Arch Public Health
2009, 67 (Supplement 1), 7-8

HELENA Study design, methodology and quality assurance

by

Moreno LA[1], Gottrand F[2]

Adolescence is a vulnerable period in life where new dietary habits are adopted, and nutrition related diseases are frequent and could have important health consequences in adulthood. In this abstract, we will describe the main methodological aspects related with the “Healthy Lifestyle in Europe by Nutrition in Adolescence” cross-sectional study (HELENA-CSS), as well as the measures we consider in order to ensure an optimal data collection.

The HELENA-CSS was designed to assess the nutritional status of the adolescent population in Europe. As the majority of the European adolescents are leaving in urban areas, we aimed to assess adolescents in ten cities, with more than 100.000 inhabitants: Athens, Dortmund, Ghent, Heraklion, Lille, Pecs, Rome, Stockholm, Vienna, and Zaragoza. The goal was to examine at least 300 adolescents per city (13.0 to 17.0 years). The sample size was estimated considering the variable with the largest variability that was the body mass index (BMI). The sampling selection was performed centrally considering the type of schools in the different cities (i.e. public and private ones). In every school one or more school classes were selected. If less than 70% of the adolescents did not accept to participate, another classroom was invited to participate. One third of the adolescents were also invited to have a blood sampling for further analysis. In all the cities, the study protocol was approved by the corresponding Ethics Committees. The adolescents and their parents signed the written informed consent. Inclusion criteria were: not to participate simultaneously in another clinical trial, be free of any acute infection lasting less than 1 week before the inclusion, and have valid data for age, sex and BMI.

The HELENA-CSS was conceived to obtain standardized, reliable and harmonized data on dietary intake, food choices and preferences, anthropometry, serum indicators of lipid and glucose metabolism, vitamin and mineral status, immuno-inflammatory markers, physical activity and fitness, and genetic polymorphisms. Before the study began, all the procedures and devices were harmonized during training sessions involving field-workers from each city. A pilot study including one class in each city allowed correcting all difficulties and discrepancies between the centres. Traceability of all blood samples from each HELENA-CSS partners was assessed.

[1] GENUD Research Group, E.U. Ciencias de la Salud, Universidad de Zaragoza, Spain

[2] EA3925, University Lille2, Lille, France

Correspondence: lmoreno@unizar.es, fgottrand@chru-lille.fr

Participation rate in the study was 67% and data from non participating subjects were recorded to assess representativity of the sample. Monitoring (on site visit) of all the cities involved in the CSS was done including “quality assurance concerning collection of data”, absence of protocol violations, and review of case report forms (one every 5 CRF were checked in a random selection method), questionnaires, documentation and report of any non-serious and serious adverse events. Finally the definitive database was checked for inconsistency and aberrant data. At total 3865 adolescents were included (1097 with blood sampling).