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ORIGINAL ARTICLE

Socioeconomic questionnaire and clinical assessment in the HELENA Cross-Sectional Study: methodology

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Rationale: Environmental factors such as dietary habits, breastfeeding, socioeconomic conditions and educational factors are strong influences on nutritional and puberty status, physical activity, food choices and their interactions. Several diseases of adulthood seem to be linked to, or to originate from, lifestyle in childhood and adolescence.
Objective: The aims of this study are to describe birth parameters and socioeconomic factors and to assess clinical status in adolescents aged 13–16 years from 10 European countries participating in the Healthy Lifestyle in Europe by Nutrition in Adolescence (HELENA) Cross-Sectional Study (CSS).
Methodology: A self-report questionnaire on the socioeconomic status, a parental questionnaire concerning neonatal period and also a case report form (CRF), in which clinical items during clinical examination (such as medical history, treatments, anthropometry, Tanner staging, blood pressure, heart rate) were assessed. To develop these documents, first a list of items was established, a search of existing documents was performed and the advice of local and international experts was taken. All documents (questionnaires and an operations manual) were discussed in plenary HELENA meetings; a final version of these documents was fixed, and the process of translation and back translation was performed.
Results: The questionnaires and CRF were tested for validation in all 10 participant cities; 208 adolescents were enrolled during the pilot study. All items that caused problems or questions in one or more participating centers or were completed by $< 85\%$ of the adolescents were reviewed before the beginning of the HELENA-CSS.
Conclusion: These final questionnaires and CRF will contribute to better understanding of the inequalities in nutrition, behavior and health in the European adolescent population. The experience and process should be useful for other multicenter studies.
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Introduction

Adolescence is a crucial period in life when the individual experiences multiple physiological and psychological changes that affect his nutritional needs and habits.[1,2]

The most important adult morbidities affecting a large portion of the population in Western countries, such as cardiovascular diseases, obesity, metabolic syndrome and allergies, may begin early in life, during childhood and adolescence.[3–7] The respective roles of environmental, genetic and socioeconomic factors in the development of these conditions in adolescence are poorly understood.

The aims of the HELENA multicenter, Cross-Sectional Study (CSS) are:

- To describe inequalities in health considering the social, economic, ethnic, sex-related, early nutritional and

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[15]See Appendix at the end of the supplement on page S82.

microenvironmental variables related to dietary intake and nutritional status.
- To describe medical history, allergy, administered treatment or supplementation and clinical status variables such as body mass index, anthropometry, body composition, adipose tissue distribution, Tanner stage, blood pressure and heart rate in adolescents of different European countries, to investigate whether dietary intake or physical activity influence these parameters, and to identify adolescents at risk of different morbidities in adulthood.

The Healthy Lifestyle in Europe by Nutrition in Adolescence (HELENA) project is an integrative approach to study the inequalities in health, nutrition and physical activity in adolescence, and is detailed in this special issue on page S4–S11. On account of the importance of socioeconomic and clinical characteristics on nutritional status it is important to have accurate and detailed information on these characteristics of the population we will study.

Strong evidence indicates that the early nutritional environment influences the long-term genesis of body composition and chronic disease.[8] Pre- and postnatal events such as low birth weight or intrauterine growth retardation are thought to influence the health status of adolescents and youth; many population-based studies have reported that low birth weight is predictive of an increased risk for diseases in adulthood such as cardiovascular diseases, type 2 diabetes and hypertension.[9–13] The prevalence of type 2 diabetes has increased among children worldwide during the past decade. Hales, Barker and colleagues[10] hypothesized that low birth weight and reduced growth early in life are strongly linked with impaired glucose tolerance and noninsulin-dependent diabetes.[10,11] The association between low birth weight in girls and coronary heart disease is thought to reflect the persistence of changes in morphology and physiology that accompany slow fetal growth and seem to be independent of indices of living standards in childhood and adult life.[12,13] Reduced intrauterine growth is linked to high blood pressure (BP), which may explain the association between hypertension and impaired glucose tolerance.

Current research focuses on the influence of breastfeeding on aspects of growth, immune-related effects, especially in relation to allergic diseases, mental development and later development of overweight and obesity. Breastfeeding may play a role in preventing the development of allergies and appears to protect children from obesity and atherosclerosis.[14–16] The relationship between lactation and obesity is not fully understood, probably because of the different methods that women use to balance their energy intake and expenditure.

The importance of the composition of dietary fats during the gestation/suckling period, that is, an excess of the essential polyunsaturated fatty acids of the n-6 series, in the hypertrophic or hyperplastic development of adipose tissue, which has been associated over the last decades with increasing prevalence of childhood obesity, has been recently underlined.[17]

The presence of overweight or obesity in adolescents and their associated risks with blood lipid analysis shows that the correlation between systolic BP (SBP) and diastolic BP (DBP), total cholesterol, low-density lipoprotein cholesterol and high-density lipoprotein cholesterol all track significantly from childhood into adulthood.[18–21] In addition, BP and blood cholesterol concentration seem to be slightly lower in breastfed infants. SBP and DBP are parameters of the metabolic syndrome. Heart rate predicts subsequent elevated BP and is also linked with cardiovascular risk.[22] BP is influenced by gender and low socioeconomic status (SES) in youth,[23] and overweight and sedentary behavior are positively associated with SBP.[23]

The effects of adolescent obesity on adult morbidity can be explained either by the locus of fat deposition during adolescence or by the independent effect of total body fat on other morbidities. Moreover, Ailhaud[24] emphasized that the secretion of factors from adipocytes and preadipocytes (beneficial or deleterious) in the presence of the products of macrophages (cytokines) and the excess of fat mass could give rise to various features of the metabolic syndrome, type 2 diabetes, hypertension and dyslipidemia.[24]

In developed societies, obesity in women is inversely associated with socioeconomic status.[25,26]

Knowledge about socioeconomic factors is very useful in a nutritional study because socioeconomic factors strongly influence diet quality and health inequalities. Multinational and consumption pattern studies show that this relationship may be influenced by gender, family education level (family characteristics, intellectual ability, scholastic achievement) and demographic variables.[27] Early development during childhood of chronic diseases such as obesity, type 2 diabetes, hypertension and coronary heart disease differs between populations,[28,29] and several studies have shown that SES strongly influences the risk of such diseases.[25,30] Health inequalities are most prominent during childhood,[31] and SES inequalities may influence risk of cardiovascular diseases and health.[32,33] In addition, data published indicate that SES differences in adolescent health influence diet quality and both dietary and physical activity patterns.

Methodology

The purpose of this paper is to report on the development and selection of the variables describing the neonatal period (pre- and postnatal items on height and weight at birth and the duration of breastfeeding), the social background of the adolescents (self-administered status SES questionnaire) and clinical parameters (case report form (CRF)) we developed to obtain information about the factors influencing physical performance and nutritional status in adolescents aged 13–16 years in 10 European cities.

A list of potentially useful items for clinical examination, birth-related events, self-reported assessment of SES was composed to have general information about living conditions, parents' full-time and part-time work, the type of organization (such as industry, shop, hospital, government, self-employed, own businesses) and education level of both parents.

Next, a search of existing documents in the literature and other similar epidemiological projects was performed,[34–38] and advice of the HELENA partners and international experts in the field was taken in case of doubt. We decided to use more recently developed multiple non-occupational SES indicators.[37–38]

All documents, including questionnaires and study procedures, were then circulated to all HELENA partners and were discussed in plenary HELENA meetings. A first version of these documents was fixed, and all self-report questionnaires to be completed by the adolescents were translated and back translated into the native language of the participants. Then, feasibility of all personal anonymous HELENA Study questionnaires, clinical examination and CRF (previously prepared by the Centre of Clinical Investigation (CIC-9301-INSERM-CHU de Lille) were completed in a training pilot study in each city.

Clinical assessment of the adolescents in the HELENA Study are recorded in the CRF (Table 1), which includes chapters concerning medical history, medical treatments and vitamins and micronutrient supplementation, body mass index, anthropometry, BP, heart rate, Tanner staging, age of onset of menses in girls. All of these factors were considered important for assessing nutritional status and physical activity patterns of our study population and were reported in the CRF upon the rules stipulated in the manual of operations.

All items for the clinical evaluation of adolescents including pubertal staging were assessed during the general clinical examination to exclude somatic problems that might interfere with the study (for example, cardiac murmur, spleen or liver enlargement).

Although we knew that some adolescents would be reticent about the genital examination, we decided to include an evaluation of Tanner staging by a medical doctor during the general clinical assessment because self-reporting Tanner staging is much less accurate. An earlier study showed that breast and pubic Tanner stages are incorrectly self-assessed by 40 and 23% of girls, respectively, and 39% of boys self-assess their pubic stage incorrectly.[39] Girls were additionally asked for age of menarche and the date of the last menses.

Body mass index was defined as a criterion for a valid subject for the study; if not determined all other parameters or questionnaire responses will not be considered for the final study analysis. Anthropometry and body composition will be noted in the CRF and results will be discussed separately.

Systolic BP, diastolic BP and heart rate were measured in all centers using the same type of automated digital BP device for clinical use (OMRON M6) approved by the British Hypertension Society.[40] All devices were calibrated by measuring BP in five resting individuals using 20 devices (two were bought by each center) following the procedure in the operations manual; we observed no significant differences between devices (Table 2). The interdevice coefficient of variation was $< 5\%$ for measurements of SBP, DBP and heart rate. SBP and DBP were measured in mm Hg, and these variables and heart rate were analyzed according to normative BP tables for children and adolescents, which now also

Table 2 Reproducibility of the measurement of blood pressure (BP) using the same type of device, OMRON M6

	Mean (mm Hg)	*s.d.*	*CV (%)*
Systolic BP	111.1	2.4	2.1
Diastolic BP	63.4	2.3	3.6
Heart rate	86.7	1.7	2.0

Abbreviations: CV, coefficient of variation between devices; s.d., standard deviation. The mean represents the average of five measurements in 20 devices for each measurement.

Table 1 Rate of response for clinical items in each participating city

Clinical Items (medical assessment)	*Valid and controlled data (%) City*[a]									
	1	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*
BMI	100	100	75	100	100	100	100	94.7	100	100
Clinical history	100	100	75	100	100	100	100	94.7	100	100
Allergy	100	100	75	100	100	100	100	100	100	100
Clinical examination	100	96.2	75	100	100	100	100	94.7	90	100
Treatments	100	96.2	75	100	100	100	100	94.7	96.6	100
Tanner staging	100	96.2	75	NDA	100	100	100	94.7	100	100
Blood pressure	90.9	100	75	100	100	100	100	94.7	93.3	100
Heart rate	90.9	100	75	100	100	95	100	94.7	93.3	100
Anthropometry completed	100	100	100	96.8	100	100	100	94.7	100	100
Total number of adolescents	11	26	12	32	18	20	20	19	30	20

Abbreviations: BMI, body mass index; NDA, no data available. 1, Athens (Greece); 3, Dortmund (Germany); 4, Ghent (Belgium); 5, Heraklion (Greece); 6, Lille (France); 7, Pécs (Hungary); 8, Rome (Italy); 9, Stockholm (Sweden); 10, Vienna (Austria); 11, Zaragoza (Spain). [a]2, Birmingham (not participating in the pilot HELENA-CSS).

include height percentiles according to age and sex (National High Blood Pressure Education Program Coordinating Committee[41]).

As information about the neonatal period is important for this study and because these adolescents may not be aware of such information, we developed a questionnaire for parents to collect data relating to birth (weight and height at birth, duration of gestation) and duration of breastfeeding (Table 3). This questionnaire was sent with the information letter and consent forms to the parents, and then collected at school at the beginning of the study. If information on the parental questionnaire was lacking the local investigators were advised to send a new questionnaire form to the parents.

The objective of the self-reported socioeconomic questionnaire was to categorize children according to SES and to be able to analyze relationships between SES and nutritional and clinical data.

In large-scale surveys in children and adolescent populations it is not always possible to use registered data or to obtain information directly from the parents; in these cases reports by the adolescents are used. An early review by Looker[43] on findings of over 30 studies concluded that proxy reports from children can be seen as accurate indicators of parental status characteristics if the child responders are high school seniors, when most of the children in the sample can be expected to be living at home with the relevant parent and when the children are asked to report on current status characteristics that are likely to have some salience to them.[42] Recent studies showed that children of 11–12 years old were also able to describe their parents' occupation in sufficient detail in a survey setting.[43,44]

The self-reported SES questionnaire collected information on:

- living conditions (town that adolescents live, number of computers possessed by the family)
- family structure (living with both or one parent, including number of sisters/stepsisters, brothers/stepbrothers)
- employment status of both parents (full-time or part-time, housewife, trainee, temporary employment, pensioner, or whether the child did not know) [45]
- occupation of both parents (managerial staff, intellectual and scientific occupations, intermediate occupations, administration/clerical, business services, skilled agricultural and fishery workers, craft and manual workers, machine operators and assemblers, workers and elementary occupations, armed forces, other); for each item examples are proposed to the adolescents
- education level of both parents [46]
- subjective family influence ('well-off').[47]

Table 3 Information from parents of the 208 adolescents about their neonatal period

Parental Questionnaire	*Answers (%)*
Weight at birth	93.8
Height at birth	93.8
Duration of gestation	93.8
Total duration of exclusive breastfeeding (using only breast milk)	88.3
Total duration of breastfeeding (including bottle feeding)	84.8

Values are the percentage of adolescents whose parents provided the information.

Results of the pilot study

The pilot HELENA-CSS was conducted from March 2006 to June 2006 to test and adapt the procedures and questionnaires. This pilot study involved 208 adolescents from 10 European cities (Athens, Dortmund, Ghent, Heraklion, Lille, Pècs, Rome, Stockholm, Vienna, and Zaragoza) who met the inclusion criteria and were enrolled in the study. All measurements noted in the CRF were done following a standard protocol in the operations manual. All items of the CRF were tested (Table 1) and problems (such as the absence of notified BMI or Tanner staging) were reviewed by Work Package 5 for a decision about an eventual modification of the operations manual. One hundred and seventy adolescents (75 females and 95 males) of the 208 were assessed for puberty status (Table 2); the data distribution is reported in Figure 1 for breasts in girls and in Figure 2 for gonads in boys.

Blood pressure was measured in duplicate, and the duplicate values showed good agreement in the pilot study (Figure 3); 189 adolescents of 208 could be evaluated (Table 1). The mean and standard deviation of measurements did not differ significantly between the first and the second BP determination (120.9 ± 0.9 mm Hg versus 117.1 ± 0.9 mm Hg for SBP and 66.4 ± 0.6 mm Hg versus 65.1 ± 0.6 mm Hg for DBP). Socioeconomic and parental questionnaire items that either caused problems or questions for one or more of the participating centers or that were completed by $<85\%$ of the adolescents were reviewed for deletion or modification (Tables 3 and 4). The final report included the adapted CRF, questionnaires and the modified operations manual,

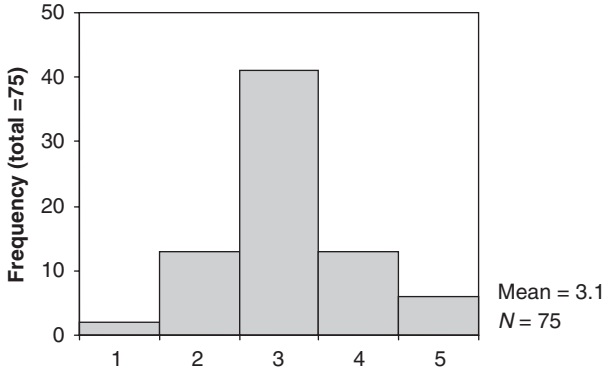

Figure 1 Girls' breast Tanner stages in pilot study.

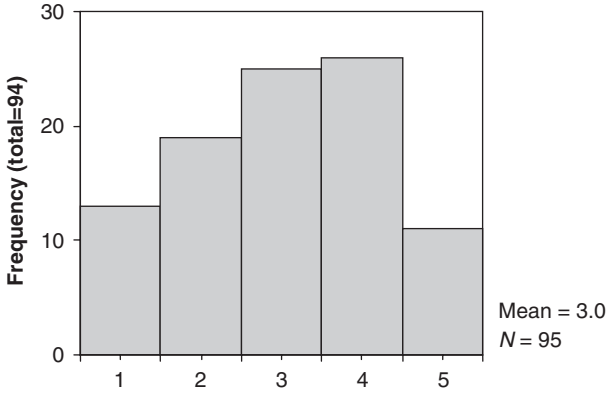

Figure 2 Boys' gonad Tanner stages in pilot study.

