

"Are You Too Sweet?" project

Submission date 30/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/11/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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

Study website

<https://www.food.dtu.dk/nyheder/nyhed?id=405a18e5-1093-4aba-b191-b8bdf9a75da2>

Contact information

Type(s)

Scientific

Contact name

Ms Sidse Bestle

ORCID ID

<http://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 Bilottoft-Jensen

ORCID ID

<http://orcid.org/0000-0002-6607-7575>

Contact details

Senior researcher

Kemitorvet, Building 201

Kgs Lyngby

Denmark

2800

+4593518941

apbj@food.dtu.dk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

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.

Study design

Cluster-randomized non-blinded controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Home, Other therapist office

Study type(s)

Prevention

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

01/07/2019

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

Age group

Child

Lower age limit

5 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

200

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

Sponsor details

Kemitorvet, building 201
Kongens Lyngby
Denmark
2800
+ 45 35 88 74 25
apbj@food.dtu.dk

Sponsor type

University/education

Website

<http://www.dtu.dk/english>

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**Publication and dissemination plan**

Study protocol (published in 2020)
Dietary outcomes (under review in Public health Nutrition)
Qualitative evaluation (two papers published in 2022)
Secondary quantitative outcomes: mediation mechanisms (under preparation)

Intention to publish date

01/11/2023

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?
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
Protocol article		21/12/2020	08/09/2023	Yes	No
Results article		26/03/2024	05/11/2024	Yes	No