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"Are You Too Sweet?" project

Submission date	Recruitment status	[_] Prospectively registered
30/08/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Danish children generally consume too many sweets and sugary drinks, which negatively impacts their health. Candy, cake, soda, ice cream, and fruit juice take the place of healthy food, increasing the risk of obesity and tooth decay. The purpose of the "Are You Too Sweet?" project is to assist Danish families in reducing their consumption of sweet treats and sugary beverages while maintaining good family times.

Who can participate?
All preschool children and their parents in the project schools can participate in the study.

What does the study involve?
Participant families will have the opportunity to test various games, tips, and other materials to gain insight into how they might change their sweet habits. The project is a collaboration with the healthcare services at the child's school and will be a part of the health consultation that all school children in Hvidovre Municipality are invited to. Children participating in the study will, in addition to height and weight measurements, also have their waist circumference measured. All participating families contribute to creating important knowledge that will be used to ensure children's health as best as possible. Families will receive a SWEET box, including interactive games, books, and more. After the project, they are welcome to keep everything.

What are the possible benefits and risks of participating?
The benefits of participating in the study are to try a range of materials and games to strengthen skills to structure discretionary choices and get insight into a child's dietary habits. No harmful effects are anticipated.

Where is the study run from?
DTU Food Institute (Denmark)

When is the study starting and how long is it expected to run for?
July 2019 to July 2021

Who is funding the study?
The Nordea Foundation (Denmark)

Who is the main contact?
Ms Sidse Marie Sidenius Bestle, simsib@food.dtu.dk

Contact information

Type(s)
Scientific

Contact name
Ms Sidse Bestle

ORCID ID
https://orcid.org/0000-0002-1465-6954

Contact details
DTU Food Institute
Kemitorvet
Bygning 201
Kgs. Lyngby
Denmark
2800
+4560383707
simsib@food.dtu.dk

Type(s)
Principal investigator

Contact name
Dr Anja Pia Biltoft-Jensen

ORCID ID
https://orcid.org/0000-0002-6607-7575

Contact details
Senior researcher
Kemitorvet, Building 201
Kgs Lyngby
Denmark
2800
+4593518941
apbj@food.dtu.dk

Additional identifiers

Study information

Scientific Title
A school health nurse delivered cluster randomized control intervention trial for reducing schoolchildren's intake of discretionary foods and drinks: the Are You Too Sweet? study.

Acronym
AYTS

Study objectives
The hypothesis of the "Are You Too Sweet?" trial was that providing families with a multi-component intervention, consisting of dietary guidelines on discretionary choices, tools, and personalized consultation delivered by the school health nurses, would reduce child intake of discretionary choices, through increased family knowledge, awareness, and skills.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The intervention is non-invasive and of educational character. To ensure that the trial did not require ethical approval, we received a confirmation from the regional research ethics committee. Approved 23/06/2020, Lone Gundelach, Regional scientific ethical committee (De Videnskabsetiske Komiteer for Region Hovedstaden), Kongens Vænge 2, 3400 Hillerød, Denmark; +45 38666395; vek@regionh.dk; ref: H-20036402.

Primary study design
Interventional

Study design
Cluster-randomized non-blinded controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of the negative impact of discretionary food on the health of preschool children

Interventions
The study is designed as a 3.5-month cluster-randomised non-blinded controlled trial. The cluster-randomisation of the schools will be conducted using R software, taking into account local socioeconomic status (municipalities ranking). Six schools from a Danish municipality will be randomised to either the intervention group (n = 4) or the control group (n = 2). Families with schoolchildren (5-7 years) starting in one of the participating schools are eligible for participation. Data collection will take place at baseline before the intervention starts and 3.5 months after the intervention starts.

In addition to standard health guidance by the school health nurses, families are required to register their children's intake of discretionary choices, which will be shared with the school health nurse to provide individualised guidance on discretionary choices. The school health nurse will give the child and parent a box with home-use materials to motivate, inspire, and provide skills for reducing discretionary choices. The control group receives the standard health consultation, which is mandatory in Denmark. Parents in both intervention and control groups will be asked to answer a questionnaire and a 7-day dietary record (on behalf of their child) before the consultation and again 3.5 months after.

Intervention Type
Behavioural

Primary outcome(s)
Child intake of discretionary food and drinks measured using a seven-day dietary record in October - November 2020 (seven consecutive days, by continuous enrolments) at baseline and 3.5 months after the start of the intervention in February – March 2021

Key secondary outcome(s)
1. Energy from added sugar, other macronutrients and food groups measured using data from a food data bank and a seven-day dietary record in October - November 2020 and 3.5 months after the start of the intervention in February – March 2021
2. Parental practices, parental knowledge, and self-efficacy measured using a Parent completed questionnaire in October - November 2020 and 3.5 months after the start of the intervention in February – March 2021

Completion date
01/07/2021

Eligibility

Key inclusion criteria
All children aged between 5 and 8 years old attending one of the six project schools, if one parent has sufficient Danish to fill out a questionnaire

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
8 Years

Sex
All

Total final enrolment
153

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
01/04/2020

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
Denmark

Study participating centre
The Children's Health Center (Børnesundhedshuset)
Hvidovrevej 274
Hvidovre
Denmark
2650

Sponsor information

Organisation
Technical University of Denmark

ROR
https://ror.org/04qtj9h94

Funder(s)

Funder type
Charity

Funder Name
Nordea-fonden

Alternative Name(s)
Nordea Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available on request. from Sidse Marie Sidenius Bestle, simsib@food.dtu.dk. Details of data anonymization will be provided at a later date. Consent was obtained from all participants, for use in the current research question.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/03/2024	05/11/2024	Yes	No
Protocol article		21/12/2020	08/09/2023	Yes	No
Other publications	parents' perceptions and use of the 'Are you too sweet?' intervention components and tools	29/06/2022	08/09/2023	Yes	No
Other publications	qualitative sub-study	15/09/2022	08/09/2023	Yes	No
Participant information sheet			08/09/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes