ian·af

INQUÉRITO ALIMENTAR NACIONAL
E DE ATIVIDADE FÍSICA

Summary
Protocol

CONSORTIUM

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INSTITUTIONAL SUPPORT

General Directorate of Health (DGS)
Central Administration of the Health Sistem (ACSS)
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INTERNATIONAL CONSULTANTS

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BACKGROUND

Portugal is among the few European countries with no harmonized individual information of food habits in the last three decades. The first National Dietary Survey was conducted in 1980 by the National Institute Dr. Ricardo Jorge (INSA) with the collaboration of the Ministry of Agriculture and Fishery. Data is out of date and unable to allow the study of current eating patterns and behaviors of the general Portuguese population, as empirical evidence shows that the eating habits of the Portuguese are experiencing profound changes due to new living habits, with significant impact on health. The urgency of this survey is recognized by the Strategic Guidelines of the National Health Plan 2012-2016, by the National Program for Promoting a Healthy Diet and its need is being expressed by several national and European entities.

Recognizing the importance of diet and nutrition in health promotion is of the utmost importance to know the food consumption and nutritional status of the European population, in a harmonized way that allows comparison between countries. The European Food Safety Authority (EFSA) has conducted the Pan-European Survey (EU-Menu) to know "What's in European menu?", promoting the development and testing of instruments and protocols, harmonized, for evaluation of food consumption in European countries.

Portugal through a national Consortium, which integrates different institutions, is involved in this project (Support to national dietary surveys in compliance with the EFSA Guidance on General principles for the collection of national food consumption data in the view of the pan-European dietary survey (Ref. EFSA CFT/ EFSA/DCM/2012/01-CT03) and is committed to present its findings by October 2016.

The study of national dietary intake and physical activity of the Portuguese population and the development of an information system to monitor consumption and eating behaviors and physical activity have now been supported by the EEA Grants program - Initiatives in Public Health and will allow addressing strategic priorities in health, at national and international levels.

The development of **the National Food, Nutrition and Physical Activity Survey (IAN-AF)** will provide a solid basis for the development of nutrition education and physical activity policies and food security policies in Portugal and at the European Union. A functioning national registration system on dietary and physical activity information will assist public health officials with the information needed to assess and monitor population health, and to compare these behaviours with other European countries. This is important to understand their associations with health, but also to monitor secular trends in behaviour and to evaluate the effectiveness of interventions. Additionally, this information system will allow the assessment of food safety and security dimensions. The information of risk assessment related with food biological and chemical hazards is fundamental for Portugal to be in line with European standards.

OBJECTIVES

The IAN-AF aims to collect national data on dietary intake and physical activity, and their relation with health determinants, namely socioeconomic factors. It has as specific objectives: 1) To assess food consumption of the Portuguese population, including: a) foods, nutrients, dietary supplements and other food-related risk behaviours; b) food contaminants and biological hazards; c) food insecurity; 2) To assess physical activity (PA) levels, including sedentary behaviours and sporting activities; 3) To characterize dietary, PA and anthropometric dimensions by region, socioeconomic conditions and other health-related determinants.

SAMPLING

The study population is a probabilistic sample of the general Portuguese population aged between three months and 84 years of age.

The sampling will be performed by multistage sampling, following these steps:

- Stratification by the seven Statistical Geographic Units - NUTS II (North, Centre, Lisboa e Vale do Tejo, Alentejo, Algarve, Madeira and Azores).
- Random selection of Primary Health Care Units in each region.
- Random selection of registered individuals in each Primary Health Care Unit, according to sex and age groups.

At the five Geographic Units of Continent, the sampling will be done in connection with the Central Administration of the Health System (ACSS). From the list of all Primary Health care Units, 21 Primary Health Units will be selected in three regions (North, Centre and Lisboa e Vale do Tejo) and 12 Units in two regions (Algarve and Alentejo). In the islands (Madeira and Azores), the sampling will be performed in connection with the Regional Departments of Health and 6 Units will be selected.

Considering a dependency effect of exposures (such as body mass index) according to Primary Health care Units, and assuming a design effect of 1.20 (20%), the number of Health Units for assuring representativeness by region was estimated to be 21 (ICC=0.58%). In some regions, namely in Alentejo and Algarve, the dependency is lower and thus 12 Primary Health Units would be sufficient (to obtain the same design effect of 1.20). In each region, the sampling will be weighted taking into account the number of individuals in each Primary Health Care Unit.

By assuming a maximum difference of 8% of one standard-deviation with a confidence level of 95%, the sample size for each region should be 603 individuals (total of 5068 individuals in the 7 regions). Considering a 20% design effect, each region should have assessed 724 individuals (total 5068). Thus, the sample size required to have representation at national level is of 5068 individuals: 935 children and adolescents (0-17 years), 3262 adults (18-64 years) and 871 elderly (65-84 years). Table 1 shows the sample size for each age and sex group, weighted for the distribution of the Portuguese general population.

Table 1: Estimation of the sample size by sex and age group, weighted for the distribution of the Portuguese population.

	Age groups (years)								
	< 1	**1-2**	**3-9**	**10-17**	**18-34**	**35-64**	**65-74**	**75-84**	**Total**
Total	47	94	353	440	1101	2161	514	357	5068
Men	24	48	181	225	547	1038	232	144	2439
Women	23	46	172	215	554	1123	282	213	2629

To accomplish EFSA requirements, an oversampling of children <1 year (3-11 months) and 1-2 years will be performed to obtain a minimum of 260 individuals in each age group (130 by sex). **Table 2** presents the final distribution according to sex and age group.

Table 2: Estimation of the sample size by each age group and sex, considering the oversampling of younger age groups.

	Age groups (years)								
	< 1	**1-2**	**3-9**	**10-17**	**18-34**	**35-64**	**65-74**	**75-84**	**Total**
Total	269	266	339	422	1047	1978	457	324	5102
Men	136	136	174	214	523	957	205	130	2475
Women	133	130	165	208	524	1021	252	194	2627

An oversampling of pregnant women will be also obtained (n=200) using the same sample frame, thus 2-3 preganant women will be selected in each Health Care Unit.
Considering a participation rate of 70% in the first visit and 70% in the second visit (70%*70%=49%), we expect 50% of non-response, individuals unreachable, incomplete questionnaires and drop-offs, thus 10204 (≈5102 x 2) participants will be selected and contacted.

The following exclusion criteria will be considered:

- Individuals living in collective residences/institutions (e.g. elderly in retirement homes or individuals in hospitals, at prisons or military barracks);
- Individuals living in Portugal for less than 1 year (non-applicable to infants);
- Non-Portuguese speakers;
- Individuals with insufficient/incorrect information in the lists (e.g. birth date, contacts);
- Dead individuals;
- Individuals with no availability for the two interviews during the evaluation period;
- Individuals with diminished physical and/or cognitive abilities that hamper participation (e.g. blind, deaf, with diagnosed dementias);
- Individuals with no established contact after all planned attempts.

In addition, for those aged 65 years old or more, a screening of cognitive impairment will be performed by using the Mini-Mental State Examination test and those with cognitive impairment won't be interviewed.

DATA COLLECTION (SUMMARY)

Participants will be contacted by telephone to check their willingness to participate. If an oral acceptance is provided, an invitation letter with participation details (overall project aims, time and place of interview) will be sent by post mail. If individuals refuse to participate a short refusal questionnaire will be applied by phone.

The field work will be run during 12 months to minimize seasonal variability. Data will be collected by trained fieldworkers by using Computer-assisted personal interviewing (CAPI). Each region will have several interviewers and one Regional Coordinator. Regional and National Coordinators will be trained by the team members who will subsequently train and supervise the interviewers. This process will continue during the fieldwork.

Two face-to-face interviews will be conducted, performed at participant's home or in a health care centre (according to participant's preference).

The national survey includes the evaluation of the following dimensions:

1) dietary intake (24-hours recall, food diaries, food propensity questionnaire);
2) eating habits and behaviours;
3) salt intake;
4) dietary supplements use;
5) food insecurity;
6) physical activity (IPAQ, diaries);
7) socio-demographics;
8) general health data;
9) anthropometrics.

Dietary intake will be obtained by two non-consecutive days of food diaries for children (<10 years old) and two non-consecutive 24-hours recalls for the other age groups (with lag time between 8 and 15 days), complemented with a Food Propensity Questionnaire.

PA will be assessed by physical activity diaries (2 consecutive days during the week and 2 of the weekend) for children (6-9 years) and adolescents (10-14 years) and by the IPAQ – International PA Questionnaire for the other age groups (≥15 years old). Questions on sedentary behaviors will be also applied in children since 3 years of age.

An electronic platform ("You eAT&Move") based on a client-server architecture will be used to manage the field work and common files (at server) and to collect data, at the client level. "You eAT&Move" includes 3 main components (modules): a) "You" module (including socio-demographics, anthropometrics, general health data, diet by a food propensity questionnaire, and food insecurity); b) "eAT24" module, including the eAT24 software which allows the collection and description of food consumption data by a 24-hours recall (or food diaries) with food models for portion size estimation, synchronized with nutritional composition data of foods and recipes; c) "Move" module, including the Move software, which allows the collection of physical activity data (including the IPAQ questionnaire and physical activity diaries), synchronized with metabolic equivalents data associated with each type of PA.

The eAT24 software (Electronic Assessment Tool for 24-hours recall) allows the collection of dietary data by an Automated Multiple-Pass Method for 24-hours. The software allows subsequent conversion of foods into nutrients, using by default the Portuguese food composition table.

All foods, including beverages and food supplements consumed during a 24-hour period, will be recorded per consumption occasion and quantified and described as eaten. The software eAT24 uses several quantification methods (e.g. household measures and food photos series). The eAT24 methodology requires the description of consumed foods during the dietary interview through various facets and respective descriptors (using the EFSA FoodEx2 classification system). The place and time (meal) of consumption will also be recorded for each eating occasion.

Recipes are described according to six facets (Production Method, Brandname, Preservation Method, Packaging Format, Packaging Material, Reheating Method) and are subsequently disaggregated into their ingredients. Recipe ingredients are described according to EFSA FoodEx2 classification system. Nutritional

composition of recipes is calculated according the methodology proposed by the EUROFIR network of excellence "Proposal for the harmonisation of recipe calculation procedures" (available at http://www.fao.org/uploads/media/reinivuvo_laitinen_2007_Eurofir_recipe_harmonisation_D2.2.12_M2.2.4_02.pdf). This module includes around 500 predefined recipes (including 200 recipes with infant foods - milks and baby cereals). Modifications of predefined recipes and inclusion of new recipes is planned in the next semester but not implemented at this point. During this period, free text remarks are used to point modifications of predefined recipes or inclusion of new recipes; the information collected in free text remarks will be continuously checked and compiled by compilers and updated recipe lists will be regularly released.

This interview-based dietary assessment instrument allows obtaining a very detailed description and quantification of foods, recipes, and food supplements consumed in the course of the preceding day. For quality control the software provides, in the end of the interview, the individual energy and macronutrient intake for the corresponding evaluated day.

Data will be inserted directly into a computer program, which facilitates the introduction and checking of the validity of the data in real time during the interview. For all Foods a Maximum Quantity is predefined and if exceeded during the data collection an alert question is triggered. For quality control the software provides, at the end of the interview, the individual energy and macronutrient intake for the corresponding evaluated day (if above or below the normal range, we will double check the quantities recorded). Nutritional information of new foods and recipes will not be integrated in this estimate. Information on quantities of new foods or recipes collected as free text remarks will be continuously checked by compilers.

As data is being collected, automatic checking for completeness of errors will be performed. Both food diaries and 24h-recalls will be recorded at the eAT24 software during interviews. However, for some items not previously included, namely for new recipes or food items an a posteriori codification will be performed by trained coders. Physical activity diaries will be handled in the specific module of the software, after codification. The coders will also check non-dietary data.

The process of checking for completeness of errors in data handling, namely those related with the development of new recipes or food items at the platform (according to the harmonized procedures proposed by the EUROFIR network), will be managed continuously during data collection.

STUDY PHASES

Phase 1: January 2015 to June 2015 – preparation of the manuals of procedures and the electronic platform for gathering information.
Phase 2: July to August 2015 – Pre-pilot (to test the plataform) and Pilot studies (to test all the procedures).
Phase 3: September 2015 to August 2016 – Field work: interviews by questionnaires.
Phase 4: September 2015 to December 2016 – Checking of datasets for completeness of errors, statistical analysis and final report drafting.

ETHICS

Researchers have ethical approval for the conduction of the IAN-AF from the National Commission for Data Protection, the Ethical Committee of the Institute of Public Health, University of Porto and from the Ethical Comissions of the Regional Administrations of Health.

All participants will be asked to provide their written informed consent for participation according to the Ethical Principles for Medical Research involving human subjects expressed in the Declaration of Helsinki and the national legislation. Written agreements from the parents will be required for children and adolescents below 18 years old. Adolescents (10-17 years old) will be also asked to sign the consent form together with their legal representative.

Every document with identification data will be treated separately and stored in a different dataset.