ISRCTN62310987 https://doi.org/10.1186/ISRCTN62310987

Pan-European IDEFICS/I.Family children cohort

Submission date
17/01/2018

Recruitment status
No longer recruiting

Registration date
23/02/2018

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Worldwide, nutrition-related diseases have become a major health concern. The most apparent consequence of unhealthy diets and lack of physical activity is excess body weight and resulting cardiovascular and metabolic conditions. Many of these unfavourable health outcomes have developmental origins and track into adulthood with unacceptable human, social and economic costs. Social inequalities create unequal pressures and opportunities, relating to a range of environmental, social and economic factors, some of which impinge on diet, addictive behaviours, physical activity, sedentariness, media exposure and parenting. Factors conducive to ill health cluster in certain segments of the society, such as those who come from lower socioeconomic position, those with poor mental health or poor cognitive abilities, or who are immigrants. These inequalities call for efforts of European policy to increase social cohesion and quality of life and to encourage sustainable healthy lifestyles for all citizens, especially children. The aim of this study is to increase the knowledge of health and idet, and to develop approaches to increase health behaviour.

Who can participate?
Children aged 2 to 9.9 years old of the intervention regions.

What does the study involve?
Participants are asked to take part in a series of examinations and provide information about him /herself and about his/her family. Participants undergo anthropometric measurements such as weight and height, and circumference of waist, neck and arm. They are asked to fill in questionnaires to report on their family life, their behaviour in relation to eating, media use, sleep, physical activity, smoking and alcohol consume. They are also asked to provide a sample of saliva, and blood and urine in fasting status. Participants do a quick test to measure preference of taste. They are asked to wear a small device (accelerometer) for several days for measuring physical activity. They also fill in questionnaires to report on what was eaten or drank on the previous day using a computer program.
Those who perform computer tests for measuring decision making and reaction time (only T3).

What are the possible benefits and risks of participating?
Participants receive feedback on their examinations, for example their anthropometrical measurements, blood pressure, blood values, information on their sleep and nutritional and physical activity status, which they can discuss with their family physician. Participants also

receive their results of the calcaneal ultrasonography for measuring bone stiffness. Participation at the IDEFICS/I.Family studies involves no risks.

Where is the study run from?
This study is being run by Leibniz Institute for Prevention Research and Epidemiology – BIPS (Germany) and takes place in Estonia, Germany, Hungary, Italy, Poland, Spain, Sweden, Belgium and Cyprus.

When is the study starting and how long is it expected to run for?
September 2006 to February 2017

Who is funding the study?
1. Sixth Framework Programme (EU)
2. Seventh Framework Programme (EU)

Who is the main contact?
1. Professor Wolfgang Ahrens (Scientific)
i.family@leibniz-bips.de
2. Mrs Ina Alvarez (Public)
alvarez@leibniz-bips.de

Contact information

Type(s)
Scientific

Contact name
Prof Wolfgang Ahrens

ORCID ID
https://orcid.org/0000-0003-3777-570X

Contact details
Leibniz Institute for Prevention Research and Epidemiology - BIPS
Dept. Epidemiological Methods and Etiologic Research
Achterstrasse 30
Bremen
Germany
28359
+49 421 218 56820
i.family@leibniz-bips.de

Type(s)
Public

Contact name
Mrs Ina Alvarez

Contact details
Leibniz Institute for Prevention Research and Epidemiology - BIPS
Dept. Epidemiological Methods and Etiologic Research

Achterstrasse 30
Bremen
Germany
28359
+49 421 218 56837
alvarez@leibniz-bips.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EC 016181/EC 266044

Study information

Scientific Title
Identification and prevention of dietary- and lifestyle-induced health effects in children and infants (IDEFICS), and determinants of eating behaviour in European children, adolescents and their parents (I.Family)

Acronym
IDEFICS/I.Family

Study objectives
IDEFICS:
1. Enhance knowledge of health effects of changing diet and altered social environment and lifestyle of children, 2-10 years, in Europe
2. Develop, implement and evaluate specific intervention approaches to reduce the prevalence of diet- and lifestyle-related diseases and disorders

I.Family:
1 Understand the interplay between barriers and main drivers of a healthy food choice
2. Identify predictors of unnecessary weight gain and cardio-metabolic risk by linking them to diet, physical activity and interacting factors while focusing on child and his / her family and assessing how different factors affect children as they grow up
3. Develop and convey strategies to induce changes towards a healthy behaviour

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Belgium: Ethics Committee of the Gent University Hospital, 15/10/2007, ref: No. EC UZG 2007 /243 and 19/02/2013, No. B670201316342
2. Cyprus: Cyprus National Bioethics Committee, 12/07/2007, ref: No. EEBK/EM/2007/16 and 21 /Feb/2013, No. EEBK/ETI/2012/33

3. Estonia: Tallinn Medical Research Ethics Committee (TMREC), 14/06/2007, ref: No. 1093 and 17 /January 2013, No. 128
4. Germany: Ethic Commission of the University of Bremen, 16/01/2007 and 11/12/2012
5. Hungary: Medical Research Council, 21/Jun/2007, ref: 22-156/2007-1018EKU and 18/12/2012, 4536/2013/EKU
6. Italy: Ethics Committee of the Local Health Authority (ASL) in Avellino, 19/06/2007, ref: No. 2 /CE and 18/Sep/2012, No. 12/12
7. Spain: Ethics Committee for Clinical Research of Aragon (CEICA), 20/06/2007, ref:No. PI07/13 and 13/Feb/2013, No. PI13/0012
8. Sweden: Regional Ethics Research Board in Gothenburg, 30/07/2007, ref: No. 264-07 and 10 /Jan/2013, No. 927-12
9. Poland: Bioethical Committee of the University of Rzeszów, 05/06/2013 and 01/12/2015

Study design
The IDEFICS/I.Family was a prospective multi-centre cohort study. IDEFICS was complemented by a setting-based community-oriented intervention programme for primary prevention of obesity. It also included a case-control study component focussing on a) overweight/obesity, b) metabolic syndrome, and c) bone stiffness/bone health.
The funded period of each study was 5 years, with an extension of 6 months for the IDEFICS study.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Nutrition and lifestyle-related disorders with a particular focus on overweight/obesity

Interventions
The community-oriented, setting-based IDEFICS intervention was developed using the intervention mapping protocol as a non-randomized controlled trial targeting physical activity, dietary behaviour and stress coping. Different modules at the community level, the (pre-) school level and the family level addressed six different target behavioural changes.

The baseline survey (T0, 2007-2008) took place in the intervention and control regions selected in Belgium, Cyprus, Estonia, Germany, Hungary, Italy, Spain and Sweden, enabling researchers to assess and describe the status quo of health and dietary and lifestyle habits of children in Europe taking into consideration regional, social, biological, and gender specific aspects. After this phase, the primary prevention programme was implemented only in the selected intervention regions, in which activities were offered for health promotion and prevention in kindergartens and schools. Each country selected one control and one intervention region. The short-term effects of the intervention were assessed during the second survey (T1) 2 years after baseline (2009-2010), repeating the same examinations in children from both, the control and intervention areas, for comparison between both regions. A mailed questionnaire was completed by parents at T2 (2010-2011) to assess the sustainability of the intervention. A third examination of the cohort members and their families took place in 2014/2015 (T3) when a ninth survey centre in Poland joined the cohort study with a baseline examination.

The IDEFICS intervention was designed to address three key obesity-related behaviours (diet, physical activity and stress coping) at four levels: individual (children), family (parents), schools and community. Six messages –two per key obesity-related behaviour- were delivered through 10 intervention modules across all levels: (i) increase the consumption of water, (ii) increase the consumption of fruit and vegetables, (iii) decrease daily television (TV) viewing time, (iv) increase daily physical activity, (v) strengthen parent–child relationships by spending more time together and (vi) establish adequate sleep duration.
The 3 first modules of the intervention were implemented at the community level:
Module 1. A "community platform" was established for the implementation of the other 2 modules. All local and relevant community members (local municipality, social services and welfare sector, private actors) were represented in this group.
Module 2. A long term multimedia and public relations campaign was performed to make the community aware of the intervention and the key behaviours targeted by the programme.
Module 3. It involved the development of a short and a long-term perspective for the prevention of childhood obesity to establish and induce environmental and policy interventions in the community.
The intervention at the school level consisted of 6 intervention modules:
Module 4. A school working group was established in all local participating schools, representing the school and parents' perspective on the intervention program, to provide insight in the realities of working with schools.
Module 5. It consisted of a curriculum-based intervention integrating the key behaviours in the classroom activities. "Healthy Weeks" focusing on a specific key behaviour related to nutrition or physical activity were organized during the school year, including homework for increasing the involvement of parents.
Module 6. It focused on environmental changes related to physical activity. Active playgrounds were created by providing attractive play tools (e.g. balls, ropes, small bikes) and/or by changing the physical design of the playground (e.g. hopscotch, soccer goal posts, basketball hoops).
Module 7. Practical guidelines were provided to teachers for reaching high(er) activity levels during physical education classes.
Modules 8 and 9. A supportive school environment was created by inducing changes in the school environment and policy related to water and fruit and vegetable consumption, e.g. providing the opportunity to drink water in class, making fruit and vegetables available and accessible in the class room or the school canteen.
The intervention at the family level (module 10) consisted of educational materials (posters and flyers) for parents providing them with strategies to remove barriers and support them in creating health promoting family environments.

