoji-style face to express liking (smiley face), disliking (frowny face), or indifferent/don't know (flat mouth face), using a colour scheme to match the face to the foods. This self-reporting is supervised to ensure that children report all tastings, and do not falsely report tasting (i.e. draw a face without tasting). However, the form of the face they draw is not strongly supervised. Therefore the presence of a face (any face) in the colour spot for a given food is a reliable indicator that tasting occurred. However, liking (smiley/frowny /flat) is less reliable. Some drawings are not decipherable, and children may change their minds or get creative with the drawings, such that for some children, liking may be difficult to measure. This is why liking is a secondary measure, whereas willingness-to-taste is a primary measure.

Intervention Type

Behavioural

Primary outcome measure

'Curiosity and confidence' in tasting vegetables and fruit assessed through investigator analysis of video footage of the 'FlavourExplorers' activity at baseline and 12 weeks, specifically measuring willingness-to-taste (number of samples tasted from range offered), non-verbal behavioural engagement (facial expressions during a tasting activity), and verbal behavioural engagement (speaking/conversation during a tasting activity)

Secondary outcome measures

- 1. Does the Flavour School sensory food education programme increase the overall level of liking for the offered range of foods? This will be measured through children's responses on the 'My Tasting Card' during the 'FlavourExplorers' activity at baseline and 12 weeks
- 2. The user experience of Flavour School measured through interviews and teacher survey responses at 12 weeks to determine how workable it is for teachers and schools, how could it be improved, and made more usable and accessible, and what the perceived value is for teachers and for children
- 3. Can the human observer analysis of facial expression and verbal behaviour be automated? Specifically measuring if Noldus FaceReader can provide valid assessments of facial expression in this experimental context and if SoapBox Lab's child-specialist Automated Speech Recogniser can provide valid assessments of relevant verbalisation, conversation, and vocabulary richness. This will be assessed through comparison of automated and investigator analysis of video footage of the 'FlavourExplorers' activity at baseline and 12 weeks

Overall study start date 01/10/2019

Completion date 31/08/2022

Eligibility

Key inclusion criteria

- 1. Children in the first three years (Reception, Year 1, Year 2) of a participating UK primary school (and therefore an age range of 4 to 7 years)
- 2. Informed consent obtained from parent/caregiver, for the school to release a child's data for the study

School inclusion criteria:

- 1. Volunteer/self-selected schools
- 2. Based in London and Leeds
- 3. Two form entry or smaller schools able to twin with a nearby school (as the randomization regime requires matched classes for Control-Intervention allocation)
- 4. Schools serving communities with high levels of deprivation are especially welcome

Participant type(s)

All

Age group

Child

Lower age limit

4 Years

Upper age limit

7 Years

Sex

Both

Target number of participants

320+ individual children, 14+ clusters of approximately 30 individuals per cluster (class sizes vary)

Total final enrolment

358

Key exclusion criteria

Children identified by the school as at risk or unable to participate (e.g. due to multiple severe food allergies, or severe developmental disorders)

Date of first enrolment

15/09/2021

Date of final enrolment

22/07/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Leeds

School of Food Science and Nutrition Leeds United Kingdom LS2 9JT

Sponsor information

Organisation

University of Leeds

Sponsor details

School of Food Science and Nutrition Leeds England United Kingdom LS2 9JT +44 (0)113 34 32876 c.e.l.evans@leeds.ac.uk

Sponsor type

University/education

Website

http://www.leeds.ac.uk/

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type

Government

Funder Name

H2020 Marie Skłodowska-Curie Actions

Alternative Name(s)

H2020 Excellent Science - Marie Skłodowska-Curie Actions, H2020 EXCELLENCE SCIENTIFIQUE - Actions Marie Skłodowska-Curie, H2020 WISSENSCHAFTSEXZELLENZ- Marie Skłodowska-Curie Maßnahmen, H2020 CIENCIA EXCELENTE - Acciones Marie Skłodowska-Curie, H2020 ECCELLENZA SCIENTIFICA - Azioni Marie Skłodowska-Curie, H2020 DOSKONAŁA BAZA NAUKOWA - Działania "Maria Skłodowska-Curie', Marie Skłodowska-Curie Actions, Excellent Science: Marie Skłodowska-Curie Actions, Actions Marie Skłodowska-Curie, Marie-Skłodowska-Curie, Działania "Maria Skłodowska-Curie', EXCELLENT SCIENCE - Marie Skłodowska-Curie Actions, EXCELLENCE SCIENTIFIQUE - Actions Marie Skłodowska-Curie, WISSENSCHAFTSEXZELLENZ- Marie Skłodowska-Curie Maßnahmen, CIENCIA EXCELENTE - Acciones Marie Skłodowska-Curie, ECCELLENZA SCIENTIFICA - Azioni Marie Skłodowska-Curie, DOSKONAŁA BAZA NAUKOWA - Działania "Maria Skłodowska-Curie', MSCA, MSCM, AMSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 07/09/2020:

- 1. Protocol paper, to submit in September 2020
- 2. Interim results may be reported in a conference submission in Summer 2021, ahead of publication in a journal
- 3. Two to three journal papers detailing findings of methods and validations, RCT outcomes, and accompanying user experience and perceived value findings, to submit around September /October 2021

Previous publication and dissemination plan:

- 1. Protocol paper, to submit in March 2020
- 2. Interim results may be reported in a conference submission in autumn 2020, ahead of publication in a journal
- 3. Two to three journal papers detailing findings of methods and validations, RCT outcomes, and accompanying user experience and perceived value findings, to submit around January February 2021

Intention to publish date

20/07/2024

Individual participant data (IPD) sharing plan

Current IPD sharing plan as of 19/07/2024:

The datasets generated during and/or analyzed during the current study will be published as a supplement to the results publication.

Video data from the study will not be made publicly available to protect the privacy of participants.

Previous IPD sharing plan:

The datasets generated during and/or analyzed during the current study will be stored in a publically available repository

IPD will be stored in the Research Data Leeds repository (http://archive.researchdata.leeds.ac.uk /)

Anonymized individual-level data for all quantitative measures will be made available through Research Data Leeds. This will be made available to researchers in order to enable checking of our findings and reproduction of the study, and to support related work or further analysis where this is relevant and compatible with the aims of the study. Caregiver consent for children's participation will include the publication of anonymized data. All individual participant-level data will be referenced by an arbitrary, unique participant ID.

Any software or designs required to reproduce this study will we made available free of charge, alongside publications.

Personal data: Individual-level data will include video recordings of child participants. These will be treated as private, and not published or hosted on Research Data Leeds. Video data will be shared only to enable further analysis by the OASES research team and close collaborators, for specific, limited time periods to enable analysis. Caregiver consent for child participation includes the use of video recordings for related work, appropriate to the personal nature of the data.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		22/03/2022	15/06/2022	No	No
Other files	Data management plan	12/07/2022	26/07/2022	No	No
Protocol article		24/08/2022	25/08/2022	Yes	No
Results article		29/08/2024	09/09/2024	Yes	No
Results article		07/11/2024	20/11/2024	Yes	No