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Instruments for Health Surveys in Children and Adolescents

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Editors
Karin Bammann
Working Group Epidemiology of Demographic Change, Institute for Public Health and Nursing Research (IPP)
University of Bremen
Bremen, Germany

Lauren Lissner
Department of Public Health and Community Medicine, Sahlgrenska Academy
University of Gothenburg
Gothenburg, Sweden

Iris Pigeot
Leibniz Institute for Prevention Research and Epidemiology—BIPS
Bremen, Germany

and

Faculty of Mathematics and Computer Science
University of Bremen
Bremen, Germany

Wolfgang Ahrens
Leibniz Institute for Prevention Research and Epidemiology—BIPS
Bremen, Germany

and

Faculty of Mathematics and Computer Science
University of Bremen
Bremen, Germany

ISSN 1869-7933 ISSN 1869-7941 (electronic)
Springer Series on Epidemiology and Public Health
ISBN 978-3-319-98856-6 ISBN 978-3-319-98857-3 (eBook)
https://doi.org/10.1007/978-3-319-98857-3

Library of Congress Control Number: 2018951705

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Preface

Epidemiology is one of the basic sciences of public health. It helps shaping practices and policies for pursuing the universal goals to prevent disease and promote health through the life course. A key tool of epidemiology is the population-based field study where primary data are gathered to investigate defined research questions. The European projects IDEFICS and I.Family, funded within the 6th and 7th European Framework Programme, respectively, are studies on prevalence, aetiology and prevention of lifestyle-related diseases focusing on overweight and obesity in children and their families. Over a decade, the IDEFICS and I.Family studies undertook a major research endeavour of collecting standardised data from children, families, neighbourhoods, kindergartens, preschools and schools in eight European countries. This resulted in a rich picture of the daily lives and living contexts of children and their families, who were followed over several years. This book presents the design, methods and instruments for data collection used in the IDEFICS and I.Family studies, which we would like to share with other researchers in the field.

For this purpose, we invited the key experts to explain the development and background of the instruments applied for the surveys and to summarise current knowledge. We had the opportunity to work together with these experts within the framework of the IDEFICS and I.Family studies. Therefore, we would like to acknowledge the outstanding expertise of all contributors and their efforts in providing the best available knowledge on the instruments and methods presented in the chapters that follow. We are grateful for their valuable contributions and their enthusiastic support in producing this book.

During our fieldwork, we faced some major challenges. As enchanting as they are, children are complicated study subjects. Because young children are still in their development, they are intellectually not able to follow abstract directions, which hampers their participation in experiments and test settings. Moreover, when quantitative questionnaires are impossible for them to complete, questionnaire data have to be obtained from proxy respondents, usually the parents. But information

on children's behaviours that is not under parental observation as well as on undesirable parenting practices cannot be assessed by this route. Also, for legal and ethical reasons, both the children and their parents have to consent to each survey procedure. This is straightforward, but it multiplies the effort and time going into the consenting process, including age-appropriate explanations for each procedure, and complicates scheduling and other survey logistics.

Another difficulty is that the IDEFICS and I.Family projects were multi-centre studies conducted in eight European countries stretching from Sweden to Cyprus and from Spain to Estonia. While it is quite feasible to overcome challenges of a multi-centre study with strict standardisation and quality control, conducting pan-European fieldwork is not an easy task. Europe, although homogenous in many ways, has considerable between-country heterogeneity in lifestyle and culture. This may require country-specific research solutions, e.g. dietary questionnaires adapted to local food cultures. Other challenges arise from differences in data protection regulation, ethical standards and varying attitudes towards respecting privacy during physical measurements.

Finally, diet- and lifestyle-related diseases constitute an infinitely wide topic due to their multi-factorial aetiologies. Thus, we had to walk a fine line between excessive burden on subjects, survey teams, budgets and general logistics on one hand, and collecting too little data to answer a wide range of scientific research questions, on the other. This point is especially challenging as there is never an ideal set of variables. Rather, this remains a point of constant discussion and sometimes, modification. This is compounded with the longitudinal design of our study which requires comparability of questions asked to individuals over time, wherever possible.

The book is organised as follows: Chapter 1 gives an overview of the design of the IDEFICS and I.Family studies and briefly introduces the methods described in detail in subsequent chapters of this book. Chapter 2 additionally introduces a modular control and documentation system to guide and track the recruitment of study participants in epidemiological studies. The remaining twelve chapters focus on certain instruments used in the overall examination and survey programme. Each chapter gives the rationale for choosing the respective instrument and closes with practical experiences gained during fieldwork. All instruments and the General Survey Manuals of both studies that comprise all standard operating procedures are provided on the following website: www.leibniz-bips.de/ifhs upon registration. Each third partner who wants to use a specific instrument or standard operating procedure is kindly requested to cite the chapter where the instrument or standard operating procedure is described. Instructions on the reference style are given towards the end of each respective chapter.

This book not only introduces the instruments used for our surveys but also describes survey experiences in which practice does not always follow theory. Reactions of respondents can be unexpected and unpredictable, but meeting these

challenges can also enrich epidemiological surveys and result in methodological refinements. We wish you the best of luck for your own research adventures. We sincerely hope that the book and the online material will be of value to other research teams.

Bremen, Germany
May 2018

Karin Bammann
Lauren Lissner
Iris Pigeot
Wolfgang Ahrens

Acknowledgements

The development of instruments, the baseline data collection and the first follow-up work as part of the IDEFICS study (www.idefics.eu) were financially supported by the European Commission within the Sixth RTD Framework Programme Contract No. 016181 (FOOD). The most recent follow-up including the development of new instruments and the adaptation of previously used instruments was conducted in the framework of the I.Family study (www.ifamilystudy.eu) which was funded by the European Commission within the Seventh RTD Framework Programme Contract No. 266044 (KBBE 2010–14).