Intervention Type
Mixed

Primary outcome(s)
1. Weight based on the age and sex specific BMI cutoffs were measured at T0, T1, and T3 using:
1.1. BMI was calculated as weight [kg] divided by height [m] squared
1. 2. Body weight and height were objectively measured using an adapted Tanita digital scale, BC 420 MA for children ≤6 years and BC 418 MA for children >6 years (weight) and a Seca 225 stadiometer (height)
3. Quality of the diet was measured using a healthy diet score and propensity scores based on a semi-quantitative food frequency questionnaire
4. Bone stiffness was measured by calcaneal ultrasonography (Lunar Achilles Insight) in in a sub-sample

5. Diet was measured using self-reported questionnaires (parents reported for their children at T0 and T1, and for children <12 at T3). Additionally, dietary assessment was conducted by a computer-based 24-hour dietary recall which was web-based in T3
6. Physical activity was measured using self-reported questionnaires and objectively measured using accelerometry (ActiTrainer or GT1M at T0 and T1 and ActiGraph GT3x at T3; Actigraph, LLC)
7. Sleep was measured using self-reported questionnaires (parents reported for their children at T0 and T1, and for children <12 at T3), and objectively measured using accelerometry in a subgroup at T3 (ActiTrainer or GT1M; Actigraph, LLC)
8. Family life was measured using self-reported questionnaires (parents reported for children below the age of 12)
9. Well-being was measured using self-reported questionnaires (parents reported for children below the age of 12)
10. Metabolic and nutritional biomarkers were measured using fasting blood and urine samples
11. Sensory taste perception was measured using questionnaire and by standard sensory tests in a subsample of children

Key secondary outcome(s))
1. Waist circumference was measured using a Seca 200 tape at the 3 time points (T0-T3)
2. Fat mass index and free fat mass index were calculated by skinfold thickness (subscapular, triceps and biceps) using Holtain Tanner/Whitehouse skinfold calipers and by bioelectrical impedance analysis using a digital TANITA BC 420 SMA scale at T0-T3
3. Blood pressure was measured using an automatic sphygmomanometer (WelchAllyn) at T0-T3
4. Metabolic syndrome at T1. This is calculated using a z-score standardisation to calculate a continuous score combining the MetS components (waist circumference, blood pressure, dyslipidaemia and hyperglycaemia). Three widely accepted definitions of the paediatric metabolic syndrome (MetS) are applied and suggested a new definition to guide paediatricians in decisions about close monitoring or even intervention (values of at least three of the MetS components exceeding the 90th or 95th percentile, respectively).
An online tool was developed to assist paediatricians when assessing the risk of metabolic syndrome in children aged 3-10 years. This tool and details on the MetS score can be found here: https://www.bips-institut.de/en/research/software/mets-score.html
5. Coordination was measured using physical fitness tests at T0 and T1
6. Motor fitness was measured using physical fitness tests derived from the EUROFIT test battery at T0 and T1 (Eurofit, (1993), Eurofit Tests of Physical Fitness, 2nd Edition, Strasbourg)
7. Cardiorespiratory fitness was measured using physical fitness tests derived from the EUROFIT test battery at T0 and T1 (Eurofit, (1993), Eurofit Tests of Physical Fitness, 2nd Edition, Strasbourg)
8. Handgrip strength was measured using a digital hand dynamometer TKK 5401 at T0 and T1
9. Built environment (regard to food outlets and opportunities for physical activities) was assessed by using objective data from geographic information system (GIS) at T0 and T3 in 2 study centres