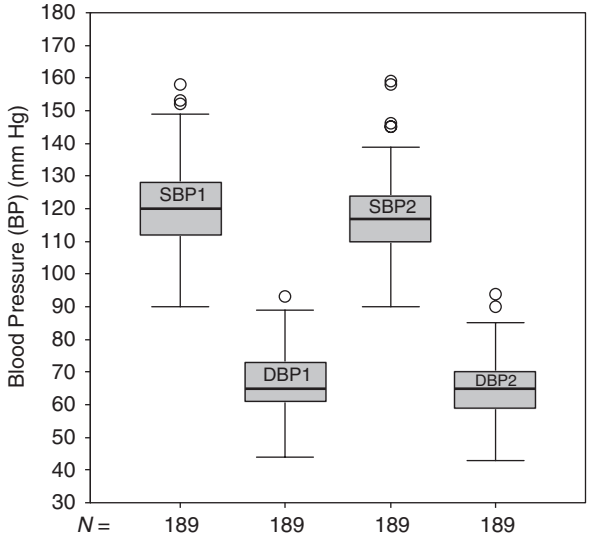

Figure 3 Systolic and diastolic blood pressure in pilot HELENA-CSS.

and this report was sent to all local investigators before it was applied in the HELENA-CSS, which will involve 3000 adolescents.

Discussion

The rationale and methodology behind the socioeconomic and clinical assessment of a population of the HELENA Study are described. Analysis of the HELENA-CSS pilot data gave us the opportunity to modify or clarify items, especially those addressed directly to the adolescents. We decided to ask the parents questions about the pre- and postnatal period and breastfeeding because adolescents are not often aware of such information and to check the response during the medical visit. Several questions of the SES questionnaire, relating to the number of computers possessed by the family and the kind of business or industry where the parents work

Table 4 Socioeconomic information about the 208 adolescents

	Questions	*Answers (%)*
Conditions of living and family structure	City of residence	100
	The child has his/her own bedroom	95
	Number of cars per family	95
	Number of computers per family	95
	Internet connection at home	95
	Number of sisters/brothers at home	95.6
	With whom the child is living	95.6
Subjective family influence	Well-off perception	91.3
Nationality	Children	98.2
	Parents	96.3
Place of birth and language	Children	99.1
	Parents	97.2
Language at home	Language used at home	96.5
Smoking status	Yes/no	95.9
	Frequency of smoking	93.5
	Number of cigarettes	92.4
Occupation of both parents	Work status of both parents (full-time, part-time)	93.1
	Type of organization (industry, shop, hospital, government)	26.3[a]
	Type of work (self-employed, own business)	76.3[a]
	Control of other personnel	73.5[a]
	Number of employees controlled by the parent	33.1[a]
	Occupation of the parent (ISCO)	85.1
Education of both parents	Education level of both parents	87.5

[a]<85%. Values are the percentage of adolescents who provided the information.

or the number of employees under control of the parents, produced a low rate of response in the pilot study (Table 4). These questions were either reformulated to be understood better or deleted. The SES was then modified, corrected and finally approved by all partners involved in the HELENA-CSS during the last plenary meeting of the consortium.

We observed no major difficulties in recording clinical data in the pilot study, especially for the medical history and information about current treatment and nutritional supplementation, vitamins, and disease or presence of some allergic manifestations (such as rhinitis, asthma, atopic dermatitis, food allergy).

We suggest that the clinical examination should be performed before the physical activity tests to verify the absence of any acute conditions or other diseases that could contraindicate physical exercises. Tanner staging assessed during the medical examination did not cause a major problem, probably because it was included in the clinical examination. We recommend that a male doctor examine the male adolescents and a female doctor the female adolescents.

SES and neonatal parental questionnaires permitted us to describe whether a relationship exists between some SES

levels or inequalities in birth with the presence of overweight, Tanner stage, BP limits upon gender and age of the adolescents.

Finally, the CRF and questionnaires we developed provide a good compromise between the need to obtain accurate and exhaustive information and the constraints of short questionnaires because they are easy to complete and were acceptable to adolescents across Europe. This approach can be useful for future European studies addressing the adolescent population.

Conclusion

The information obtained by the HELENA-CSS will contribute to a better understanding of the inequalities in nutrition and other health behaviors in the European adolescent population, and will be useful in developing intervention strategies to decrease or prevent adult morbidity throughout Europe.

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Conflict of interest

Frédéric Gottrand has received consulting fees from Numico Clinical Nutrition, lecture fees from SMS and grant support from Danone Research. The remaining authors state no conflict of interest.

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