We thank all families for participating in the pretests and extensive examinations of the IDEFICS and I.Family studies. We are also grateful for the support from school boards, headmasters and communities. Finally, we would like to thank Regine Albrecht, Ina Alvarez and Frauke Günther for their continuous and outstanding engagement. Without their efforts, this volume would not have been possible. They have devoted many hours to this book over and above their other responsibilities. Last but not least we are grateful to Eva Hiripi of Springer Publishers for her support and confidence in us.

Contents

Contributors

Wolfgang Ahrens Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany; Faculty of Mathematics and Computer Science, University of Bremen, Bremen, Germany

Karin Bammann Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany; Working Group Epidemiology of Demographic Change, Institute for Public Health and Nursing Research (IPP), University of Bremen, Bremen, Germany

Leonie-Helen Bogl Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany; Institute for Molecular Medicine (FIMM), University of Helsinki, Helsinki, Finland

Mirko Brandes Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Claudia Brünings-Kuppe Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Kirsten Buchecker Department of Food Science, Technologie-Transfer-Zentrum (TTZ Bremerhaven), Bremerhaven, Germany; University of Applied Sciences Bremerhaven, Bremerhaven, Germany

Charis Chadjigeorgiou Research and Education Institute of Child Health, Strovolos, Cyprus

Swati Chopra Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

Ilse De Bourdeaudhuij Ghent University, Ghent, Belgium

Stefaan De Henauw Ghent University, Ghent, Belgium

Gabriele Eiben University of Gothenburg, Gothenburg, Sweden

Annarita Formisano Unit of Epidemiology and Population Genetics, Institute of Food Sciences, National Research Council, Avellino, Italy

Natalia Lascorz Frauca University of Zaragoza, Zaragoza, Spain

Katharina Gallois Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Andrea Gottlieb Unit 12 "Research Services", Academic Affairs, University of Bremen, Bremen, Germany

Wencke Gwozdz Department of Management, Society and Communication, Copenhagen Business School, Frederiksberg, Denmark; Justus-Liebig-University Giessen, Giessen, Germany

Kathrin Günther Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Holger Hassel Hochschule für Angewandte Wissenschaften Coburg, Coburg, Germany

Antje Hebestreit Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Hannah Jilani Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Jaakko Kaprio Institute for Molecular Medicine (FIMM), University of Helsinki, Helsinki, Finland

Kenn Konstabel National Institute for Health Development, Tallinn, Estonia; Institute of Psychology, University of Tartu, Tartu, Estonia; School of Natural Sciences and Health, Tallinn University, Tallinn, Estonia

Éva Kovács University of Pécs, Pécs, Hungary

Fabio Lauria Unit of Epidemiology and Population Genetics, Institute of Food Sciences, National Research Council, Avellino, Italy

Lauren Lissner Section for Epidemiology and Social Medicine (EPSO), Department of Public Health and Community Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

Annette Lübke Zentrum Für Netze (ZfN), University of Bremen, Bremen, Germany

Lea Maes Ghent University, Ghent, Belgium

Dénes Molnár Department of Pediatrics, University of Pécs, Pécs, Hungary

Luis A. Moreno Facultad de Ciencias de la Salud, Growth, Exercise, NUtrition and Development (GENUD) Research Group, Universidad de Zaragoza, Zaragoza, Spain

Borja Muñiz-Pardos GENUD Research Group, University of Zaragoza, Zaragoza, Spain

Staffan Mårild Department of Paediatrics, Institute for Clinical Sciences, The Queen Silvia Children's Hospital, The Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden

Annunziata Nappo National Research Council, Avellino, Italy

Robert Ojiambo Department of Medical Physiology, Moi University, Eldoret, Kenya

Valeria Pala Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy

Jenny Peplies Working Group Epidemiology of Demographic Change, Institute for Public Health and Nursing Research (IPP), University of Bremen, Bremen, Germany; Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Iris Pigeot Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany; Faculty of Mathematics and Computer Science, University of Bremen, Bremen, Germany

Yannis Pitsiladis Department of Movement, Human and Health Sciences, University of Rome "Foro Italico", Rome, Italy; Collaborating Centre of Sports Medicine, University of Brighton, Eastbourne, UK

Hermann Pohlabeln Leibniz Institute for Prevention Research and Epidemiology —BIPS, Bremen, Germany

Stefan Rach Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Achim Reineke Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Lucia A. Reisch Department of Management, Society and Communication, Copenhagen Business School, Frederiksberg, Denmark

Alfonso Siani Epidemiology and Population Genetics, Institute of Food Science, National Research Council, Avellino, Italy

Marc Suling Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Michalis Tornaritis Research and Education Institute of Child Health, Strovolos, Cyprus

Toomas Veidebaum National Institute for Health Development, Tallinn, Estonia

Vera Verbestel Ghent University, Ghent, Belgium

Germán Vicente-Rodríguez GENUD (Growth, Exercise, Nutrition and Development) Research Group, University of Zaragoza, Zaragoza, Spain; Department of Public Health, Ghent University, Ghent, Belgium

Garrath Williams Department of Politics, Philosophy and Religion, Lancaster University, Lancaster, UK

Maike Wolters Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany

Chapter 1
The IDEFICS/I.Family Studies: Design and Methods of a Large European Child Cohort

Wolfgang Ahrens, Karin Bammann and Iris Pigeot

Abstract Many unfavourable health outcomes such as excess body weight and resulting cardiovascular and metabolic sequelae have developmental origins and track into adulthood. The IDEFICS and I.Family studies investigated the impact of dietary, behavioural and socioeconomic factors on non-communicable chronic diseases in a large diverse sample of European children. The baseline examination of 16,229 children aged 2–9.9 years (mean age: 6.0 years; standard deviation: 1.8) from Belgium, Cyprus, Estonia, Germany, Hungary, Italy, Spain and Sweden took place between September 2007 and June 2008. Two years later, 11,041 (68%) of these children and 2555 newly recruited children participated in the second round of examinations (mean age: 7.9 years; standard deviation: 1.9) where the same examination protocols were utilised as at baseline. In the interval between the two surveys, the children participated in a controlled trial of a community-oriented primary prevention programme to reduce overweight and obesity. A third round of examinations was conducted in 2013/2014 (mean age: 10.9 years; standard deviation: 2.9) to investigate the influence of familial characteristics on the children's development with focus on diet and health outcomes. For this, we also invited siblings and at least one parent of the index child. Parents reported sociodemographic, behavioural, medical, nutritional and other lifestyle data for their younger children, themselves and their families while adolescents reported for themselves. Physical examinations of the offspring included anthropometry, blood pressure, heel ultrasonography, physical fitness, accelerometry as well as the collection of

On behalf of the IDEFICS and I.Family consortia

W. Ahrens (✉) · I. Pigeot
Leibniz Institute for Prevention Research and Epidemiology—BIPS, Bremen, Germany
e-mail: ahrens@leibniz-bips.de

W. Ahrens · I. Pigeot
Faculty of Mathematics and Computer Science, University of Bremen, Bremen, Germany

K. Bammann
Working Group Epidemiology of Demographic Change, Institute for Public Health and Nursing Research (IPP), University of Bremen, Bremen, Germany

K. Bammann et al. (eds.), *Instruments for Health Surveys in Children and Adolescents*, Springer Series on Epidemiology and Public Health,
https://doi.org/10.1007/978-3-319-98857-3_1

DNA from saliva and physiological markers in blood and urine. The built environment, sensory taste perception, neuropsychological traits and other characteristics presumably influencing children's food choice (e.g. fMRI) as well as consumer behaviour were studied in subgroups. By covering the time from early childhood until adolescence, the studies allow the investigation of sensitive developmental periods using a life-course approach. The data set is enriched by further information from the pre-, peri- and postnatal phase gathered from registries and by self-report. The inclusion of parents and siblings and the assessment of peer groups enable the I.Family study to investigate the children as members of families and other social networks.

1.1 Introduction

The European IDEFICS cohort was established in 2007/2008 with one follow-up examination 2 years later and a second follow-up as part of its successor called I. Family in 2013/2014. In addition about 1 year after the completion of the second follow-up in-depth examinations of so-called contrasting groups, i.e. subgroups of children with divergent weight trajectories, were conducted.

The IDEFICS study (Identification and prevention of dietary- and lifestyle-induced health effects in children and infants) started in 2006 and pursued two main aims. First, it assessed the health status of European children with respect to dietary- and lifestyle-induced diseases and disorders with special focus on overweight, obesity and co-morbid disorders. Using a common protocol, children's health status and potential risk factors were measured in a standardised way in eight participating European countries (Ahrens et al. 2011). Second, the IDEFICS study exploited the existing knowledge on modifiable risk factors of overweight and obesity in children to develop, implement and evaluate a controlled intervention programme for primary prevention of obesity (De Henauw et al. 2011).

The I.Family study focussed on the familial, social and physical environment to assess the determinants of eating behaviour and food choice and its impact on health outcomes (Ahrens et al. 2017). Therefore, siblings and parents were invited to the third physical examination together with all so-called index children, i.e. children who previously participated in the IDEFICS study. The study protocol was based on the IDEFICS survey manual with adaptations to account for the older age groups (adolescents and parents) and to address the new research focus. In this way, the IDEFICS/I.Family cohort provides repeated measurements of social and behavioural factors, individual characteristics and medical parameters over the early life course and allows the investigation of developmental trajectories covering the transition from childhood to adolescence.

This chapter gives an overview of the designs of both studies and also refers to the instruments that are introduced in subsequent chapters of this book.

1.2 Overall Design of the IDEFICS Study

The IDEFICS study is a prospective multi-centre cohort study that took place in eight European countries, namely Belgium, Cyprus, Estonia, Germany, Hungary, Italy, Spain and Sweden. Additional centres providing expertise on fatty acid analyses, genetics, physical activity, ethics, consumer research as well as knowledge transfer and public relations were located in France, Italy, Great Britain, Germany, Belgium and Denmark. A detailed description of the initial study design and its survey instruments is given in Ahrens et al. (2006) and Bammann et al. (2006), respectively. A description of the updated study design and of the study population at baseline can be found in Ahrens et al. (2011) which also serves as major reference for the first part of this chapter.

The study design incorporated several components, each of which may be considered as a study of its own. Figure 1.1 (left part) shows the overall timeline and the three major components of the IDEFICS study: (1) at baseline, all children were examined according to a detailed protocol. These children were invited to participate in a second examination at follow-up 2 years later. By this, a child cohort was created allowing for longitudinal investigations. (2) Between the two surveys, about half of the children participated in a community-oriented setting-based intervention that was implemented in one region of each country where the other community served as control region. (3) Further, three nested case–control studies were performed to investigate the aetiology of (a) obesity and

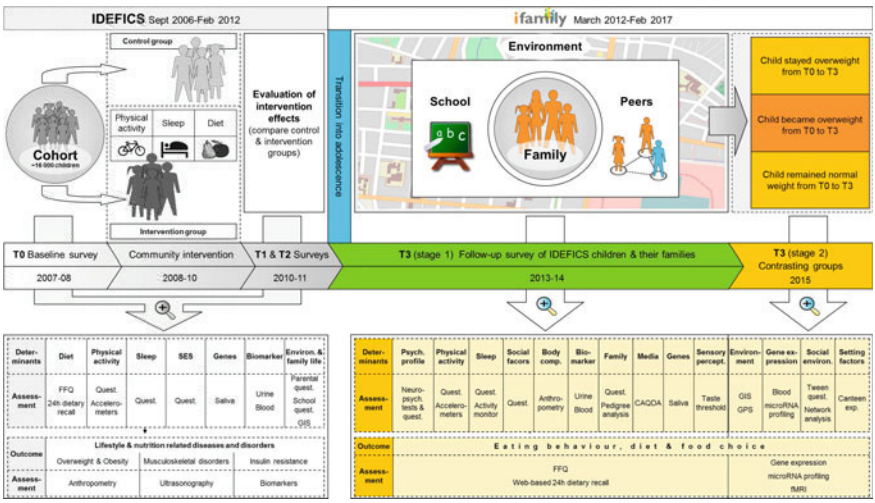

Fig. 1.1 Design and major components of the IDEFICS and the I.Family studies *Source* Ahrens et al. (2017)

overweight (Bammann et al. 2014), (b) bone health (Herrmann et al. 2015) and (c) insulin resistance. (4) Additional studies in selected countries were initiated such as a study of the influence of the food environment on children's dietary behaviour in one German survey centre (Buck et al. 2013) and of the built environment on their physical activity (Buck et al. 2011, 2015) in three countries (Germany, Italy, Sweden).

In total, 16,229 children aged 2–9.9 years were recruited in the population-based baseline survey in the eight European survey countries listed above which corresponds to 51% of all children who have been invited to participate in the IDEFICS study. Potential selection effects at baseline were investigated in the Swedish sample. Here, families with single parenthood, foreign background, low education and low income were underrepresented. However, body mass index (BMI) had no selection effect (Regber et al. 2013).

The children were approached via kindergarten and school settings which facilitated their enrolment and the implementation of intervention activities. Parents of the children were approached by letter and invited to participate. The informed consent, which was signed by parents, offered the option to participate in the full examination programme or only in parts of it. As requested by the ethics review consensus report of the European Commission, each child was informed orally by a study nurse immediately before examination about the modules using a simplified preformulated text. This was done to ensure that each participating child gave verbal assent before participating in a given module.

1.2.1 Baseline and Follow-Up Surveys

All children were examined at baseline (T_0) according to a standardised protocol between September 2007 and June 2008. Timing of recruitment was synchronised across countries to account for seasonal variation, where most countries started in October and continued until April. The baseline survey (T_0) served two aims. First, it provided data for cross-sectional analyses of risk factors for obesity and related disorders. Second, it was the starting point for the cohort study, for three case–control studies and for the primary prevention study (Ahrens et al. 2011; De Henauw et al. 2011).

In order to assess their development and to evaluate the effects of the primary prevention programme, the children were then followed longitudinally by a second round of examinations 2 years later (T_1, September 2009 to June 2010). 11,041 (68%) of the children who participated in T_0 and 2555 newly recruited children participated in this second round of examinations (mean age: 7.9 years; standard deviation: 1.9). An analysis of the dropouts showed that these children were more likely to be overweight, to report low well-being scores and to come from low-educated or single-parent families. Moreover, attrition was positively associated with a high degree of item non-response at baseline (Hense et al. 2013). In the

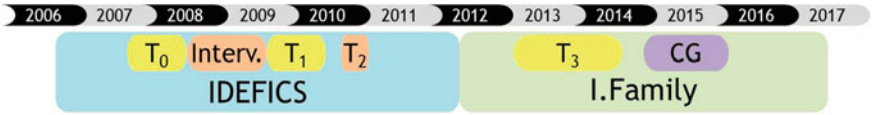

Fig. 1.2 Timeline of the follow-up examinations of the IDEFICS cohort and its extension by the I.Family study *Source* Ahrens et al. (2017) (T_0 = baseline survey; T_1 = first follow-up examination; T_2 = mailed survey; T_3 = second follow-up examination; CG = contrasting groups; extended examination in subgroups of the cohort)

German sample, an extended recruitment effort at baseline was not associated with a higher chance of attrition at follow-up (Langeheine et al. 2017).

The same instruments and examination protocols were used at T_0 and at T_1. To assess sustainability of the implemented intervention activities, a mail survey was conducted at T_2 (September 2010–December 2010); see Fig. 1.2.

1.2.2 Examination Modules

The IDEFICS study involved researchers from different disciplines with a variety of research topics. Hence, it was clear that the final set of survey instruments was a compromise between scientific ambition and feasibility. Since the overall project duration was limited to 5 years, the planned schedule for the surveys was tight. Within 6 months, each survey centre had to examine 2000 children, amounting to about 80–90 children per week. Preferably, all examinations of a child took place on the same day. However, in some cases this was not feasible, as for instance when a physician or nurse was not available for drawing blood. Usually, the survey teams established mobile examination sites that moved between participating schools and preschools. Alternative examination sites were established at the premises of the research centre, in a public building or in a hospital.

It had to be considered that a part of the examinations such as measurement of weight, waist circumference, bioelectrical impedance (BIA) and blood drawing required a fasting status of the child, and other parts required the parents, respectively, guardians to be present in some of the participating countries. The pretest showed that the order of survey modules (see Table 1.1) needed to be adapted to local conditions although there were minimum requirements for all survey centres (e.g. modules requiring fasting status had to be applied first) (Suling et al. 2011). The examination protocol was composed of compulsory modules and optional extensions (see below). The average duration of a child's examination was estimated to last about 1.5 h for the core protocol plus approximately 50 min for the full set of optional modules of the extended protocol. Parents were asked to fill in the questionnaires (see below) prior to or in parallel to their child's examination.

Table 1.1 Modules of the IDEFICS surveys

Module	Tasks	Estimated duration (min)
Reception and farewell	Welcome, handing over study documents, open questions, check completeness of interview, labels and documents, appointments, farewell	15
Physical examinations with fasting status	Application of anaesthetic patch and drawing of blood, anthropometry I (weight and leg-to-leg BIA, waist circumference)	8
Physical examinations (no fasting status required)	Medical interview, blood pressure and pulse rate, anthropometry II (height, skinfolds, other circumferences), heel ultrasound	25
Biological samples	Handing out urine cup and explanation of procedure to parents and acceptance of urine sample, saliva collection	10
24HDR	24 h dietary recall incl. assessment of school meal data for same day; second recall in 20% subsample	25
Accelerometers	Handing over and explanation of accelerometer	10
Data from official records	Centre-specific	Centre-specific
Parental questionnaires	Parental questionnaire I and II (self-administered)	0
Food tasting	Sensory perception tests (20% subsample; ages 6 +)	25
Physical fitness	Physical fitness tests (ages 6+)	25

Only instruments suitable for large-scale population-based surveys were eligible, where preference was given to established and validated methods. Moreover, each instrument and measurement had to be suitable and ethically acceptable for use in small children, time-efficient and robust against observer effects. Interviews, for examples, had generally to be conducted as proxy interviews, since children at such a young age are not able to give reliable information.

The examination modules used at baseline survey were selected in order to cover the assessment of body composition (e.g. overweight/obesity) and other health indicators (e.g. bone health) as outcome variables and putative key risk factors (e.g. diet). Moreover, innovative components, e.g. sensory tests and alternative measurements, e.g. a 24-hour dietary recall (24HDR), to assess diet were integrated into the set of measurements. In order to obtain objective growth data from the infancy period and the period preceding T_0, we also collected maternity cards and records of routine child visits.

The core protocol included all modules that were offered to all children in each country. Children were asked to provide venous blood, saliva and urine. In addition, stool samples were collected in a subgroup. The extended protocol covered modules that were optional or were only applied in subsamples of children, either (1) because they were not feasible in small children (e.g. physical fitness tests, tests on sensory taste perception), or (2) because they were too time-consuming (e.g.

questionnaires/experiments to assess to role of commercials in food choice; see Chap. 10 of this book) or (3) because they were too expensive (e.g. bone stiffness, analysis of vitamin D). Where age was the only limiting factor, it was intended to apply the extended protocol to all primary school children, while in all other cases a 20% random sample of children was selected. Accelerometry was only performed in about half of the children because of a limited number of devices. The final set of survey instruments consists of various questionnaires, physiological measurements, the collection of biological samples and the performance of several tests (see Table 1.2) which are briefly summarised here and described in more detail in the respective chapters of this book.

Reception and farewell: This module comprises reception and farewell that had to be repeated if the survey schedule of a child was distributed over several appointments. Each appointment involved a procedure for check of documents and samples, a check to ensure that identification (ID) labels were attached to each document or sample container and a check whether interviews were complete.

Physical examinations with fasting status: The physical examinations in the IDEFICS survey were organised into two modules, one comprising all examinations requiring the participating children to be in a fasting status for at least eight hours and one comprising all examinations where this was not necessarily required. This division allowed the survey centres to plan more freely their daily schedule according to their local conditions.

The fasting module comprises measuring of leg-to-leg bioelectrical impedance (BIA), body weight and waist circumference, and blood drawing. Fasting venous blood was collected from each consenting child. If venous blood could not be obtained, capillary blood was taken when possible. After finishing the fasting module, a beverage and a healthy snack were offered to the children.

Physical examinations (no fasting status required): This module comprises a face-to-face interview of the parents on the medical history of the child, the inspection of drug packages and a series of measurements. These include body height, blood pressure, hip and mid-upper arm circumferences and skinfold thicknesses. To lower the burden of survey centres and of study subjects and since some of the survey centres had less experience with skinfold measurements, only two sites (biceps, subscapular) were mandatory, whereas two additional sites (triceps, supra-illiac) were optional. For assessing bone stiffness, the heel ultrasound Lunar Achilles Insight was used. For more details on the two modules, we refer to Chap. 3 of this book.

The medical history of a child was obtained in a face-to-face interview with one parent. In order to keep the interview as short as possible, basic information on the pregnancy that was considered to be more easily recalled was assessed through self-administered questions in the parental questionnaire. In addition, all medications the child had taken within the week preceding the interview were recorded.

Biological samples: This module comprises urine and saliva collection. For blood collection see above. Morning urine was collected by the parents using a urine collection kit that was handed out on a prior occasion to the parents together with an instruction sheet. Saliva was collected for deoxyribonucleic acid

Table 1.2 Variables and age-specific instruments applied in the baseline survey of the IDEFICS study (cf. Bammann et al. 2006)

Module/instrument	Assessment methods	Variables
Physical examination —fasting status mandatory	Measurements	Weight with leg-to-leg BIA (TANITA BC 420 SMA with adapter) Waist circumference (SECA 200)
Physical examination —fasting status not required	Measurements	Blood pressure and pulse rate (automated sphygmomanometer Welch Allyn 4200B-E2 with cuffs) Standing height (SECA 225) Skinfold thicknesses (Holtain Caliper) Circumferences: mid-upper arm, hip, neck (SECA 200) Heel ultrasound (optional; Lunar Achilles Insight)
Medical history	Face-to-face interview	Ten pages containing the following sections: Health and diseases of the family Pregnancy information for the child Health information of the child Drug use of the child
Parental questionnaire —core questions	Self-administered questionnaire (parents)	26 pages containing the following sections: General information Day care, preschool and school Pregnancy and early childhood Family lifestyle Health and well-being Leisure time activities and consumer behaviour Children's spending Sociodemographic information
Parental questionnaire —diet	Self-administered questionnaire (parents)	Ten pages including questions on attitudes and eating habits and a detailed FFQ
24-hour dietary recall (24HDR)	Computer-assisted personal interview (parents)	Computer-aided 24HDR (proxy interview); complemented by recording of school meals
Questionnaire for preschools and schools	Mix of methods	Eight pages containing the following sections: Advertising and sponsorship Availability of food
Teachers and caretakers questionnaire	Self-administered questionnaire (teacher)	Seven pages including questions on attitudes, opinions, own eating behaviour, own physical activity.
Physical fitness tests ($\geq$6 years)		Flamingo balance test Backsaver sit and reach Handgrip strength Standing broad jump 40-m sprint Shuttle run test

(continued)

Table 1.2 (continued)

Module/instrument	Assessment methods	Variables
Biological samples	Saliva	Selected SNPs in candidate genes
	Morning urine	Cortisol, glucose, albumin, creatinine, sodium, calcium, phosphate, magnesium, potassium
	Fasting blood	On-site: glucose, total cholesterol, HDL cholesterol, triglycerides Fatty acid test strips: fatty acid profile (subsample of children) Central lab: core markers: insulin (in serum), CRP (in serum), HbA1c (in EDTA whole blood); additional markers of bone metabolism: calcium, NTX-peptide, vitamin D (in serum, in subsample); additional hormones of energy/fat metabolism: leptin, adiponectin (in serum, in subsample)
Accelerometers	Measurement	Physical activity [ActiGraph GT1 M (in preschool children), ActiTrainer (in school children)]
Food tasting ($\geq$ 6 years; subsample)	Forced choice tests	Threshold of taste for sweet, salty, bitter and umami Preferences of taste for sweet, salt, fat, umami and artificial flavour

FFQ Food frequency questionnaire; *SNP* Single-nucleotide polymorphisms; *HDL* High-density lipoprotein; *CRP* C-reactive protein; *EDTA* Ethylenediaminetetraacetic acid

(DNA) extraction with different collection procedures depending on age. Central laboratories were used for the majority of biological parameters. A biosample logistics database was used to record information on collection, processing, storage and shipping of all biological materials. Each centre used an individual copy of this database which provides an overview of the material collected locally. These individual copies were merged into the central database. For more details, we refer to Chap. 4 of this book.

24-hour dietary recall: A single 24-hour dietary recall (24HDR) was assessed in the full sample of IDEFICS children, and a second one was administered in a 20% subsample. The computer questionnaire containing the 24HDR was offered as a self-administered instrument at the survey centre to be filled in by the parents (proxy report). For each of the 24HDRs, school meal consumption was recorded for each child for the same day through observation by field staff at the school premises. For more details, we refer to see Chap. 5 of this book.

Accelerometers: Physical activity was measured by a 3-day accelerometer recording (two weekdays, one weekend day) partly complemented by heart rate recordings. Two different devices were used: the ActiGraph GT1 M for accelerometer measurements and the ActiTrainer (consisting of an ActiGraph and a Polar heart rate monitor) for the measurements combining acceleration and heart

rate. Due to the limited number of devices, heart rate measurements were restricted to children 6 years and older for whom data on physical fitness were collected (see below). For more details, we refer to Chap. 7 of this book.

Data from official records: Survey centres were asked to assess additional data from official records, e.g. medical records, where possible, to complete the information on the individual child. For more details, we refer to Chap. 8 of this book.

Parental questionnaires: Two questionnaires were completed by the parents. The first one (IDEFICS parental questionnaire; see Chap. 9 of this book) contains questions, e.g. on sex and date of birth of the child, use of day-care services, school and preschool, pregnancy and early childhood, family lifestyle, health and well-being, and on sociodemographic factors; the second one assesses dietary behaviour and frequency of food intake (see Chap. 6 of this book). Parents were instructed to bring the completed questionnaires to the survey centre, where completeness was checked and help was offered for omitted questions. Alternatively, it was possible to complete the parental questionnaires in a face-to-face interview, in a telephone interview or in a group session. However, any alternative mode of completion had to be documented in the electronic appointment system (see Chap. 2 of this book).

Food tasting (for children ≥ 6 years): Taste thresholds for basic tastes and food preferences of the children were assessed in an experimental setting. For this, standardised methods according to International Organization for Standardization ISO 3972 commonly used in the food industry were adapted for the IDEFICS surveys. This module was performed in a subsample of 20% of the children. Moreover, since the pretest showed that younger children need considerably more time and responses were lacking precision, we restricted the module to children 6 years and over. For details, we refer to Chap. 12 of this book.

Physical fitness (for children ≥ 6 years): This module consists of a battery of physical fitness tests in order to assess motor skills and aerobic fitness in the children. Since a maximum test was part of the test battery (shuttle run test), a person capable of giving emergency first aid to children had to be present during these tests. This module was only performed in children 6 years and older since it became apparent in the preparatory phase that it was not possible to perform the tests with younger children in a reasonable time. The module was carried out in group sessions, e.g. during physical education classes. For more details, we refer to Chap. 13 of this book.

1.2.3 Case–Control Studies

The IDEFICS study aimed to investigate the aetiology of major disorders, namely (1) obesity and overweight (Bammann et al. 2014), (2) bone health (Herrmann et al. 2015) and (3) insulin resistance, all of which may be regarded as important lifestyle and nutrition-related health outcomes in children. Each of these three conditions was analysed in a case–control study to assess the interplay of various risk factors including biological markers that could only be analysed in subsamples of the

cohort. In all three case–control studies, additional variables such as bone metabolic markers, peripheral hormones involved in energy intake regulation like insulin and leptin and specific genetic markers were assessed to allow for in-depth analyses in relation to environmental and behavioural factors.

1.2.4 Intervention Study

The intervention study was designed as a community-oriented and setting-based primary prevention trial, based on the five-step intervention mapping protocol (Verbestel et al. 2011; Bartholomew et al. 2006). The IDEFICS prevention programme was developed under participation of all relevant actors, e.g. through focus groups (Haerens et al. 2009, 2010). Local policy actors were involved to target the obesogenic environment. Based on a literature review, several intervention targets for the IDEFICS intervention programme were selected for which previous interventions had shown at least promising evidence of positive effects. The programme was standardised to enable a comparison between countries although certain aspects were culturally adapted during a preparatory phase (Pigeot et al. 2015a).

The evaluation of the overall programme addressed (1) its development, i.e. costs, expenditure of time, practical problems and solutions, (2) the process, i.e. participation, feasibility, acceptance and sustainability (see Chap. 11 of this book) and (3) the effect on various endpoints. The results of the intervention are published in a supplement volume of Obesity Reviews (Pigeot et al. 2015b).

1.2.5 Training and Quality Management

All measurements followed detailed standard operation procedures (SOPs) that were documented in the IDEFICS General Survey Manual (for access see Sect. 1.6) and finalised after the pretest of all survey modules (Suling et al. 2011). Field personnel from each survey centre participated in central training and organised local training sessions thereafter to ensure the implementation of methods and procedures according to the General Survey Manual. To be more specific, the field work training was organised as a two-step procedure. Training sessions held in English took place centrally and were followed by local training sessions in each survey centre in the local language since the local field staff in the different European countries was not necessarily capable to understand training lessons in English. The central training for the baseline survey was held in Bremen, Germany, as a 4-day meeting in July 2007. Participants from each survey centre were present where for all but one survey centre the desirable minimum number of two participants was reached. Training material was distributed to the survey centres electronically. An additional, 2-day central training session on anthropometry with a

particular focus on skinfold measurements was held in Glasgow, Scotland, in August 2007.

The coordinating centre conducted site visits of each survey location during both field surveys to check adherence of field staff to the SOPs. During the IDEFICS baseline survey (T_0) from September 2007 until May 2008, each of the survey centres was visited by the central quality control at least once. The site visits are a means for external quality control of the examinations performed in the surveys and are part of the IDEFICS quality plan. Ideally, they were complemented by internal quality control means. The internal checks were implemented by all survey centres on a non-formal basis. Questionnaires were developed in English and translated to local languages. The quality of translations was checked by back translation. All survey centres used the same technical equipment. Measurement devices and supplies for biological sampling were purchased centrally to maximise comparability of data.

Despite national differences in recruiting study subjects, a common set of variables was collected to document the participation proportion and the reasons for non-participation. For those centres that contacted parents directly with a mailed letter, a documentation software, called MODYS, was provided to record and monitor all contact attempts and by this to guide the recruitment process (see Chap. 2 of this book).

Databases and computer-assisted questionnaires included automated plausibility checks. A barcode sticker with the subject identification number (ID) was attached to each recording sheet, each questionnaire module and each vial of biological material. Where possible a bar code reader was used to enter the data. In all other cases, the ID had to be entered twice before the document could be entered in the respective database. All numerical variables were entered twice independently, and deviating entries were corrected (Ahrens et al. 2011). Inconsistencies identified by additional plausibility checks were rectified by the survey centres. All corrections were documented centrally such that the changes in the analysis data set can be traced back to the raw data set which was archived under lock and key.

To further check the quality of data, subsamples of study subjects were examined twice to calculate the inter- and intra-observer reliability of anthropometric measurements (Stomfai et al. 2011). The reliability of tests on taste perception was assessed in a group of German children (Knof et al. 2011). In addition, the reliability of questionnaires was checked by re-administering the Children's Eating Habits Questionnaire (CEHQ) and selected questions of the parental questionnaire to a convenience sample of study participants (Lanfer et al. 2011; Herrmann et al. 2011). Food consumption assessed by the CEHQ was validated against selected nutrients measured in blood and urine (Huybrechts et al. 2011). The new method to analyse the fatty acid profile in a dried drop of blood was compared to the standard analysis of serum and erythrocytes from venous blood. A validation study was carried out to compare uni-axial and tri-axial accelerometers in children and to validate them using doubly labelled water as the gold standard (Bammann et al. 2011; Ojambo et al. 2012) and to also validate body composition measures using a three-compartment model (Bammann et al. 2013). Ultrasonometry was compared to DEXA to assess the correlation between bone mineral density and bone stiffness in

a sample of children from Sweden and Belgium (Sioen et al. 2011). Annually, a quality report was written and discussed with the project review board of the European Commission.

1.3 Overall Design of the I.Family Study

I.Family pursued two strategic objectives, i.e. (1) to understand the interplay between barriers and drivers towards a healthy food choice, physical activity and lifestyle factors, and their associations with related health outcomes and (2) to develop and disseminate strategies to induce changes promoting a healthy dietary behaviour in European consumers, especially children, adolescents and their parents.

I.Family is the successor of the IDEFICS study involving the same eight cohort centres to re-examine the index children and to extend the examinations to family members. Other centres from the Netherlands, Great Britain, Finland and Denmark with expertise in functional magnetic resonance imaging, physical activity, ethics, public relations, genetics, and consumer research supported the study. A detailed description on how the I.Family study extends the IDEFICS study can be found in a recent publication by Ahrens et al. (2017) which serves as the basis for the second part of this chapter.

The parents of the index children were informed about this new examination by personal letters with a brief description of the aims and components of the study as well as a consent form with further details asking for their willingness to participate in I.Family. These letters were either sent directly to the families or delivered by the teacher of an index child. Additional phone calls by the study personnel helped to explain the aims and examinations of the study in more detail. Ethical approval was again obtained from the local ethics committees where similar procedures were followed as in the IDEFICS study with the main difference that children from 12 years onwards were asked for their written consent in addition to their parents.

1.3.1 Follow-Up Survey

The I.Family study started with the second follow-up examination (T_3) (Fig. 1.1, right part) in 2013/2014, when the age range of index children was between 7 and 17 years. The mean age (standard deviation) of participating children was 6.0 (1.8) years at T_0, 7.9 (1.9) years at T_1 and 10.9 (2.9) years at T_3 with a similar proportion of boys and girls. The role of familial characteristics, family structure and family life in relation to the children's development was a major focus of I.Family. We therefore invited, in addition to the index children, all siblings in the age range from 2 to 18 years. In addition, we strived for at least one parent of each index child to participate and to provide information on their household. In this way, we examined

9617 children at T_3, of whom 7105 participated in one of the previous examinations. In total, 6167 families with on average two children and 4.1 members (including parents) per family participated.

The IDEFICS and the I.Family studies allowed us to establish the largest pan-European children's cohort to date, to perform longitudinal analyses of biological markers and lifestyle behaviours in combination with social, cultural and environmental factors and to investigate the impact of these factors on children's health and development over the early life course. Some major results are summarised in Ahrens et al. (2017), but we expect much more exciting insights into children's health trajectories to come.

1.3.2 Contrasting Groups

Three subgroups of children with divergent weight trajectories, so-called contrasting groups, were further examined about 1 year after completion of T_3 (stage 1) as illustrated in Fig. 1.1, right part (T_3, stage 2) according to an extended protocol. The contrasting groups were defined at T_3 based on weight status at baseline and average change in BMI z-scores per year as follows: (1) children with normal weight at baseline and follow-up and no change of ± 0.1 in BMI z-score per year; (2) children who retained overweight or obesity at baseline and follow-up and no change of ± 0.1 in BMI z-score per year; and (3) children with excessive weight gain were those who started with a BMI z-score above -0.1 at baseline and who gained more than +0.1 in BMI z-score per year during the follow-up period. These contrasting groups are particularly informative to understand the major determinants and prognostic factors that help explain the differences in weight development.

1.3.3 Examination Modules

Follow-up examinations (T_3, stage 1): The examination programme at T_3 covered the majority of the modules employed at baseline and at first follow-up. Questionnaire modules that were originally designed for proxy interviews, i.e. for parents responding for their children, were adapted for completion by adolescents and parents, respectively (see Table 1.3), and addressed the following topics (see Chap. 9 of this book):

- *Parents for themselves and their family*: general information about the respondent/the family; family life and rules; meal habits of the family; parenting style; attitudes towards TV advertisements; sociodemographic characteristics; smoking and alcohol consumption; body image; physical activity; sleeping habits; dietary behaviour, dieting and food frequency.

Table 1.3 Overview of examination modules and their mode of application at T_3 (stage 1) in children, adolescents and their parents

Instrument	Target group	Estimated duration (min)	Completed by/measured in		
			Children	Adolescents	Parents
In the examination centre					
Reception and informed consent, farewell					
Welcome, handing over study documents, informed consent discussion	All subjects	5	**x**	**x**	**x**
Check completeness of received questionnaires, interviews and documents	All subjects	5	**x**	**x**	**x**
Farewell	All subjects	5	**x**	**x**	**x**
Self-administered paper questionnaire					
Food and beverage preference questionnaire	All subjects ≥ 6 years	7	**x**	**x**	**x**
Peer network questionnaire	Adolescents ≥ 12 years	4		**x**	
Maturation stages (pictorial representation)	All children ≥ 8 years	2	**x**	**x**	
Tablet (self-administered tablet questionnaire)					
Teen questionnaire	Adolescents ≥ 12 years	40		**x**	
Computer-assisted personal interviews (CAPIs)					
Interview on kinship and household	All children	5			**x** legal guardian
Medical interview (health and diseases of the family and of the child, drug use of the child)	All children	12			**x** biological parent/ grandparent
Interview on pregnancy and early childhood (different modules for index children and siblings)	All children	7			**x** biological mother

(continued)