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. At the baseline survey (T0) all children, boys and girls, 2 - 9.9 years of age, attending the participating kindergartens and schools of the selected intervention and control areas in the 8 survey countries were eligible as participants. These criteria were extended to the Polish survey

in 2014.
2. At the second wave of examinations (T1) all children who participated in T0 plus their classmates were invited to participate.
3. At the third wave (T3) all children who had participated either at T0 or T1 (index children) were re-invited together with their siblings in the age range 2-15 years, and both their parents.
4. Study subjects had to be residents of the selected control or intervention regions at T0.
5. Participant inclusion required that parents gave written informed consent for their children and in T3 also for themselves. Additionally, children from the age of 12 years onwards also had to give written informed consent.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
9 years

Sex
All

Total final enrolment
16229

Key exclusion criteria
1. Children outside the defined age rage
2. Children not living in the study regions at T0

Date of first enrolment
01/09/2007

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Belgium

Cyprus

Estonia

Germany

Hungary

Italy

Poland

Spain

Sweden

Study participating centre
Leibniz Institute for Prevention Research and Epidemiology – BIPS
Bremen
Germany
28359

Study participating centre
National Research Council, Institute of Food Sciences
Avellino
Italy
83100

Study participating centre
National Institute for Health Development
Tallinn
Estonia
11619

Study participating centre
Research and Education Institute of Child Health
Strovolos
Cyprus
2015

Study participating centre
Ghent University, Faculty of Medicine and Health Sciences
Ghent
Belgium
9000

Study participating centre
Göteborg University, Queen Silvia Children's Hospital, Department of Paediatrics
Gothenburg
Sweden
41686

Study participating centre
University of Zaragoza
Zaragoza
Spain
50009

Study participating centre
University of Pécs, Medical Faculty, Department of Paediatrics
Budapest
Hungary
1062

Study participating centre
University of Rzeszow, Faculty of Medicine
Rzeszów
Poland
35310

Sponsor information

Organisation
Leibniz Institute for Prevention Research and Epidemiology - BIPS

ROR
https://ror.org/02c22vc57

Funder(s)

Funder type
Government

Funder Name
Sixth Framework Programme

Alternative Name(s)
EC Sixth Framework Programme, European Commission Sixth Framework Programme, EU Sixth Framework Programme, European Union Sixth Framework Programme, EU 6th Framework Programme, European Union 6th Framework Programme, 6th EU Research Framework Programme, European Union's Sixth Framework Programme, The 6th EU Research Framework Programme, 6th FP, EUROPEAN UNION'S 6TH FRAMEWORK PROGRAMME, 6th Framework Programme, EC Framework Programme 6, FP6

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Seventh Framework Programme

Alternative Name(s)
Seventh framework programme of the European Community for research and technological development and demonstration activities (2007-2013), FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
All requests for accessing data of the IDEFICS/I.Family cohort are discussed on a case-by-case basis by the study Steering Committee. For this, interested parties are asked to provide details on the purpose of their request. The information is to be sent to:
Professor Dr Wolfgang Ahrens
Leibniz Institute for Prevention Research and Epidemiology - BIPS
Dept. Epidemiological Methods and Etiologic Research
Achterstrasse 30, 28359 Bremen, Germany
Tel: +49 / 421 / 218-56820
Fax: +49 / 421 / 218-56821
E-Mail: ahrens@leibniz-bips.de

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
Results article	results	09/01/2019		Yes	No
Results article	results	01/11/2019	16/07/2019	Yes	No
Results article	results	01/12/2018	08/10/2019	Yes	No
Results article	results	01/10/2020	07/10/2020	Yes	No
Results article	results	01/10/2021	23/12/2020	Yes	No
Results article		09/07/2021	12/07/2021	Yes	No
Results article	Media use trajectories and risk of metabolic syndrome	18/10/2021	21/10/2021	Yes	No
Results article		04/11/2021	05/11/2021	Yes	No
Results article		09/12/2022	12/12/2022	Yes	No
Results article		02/12/2023	05/12/2023	Yes	No
Results article	Ability to rank sweet and fat taste intensities with consumption frequency	11/12/2024	13/12/2024	Yes	No
Results article	Vitamin D status and muscle strength	11/02/2025	13/02/2025	Yes	No
Protocol article		23/09/2018	23/11/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes