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Increased Health and Wellbeing in Preschools

Submission date
17/11/2014

Recruitment status
No longer recruiting

Registration date
08/01/2015

Overall study status
Completed

Last Edited
07/11/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Energy balance is a term to describe the relationship between the amount of energy we take in (though our food and drink) and how much of that energy we use in our day-to-day activities. Our levels of physical activity, eating habits and how sedentary our life is are termed energy-balanced related behaviours (EBRBs) and they seem to vary according to socioeconomic differences (how wealthy we are and our social position). Here, we want to identify the most important factors influencing EBRBs among preschool children, taking into account their socioeconomic background (phase 1). In the second phase of our study, we then apply what we have learned from phase 1 and develop an intervention that aims to balance children's EBRBs and diminish health socioeconomic inequalities. In the third phase we will follow up the same children to examine whether early childhood environmental and individual factors (e.g., health behaviors) predict later EBRBs and weight, SR skills, recovery and learning outcomes in a longitudinal design.

Who can participate?
The study participants are recruited through preschools in Uusimaa region in Finland. Preschools are recruited based on their socioeconomic neighborhood (half in high and half in low socioeconomic neighborhoods in municipality). The neighborhoods are ranked into an order according to the statistics: the preschools belonging to the highest and lowest tertiaries are contacted. Eligible participants are 3-5 year old children in preschools and their parents.

What does the study involve?
The overall study is divided into three phases. The first phase includes both focus group interviews and a cross-sectional study in years 2014 and 2015. In the cross-sectional study, children are asked to wear a accelerometer for seven days and samples of their saliva and hair are taken. Parents and teachers fill in children's food records and complete a questionnaire. The Heads of each preschool also complete a questionnaire. The second phase includes applying an intervention in preschools in years 2016 and 2017. The content of this intervention is based on what is learned in phase 1. At this stage, each preschool is randomly allocated into either the intervention group or the control group. Those preschools that are in the intervention group receive the intervention. Those preschools that are in the control group operate as usual. Assessments are performed in all the preschools before the intervention is introduced and after it has been completed. These include comparing the activity levels, dietary habits of all participating children. In the third phase, the same children are followed up six years following

the initial intervention. Data is collected in schools and at home. Children wear an accelerometer for seven days and a Firstbeat meter measuring heart rate variability and recovery from stress. Children and parents complete questionnaires assessing dietary habits, physical activity and sedentary habits and wellbeing.

What are the possible benefits and risks of participating?
Children and their parents receive feedback of children's levels of activity. All the participating preschools receive guidebook of interventions after the follow-up measurements. Children and parents receive feedback on children's level of activity, sedentary time and dietary and schools receive feedback at group level in the follow up.

Where is the study run from?
Samfundet Folkhälsan, Folkhälsan Research Centre (Finland)

When is the study starting and how long is it expected to run for?
January 2014 to December 2024

Who is funding the study?
1. Samfundet Folkhälsan (Finland)
2. University of Helsinki (Finland)
3. Juho Vainio Foundation (Finland)
4. Gyllenberg Foundation (Finland)
5. Finnish ministry of Education and Culture (Finland)
5. Academy of Finland (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
DAGIS Increased Health and Wellbeing in Preschools

Acronym
DAGIS

Study objectives
1. The hypotheses of cross-sectional survey with needs assessment:
1.1 The modifiable factors associated with children's energy-balance related behaviors (EBRBs) are recognized.
2. The hypotheses of environments intervention:
2.1. The multi-level intervention at preschool setting balances children's EBRBs.
2.2 The multi-level intervention at preschool setting diminishes socioeconomic differences in children's EBRBs.

(added 16/10/2024)
3. The hypotheses of follow-up study:
3.1. Early childhood environmental and individual factors (e.g., health behaviors) predict later EBRBs and weight, SR skills, recovery and learning outcomes in a longitudinal design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Hospital district of Helsinki and Uusimaa, 15/05/2014, ref: Dnro 112/13 /03/00/14.
The DAGIS randomized control trial in years 2016-2017 obtained ethical approval from the University of Helsinki Ethical Review Board in the Humanities and Social and Behavioural Sciences (statement 22/2017).
The DAGIS follow-up study obtained ethical approval from the University of Helsinki Ethical Review Board in the Humanities and Social and Behavioural Sciences (statement 46/2023).

Primary study design
Interventional

Study design
1. Needs assessment study (focus group interviews and survey) in years 2014-2015
2. Randomized control trials in years 2016-2017
(added 16/10/2024)
3. Follow-up study of 2016-2017 DAGIS randomized control trial in years 2023-2024

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Sedentary time, eating habits, stress

Interventions
The content of intervention is based on the results of phase 1. Intervention group 1 receives multiple practices and methods to improve children's EBRBs. The baseline and follow-up measurements are assessed for both intervention and control groups.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 16/10/2024:

Children: sedentary time measured by accelerometer, intake of fruits and vegetables and intake of sugar-enriched foods measured by dietary assessment methods, stress level measured by hair and saliva samples and via heart rate variability. The socioeconomic differences in EBRBs.

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Previous primary outcome measure:

Children: sedentary time measured by accelerometer, intake of fruits and vegetables and intake of sugar-enriched foods measured by dietary assessment methods, stress level measured by hair and saliva samples. The socioeconomic differences in EBRBs.

Key secondary outcome(s)
Current secondary outcome measures as of 16/10/2024:

The most important modifiable factors of sedentariness, sugar-enriched food intake, and vegetable and fruit intake.
The most important modifiable factors of weight.

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Previous secondary outcome measures:

The most important modifiable factors of sedentariness, sugar-enriched food intake, and vegetable and fruit intake.

Completion date
31/12/2024

Eligibility

Key inclusion criteria
For the randomized control trials:
1. Preschool situated either in high or low socioeconomic neighborhood in municipality
2. At least 30 percent of 3-5-year old children in the preschool group need to participate in order to conduct intervention

(added 16/10/2024)
For the follow-up study:

1. Participants aged 8-12-years in primary schools (grades 3-6) in the same municipality as the randomized control trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
5 Years

Sex
All

Total final enrolment
864

Key exclusion criteria
For the randomized control trials:
1. The preschool is not situated in high or low socioeconomic neighborhood in municipality.
2. Parents/guardians of children that do not sign informed consent

(added 16/10/2024)
For the follow-up study:
Children that do not sign informed consent or parents/guardians of children that do not sign informed consent.

Date of first enrolment
01/04/2015

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Finland

Study participating centre

Folkhälsan Research Center
Helsinki
Finland
00250

Sponsor information

Organisation
Samfundet Folkhälsan

ROR
https://ror.org/05xznzw56

Funder(s)

Funder type
Not defined

Funder Name
Samfundet Folkhälsan (Finland)

Funder Name
University of Helsinki (Finland)

Funder Name
Juho Vainio Foundation (Finland)

Funder Name
Gyllenberg Foundation (Finland)

Funder Name
Finnish ministry of Education and Culture (Finland)

Funder Name

Academy of Finland (Finland)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/11/2017	26/02/2021	Yes	No
Results article	results	12/12/2019	26/02/2021	Yes	No
Results article		05/12/2022	06/12/2022	Yes	No
Results article		04/11/2020	14/02/2024	Yes	No
Results article		26/08/2020	14/02/2024	Yes	No
Results article		06/11/2025	07/11/2025	Yes	No
Protocol article	protocol	18/04/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes