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1. GENERAL INFORMATION

1.1 Project responsible

- Prof. Dr. Herman Van Oyen, Director of Operation Direction “Public Health Surveillance”.
- Dr. Jean Tafforeau, Head of the Unit “Surveys, lifestyle and chronic disease”.

1.2 Collaborators

Scientific collaborators:

- Dr. Koenraad Cuypers, Project leader, PhD in community medicine; represents Belgium as a member in the network/expert group on food consumption and exposure data.
- Gaëlle Isaac: Biostatician and master in public health
- Charlotte Stiévenart: Dietician, Master in public health
- Sarah Bel: Dietician, Master in health promotion
- Sofie Van den Abeele: Dietician, Master in health promotion
- Cloë Ost: Master in biomedical sciences
- Thérésa Lebacq:

Administrative collaborators:

- Ledia Jani

ICT- developer:

- Cedric Malache & Xavier Pretlot (previously Djamila Mansour)

1.3 Steering committee

The scientific steering committee (CSS) consists of a set of members from public health authorities and scientific organizations installed to review and guard the

quality of the scientific work. The commission of the ordering party (FOD-SPF) is also a member of this committee.

1.4 Partners

None

1.5 Subcontractors in order to develop the EPIC-soft tool

For the Food Consumption Survey edition 2014 (FCS2014) a collaborative agreement was closed with:

- The International Agency for Research on Cancer (IARC) for the secondment of EPIC-Soft methodology and the implementation and preparation of the French and Flemish country-specific versions (Annex I).

  The IARC Project leader is:
  Dr Christopher P. Wild: Director, IARC
  Cours Albert Thomas, 150
  69372 Lyon
  Cedex 08 France

  The Responsible Technical Officer (and the contact person) is:
  Dr Nadia Slimani: Head, Dietary Exposure Assessment group (DEX)
  Cours Albert Thomas, 150
  69372 Lyon
  Cedex 08 France

- The Ghent University (UGent) for a scientific collaboration on the adaptation of EPIC-Soft, a standardized food consumption assessment tool, which is provided by the university of Ghent (Sint-Pietersnieuwstraat, 25-B-9000 Ghent, Belgium) under conditions stipulated in an outsourcing contract (Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, UZ – 2 Blok A, De Pintelaan 185, B-9000 Ghent, Belgium) (Annexe II).

1.6 Co-ordinates of the Sponsor

The FCS2014 is a collaboration between the Federal Ministry of Public Health, Directorate of Public Health, Safety of the food chain and Environment, hereafter called FOD-SPF on one side and the WIV-ISP on the other side. A contract was signed between these two parties (Annex III):

- FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu/ SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement
  Eurostation II Place Victor Horta, 40 bte 10 1060 Bruxelles

- The WIV-ISP, The Scientific Institute of Public Health, Belgium
  Juliette Wytsman Street, 14 1050 Brussels

2. OBJECTIVE OF THE STUDY

2.1 Description of overall objectives

The overall objectives are:

- Assessment of food consumption, dietary habits and nutritional quality of the diet among adults and children in Belgium (3-64 years).

- Assessment of physical activity levels and sedentariness in Belgium among adults and children (3-64 years).

- Assessment of the adequacy of food and nutrient intakes and physical activity in the different subgroups of the population compared to the recommendations.

- Estimation of exposure of Belgian children and adults to contaminants, additives and other chemicals in food

- Estimation of the effect of nutrition policies (e.g. Belgian National Food and Health Plan (2005-2010), Flemish Actieplan Voeding en Beweging 2009-2015, salt reduction, fortification of foods with nutrients, ...) on food and nutrient intakes of the population.

On the Belgian level there is the need for a new national representative food consumption survey, especially among children since there are no national food consumption data for children available in Belgium. The survey will also serve as a follow-up of the previous survey among adolescents and adults carried out in 2004 (FCS2004). Frequent monitoring of food consumption is necessary as dietary habits are prone to societal and policy changes and very rapid changes of foods on the market. Additionally, there is the need for national representative information on nutritional intake and food consumption to inform adequate and timely policy responses.

An effective action against adult obesity seems to be the prevention of children's obesity; the statement of the World Health Organization (WHO) on the protection of children's health also requires special health interventions in the younger age groups. By collecting information on nutritional intake and dietary habits it is possible to support public and health policy makers in developing food recommendations and introducing effective (preferably upstream) policies to change dietary habits. It also allows to estimate the intake of macronutrients, micronutrients, additives and contaminants in pursuing food safety. Age groups younger than 15 years were not included in the FCS2004 and these are one of the focuses in the current food survey (FCS2014). Children are especially vulnerable for food safety issues as their bodyweight is lower than the bodyweight of adults.

The cornerstone objective of most surveillance systems is monitoring trends. Surveillance may provide a comparatively inexpensive and sufficient assessment of the effect of policies (1). These data will help to sustain, and if possible, improve public health in Belgium.

On the European level this food consumption survey constitutes the Belgian part of

the European project EU-MENU.[1] This project aims at collecting comparable food consumption data across the EU.

2.2 Description of specific objectives

- To estimate the intake of macro- and micronutrients;
- To estimate the exposure to additives and contaminants in pursuing food safety;
- To estimate the intake of micronutrients through food supplements;
- To study the food consumption and dietary habits by sex, age and different social groups;
- To provide information for initiation of new policies and for evaluation of existing nutrition policies;
- To characterize sub-groups at risk for deficient or excessive intake of nutrients or for unsafe exposures to chemicals and contaminants in foods;
- To use trends in food consumption and dietary habits detected through surveillance to anticipate future evolutions.

3. SCIENTIFIC RELEVANCE

3.1 Scientific background

An increasing number of studies are showing a manifest growth in the prevalence of non-communicable diseases (NCDs) in the member states of the EU. Poor diet is the leading risk factor for disease in Belgium contributing to almost 14% of disability-adjusted life years (DALYs) to the overall disease burden, while physical inactivity contributes to more or less 5% of DALYs (2). At the same time there is a growing consensus about the causal association between food consumption and physical/ sedentary activity and some NCDs. An appropriate response of the policy makers is warranted. As a consequence, the WHO and EU have recommended the development of a national plan for food and health.

[1] http://www.efsa.europa.eu/en/datexfoodcdb/datexeumenu.htm

Therefore, in 2004 the first FCS in Belgium, as one of the few countries in the EU without a representative and regular data collection on dietary habits of the population, was executed to provide information on the food consumption and nutrient intake in the general population. Based on the results of the survey the seven strategies of the first Belgian National Food and Health Plan (2005-2010) were created (3).

3.2 Public health relevance

People who develop policies to prevent or control specific diseases or public health generally need reliable information (1). Surveillance may provide the basis for identifying population groups who need treatment, prophylaxis or education and may provide information for the development or evaluation of public health policies (4).

Over time, surveillance is used to identify changes in the nature or extent of health problems, the effectiveness of public health policies and new policies which may be introduced. As a result, surveillance systems may grow from simple ad hoc arrangements into more elaborate structures. Data from the survey not only find applications in the field of food policy but also for food safety. The data are also used by several federal agencies and numerous academic and research institutions.

4. DEFINITIONS AND ABBREVIATIONS

BMI	Body Mass Index
CAPI	Computer assisted personal interviewing
CPP	Commission of Protection of Private life
DALYs	Disability-adjusted life years
EE	Energy Expenditure
EFCOSUM	European Food Consumption Survey Method
EFCOVAL	European Consumption Validation
EFSA	European Food Safety Authority
EPIC-Soft	European Prospective Investigation into Cancer and Nutrition Software
EU	European Union
FCS	Food Consumption Survey
FFQ	Food Frequency Questionnaire
FOD-SPF	Federal agency for Public Health, Safety of the food chain and Life environment
FPAQ	Flemish Physical Activity Questionnaire
IARC	International Agency for Research on Cancer
IM-app	Interview manager-application
WIV-ISP	Scientific Institute of Public Health, Belgium
NCDs	Non-communicable diseases
NPR	National Population Register
PA	Physical activity
PANCAKE	Pilot study for the Assessment of Nutrient intake and food Consumption Among Kids in Europe
PAPI	Paper assisted personal interviewing
PDS	Pubertal Development Scale
PSU	Primary Sampling Unit
SB	Sedentary Behaviour
SCC	Scientific Steering Committee
WC	Waist Circumference
WHO	World Health Organization

5. METHODS

The methodology of the FCS2014 is based on the “General principles for the collection of national food consumption data in the view of a pan-European dietary survey”, prepared by the European Food Safety Authority (EFSA) and endorsed by the EU member states (5). The national food consumption data will be prepared and transferred in the format required by EFSA and introduced in the European comprehensive food consumption database, used for the exposure assessment activities of EFSA (http://www.efsa.europa.eu). These principles were based on research conducted in the EFCOSUM (European Food Consumption Survey Method) and EFCOVAL (European Consumption Validation) projects (6;7). The methodology of the FCS2014 also follows the recommendations made after the Pilot Study for the Assessment of Nutrient Intake and food consumption among kids in Europe (PANCAKE) project (children). The PANCAKE project developed, tested and evaluates tools and procedures for future pan-European food consumption surveys among infants, toddlers, children (up to ten years) and breastfeeding women (8).

5.1 Study design

5.1.1 Study type

The design of the FCS2014 is cross-sectional* and the target population comprises the general Belgian population, aged 3 to 64 years.

**Forms submitted to the Commission for the Protection of Privacy (CPP) and Ethical Committee foresee the possibility of follow-up.*

5.1.2 Study period

The fieldwork will be carried out between 2 January 2014 and 30 December 2014.

5.1.3 Target population

The target population is defined as “all people residing in Belgium, regardless of their place of birth, nationality or any other characteristic” within the age group of 3-64 years.

5.2 Sampling

5.2.1 Sampling frame

The sampling frame is the National Register. The exclusion of children was experienced as a limitation after the first FCS2004 (9). It was necessary to compromise regarding the age of the investigated sample in relation to the available budget; consequently, the sample has been limited to the ages 3 to 64 years. The aim is to sample a study population that is representative for the target population.

The National Register is the only database which covers close to 100% of the total population with an official residence status. It is structured in such a way that individuals can be identified together with baseline demographic and administrative characteristics such as address, age, sex, marital status, links within the households and families (child of, etc…). The National Register has the best chance in reflecting most of the population because of legal obligations such as the obligation to report births, deaths, and change of address, etc. Each of those changes has to be reported within a defined time frame.

The National Register does not cover the target population completely as some people such as homeless and illegal immigrants may be not listed and will be excluded a priori. Additionally, in concordance to the recommendations of EFCOSUM, following persons are not eligible:

- Persons who reside in institutions, elderly homes, nursing homes;
- Religious community or cloister with more than 8 persons;
- People residing abroad or people who moved out of the selected municipality;
- People in prison;
- Persons who are hospitalized during the period of the survey;
- People who do not speak Flemish/French;
- People who died;
- Persons who are not able to be interviewed because of a physical or mental disability.

All these persons will be excluded a posteriori during the fieldwork. Persons who are temporarily away from home (e.g., on vacation or temporarily hospitalized) will be

eligible for participation either by participating when they return home or by following them to their temporary address when it is possible. The National Register is adapted frequently and information provided by the National Register (birth date, gender, address, vital status) will be updated.

5.2.2 Study population

The study population – the population that is reached by the study – does not cover the target population completely. Findings in biomedical research only apply to populations that resemble those studied. Biological effects differ across different populations and subgroups. Consequently, it is wise to refrain from generalizing results beyond the circumstances that describe the study setting.

The aim is to sample a study population that is representative for the target population. This aim may also be obtained besides the use of specific sampling techniques, by standardizing or reweighting the study data to match the target population distribution.

5.2.3 Sample size

The total number of successful participants for the sample is set to 3200. This sample size is based on sample size calculations* and is similar to the sample size of the FCS2004. It is also determined by budget constraints and available logistic means. This number also fulfils the requirements of the EFSA.

* Allocating 500 persons to each of the 4 strata in children and adolescents and 300 in the 4 strata in adults ensures that the estimated average intake of the different nutrients will be with 95% certainty within the 5%-interval around the real population mean.

$$N = ((1.96 * SD)/ \text{Margin of error})^2$$

Margin of error at 95% confidence ≈ 0.98/square root of n

The final study sample will include 500 children (3-5 years old), 500 children (6-9 years old), 1000 adolescents (10-17 years old) and 1200 adults (18-64 years old).

This classification in different age groups is in concordance with the EFCOSUM report (10) European Commission p.51.

5.2.4 Sampling methodology

The sampling will be carried out in several steps (multistage sampling). Two main sample techniques will be used: stratified cluster sampling and systematic random sampling. Figure 1 gives an overview the sampling scheme.

Simple random sampling cannot be used in this study because of two main reasons:

- A simple random sample may not be efficient as the geographical spread of the selected individuals may be large, inducing a logistical and financial burden.
- It does not guarantee a representative sample with respect to predefined characteristics such as age and gender.

A stratified cluster design is selected. Stratification by province will be performed. Municipalities will serve as primary sampling unit (PSU), while individuals within the municipalities will be the secondary sampling units (SSU).

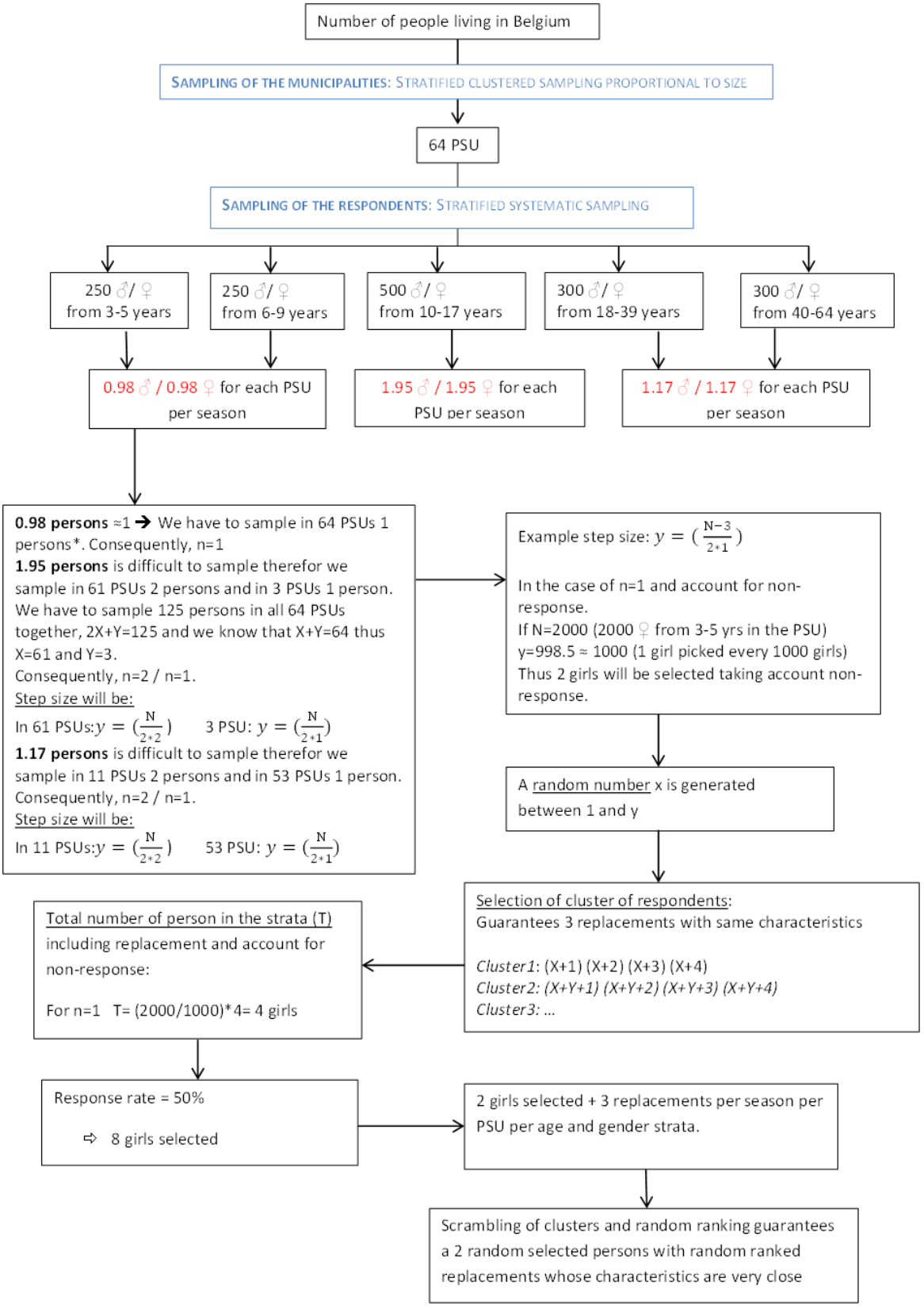

Figure 1. Sampling scheme

Stage 1: Stratification of the Belgian population at the level of province

To account for the population size of the 11 provinces (defined as the 10 Belgian provinces and the Brussels-Capital region) a stratification at the provincial level is defined and the sample size within each of the 11 strata is proportional to the population size of the province (all ages). This is based on the population at the 1st December 2012[2]. Choosing a stratified sample has the advantage of higher precision (smaller bounds on the errors of estimation) especially if the strata are largely homogenous (variability intra-strata smaller than variability inter-strata), which is the case.

Stage 2: Stratified clustered proportional to size: selection of municipalities (PSU)

Within each provincial stratum municipalities are selected, using a systematic sampling approach, with a selection chance proportional to their size. Thus, the number of municipalities to be selected is defined by the sample size of the provincial stratum. These municipalities are called the primary sampling units (PSUs). One PSU is a group of 50 individuals (a large municipality has 1 or more PSU according to its size). By selecting a limited number of municipalities a clustering is induced which may increase the variance of the estimates. However it is assumed that the clustering effect is minimal given the heterogeneity of the variables of interest within the level of municipality. Therefore the logistic advantage outweighs the limitation related to the clustering at municipality level.

The distribution of PSUs across the 11 provinces is presented in table I. The column “E” gives the number of PSU within each province. This number has been calculated so that the probability for an individual to be selected is the same in each province. It is impossible to assign the number of PSU so that the probability of selection is totally equal. The probability varies between 0.27/1000 (West-Vlaanderen) and 0.36/1000 (Luxembourg). All probabilities are close to the overall average (0.29/1000).

[2] SPF Intérieur - Registre National. (2013, January 24). *Chiffre global de la population par commune.* Retrieved February 13, 2013, from Direction générale Statistique et Information économique: http://www.ibz.rrn.fgov.be/fileadmin/user_upload/Registre/fr/statistiques_population/stat_1_f.pdf

Table I. The distribution of the sample size by provinces.

PROVINCES	(A) Population	(B) %	(C) Theoretical Number of individuals to be interviewed	(D) Effective Number of individuals to be interviewed (Multiple of 50)	(E) Number of groups of 50 individuals (PSU)	(F) Probability for an individuals to be selected
Antwerpen	1801539	16.2	518	500	10	0.28
Vlaams Brabant	1103261	9.9	317	300	6	0.27
West-Vlaanderen	1177276	10.6	339	350	7	0.30
Oost-Vlaanderen	1464442	13.1	419	400	8	0.30
Limburg	855597	7.7	246	250	5	0.29
Bruxelles/Brussel	1161657	10.4	333	350	7	0.30
Brabant Wallon	389333	3.5	112	100	2	0.26
Hainaut	1331450	11.9	381	400	8	0.30
Liège	1095596	9.8	314	300	6	0.27
Luxembourg	278167	2.5	80	100	2	0.36
Namur	485847	4.4	141	150	3	0.31
Belgium	**11144165**	**100.0**	**3200**	**3200**	**64**	**0.29**

(C) = (3200* (B)/100) ; (F) = ((D/A)*10^3)

In this step, the municipalities are selected within the provincial stratum. To guarantee the efficiency of the fieldwork, some additional rules are built into the random selection:

- The chance of selection of a municipality should be proportional to its population size, ensuring that larger cities have a higher selection probability to have at least

one PSU or even more than one PSU (depending on its size in relation to the size of the stratum). The methods ensures that at least one of the larger cities is selected.

- A similar remark holds for the smaller towns and villages. Also from this group elements should be present. By grouping smaller communities by ordering the whole set of communities according to size, the representation of smaller communities out of the pool of smaller communities is ensured. The assumption is made that smaller communities of about the same size are exchangeable with respect to the items of interest.

The requirements listed above are achieved by a weighted systematic sampling where the municipalities are ordered (from large to small) and expanded proportional to their size (area probability sampling). As a consequence the chance for a municipality to be selected is proportional to the number of inhabitants.

The software used for this procedure is “SAS 9.3” (SAS® Institute Inc., North Carolina 27513, USA). A survey selection procedure 4 steps was used to select units with probability proportional to size and with replacement. These steps are:

- Calculation of the number of municipalities in the stratum
- Calculation of the cumulative population
- Generation of a random number and calculate interval
- Selection of groups

Because units are selected with replacement, a unit can be selected for the sample more than once. At least, from 589 Belgian municipalities, 64 PSUs (64*50=3200) are selected (Annex IV).

Stage 3: Stratified systematic random sampling: selection of individuals (SSU)

Within each municipality (PSU) 50 respondents will be selected randomly within strata defined by gender and age and a fixed number of successful participants equally divided in each of the 10 gender/age strata. Limiting the selection to 50 individuals ensures a logistic advantage but at the same time a sufficient spread and inclusion of the number of municipalities.

Choice of sampling procedure in relation to the replacement strategy of the non-participants.

Any sample size is partially based on the total number of successful interviewees who are needed in the final study. In practice, eligible subjects will not always be willing to take part because participation in the survey is voluntary or certain persons registered in the National Population Register cannot be contacted due to moving, death, wrong addresses or are not eligible to participate. Consequently, it will be necessary to take reserve persons into account. The persons who refused or who were not contactable, are replaced by reserve-individuals who will have three characteristics in common with the originally selected individual:

- residing in the same municipality
- the same gender
- same age stratum

The procedure is called “stratified oversampling”. For every selected person three other persons will be selected at the same time before the start of the survey. In this way groups of four persons (clusters of individuals) will be created. Additionally, the number of clusters was doubled, bringing the final number of persons to be sampled to 3200*4*2 = 25,600 persons. The selection of the clusters of persons is done by means of a systematic sampling procedure. For the final selection of the sample, the individuals will be ranked in each municipality by gender and age. When one person does not want to or is not found to participate, the next person in the group of four persons is activated and contacted. This procedure continues until a person is successfully interviewed. Consequently, the other persons of the group who were not activated are labelled: “not activated” and are not taken into account during the further process of the survey.

The survey calendar must be organized in such a way that an adequate proportion of weekdays as well as weekend days will be captured. In addition, the survey will continue during a whole year and will be executed during the four seasons. 3200 persons will be interviewed. This means 800 persons have to be interviewed in each season and in each season a sample of 6400 individuals are selected. These 800 persons have to be divided into 10 strata: five age groups (3-5;6-9;10-17;18-39;40-64) and for both genders from the population of the 11 provinces. In advance 64 PSU’s, i.e. municipalities will be randomly sampled, depending the magnitude of the

11 provinces. Altogether, 64 dieticians will interview about 260-270 interviewees each month.

There are two alternatives for sampling the study sample with respect to the replacement of the non-participants:

- In the *first alternative (I)* the seasonal sample will further be divided in two periods and the study sample, extended to include the expected non-participants (taking 50% participation rate into account) is provided to the dieticians in consequently 8 waves of 6 weeks. Consequently, in case of refusal the dietician will already have the data on the next replacement individual. The administrative personnel at WIV-ISP will send in the start of the first sub period, i.e. 6 weeks, invitation letters with information to the 12 selected persons, of which expectedly 6 will participate and provide the name and address of the new individuals to interview to the interviewer. Six weeks after the administrative personnel of WIV-ISP will send out data of the 12 next persons to the dieticians and information letters to the selected persons of which 6 are expected to participate. For the second season the NPR will be asked to sample another study sample taking the observed participation rate and the characteristics of the participants into account. The characteristics of the strata which will be taken into account will be gender.
- In the *second alternative (II)* the study sample is provided in four waves including a system in which in case of refusal the administrative personnel of WIV-ISP will provide using a software application the next selected individual to the interviewer. The WIV-ISP administrative personnel will send an information letter and the dietician can consecutively contact the replacement person as soon as possible. The replacement persons have to be selected in clusters in advance and will be guarded in databases at WIV-ISP.

In the alternative II it is needed to implement a software application that can guard the rest of the individuals as selected in the available clusters and that another replacement has to pop up to provide to the dietician who reported a non-participant. A SWOT-analysis of both alternatives gives different issues to think about (see table II).

Table II. Presentation of the two alternatives for study sampling

	ALTERNATIVE I	ALTERNATIVE II
Replacement	Will be quick, but danger for outrunning the available replacement persons (moved, death…)	Takes extra time, but extra persons up to 7 in the first cluster and next 8 in the second are available
Privacy/selection issue	Study sample data handled by dieticians	Study sample data handled by administrative personnel
Information flow	Time lost between letter and interview	Timely information upon contact.
ICT application	Limited	Extensive
Matching of replacement	Gender, age	Gender, age
NPR- data	Recent	Recent
Replacement of dietician	More complicated because they have to handle more data	Less complicated because dietician has less data. More flexible.
Work load for National Population Register	Sampling in 8 waves extensive adjusting of sampling programs and they have to react more timely including information on progress of fieldwork	Sampling in four waves Less extensive adjustment of sampling programs
Costs	National Population Register	ICT WIV-ISP

Taking all the different strengths and weaknesses into account and realising the problem of snowball-effect which can move the sampling numbers to the next wave and that more steps and parts of the proceedings are controllable and in the hands

of WIV-ISP personnel in alternative II, we decided to go for **alternative II**. This conclusion is made based on the experience of the Health Interviews Surveys implemented by WIV-ISP in Belgium and the possibility of adapting the software-application used in the Health Interview Survey (HIS) 2008 and Food Consumption Survey 2004.

Precise sampling in relation to guarantee a realistic picture of the Belgian population is necessary. A representative study population will be randomly sampled within gender and age strata:

- Gender (1 – 2)
- Age (3 – 5; 6– 9; 10 – 17; 18 – 39 ; 40 – 64)

Stratified systematic sampling according to age is a method of sampling that involves the division of a population into smaller groups but ensures that the age distribution within the age band is respected. In systematic stratified random sampling, the strata are formed based on members' shared attributes or characteristics.

The sample includes 10 strata: with each five age groups and both genders. Choosing a stratified sample has the advantage of higher precision (smaller bounds on the errors of estimation) especially if the strata are largely homogenous (variability intra-strata smaller than variability inter-strata) which is the case. Another important advantage is that estimates at the level of each stratum can be presented with a reasonable precision.

Persons in the National Population Registry are ordered hierarchically (per municipality and per age/gender stratum) by age of the respondents. 64 PSUs (municipalities) are defined with each 50 SSUs (persons):

- 250 girls and 250 boys aged 3-5 years,
- 250 girls and 250 boys aged 6-9 years,
- 500 girls and 500 boys aged 10-17 years,
- 300 women and 300 men aged 18-39 years and
- 300 women and 300 men aged 40-64 years.

These results are respectively 0.98, 0.98, 1.95, 1.95, 1.17 and 1.17 persons per PSU per season. Selecting 0.98, 1.95 or 1.17 persons per stratum per season and per PSU is quite difficult, but we know that we have to end up with 125 respectively (or

75) persons per stratum per season for all PSUs together. Therefore, we decided to select either 1 or 2 persons in each group.

We used an algorithm to calculate in how many groups 2 persons are needed to end up with a total of 125 (respectively 75). The groups in which 2 persons (instead of 1 person) are needed are randomly selected. A schematic presentation is given in Table III.

Table III. The ordered sampling frame for the selection of the respondents within each age stratum

	Gender of respondent	**Age of respondent**
Age stratum within a municipality (3-5 years old)	1	3 5
	2	5 3

AND SO ON for each age stratum

Calculation of the step size

The step size for the systematic sample is calculated by dividing the total number of inhabitants in the municipality by the required number of respondents. The required number of respondents is obtained as described in table I. Hence, the ***step size (y)*** is given by:

$$y = \left(\frac{N}{2 * n} \right)$$

where N = the number of people in the group municipality/age/gender stratum

n = the number of people to be sampled in the group

2 = put in the formula because we want to select twice as many clusters as required to cope with non-response

To sample 125 persons in all 64 PSUs we need 2 persons in 61 PSUs and 1 person in 3 PSUs. To sample 75 persons in 64 PSUs we need 2 persons in 11 PSUs and 1 person in 53 PSUs For the PSUs and strata in which 2 persons will be selected the step size will be:

$$y = \left(\frac{N}{2*2} \right)$$

For the PSUs and strata in which 1 person will be selected the step size will be:

$$y = \left(\frac{N}{2*1} \right)$$

Further steps that are required;

Generate a random number

A random number *x* is generated between 1 and y.

Selection of clusters of respondents

In regard to the replacement strategy, instead of selecting one person at each step of the sampling, the selected person and three consecutive persons are selected. Such a group of people is called a cluster.
The first cluster constitutes of person x, x+1, x+2 and x+3.
The second cluster contains the people x+y, x+y+1, x+y+2 and x+y+3.
And more general, the n-th cluster contains the people x + (n-1)y, x + (n-1)y +1, x + (n-1)y +2 and x + (n-1)y +3.

For most groups the step size is not an integer. Therefore the first person of the n-th cluster is person number **ROUND(x + (n-1)y)** on the list.

After having performed a horizontal and vertical scrambling, the order in which the persons will be activated will be randomly determined.

The outcome of this procedure is a number of clusters consisting of 4 people, similar in terms of municipality, gender and age. The number of clusters is twice the number of required persons. Hence the total sample size is 8 times as large as the number of required persons.

Selection of respondents

After the implementation of the sampling procedure a four columns table is formed where each row represented a cluster of the (four) respondents. There are as many rows as there are clusters selected. The first column is the first person to contact. If this person is not eligible or if it does not lead to an interview, the next person (in the second column) is contacted and so on. When all the persons of the cluster are used and further replacement is necessary, the first eligible person of the next available row is selected. To prevent any order effect the person within each row are randomized (= horizontal scrambling).

Also the rows themselves are randomized (= vertical scrambling). Then there are no row-effects and it is possible to work from top to bottom until a sufficient number of interviews is realised.
Tables IV and V give a schematic presentation of the sample before and after scrambling.

Table IV. Selection of replacement persons - BEFORE Scrambling

Row	**Replacement persons**			
	1	**2**	**3**	**4**
1	nr 011	nr 012	nr 013	nr 014
2	nr 021	nr 022	nr 023	nr 024
3	nr ij*			
4				
...				
13				
14	nr 141	nr 142	nr 143	nr 144

Table V. Selection of replacement persons - AFTER scrambling

Row	**Replacement persons**			
	1	**2**	**3**	**4**
1	nr 034	nr 033	nr 031	nr 032
2	nr 102	nr 103	nr 104	nr 101
3				
4				
...				
13				
14	nr 123	nr 121	nr 124	nr 122

The sampling scheme above solves many issues at once:

- By taking a systematic sample from an ordered list, it is ensured that the characteristics of the sample is close to that of the municipality with respect to the variables gender and age of the person.
- By taking a cluster of four persons in each step, one forms a homogeneous group of people in a natural way which can be used to replace one another in case of non-response. If none of the four persons in a row resulted in an interview, then a new row can be started. The latter is only necessary if the other rows that have already been started are not sufficient.
- By making a list in advance, the organisation of the fieldwork is facilitated because no algorithm is necessary to decide about the next replacement and all contact information is present. Once a person of a household has participated, no other person of the same household will be selected and the household will a priori be excluded for the next waves.

Output

The output file of the sampling procedure is a file listing all selected individuals with their replacement individuals. The following information will be extracted:

1. Identification number of the respondent (8-digit number)
2. Name of the person (family name and surname)
3. Address
4. Postcode of municipality
5. Gender
6. Age
7. Household size
8. Cluster number

A list of checks will be performed to ensure that the sample is in line with the requirements specified in the study protocol. The data file with all selected people will be imported in NUTRIS; this is an ICT application developed by the WIV-ISP for management of the fieldwork. The scrambling procedure will be carried out in order to define initially selected and replacement persons. Replacement people will be identified as follows:

- In case of a person’s non-response, the replacement is the next eligible person within the cluster. Once a cluster is initiated, the algorithm continues to select the

next eligible person within the cluster independently of the number of successful interviews attained. Therefore, once a cluster is started, all efforts are taken to have a successful contact with a person within the cluster.

- In case a cluster is exhausted in the stratum a new cluster is always activated.

5.2.5 Recruitment

Trained dieticians will perform the fieldwork and the recruitment of selected individuals. Whenever “interviewer” is mentioned in the following section, a dietician/nutritionist-interviewer is meant.

An invitation letter to participate in the survey will be sent to the first selected individual of each cluster. At the same time a list of all these ‘activated’ persons will be sent to the interviewers for recruitment. The first attempt to contact should happen as soon as possible after the interviewer receives the list of selected individuals (preferably by performing a house visit). A procedure for contact and recruitment is established to ensure that all interviewers work in a fixed and standardized way and to ensure a strict timing of the fieldwork. The purpose of the first contact is to ask (the parent(s)/guardian(s) of) the individual whether he or she want to participate in the survey or not and to set a date for the first home visit.

When receiving the list of selected individuals, the interviewer will have to check five elements:

1) Check if the address of the selected individual exists;
2) Check if the selected individual lives on the address provided. It is possible that this person has moved to another address in the same PSU or outside the PSU. If the individual lives in the same PSU he or she is still eligible to participate;
3) Check if the selected individual meets all the inclusion criteria (eligible);
4) Check if the selected individual is contactable;

At least five attempts to contact should be done for each individual:

- At least one attempt to contact should be a house visit.

- At least two attempts to contact should happen during the weekend.
- At least two attempts to contact should be during the week outside the working hours

Every attempt to contact the individual will have to be noted on the communication form.

5) Check if the selected individual wants to participate to the survey.

If the selected individual is not eligible or contactable or has refused participation (or other), the information of a replacement individual (the next selected person of the cluster) will be sent to the interviewer by the WIV for recruitment.

5.3 Data management

5.3.1 Data collection and data source

The fieldwork will be performed by interviewers with an extensive nutritional background. Due to the nature of the work only graduate dieticians or nutritionists will be selected to perform the fieldwork. They will be thoroughly trained in recruitment and interviewing techniques, programs (EPIC-Soft (11), BLAISE and Actilife Lite 6), and measurement procedures for anthropometry and physical activity.

A dietician/nutritionist with ample experience in food consumption studies and EPIC-Soft will have the responsibility for the training (Flemish and French training), coordination and supervision of the interviewers (“fieldwork supervisor”) and management of the EPIC-Soft files of the completed interviews or records. This coordinating dietician/nutritionist also received a tailored training from IARC. Furthermore, an experienced database manager will support the survey.

All data collection procedures will follow strict routines as outlined in this protocol. All days of the week have to be represented equally. This means that for 100 interviews or records (two visits per 50 persons) in one PSU, each day of the week is represented approximately 14 times. Therefore, for the first and the second interview, each day of the week has to be represented about 7 times. This will be supervised by the fieldwork supervisor.

The questionnaires of the FCS2014 are based on the previous FCS2004 and will follow existing European, EFSA and EFCOSUM guidelines. The development of the questionnaires is surveyed by several working groups and experts. However, the questionnaires are subject to some constraints. Because the primordial aim of the FCS is to monitor the food consumption and dietary habits of the Belgian population and time trends are studied, the questions have to be comparable to the ones used in the previous FCS. Also, the length of the questionnaires has to be minimized due to the complexity of the survey, the age-differences of the participants and to prevent drop-out and increase the quality of response.

Data collection procedures in children were based on the experiences of PANCAKE study (http://www.efsa.europa.eu/en/supporting/doc/339e.pdf) and the recommendations by the EFSA (http://www.efsa.europa.eu/) and EFCOSUM. In adults, the methods will be based on widely recognized EFCOSUM guidelines, which were used in the previous FCS as well. Efforts were made to make the questionnaires comparable between children, adolescents and adults. However, age-specific versions of questionnaires and age-and-gender-specific questions were included.

5.3.1.1 Data collection methodologies

A) Food consumption data

1. 24-hour recall interview

The diet of the participants will be assessed by performing two non-consecutive 24-hour recalls using the EPIC-Soft dietary assessment tool (12).

EPIC-Soft is a menu-driven software developed to conduct standardized interactive 24-hour recall interviews or to enter dietary records in a standardised way. EPIC-Soft was initially developed for use in a large-scale European multi-centre study, the European Prospective Investigation into Cancer and Nutrition (EPIC). It was developed by the International Agency for Research on Cancer (IARC) in collaboration with all national EPIC centres. The software was adapted for each

participating country and translated into local languages to standardize interviews between the 24 EPIC centres (used as a calibration method).

The European Food Consumption Survey Method (EFCOSUM) project published recommendations for the methods to be used in pan-European monitoring surveys including the advice to use EPIC-SOFT to standardize 24-hour recalls (7). The EFCOVAL project aimed to further develop and validate the use of repeated 24-hour recalls using EPIC-Soft for the intake assessment of foods, nutrients and potentially hazardous chemicals for surveillance purposes relevant to health and safety policies in Europe (13). In EFCOVAL, EPIC-Soft was updated and further developed on various aspects. One of the major improvements of the updated EPIC-Soft is the possibility of a project-specific customization as described. During the previous FCS in 2004 a dos version of EPIC-Soft was used which was less user-friendly.

Within the PANCAKE project, a project funded by the EFSA, a data entry version of EPIC-Soft for children was developed (8). This data entry version should facilitate and standardize food consumption data collected by food diaries or similar methods among children and ensure the highest possible level of comparability with the data collected in adults using interviews with EPIC-Soft.

Although EPIC-Soft has been designed in such a way that most of the rules and criteria for conducting the interview or for entering data are already pre-defined and can be easily updated and adapted (e.g. list of foods or recipes, type and number of questions to be systematically asked in order to describe foods, quantification methods to estimate food or recipe portion sizes), the role of the interviewers/operators remains essential to ensure the quality and the standardization of the data collection. It is important that, before using EPIC-Soft, the dietician-interviewer has followed a training.

The 24-hour recall interview performed with EPIC-Soft is divided into five main steps: (1) general non-dietary information; (2) quick list (chronological list of consumed foods and recipes); (3) description and quantification of foods and recipes; (4) quality controls at nutrient level and (5) dietary supplement information.

I) General non-dietary information
   a. Name (first letter)
   b. Surname (first letter)
   c. ID Code
   d. Birth Date
   e. Gender
   f. Height
   g. Weight

II) Information about the recall day
   a. Special day (Festive day, holiday,…)
   b. Special diet (Allergy, Vegetarian,…)
   c. Wake up time (from the recalled day and the next day)

III) Quick list: enables a global vision and ensures that nothing is forgotten later on
   a. Selection of food consumption occasions
   b. The time
   c. The place
   d. Broad description (e.g. pizza, milk, …) without detail

IV) Food/recipe description and quantification
   a. All the items of the quick list will be checked.
   b. Supplementary questions (facets) will be asked in accordance with the food product selected. More details can be obtained about the consumed foods :
      1. The physical state (liquid, flesh, sauce, …)
      2. The cooking method (boiled, baked, fried,…)
      3. The preservation method (canned, frozen, smoked, fresh,…)
      4. The packing method (in oils, in vinegar, in syrup,…)
      5. The flavouring (spices, coconut, vanilla,…)
      6. The sugar content (sweetened with saccharose, sweetened with fructose,… …)
      7. The fat content (whole, skimmed, …)
      8. The type of packaging (in paper, in can, in glass)
      9. Enriched/fortified (vitamin,…)
      10. Brand name/product name

11. Skin consumed
12. …

c. A recipe can be selected. Afterwards you have the choice to keep it the unchanged or to change the quantity or the ingredients.
d. The quantity will be estimated with a picture book

V) Quality control at the energy and macronutrient level

The calculated energy requirement, based on age, length and weight, will be compared with the calculated energy and macronutrient intake, based on the 24-hour recall. The program will also point out potentially missing information.

VI) Dietary supplement information

Finally, the intake of vitamin or mineral supplements will be asked for.

EPIC-Soft is a standardised tool. It shares the same interface and general concept across country-versions and standardised procedures to collect, search, describe, quantify, probe, calculate, export and maintain 24-hour recalls within and between countries. All the detailed information is systematically collected, stored and entirely retrievable. As an example, the identification, search and description level of the foods consumed by the study subjects is controlled by using the same sets of questions (facets such as preservation method, physical state, cooking method, skin consumed) and their related pre-coded answers of descriptors (e.g. different baked, fried, etc…) specific to each facet.

How the EPIC-Soft is built:

- Computerized 24-hour recall → standardized procedures which have to be followed by all interviewers (to minimize differences in interviewing between dieticians-interviewers)
- Stepwise approach:
  - First brief overview of foods/drinks consumed the day before (Quick list)
  - Secondly in depth description and quantification
  - Quality controls built in the software

Question (facet) – Answer options (descriptors) system. Extra tools are available to optimize portion size estimations (e.g. photo book).

Epic-Soft has the possibility to add a new food, recipe, facet or descriptor.

The internal structure of EPIC-soft presents two main pathways (see figure 3): a food pathway or a mixed recipe pathway.

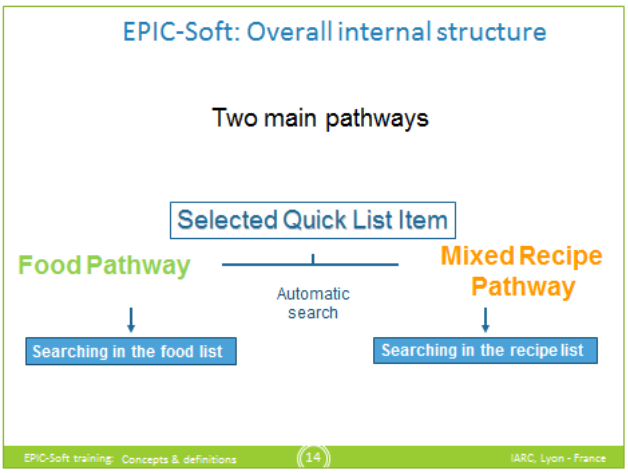

Figure 2. EPIC-Soft overall internal structure

An example:

Potato---Facet (question): cooking method------descriptor (answer possibility): cooked-------facet (question):consumed-----descriptor (answer): without skin. Important, the information on food exponentially increases with every facet!

Based on the version of EPIC-Soft, used in the pilot PANCAKE study in 2009, the recommended adjustments were executed by IARC. These adjustments, adding or removal are done to simplify the use of EPIC-Soft and to limit the extent of the questionnaire; always with the concerns as stipulated in the contract in mind. It is important to prevent an excessive interview time, otherwise the quality of the survey will drop substantially and the risk for drop-out will increase. A Flemish and French version of the EPIC-Soft data entry program will be adapted to Belgian conditions.

Nutritional intake and the dietary habits in children will be measured using two self-administered non-consecutive one-day food diaries (at least 2 weeks apart) followed by an EPIC-Soft completion interview with the parent/caretaker: one by telephone and one face-to-face at the respondent's home. All food-diaries are open-ended (no pre-coded food lists). For food quantification a picture book will be used, which has already been developed and validated for children of 0-10 years of age (14).

Food portion sizes will also be estimated with a **picture book**, household measurements and food portions obtained from of manufacturer's information. The adapted consumption picture books, which were used in the PANCAKE study, will be employed and the full number-letter combination will be written down with special attention to the plate size, the ruler, the type of food and the use of comparable foods. The description of the food or drink is noted carefully. There will also be special pages available for home-made recipes and supplement intake. In every booklet examples how to fill out the diary will be provided. The telephone number of the responsible person of the survey will be available in the introduction of every questionnaire.

2. Food Frequency Questionnaire

The EFSA guidelines advise to collect specific information on the frequency of consumption of episodically consumed foods using a Food Frequency Questionnaire (FFQ). The frequency information can be used as a covariate to model the estimation of usual intake (5). The objective of the FFQ is to get information on the main individual consumption of episodically consumed foods, to rank the respondent in order of their consumption frequency and to distinguish the ever-users from the never-users. The FFQ may provide extra information on the consumption frequency of consumed foods more specific on the episodically consumed ones. In the FFQ the respondents are asked to report the frequency of pre-chosen foods during the last year (last 12 months). The possible consumption frequency answers are: never, less than once a month, 1-3 times a month, once a week, 2-4 times a week, 5-6 times a week, once a day, 2-3 times a day, more than 3 times a day. An additional part was added to the FFQ in March 2014 to assess the habitual intake of supplements (in the last 12 months) for: vitamin A, D, E, K, C, multivitamins, omega-3, calcium, fluoride, iron and others. A difference is made for intake in winter time and the rest of the year.

B) Physical activity and sedentary behaviour

Physical Activity (PA) is "any bodily movement produced by skeletal muscles that results in energy expenditure". However, the energy cost of physical activity may not

necessarily be equivalent to body movement (15). Physical activity is positively related to physical fitness and health both in adulthood and later life (16).

Physical fitness is a set of attributes related to people's ability to perform physical work and is measured as cardiorespiratory fitness (maximum oxygen uptake). The cardio respiratory component of physical fitness is related to the ability to perform large muscle mass work at moderate to high physical intensity over a prolonged period. The dose-response gradient for various health outcomes is steeper across categories of cardio-vascular fitness than across groups with different levels of physical activity (17).

Muscle-strengthening (resistance) activity – which includes resistance training and lifting weights – comprises highly intensive movements of short duration of the major skeletal muscles. The fraction of maximal force used for a contraction, the number of repetitions per set, the number of sets performed and the duration of recovery intervals between sets are influential factors for characterising types of muscle-strengthening activity. Muscles strengthening activity leads to an increase in muscular strength and improves the metabolic processes in the passive structures of the musculoskeletal system (muscles, joints, tendons, ligaments…) (8).

Sedentary behaviour is conceptualised as sitting, TV-viewing, sleeping or automobile transportation and is distinct from physical inactivity, which is defined as lack of moderate-to-vigorous physical activity. This behaviour will be assessed using questions about the time sitting at work, at home and during leisure time (4).

Lifestyle characteristics like physical activity are important to investigate the relation with food consumption and nutritional status together with other unhealthy behaviours (physical inactivity or sedentary activity) and also to determine underreporting of food intake.

Physical activity has been reported to be positively associated with health indicators, whereas sedentary activities are suggested to be associated with increased risk for all-cause mortality and morbidity (18). Both behaviours seem to be independently related to health outcomes in both children and adults (15).

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moderate-to-vigorous physical activity. This behaviour will be assessed using questions about the time sitting at work, at home and during leisure time (19).

WHO recommendations for physical activity:

Global recommendations on physical activity for health, WHO 2011.

- Children and adolescents: they should accumulate at least 60 minutes of moderate-to vigorous-intensity (aerobic) physical activity daily.
- Adults: they should do at least 150 minutes of moderate-intensity aerobic PA throughout the week or do at least 75 minutes of vigorous-intensity aerobic PA throughout the week or an equivalent combination of moderate- and vigorous-intensity activity.

Physical and sedentary activity self-report in adolescents

In adults, two different self-report questionnaires will be used during the first visit: the commonly used International Physical Activity Questionnaire (IPAQ) (www.ipaq.ki.se) and the newly developed European Health Interview Survey Physical Activity Questionnaire EHIS-PAQ, which use is regulated by the European Commission Regulation No 141/2013 of February 2013,. (http://www.docstoc.com/docs/42385495/The-European-Health-Interview-Survey).

The adults who are selected for participating in the validation study of the EHIS, the EHIS-PAQ will also be administered during the second visit in addition to an accelerometer and log book (see Annex V).

The IPAQ is extensively validated, but the validity of the obtained information on physical activity is questioned (20),(21). Intensity, frequency and duration of physical activity is assessed. Whereas the reliability is usually good to excellent (r = 0.7 – 0.95), the criterion validity is poor to moderate (although significant, Short forms = 0.32; Long forms = 0.36) and the absolute validity is questionable (18). Outcome results are denoted in Metabolic Equivalent of Tasks (METs) and physical activity levels.

The EHIS-PAQ covers work-related physical activity, commuting activity, leisure time physical activity and muscle strengthening to be able to measure the compliance with the new WHO physical activity recommendations. In the final report (Improvement of the European Health interview Survey modules on alcohol

consumption, physical activity and mental health, Berlin 2011) the EUROSTAT working group on the development of the new physical activity assessment questionnaire noted following main advantages:

- Measuring compliance with the new WHO physical activity recommendations for Europe.
- Focus on health-enhancing PA instead of total PA
- Focus on “at least moderate-intensity”
- Assessment of walking and bicycling separately
- Offers benefits of a PA-domain based instrument without jeopardising the length of the questionnaire.

Thus, questionnaires provide estimates of current/usual physical activity and provide the possibility to categorise respondents into activity categories. Finally, questionnaires provide a poor measure of the absolute time spent at different intensity levels and the associated energy expenditure.

Whereas the PA-questionnaire measures intensity, frequency, duration and type of activity accelerometers have as outcome energy expenditure (EE) and activity score.

The assessment of physical and sedentary behaviour relying on self-reports has showed varying validity and reliability. Surely, in paediatric populations survey and recall instruments have to be used cautiously because children have difficulties recalling such information and because of the possibility of reporting bias due to social desirability.

Accelerometers measure accelerations caused by body movements in three orthogonal planes (vertical, mediolateral and anteroposterior). When a person moves, the body is accelerated in relation to the muscular forces responsible for the acceleration of the body, and in theory to EE. Accelerometers generate the activity counts and minutes spent above predefined thresholds (22). Accelerometers are shown to provide accurate information on levels of physical activity, including sedentary behaviour (23). Therefore, accelerometers may be used in validation studies as a tool to test the criterion validity.

The use of accelerometers in youth warrants for extra attention to the compliance. However, EE from complex movements are not always reflected by acceleration of the body (i.e. bicycling, upper body work, walking up/down, carrying goods etc.)

The accurate measurement of physical activity (PA) and sedentary behaviour (SB) is essential to further explore relations between activity patterns and health and to provide evidence to be used in public health recommendations.

Self-reported measures have been found inaccurate in assessing PA and SB in children and adolescents due to recall bias and/or reporting bias by social desirability (24). Furthermore, earlier research indicated that there is currently no questionnaire for children neither for youth with both acceptable reliability and validity (25). Consequently, more objective measurements to assess both behaviours are recommended.

Accelerometers are considered to be valid and reliable measures to assess both PA and SB in youth (26). Moreover, they provide an accurate and precise measurement of all intensity levels of PA ranging from sedentariness to very vigorous which makes it possible to focus on activity patterns rather than energy expenditure (26).

Thus, in the FCS2014, accelerometers will be used for measuring PA and SB in children (3-9 years old) and adolescents (10-17 years old). Accelerometers measure accelerations caused by body movements and generate the activity counts and minutes spend above predefined thresholds (27).

However, despite of the accurate assessment of the frequency, duration and intensity of PA by accelerometers, they provide no information about the type of PA/SB behaviour or in what context and where the activity was performed. Moreover, accelerometers are insensitive to many forms of activities (i.e., stair climbing and bicycling, water-based activities). Consequently, activity monitoring logbooks will be used in addition (see below).

Furthermore, the use of accelerometers in children and youth warrants for extra attention to the compliance as previous research indicated that children and/or adolescents can be unwilling to wear accelerometers at school and during sport because of physical discomfort, risk of being bullied, public embarrassment, involvement, involvement in water sports, and not being allowed to wear accelerometers during organized sport (28). Consequently, strategies to increase compliance are warranted and will be included in the FCS2014 (see below).

Type of accelerometer

GT3X+ Actigraph® accelerometers will be used (see figure 3). These are tri-axial accelerometers which measure acceleration in three planes. GT3X+ accelerometers (dimensions: 4.6 cm x 3.3 cm x 1.5 cm) are lightweight devices weighing 19 grams.

Figure 3. Actigraph GT3X+

Table VI. Specifications of the Actigraph GT3X+

Dimensions	4.6cm x 3.3cm x 1.5cm
Weight	19 grams
Sample Rate	30 – 100 Hertz in 10 Hz Increments
Memory / Storage Capacity	512 MB
Battery Life	30 Days (Fully Charged)
Communication	Full-Speed USB 2.0. Full device download in less than 45 sec.
Water Resistant	1 meter for 30 minutes
Lux Range	350-850 nm, 600 nm peak
Transducers	Tri-axis, solid state accelerometer Ambient Light Photodiode
Dynamic Range	+/- 6G
Capacity	40 Days (Raw data at 30 Hz)*
Resolution	12-bit A/D conversion; 2.93 mG (Raw Data)
Parameters	Activity, Steps, Inclinometer, Light

Epoch length and duration of measurement

The accelerometer collects and sums the activity counts over a user-defined epoch (29). Previous research has indicated that children tend to have very short bursts of high intensity activities (i.e., the median duration of a high intensity activity was 3 seconds with 95% lasting < 15 seconds (29;30). Consequently, in children an epoch length of 15 seconds seems recommended. For adolescents an epoch length of 15 seconds will be used and in adults an epoch length of 60 seconds.

The duration of the measurement should reflect habitual activity and variability in activity and sedentary behaviour patterns from day to day (27). To acquire a valid

representation of activity for children and adolescents four to nine days of monitoring are needed.

Due to differences between weekday and weekend activity patterns, it is advised to combine weekdays and weekend days. Measurement protocols (31) examined age-related trends in the reliability of objectively measured physical activity of children and adolescents and found that 7 days of monitoring produced acceptable estimates of daily moderate-to-vigorous physical activity for both children and adolescents and accounted for significant differences in weekday and weekend physical activity. Other studies exploring the number of monitoring days necessary to reliably assess PA found similar results (29).

Based on these findings it was decided to collect PA and SB data during seven consecutive days including two weekend days.

Practical procedure

Handlers of the accelerometers should carefully read the manual accompanying the accelerometers and a website based film. Attempts to set-up the device without carefully reading the instructions might lead to inaccurate results.

- *Initialising the accelerometers*

Before initialising, the accelerometers need to be fully charged. Charging accelerometers can be done by connecting mini-USB's to the computer. ActiLife® software (6 custom) will be used to initialise the accelerometers and upload the collected data. The start date will be set at the day after the day when the devices will be handed out to the children or adolescents starting at 05.00 AM. In order to monitor 7 complete days no stop date and time will be set.

- *Placement of accelerometers*

Previous studies have examined the different options to place an accelerometer and found that the hip or lower back are the best options (29). Children/adolescents will be fitted accelerometers located at the hip at the right side of the body in an elastic belt during the first home visit. Children will be asked to wear the device either under or on their clothes during all waking hours, apart from water-based activities. We will

mark the top of the device with a sticker and instructed the children to be aware that the accelerometer should be placed with the sticker on top.

- *Data collection*

Interviewers distribute the accelerometers during the first home visit. Information about the use of the accelerometer will be given to the children/adolescents and their parents (and the adults who participate in the validation study) orally and the accelerometers will be handed out. The accelerometers need to be placed with the elastic belt on the participant's right hip.
Additionally, children and their parents, adolescents and selected adults receive a brochure about the correct use of the accelerometer (See additional file: instructions and information brochure). The accelerometers need to be worn seven complete days (including 2 weekend days) and will be collected during the second home visit.

- *Data processing and reduction*

Downloading the data from accelerometers needs to be done as soon as possible on the same computer where it was initialised to prevent disturbances that can be caused by the time offset between computers.

Meterplus® (http://meterplussoftware.com) downloaded on the computers of the Nutrition and Health team of the WIV-ISP will be used for data reduction and analysis. Meterplus® is a Windows-based program developed by researchers from San Diego State University in partnership with Actigraph®. The Meterplus® program will be used to prepare and clean the accelerometer data files according to non-wearing time (as described below), invalid data (i.e. days that have not enough wearing time and implausibly high count values) and specific activity bout definitions such as bouts of sedentary time.

PA and SB results may change substantially depending on how data is processed. Therefore, the quality of the accelerometer data should be checked first using systematic data reduction procedures. The decisions on minimum daily wearing time and number of required days for data analysis are critical data reduction issues. Wearing time calculation is not solely excluding all zero count values from data, since sedentary behaviour is part of the data. For this reason decisions should be made regarding duration of consecutive zeros (i.e., the allowable interruption period)

to distinguish between non-wearing and sedentary time. Periods of consecutive zeros lasting longer than the allowable interruption represent non-wearing time, that is the time period that participants did not wear the device such as during sleeping or water sports/activities.

Intervals of continuous zero accounts that are shorter than the allowable interruption period are preserved as wear time, and are believed to indicate sedentary behaviour (32). In the FCS2014, non-wearing time will be calculated as periods of more than 20 minutes of consecutive zero counts in children and adolescents and 60 minutes in adults (33).

Wearing time will be calculated by subtracting non-wearing time from 24 hours (34). The minimum daily wearing time was set at 10 hours for weekdays and 8 hours for weekend days considering different sleep patterns at weekends (24;35). Another critical issue is to include enough days to be able to reflect children's habitual PA pattern. A valid day requires a minimum number of hours of wearing (see above). Children who have at least two valid weekdays and one valid weekend day will be included in the further data analysis (36).

The Hawthorne effect, i.e. 'the process of observation, alters the phenomenon being observed' will be evaluated to see whether there is difference between the total activity on the first day and the mean of the consecutive days. If a substantial difference is found as in Corder et al., 2008 (3%) the difference may be scaled. On the contrary Mattocks et al., found no substantial difference (< 0.1 SD') and concluded that this effect would not introduce bias in the study. If the first or last day do not capture the fully 8 or 10 hours we will discount the first/ last monitoring day (37).

- *Cut-points for activity categories*

The end results from accelerometer measurements are count values. Counts have been calibrated against energy expenditure in order to get a biological meaning (38). The first aim is to determine the amount of time per day spent in vigorous and moderate activities and to evaluate this compared to the recommendations for PA.

To estimate time spent in a specific activity category is to develop a regression equation that defines the relationship between counts and energy expenditure, allowing counts to be converted to units of energy expenditure.

To date, a number of calibration equations for children and adolescents were developed for the Actigraph® accelerometers, though the methods used were rather different (39). Table VIII presents the most commonly used cut-points that are appropriate for children and adolescents.

Table VII. Actigraph® accelerometer cut-points that are appropriate for children and adolescents (3-18 years)

Study		**Cut-points**			
Authors (year)	**Sample**	**Sedentary**	**Light**	**Moderate**	**Vigorous**
Evenson et al. 2008(40)	5-8 y, n=33	0-11 counts/15s	12-507 counts/15s	508-718 counts/15s	>718 counts/15s
Pate et al. 2006(41)	3-5 y, n=29	0-37 counts/15s	38-419 counts/15s	420-840 counts/15s	>841 counts/15s
Reilly et al. 2003(42)	3-4 y, n=30	0-1099 counts/min			
Peiffer et al. 2005(43)	3-5 y, n=16	3y: 0-301 counts/15s	3y: 302-614 counts/15s	3y: 615-1230	3y: >1230 counts/15s
Trost et al.(30) in press	1-3 y, n=22	0-48 counts/15s	49-418 counts/15s	>418 counts/15s	/
Van Cauwenberghe et al. 2010(44)	4-6 y, n=114	≤373 counts/15s	374-584 counts/15s	585-880 counts/15s	>881 counts/15s
Freedson et al. 2005(45)	6-18 y, n=80		100-2219 counts/min	2220-4135 counts/min	≥4136 counts/min
Puyau et al. 2002(46)	6-16 y, n=26	≤800 counts/min	801-3199 counts/min	3200-8199 counts/min	≥8200 counts/min
Treuth et al. 2004(47)	13-14 y, n=74	≤100 counts/min	101-2999 counts/min	3000-5199 counts/min	≥5200 counts/min
Mattocks et al. 2007(48)	12 y, n=163			3581-6129 counts/min	≥6130 counts/min

Motivation for choice of cut-points

The study of Hislop et al. 2012 (49) compared the accelerometer cut-points for PA and SB in Scottish preschool children and found that the Sirard et al. (50) cut-points provide accurate group-level estimates of moderate to vigorous intensity activity

(MVPA) in preschool children. Because there is a certain amount of time between the writing of this protocol and the time of downloading the accelerometer data, we will adjust the decision on using which cut-points in regard to most up to date information available at that time (adjustment 10.01.2014: see below).

The conclusion related to cut-points based on the design paper of the accelerometer study of ENERGY (51):
Cut-points by Freedson et. al. (2005)(45) are completely laboratory-based. Puyau et. al. (2002)(46) and Treuth et al. (2004) (47) used more free living activities, ranging in intensity from sedentary to vigorous. Mattocks et. al. (2007)(48) also used free living activities but only for moderate and vigorous activity intensities. Treuth et al. (2004)(47) measured energy expenditure at rest and during activity with portable indirect calorimetry and used resting energy expenditure to establish MET-levels. This is important since children have higher resting metabolic rates than adults.

A recent study comparing the different cut-points for sedentary behaviour (100, 300, 800, 1100) with the observation of children's behaviour showed that Actigraph® cut-point of ≤ 100 cpm is the most appropriate one for quantifying time children spent on sedentary activities (Fischer et. al. unpublished data). Another study by Trost et al.(2010) evaluated the classification accuracy of cut-points using energy expenditure measured by indirect calorimetry. They reported that the cut-points from Freedson et. Al (2005) and Treuth et. al. (2004) (47) showed good classification accuracy. They also reported that 100 cpm as a cut-point for sedentary behaviour showed good to excellent classification accuracy. Moreover, Esliger et. al. (2005) (52;53) found that count values higher than 15.000 per minute are very unusual and implausible. For this reason the count values higher than 15.000 per minute will be considered as missing values.

Because there is no consensus on the ‘best’ cut-points for the classification of children and youth MVPA (Kim et al. 2012) and based on the available information, we have concluded to determine cut-points as follows: The epoch widths will be 1 minute in adults and 15 seconds in children and adolescents.

Based on their use in other studies in Belgian individuals the count cut-points will be set for respectively sedentary, light, moderate, vigorous at following levels in

children:

Study		Cut-points			
Author	**Sample**	**Sedentary**	**Light**	**Moderate**	**Vigorous**
Evenson et al. 2008(40)	**5-8 y, n=33**	**0-11 counts/15s**	**12-507 counts/15s**	**508-718 counts/15s**	>**718 counts/15s**

Adjustment of cut points used

After discussion with prof Greet Cardon, we decided to use Puyau (MVPA: ≥3200 activity counts/min) (Puyau et al. 2002).

This is supported by the doctoral thesis of Femke de Meester:

"Currently, a wide range of cutpoints are available for use in young people. The intensity cutpoints, specifically derived for the Actigraph accelerometer, vary between 1017 counts/min (54) to 3581 counts/min (55) for time spent in moderate to vigorous intensity physical activity. The large discrepancies between the different cutpoints highlight the lack of agreement regarding the data-reduction process and interpretation of accelerometer output (Kim et al. 2012; Rowlands, 2007a). Furthermore, inconsistent use of the different cutpoints hinders comparability between research studies (Guinhouya et al. 2006; Kim et al., 2012). Until a consensus is reached, researchers are encouraged to use multiple cutpoints (Ekelund et al., 2011; Guinhouya et al. 2013) or to move away from the cutpoints and to use counts/registered time as outcome variable (Corder et al., 2007; Ekelund et al. 2001; Sirard & Pate, 2001). For the purposes of the different studies of this thesis, the cutpoints of Puyau (56) and the age-specific equation of Freedson (54) were used and complemented with the more raw accelerometer output: the mean number of counts per minute. The cutpoints of Puyau (56) were chosen based on the conclusion of Reilly and colleagues (57) stating that the most appropriate cutpoint lies between 3000 and 3600 counts per minute. Due to the widespread use of the age-specific equation of Freedson (Cain et al. 2013; Freedson, 2005) and to increase the comparability of the results of our research study regarding accelerometry, this equation was used supplementary to the cutpoints of Puyau (56)."

Children and adolescents:

Study		Cut-points			
Author	**Sample**	**Sedentary**	**Light**	**Moderate**	**Vigorous**

Puyau et al. 2002(46)	6-16 y, n=26	≤800 counts/min	801-3199 counts/min	3200-8199 counts/min	≥8200 counts/min

In **adults:**

Study		**Cut-points**			
Author	**Sample**	**Sedentary**	**Light**	**Moderate**	**Vigorous**
Freedson et al. 1998	adults, n=50	**0-99 counts/min**	**100-1951 counts/min**	**1952-5724 counts/min**	≥5725 **counts/min**

Outcome measures

Based on the data of FCS2014, total counts per day (the volume of activity), mean counts per minute (total counts divided by wearing time), and the amount of time spent in sedentary, and in light, moderate and vigorous intensity PA based on the vertical axis counts will be calculated to classify the respondent in sedentary, light, moderate and vigorous usual PA level

Strategies to promote compliance

Compliance with the monitoring protocol is essential in accelerometer studies to quantify physical activity behaviour. As already mentioned, children and adolescents can be unwilling to wear accelerometers because of several reasons. Therefore, strategies to promote compliance seem necessary. Some earlier studies examined the use of strategies to ameliorate accelerometer wearing and returning. These authors found that the use of gift vouchers, supplying information about the cost of accelerometers, individual graphs of activity, regular contact with participant/reminders to wear the accelerometer, completing a log book daily, could have a positive influence on compliance (58).

Logbooks (diaries)

As accelerometers cannot distinguish between sitting and standing time as both require little vertical acceleration (59), and additionally, accelerometers do not provide any information on activity or sedentary behaviour type (e.g., TV viewing versus reading) and context (e.g., transport or leisure activities), children will be asked to fill in a diary/logbook recording the time of getting up in the morning and

going to bed for sleeping. They will also need to note the time and reason why the device was removed for 5 minutes or more for any activity such as swimming, or showering. In addition, they need to write down all the different activities conducted during each monitored day. The logbook data will be entered manually in a data entry programme in Blaise®.

Physical and sedentary activity self-report in adolescents

In all adolescents the Flemish Physical Activity Questionnaire (F-PAQ) will be administered during the first visit (60;61).

Motivation

Several physical activity questionnaires have been used: the WHO Health behaviour in school aged children, the IPAQ and the FPAQ.

The WHO HBSC questionnaire (62) records the responder's PA level in sports and exercise by asking the adolescent to report the frequency and total amount of time spent exercising vigorously outside school hours. The frequency question was: "Outside the school hours, how often do you usually exercise in your free time so much that you get out of breath or sweat?" Eight response alternatives are available ranging from every day to never. The duration question was: "Outside the school hours, how many hours do you usually exercise in your free time, so much that you get out of your breathe or sweat?" Six response alternatives are available ranging from 7 hours per week or more to none.

The IPAQ self-administered short version (http://www.ipaq.ki.se/) was designed for use among persons from 15 to 69 years old. The questionnaire inquires activity during the last week. The questions activity types: vigorous activity for at least 10 minutes, moderate activity periods for at least 10 minutes; walking periods for at least 10 minutes and times spent sitting on weekdays. Frequency is measured in days and duration in hours and minutes.

But none of the questionnaires seem to be a valid instrument for measuring PA among all adolescents of both genders. However, the validity and reliability of the HBSC was acceptable for measuring cardio vascular fitness, the reliability being

better than this of the IPAQ. The strength of the validity of the IPAQ was gender dependent (63).

The FPAQ consists of items regarding screen behaviour, active transportation, physical activity at school and physical activity in leisure time. Also sport participation is reported. This questionnaire has been shown to be a reliable and reasonable valid instrument to assess different dimensions of usual physical activity and sedentary behaviour in children, especially when completed with parental assistance (60).

We have chosen to implement the FPAQ because this questionnaire is measuring physical activity, not mainly physical fitness as the HBSC, and is validated in adolescents from 12 to 18 years of age in Belgium.

Also the collaborating scientists are more acquainted with this questionnaire and have carried out, but not published yet, a validation study. The results of this study show that the validity is acceptable, but the reliability is lower (personal communication: Wijndaele et al., 2013).

Physical and sedentary activity self-report in children

The self-report physical activity questionnaire as employed in the TOYBOX-study will be used. The questionnaire is based on the questions as partly used in the study of Burdette et al., 2004. She found that parental measures of outdoor playing were significantly correlated to a direct measure of physical activity. This questionnaire is and will be extensively used across Europe in regard to the TOYBOX project. Validation studies are in progress, however preliminary results indicate a low validity (personal communication, G. Cardon 2013). More detailed information can be found in multiple publications (64;65).

Hence, the data produced by accelerometry will be more valuable and useful.

C) Anthropometry

The aim

The aim of the anthropometric data is to establish the prevalence of obesity and overweight in Belgium. Using this data in relation with food consumption, activity

level, health indicators and other socio-demographic data, will be useful when defining population groups at risk of overweight and other health problems. Measurement of body fat is a challenge in children, especially in adolescents due to growth spurt and maturation.

The targets

Three anthropometric indicators have been selected:

- weight,
- height and
- waist circumference.

The measurement of these characteristics are cheap, quick, universal and non-invasive. The Body mass index (BMI) will be calculated in kg/m^2. In children and adolescents BMI-data may be distorted by residual correlation with height and seem to have low sensitivity (66). Whereas BMI is thought to be an indicator for overall adiposity, waist circumference (WC) has been advocated to be an indicator for central body fat (67). Although BMI is correlated with WC, WC seems to predict health risk beyond that predicted by BMI alone. BMI and WC are correlated with conditions such as cardiovascular disease, type 2 diabetes, certain cancers and early mortality.

Selection of the method

Unlike the national FCS in 2004, it was decided to measure the anthropometric measures and not use self-reported anthropometric measurements. The validity of self-reports may vary due to under- and overestimation. Specifically, overweight people tend to underestimate their weight and underweight people, on the contrary, overestimate their weight. Also adults tend to overestimate their height, which can further accentuate the difference in the calculation of BMI (68).

Anthropometric measurements will be taken by trained dieticians following standardised protocols and devices. Height and weight will be measured to the nearest half centimetre, respectively to the nearest half kilogram with light cloths, without shoes, jacket, or outdoor garment. The WC will be measured to the nearest half centimetre, using a non-stretchable measuring tape horizontal at the umbilical

level after the participant emptied their lungs or midway between the last rib and the iliac crest if the latter was largest.

Ethical considerations

Some people may have a feeling of intrusion during the collection of anthropometric measures. Therefore, it is important that the investigator explains the aim and the content of the investigation to the concerned people. Informed consent from parents or a legal representative of children and adolescents participating in the survey is essential. This consent must be obtained before administering the questionnaire.

The equipment

In order to perform the measurements it is necessary that the interviewers receive training on the use and maintenance of the equipment. The equipment required for collecting anthropometric data are based on :
http://www.fantaproject.org/sites/default/files/resources/anthropometry-2003-ENG.pdf

- **The balances (Type SECA 815 en 804)** For weighing people, it is necessary to have standardized scales and a precision of 0.1 kg. They must be portable and durable. With a capacity of up to 180 and 150 kg.
    - REM: For people with a weight > 180/150 kg, it has to be noted on the registration form.

  The personal scale SECA 815 largely fulfills the electromagnetic compatibility guideline 89/336/EEC.

- **The stadiometer (Type SECA 213):** it is necessary to have standardized devices and a precision of 0.5 cm. They must be portable and durable. With a size of up to 2 meters. The equipment for measuring length meets the applicable requirements of Directive 93/42/EEC (class I with measuring function) on medical products.

- **The measuring tapes (Meterex)**: non-stretchable tapes.

Training will be required to standardize collection methods in all measures investigators.

Standard references for classification

Population-cut-off values for body fat determined by body mass reference methods are supposed to be the best criteria for the definition of the different adiposity classes. However, the definition of excess body fat is arbitrary because during childhood, especially adolescence, the level of adiposity varies by age, gender and pubertal timing.

1. **Body Mass Index (BMI)**

- *For adults (18-64 years old)*

We will use a simplified form of "The International Classification of adult underweight, overweight and obesity according to BMI" (see table IX).

Table VIII. WHO Classification of weight according to BMI (http://www.who.int/childgrowth/publications/physical_status/en/index.html)

BMI (kg/m²)	Classification
< 18.5	**underweight**
18.5–24.9	normal weight
25.0–29.9	overweight
30.0–34.9	obesity
35.0–39.9	severe obesity
≥ 40.0	morbid obesity

- *For children and adolescents (3-17 years old)*

The International Obesity Task Force (IOTF) has accepted age- and gender-specific BMI-cut-off points to classify children and adolescents as underweight, normal-weight, overweight or obese (69;69). The IOTF cut-offs are defined to correspond to BMI of adult overweight and obesity thresholds at age 18. However, the choice of age as adult age may be questionable.

2. Waist circumference

- *For the adults (18-64 years old)*

Central overweight will be defined as follows (70):

Table IX. Cut-off points for waist circumference

Gender	Increased Risk	Substantially increased
Men	>=94 cm	>=102 cm
Women	>=80 cm	>=88 cm

- *For children and adolescents (3-17 years old)*

As children grow in size, anthropometric cut-off points for fatness need to be adjusted for age. For this reason, grades of nutritional status are usually assessed according to a reference population. For the classification of childhood and adolescent obesity using waist circumference there are still no nationally accepted cut-off points. For children the cut-off points vary with the age and differs in accordance to gender. In a cross-sectional study (71) in over 14,500 children of Dutch origin, references for the WC have been established. In this study they used a cut-off point of 1.3 standard deviation score (SDS) to define overweight and 2.3 SDS to detect obesity. McCarthy et al., 2003 (72) defined the 91st percentile as the cut point for overweight and 98th for obesity. Katmarzyk et al.,2004 (73) calculated reference data to identify youth with elevated risk of developing obesity-related disorders. Obese children with a waist circumference at or above the 90th percentile are supposed to be at a higher risk for dyslipidaemia and insulin resistance and greater visceral and subcutaneous abdominal fat than the other obese children with a normal waist circumference (72).

The measurement method

1- The standing height

Standing height will be measured using a portable stadiometer (Type SECA 213), including a bottom platform, a vertical backboard and a moveable headboard.

Method:

- The stadiometer stand is placed on a solid surface. The interviewer must follow the instructions for constructing the stadiometer.
- The person must stand on the bottom platform of the device with the heels of both feet together and the toes pointed slightly outward at approximately a 60º angle.
- The body weight must be evenly distributed and both feet are flat on the balance.
- The person's trunk will be vertical above the waist, and the arms and shoulders are relaxed.
- The head must be aligned in the Frankfort horizontal plane. The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. Many people will assume this position naturally, but for some the people, the interviewer must make minor adjustments. If required, the interviewer must gently tilt the chin up or down until proper alignment is achieved with eyes looking straight forwards.

  Once correctly positioned, the interviewer will lower the headboard and instruct the investigated person to take a deep breath and stand as tall as possible. A deep breath will allow the spine to straighten, yielding a more consistent and reproducible stature measurement.
- The interviewer must position the headboard firmly on top of the head with sufficient pressure to compress the hair.
- The interviewer will write down the results (in cm with 0.5 cm precision) on the anthropometry form.

2- The weight

The instrument to measure the weight will be a personal electronic weighing scale (Type SECA 815 or SECA 804), with following specifications: the weight should be indicated in kg with 0.5 kg precision. The weight should be shown for at least 10 seconds, and clearly indicated in large digits (at least 2 cm). The balance should be shockproof for transportation and have an automatic switch off.

The quality of the scales need to be checked before the start of the study, at the end of the study, and every 6 months, using official calibration weights in the proper weight range. Scales that deviate 1 kg or more should not be used. Results of the quality check should be sent to the coordinating centre at WIV-ISP.

Method:

- The subject must remove heavy upper clothing and empty their pockets from heavy items.
- The scale must be adapted to room temperature.
- The scale will be positioned horizontally on a solid surface.
- The interviewer must switch on the scale if this is not done automatically when stepping on the scale.
- The interviewer must ask the participant to stand still in the center of the scale platform, with a little space between both feet, facing the recorder, hands at side, and looking straight ahead.
- The weight must be showed in kilograms with 0.1 kg precision when the digital readout is stable. The results must be noted (in kg with 1 decimal) on the anthropometry form.

3- The waist circumference (74)

The WC is measured while the participant is in a standing position. A non-stretchable measuring tape of 150 cm is used (Type Meterex). The interviewer must avoid twists in the tape. The WC is not measured within 1 hour of a large meal. The dietician places the participant in front of her/him.

Method:

The participant is requested to separate the feet of ± 20 cm, while distributing the body weight on two legs. The tape will be placed in the middle between the last rib and the iliac crest or at umbilical level if the latter was the largest. The participant must inhale and exhale calmly. The measurement should be taken at the end of an quiet expiration (which prevents the participant from contracting the abdominal muscles or hold his/her breath). It is recommended to ask all women between 15 to 55 years of age if they are pregnant. No physical measurements should be taken from women who are pregnant. Reading is close to a half centimeter. The result is rounded to half the nearest centimeter (e.g. 97.8 becomes 98.0 cm or 105.6 is 105.5 cm). The results must be noted (in cm with 0.5 cm precision) on the anthropometry form. The reproducibility of WC measurements depends on the skills of the observer.

Incorrectly positioning the tape measure on the subject's body can be a source of measurement error.

D) Other variables

Socio-demographic information (age, gender, education (of parents), employment (of parents), family composition, nationality, language) and health (perceived health and psychological health) are important for the description of the study population and the identification of bottleneck groups.

Questionnaire on health (/puberty)

Psychological distress in adolescents and adults will be measured with a questionnaire (Annex VI).

Pubertal development in adolescents will be measured with a questionnaire (Annex VII).

Eating disorders will be measured in adolescents and adults using the Eating Attitude Test (EAT) (Annex VIII).

Questionnaire on food safety

The Food Safety Questionnaire (FSQ) assesses the knowledge, attitude and behaviour regarding food safety on the level of the household and has to be filled out by the person in the household that is usually responsible for the preparation of meals. Questions are asked regarding the knowledge on food safety, the following questions address the attitude regarding the time of food conservation and cross-contamination, the last part assesses the behaviour regarding preparation and cooking of the meal, food conservation and hygiene and cleaning.

Data collection in the FCS2014 will be performed using two types of interviewing methods:

With the CAPI-method data is collected via computer assisted personal interviewing (the interviewer asks the questions, while showing the possible answer categories to the respondent on a card and enters consecutively the answers directly into a portable computer).

With the PAPI-method data is collected via paper and pencil interviewing (the respondent fills in the questionnaire themselves, using a paper and pencil approach, without the intervention of the interviewer).

5.3.1.2 Data collection in children (3-9 years old)

In children (3-9 years) the data collection procedures will follow those outlined in the PANCAKE project, and have been pilot tested in Belgium in 2010-2011. The parents of the children will be used as a proxy. The fieldwork will be performed in four steps. Figure 4 provides an overview of the different steps of the data collection in children.

Figure 4. Timeline of data collection in children

Type of instruments

- PAPI (which the parent/guardian of the selected child has to fill out in the period between the two visits)
    - Nutritional intake and the dietary habits will be measured using two self-administered one-day (non-consecutive) food diaries (at least 2 weeks apart);
    - A FFQ;
    - A FSQ filled in by the person who is in charge of the household;
    - The completed questionnaire on health will be placed in a sealed envelop with coded ID number;
    - A logbook has to be filled out during the days the children wear the accelerometers (PAPI).

- CAPI
    - The general questionnaire is a short interviewer-administrated CAPI. Socio-demographic information and other lifestyle behaviour variables (eating behaviour, physical activity, sedentary behaviour) will be assessed;
    - Two computer assisted completion interviews using EPIC-SOFT, one by telephone and one face-to-face at the respondent's home.

Timeline of implementation of the instruments: four-step procedure

The first home visit consists of:

- Signing of the informed consent;
- Face-to-face administration of the general questionnaire (CAPI)
- Instructions for completing the food diaries. During the first home visit it will be explained to the parents/guardians what kind of information on consumed foods and drinks should exactly be recorded and a short exercise will be performed (e.g. on breakfast of that day). Time and place of consumption will be registered. The diaries for the children are structured according to eating occasions, e.g. before breakfast, breakfast, during the morning,…;
- Handing over the accelerometer, logbook and instructions for usage; and distribution of the FFQ, FSQ and questionnaire on health (PAPI);
- Confirmation of the appointment for the telephone interview on the day after completion of the first food diary, or with a maximum of one day or exceptionally two days in between;
- Confirmation of the appointments for the second record day and the following face-to-face interview;

Materials that the interviewer will need for the first home visit:

- Informed consent (2 copies)
- Information form
- Two one-day food diaries
- A picture book
- A laptop with EPIC-Soft and CAPI questionnaire
- Answer cards
- FFQ, questionnaire on food safety and questionnaire on health

- Accelerometer, logbook and instruction booklet

This first home visit should be performed preferably the day before the first food diary, with a maximum of one day or exceptionally two days in between. The visit is expected to take about 1.30 hours.

First, the informed consent will be obtained of the parent/guardian.

In the one-day diaries only time, place, name of food or drink, description and consumed quantity need to be registered. More details will be asked for during the completion interview with EPIC-Soft (done within 24-48 hours by telephone or at home).
The structure of the diary will be shown to the participant. The diary will also include examples on how to complete the questionnaire. The interviewer will fill out the front page of the day-1 diary: the ID-number, day of birth and gender of the participant, and the day of the week and date of the record day. To get representative results the participant has to stick to the agreed day of the record day as noted on the front page of the diary. Notably, if the child is at least 7 years old and capable of giving information to the parents/guardians the child will be involved in the instruction, especially in regard to the food consumption out of home. This way the child will also be extra motivated.

In regard to the food diary the parent/guardian will ask for the cooperation of the out of home caretakers and hand over the picture book. When the food diary and the picture book is returned, the parent will check whether the food diary is properly filled out. If this is not the case, additional information will have to be asked for.

The interviewer will already during the first visit make an appointment for the telephone interview, one or maximum two days after the record day. The date and time of the telephone interview is noted at that time on the introduction page of the day-1 food diary. The day-2 food diary is also handed over during the first visit. The picture book is also to be kept by the parent/guardian for use for the completion of the second recording which will be carried out two – three weeks after the first recording or to be handed over to the caretaker out of home. The date of the second recording, ID, day of birth will also be noted on the front page of the second

recording booklet. Additionally, the date of the last telephone call and the second home visit for a face-to-face interview two days after the second recording day is noted on the introduction page of the day-2 diary.

In addition to receiving an accelerometer and a log book, the interviewer will accurately explain interviewees how to administer and use the accelerometer on their child, in addition to the explanation in an instruction book. The use of the device has to start the morning after. The device can be taken of every evening when going to bed and has to be put on first thing in the morning and this during four weekdays and two weekend days (more details in the section on physical activity and sedentary behaviour measurement).

The first telephone call to execute a completion interview with EPIC-Soft

The subject has kept a food diary on the fixed day which was agreed upon. The day after, or with a maximum of one or exceptionally two days in between, the first EPIC-Soft completion interview in combination with the food diary is executed by telephone. The telephone call is expected to take about 30-45 minutes. The participant will have the diary and picture book within reach and use them during the interview. The dietician conducts the EPIC-Soft interview without having this written information. The interviews are conducted with the regular Windows version of EPIC-Soft for interviews. Seven eating occasions can be distinguished: before breakfast, breakfast, during the morning, lunch, during the afternoon, evening meal, during the evening and night. For the eating occasions the time and not the content of the meal is primordial in determining the eating occasions. The time in hours and minutes, as registered in the diary by the participant, will also be entered in EPIC-Soft. The places of consumption will also be entered as predefined places including at home; school/childcare; friends/family; restaurant; street/market/park/beach; bicycle/car/ boat/plane or other if it does not correspond to any of the previous possibilities. The anthropometric measures will also be imputed in the EPIC-Soft program.

To specify the quantities all quantification methods available in EPIC-Soft illustrated in the picture book will be used. EPIC-Soft will calculate the weight in grams using the density factor of the specific food.

The interactive procedure in EPIC-Soft will be followed to ask all facets. If the respondent does not know the specification, it can be entered as “undefined”. Several checks will be done during the data entry in EPIC-Soft. If a food quantity exceeds the defined maximum an automatic warning will be given and the interviewer will check the data entry. If the quantity seems to be in concordance with the diary a note that the entry is correct can be made. Probing questions will be asked to check the completeness of the reported food. The intake of energy and macronutrients will also be checked. The EPIC-Soft program checks the preliminary calculated intake per interview day with the energy and macronutrient requirements based on gender and age. If the intake is much higher or lower, it will automatically be mentioned. If the calculated intake is in concordance with what the interviewer expects, it will be noted. If not, the interviewer will check for data entry errors and correct errors if necessary.

Before closing the telephone call the interviewer will remind the respondent on which date the second record day and the second home visit will take place. The parent/caretaker has to keep the day-1 diary and the picture book.

The second telephone call as a reminder

The parent/guardian of the subject will be reminded to record the consumption of foods and drinks in the day-2 diary. The interviewer will call the parent/guardian preferably one day or at maximum two days before the second record day to remind him or her to record the second food intake in the day-2 diary. If the participant does not have the day-2 diary or picture book any more, the interviewer will re-establish the appointments on the same day as previously agreed and will provide new specimen.

The second home visit

This home visit should preferably take place the day after the recording of the second food diary or with one day or exceptionally two days in between. The visit is expected to take about 45-60 minutes.

The second home visit consists of:

- Performing anthropometric measurements (weight, height and waist circumference;
- The second EPIC-Soft completion interview in combination with the food diary;
- Checking if the FFQ, FSQ and logbook were filled in properly;
- Taking along day-1 and day-2 diaries, picture book, accelerometer, logbook and envelope with health questionnaire.

Materials that the interviewer will need for the second home visit:

- A laptop
- A body weighing scale
- A stadiometer
- A non-elastic measuring tape
- The anthropometric registration form

During the second home visit the same procedure as described for the first completion of the first EPIC-Soft record will be carried out. However, this time it will be performed face-to-face instead of by telephone. The routines for performing the anthropometric measurements was explained earlier. The measurements will be written on the registration form. The interviewer will also check the FFQ, FSQ and logbook for incompleteness and uncertainties. If the questionnaire is incomplete or not completed at all the FFQ or FSQ will be performed by interview.

In regard to the incentives we have to keep in mind that the best incentive to participation may be providing information back, after completion of the study, to those who contribute to the study and demonstrating the usefulness of the collected information.

5.3.1.3 Data collection in adolescents (10-17 years old)

The routines in adolescents are the same as in adults except that adults don't wear an accelerometer (expect the adults who participate in the validation study). Figure 5 presents an overview of the data collection in adolescents.

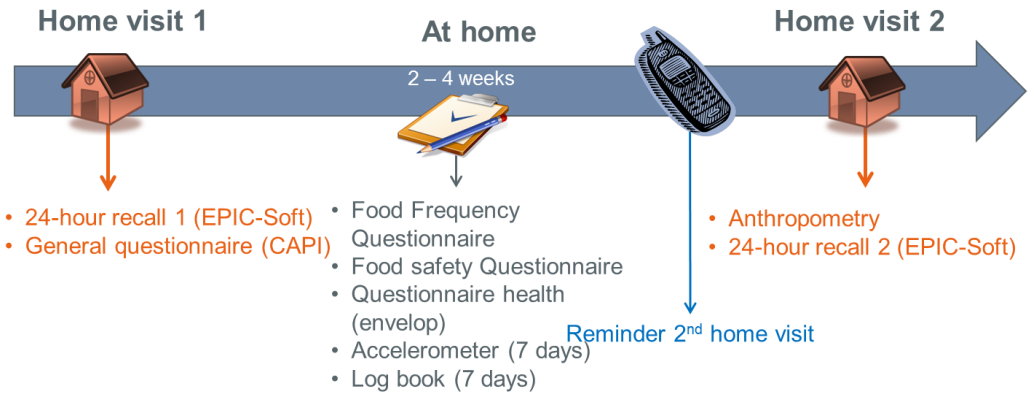


Figure 5. Timeline of data collection in adolescents

Type of instruments

- Nutritional consumption and dietary habits will be investigated with <u>two face-to-face 24-hour recall interviews with EPIC-soft</u> on two non-consecutive days all with minimum 2 weeks in between, including the use of a picture book to quantify the consumed portions

- PAPI (which the selected adolescent has to fill out in the period between the two visits)
    - A FFQ;
    - A FSQ filled in by the person who is in charge of the household;
    - The completed questionnaire on health (physical health, psychological health) will be placed in a concealed envelop with coded ID number ;
    - A logbook has to be filled out during the days the accelerometer is worn.

- CAPI:
    - The general questionnaire is a short <u>interviewer-administrated</u> CAPI. Socio-demographic information and other lifestyle behaviour variables (eating behaviour, physical activity, sedentary behaviour) will be assessed.

Timeline of implementation of the instruments for adolescents

The first home visit consists of:

- A written consent is asked from the parents/guardians of the adolescent and the adolescents themselves (>12 years old).
- A 24-hour recall interview face-to-face with EPIC-Soft.
- The general questionnaire will be filled out face to face with a CAPI, while showing the different answer categories on a card.
- Giving information about the FFQ, FSQ and the Questionnaire on health ((envelope) which have to be self-administered between the two visits (PAPI).
- In addition to the accelerometer and logbook, information on how to use them are provided to the adolescents.

The second home visit consists of:

- Another EPIC-Soft 24-hour recall using CAPI will be filled out.
- The interviewer will look over the FFQ together with the participant; it will be further filled in and taken along together with the questionnaire on health (which is placed in a closed envelope).
- Anthropometric measurements (weight, height and waist circumference) will be taken. The measures will be written on the registration form.
- The accelerometer and logbook will also be recollected.
- In adults, who are selected to participate in the validation study the EHIS-PAQ (with CAPI) has to be repeated.

5.3.1.4 Data collection in adults (18-64 years old)

Figure 5 presents the timeline of data collection in adults. Adults that are participating in the EHIS-PAQ validation study will have to wear an accelerometer in the weeks between the two home visits.

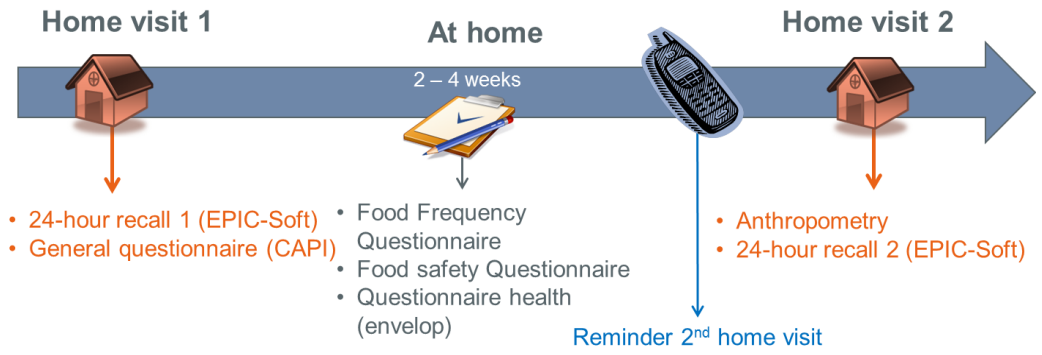


Figure 6. Timeline of data collection in adults

Type of instruments

- Nutritional consumption and dietary habits will be investigated with two face-to-face 24-hour recall interviews with EPIC-soft on two non-consecutive days all with minimum 2 weeks in between, including the use of a picture book to quantify the consumed portions

- PAPI (which the selected adult has to fill out in the period between the two visits)
    - A FFQ
    - A FSQ filled in by the person who is in charge of the household
    - The completed questionnaire on health (physical health, psychological health) will be placed in a concealed envelop with coded ID number

- CAPI:
    - The general questionnaire is a short interviewer-administrated CAPI. Socio-demographic information and other lifestyle behaviour variables (eating behaviour, physical activity, sedentary behaviour) will be assessed.

Timeline of implementation of the instruments for adolescents

The first home visit consists of:

- A written consent is asked from the parents/guardians of the adolescent and the adolescents themselves (>12 years old).
- A 24-hour recall interview face-to-face with EPIC-Soft.
- The general questionnaire will be filled out face to face with a CAPI, while showing the different answer categories on a card.
- Giving information about the FFQ, FSQ and the Questionnaire on health (envelope) which have to be self-administered between the two visits (PAPI).
- In addition to the accelerometer and logbook, information on how to use them are provided to the adolescents.

The second home visit consists of:

- Another EPIC-Soft 24-hour recall using CAPI will be filled out.
- The interviewer will look over the FFQ together with the participant; it will be further filled in and taken along together with the questionnaire on health (which is placed in a closed envelope).
- Anthropometric measurements (weight, height and waist circumference) will be taken. The measures will be written on the registration form.
- The accelerometer and logbook will also be recollected.
- In adults, who are selected to participate in the validation study the EHIS-PAQ (with CAPI) has to be repeated.

The difference in implementation frequency between adults, adolescents and children are presented in table X.

Table X. Data collection

Type	Children	Adolescents	Adults
1st home visit	• General Questionnaire	• 24-hour recall EPIC-Soft	• 24-hour recall EPIC-Soft

At home	• Food diary 1 + Completion interview EPIC-Soft • FFQ • FSQ • Health questionnaire (envelop) • Accelerometer (7 days) • Logbook (7 days) • Food diary 2	• FFQ • FSQ • Health questionnaire (envelop) • Accelerometer (7 days) • Logbook (7 days)	• FFQ • FSQ • Health questionnaire (envelop)
2nd home visit	• Completion interview EPIC-Soft • Anthropometry	• 24-hour recall • Anthropometry	• 24-hour recall • Anthropometry

Table XI gives an overview of the modules an data collection method.

Table XI. Data collection methods

Modules	CAPI	PAPI	Other
Individual nutritional consumption			
24h-recall	X		
Food frequency questionnaire (FFQ)		X	
Lifestyle			
Nutrition	X		
Smoking	X		
Physical and sedentary behaviour	X (Toybox, IPAQ, EHIS-PAQ or FPAQ)		Accelerometer
Socio-demographic characteristics			

Household composition Education Employment Age	X X X X		
Questionnaire on health Health (physical and psychological health and well-being) Puberty Eating disorders		X X X	
Food safety questionnaire (FSQ) Knowledge, attitude and behaviour		X	

5.3.2 Data flow and management

5.3.2.1. Data entry procedures

There are two data entry procedures for the FCS2014 data:

- Data that are collected from the face-to-face questionnaire using the computer assisted personal interviewing (CAPI) approach do not need a specific data entry procedure as the data are entered during the interview. Data collected by the accelerometers (*.agd file) will be downloaded onto the PC of the dieticians using the software application Actilife 6®. Consecutively, all these data have to be send electronically to the database at the WIV-ISP using safe routines.
- Data from the self-completed questionnaires which are collected using the paper and pencil (PAPI) approach require a specific data entry-procedure. After conducting the face-to-face interviews, the interviewers will take along the completed questionnaires and send them by mail to the WIV-ISP. At the WIV-ISP, a specific team will be responsible for the data entry into the database. During the pilot study three different data entry techniques will be tested: teleform scannable data entry, a PDF-form and manual data entry with Blaise software.

5.3.2.2. Record identifier

To identify respondents in the context of the data transfer between the dieticians and the WIV-ISP, a system of a unique identifier for each respondent has been developed. The unique identifier code exists of a 8-digit number (see figure 7). A key data set comprising both the unique code number at the individual level and the individual National Register number will be transferred and saved by a Trusted Third Party.

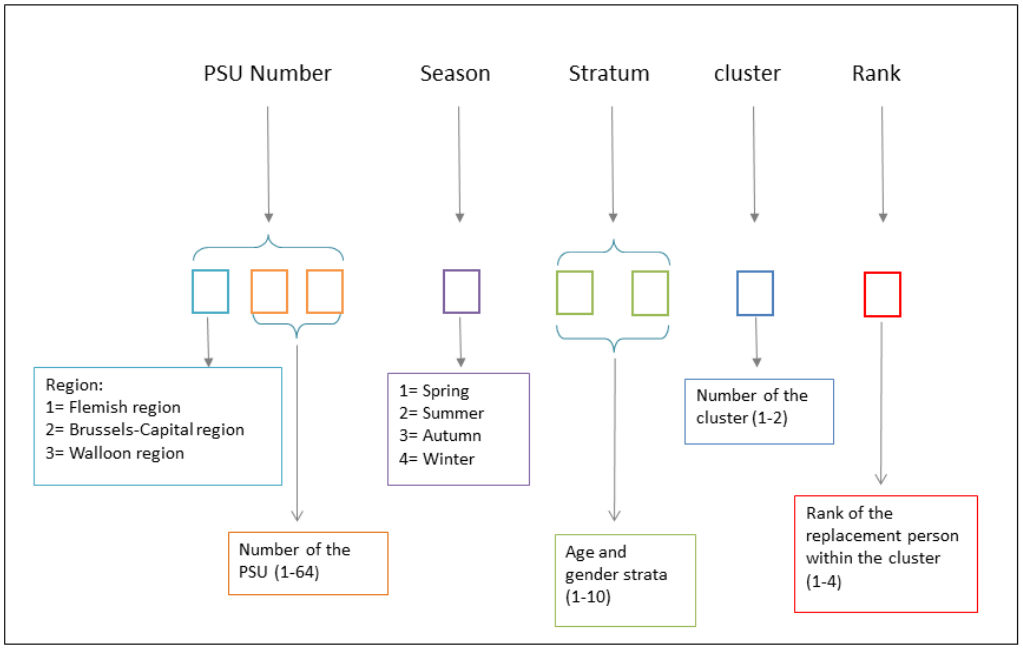


Figure 7. Construction of the eight-digit ID number

5.3.2.3. Creation of working database

Four different data files in regard to the different questionnaires will be created. Consecutively, all different files will be merged into an initial working database. Different steps have to be executed while creating the file:

Input of data

- Checks of consistency between information from reception form and the received files
- Creation of one data-file by merging the different files by ID number

- Allocation of labels
- Creation of survey weights

5.3.2.4. Control of working database

The CAPI-programmes contain several systems aimed at the production of quality data. The system follows the logic of the questionnaires, i.e. when a question is not applicable the data entry jumps to the next relevant question. Every question has to be answered before jumping to the next question. The design of the answer categories permits only the right number or way of data-entry. A warning will be given if the answering method is not appropriate. The programme will be tested in advance and during the pilot study before using it in the survey. After the creation of a working dataset, two types of control checks are performed to create a final clean database:

- VERTICAL CHECKS

Vertical checks are performed to check whether each person that has participated in the survey based on the contact form has all the different data files attached. If inconsistencies are detected, they are verified by physical checks in the entry data bases or dieticians. The corrections are noted in the programme.

- HORIZONTAL CHECKS

Horizontal checks are performed to control the internal consistency of the data, i.e. to see whether the answer to a specific question is coherent with the rest of the questionnaire. This check will be limited in the data sets of the CAPIs because of the build-in safety systems. Routing errors and inconsistencies are avoided because the interviewer and interviewee are guided through the questionnaire. Data collected by PAPI questionnaires require a specific phase of data checks because routing errors as well as inconsistent replies may be possible. The PAPI forms have to be checked to see if the PAPI is encoded correctly or if no corrections have to be made.

Storing and archiving

A number of different databases are created for different purposes. These databases will be stored on the database server of the institute. A backup of the database is

made every day on a separate hard disk and archived as another file. Secondly, a final common database is created in which variables and indicators are available. The merging stage will be performed by hand or automatically using a programme.

Databases for external users will be created on demand and need for variables. In these data files variables which may include an indication for identifying the individual will be removed. A manual for external users will provide all information that is needed to understand and use the data.

A software system, based on an FCS2004 version will be adapted to control the fieldwork.

A pilot study will be carried out in October to test out the interview procedure and the import of data in both the PCs of the interviewers and in the central database and its accessibility, handling and use by the researchers and administrative personnel.

The software system will be in use for about 20 months, to know during the 12 month in which the survey will take place and 4 months before during the pilot test and 4 months afterwards during which the procedure of encoding of the questionnaires will be finalised.
The power and the memory capacity of the software system have to be sufficient to deal with following constraints:

- all the interviewers may be connected on the same moment
- response time may not exceed the maximum permitted time-period 0.50 to 1 second ?
- using a database management system generating and treating a large number of requests

The number of connected users on two different levels:

First level: 1 – 6 users for the management of the fieldwork (2 administrative persons, 2 dieticians, 2 researchers)
Second level: 1 – 64 interviewers for the encoding and sending of the questionnaires
The safety level of the software system and the encoded data has to be very high. The safety has to implemented on two different levels:

1. On the level of the database a user application has to be created with limited accessibility. Access to the system can only be granted by identifying the user by login and password. The system is also divided in subsystems: encoding of the questionnaires, management of the fieldwork and interviewers, …. A set of profiles is predefined. Each user is linked to one profile which gives the owner of the profile the right to access the database in regard to the different levels. The rights of function include visualisation, creation, modification, deletion on the different levels in the database. But, the rights depend on the level of the user. Interviewers and administrators can only import, while two dieticians and researchers have all rights.
2. Safety at the level of the portable computer: login and password, encryption of the data, safe transfer to central server.

The workstations of the interviewers have to function independently and in Windows 7. All the programs which are provided to the interviewers have to be accessible and useable by persons not trained in informatics. A manual, in addition, will explain step by step the proceedings in the usage of the interface has to be developed in both languages (Flemish and French). The importation and exportation of data will be carried out continuously. There will be a flow of data which has to be safe and controllable. Thus, in both alternatives there has to be personnel to:

- Manage the interview manager application
- Receive and merge the data files which are send on a very regularly base to the WIV-ISP
- Control the fieldwork
- At the WIV-ISP, researchers will have access to the data system to monitor the imported data. This requires from the system high handling of data, getting an overview of the dataflow and content, this to be able to react promptly on eventual incorrect reporting.

5.3.2.5. Management of the dataset of individuals as given by national register

Each individual of the sample has to receive a unique identification number. The updates and the modification of the data is only allowed when using this identification number. The requests must be made read-only to prevent accidental changes.

The National Register will provide eHealth one file (file n°1) containing the national number and the personal data (name, address, day of birth, gender, marital status, nationality and composition of household) of all the selected persons. This file will be anonymized by eHealth (the third trusted party) using an algorithm in order to create a second file (file n°2) containing an arbitrary ID number and the personal data (name, address, …). This will then be sent to the WIV-ISP who will transform the arbitrary ID into a study specific ID number (8 digit) (file n°3).

This third file will be saved as it is on a secured server at WIV-ISP (with the access only available via a private username and password) and also sent to the dieticians/interviewers. The interviewers can have access to the personal data of the people they have to interview (12 per trimester) only on their PC (given by the WIV-ISP) with a private and unique username and password.

When the data have been collected, they are recorded in a fourth file (file n°4) containing the ID number of the participant and the data on nutrition and health. This file will be encrypted before being sent to WIV-ISP on a secured server. Each interviewer will be able to connect (distance) to this server and upload their data file without seeing or having access to the data file of the other dieticians.

5.3.2.6. Receiving the data into SQL data file (DF1)

The National Population Register (NPR) implements the sampling of the study population using the sampling protocol as designed and written by the WIV-ISP. At that time the individuals receive a unique identification number. The file of the sample contains important sensible data (family name, name and address, etc…). The NPR will carry out the sampling process four times a year. Each time, the file will be imported and processed in the system. The process includes mixing the individuals in a random manner, selecting the individuals and providing a file with the addresses of the selected individuals. These processed files constitute the foundation on which the management of the individuals takes place on.

<u>Making an anonymised data file from data file (DF2) with creation of key to DF1 for management of survey fieldwork</u>

Identification numbers will be used to anonymize the database. Every individuals will receive a unique identification number 8 number coded digit.

Selection of individual from DF2

Selection of individual from DF2 and replacement of the non-participant is explained in the following paragraph.

The study sample is provided in four waves including a system in which in case of refusal the administrative personnel of WIV-ISP will provide the next selected individual, using a software application. The WIV-ISP administrative personnel will send the information letter to the selected and activated person and the dietician can contact the replacement person as soon as possible. The replacement persons have to be selected in clusters in advance and will be guarded in databases at WIV-ISP. The clusters will be based on gender, age and municipality.

Inviting selected individuals in personalized way

Management of the individuals

A secretariat will be organized at the WIV-ISP, including two dieticians and two administrative persons, who will manage the fieldwork and encode the data from the PAPI. At the start of each season the secretariat will send a list with the selected activated individuals to the interviewers and an invitation letter with information to the activated individuals.

The addresses of the interviewees are printed on the letter/envelope using mail-merge. If the person is under the age of 18 years a modified letter has to be sent to the parent or guardian. This letter has be in the language that is spoken in the region: French in Wallonia, Flemish in Flanders and in Brussels the letter will be printed recto-verso in both languages. At the same time a list will be sent to the interviewers with the address, name, age and code of the interviewees which have to be contacted. The interviewers will also receive a communication form to describe the details of the contact with the respondents. The dieticians have to send regularly (minimum every two weeks) feedback to the secretariat at the WIV-ISP.

The PAPI questionnaires, logbook and informed consent which are filled out by the respondents have to be send back via post to the secretariat at the WIV-ISP together with the individual forms contenting the individual information on every interviewee separately. The CAPI information will be downloaded onto the PC's at first (possibility to download / update application via central server ?) and then exported to the main server at the WIV-ISP in addition to be saved on a memory stick.

A software program will be used to test the integrity of the CAPI questionnaires. The secretariat may also visualize a list with all the communication forms with date of entry. It will be important to note the time of the interview of EPIC-soft, because this CAPI is taken twice.

Management of datasets imported by administrator

Enter data from PAPI FFQ.
Data collection on personal computers of the interviewers

The interviewers will work from 17.00 PM until 20.00 PM during one year and they will interview approximately 4 – 5 interviewees per month. Consequently, the system has to be powerful enough to withstand peak moments in data import.

The requested software on the 64 personal computers has to be capable to import the collected data of the CAPI EPIC-Soft (two times), the CAPI general questionnaire and the data recorded by the accelerometer after being downloaded by different software programs, respectively EPIC-Soft, Blaise and Actilife.

- Quality check
- Re-compute and export software for simple descriptive analysis

Management of datasets imported by dieticians

- CAPI: EPIC-Soft, Blaise
- Quality check
- Re-compute and export software for simple descriptive analysis

Data collection on the server

The interviewers have to send the data on paper (PAPI questionnaires, logbook on PA and informed consent) and electronic data (EPIC-Soft, general questionnaire and accelerometer data).

Electronic data will be send by eHealthbox, a secure electronic mailbox, proposed by the eHealth platform. This service requires a certificate to encrypt and sign messages. The interviewers will have to identify themselves via eID or a token.

Additionally, they have to return the completed the two 1-day diary booklets, the out of home form, the photo book and accelerometer to the WIV-ISP. The number of returned items and imported data in the central server will be used as a control in regard to the number of activated interviewers and interviewees. If one of the above mentioned items is missing or not returned, this has to be reported. The WIV-ISP is also responsible for the verification in depth of the files, the identifications of the flaws and changes to make to the program as well as the update of the 24h- recall when incomplete.

Specifications of the output of data files

Accelerometer collected data has to be downloaded by the interviewers using a provided commercial software package (Actilife Lite): 1 *.AGD-file. Tis file has to be sent to the WIV-ISP (with an identification number of the participant). This files will be cleaned and handled by the administrators using a provided software package (Meterplus®) which is situated on the server. During this process a *.CSV-file will be created which will be converted to a *.MPD-file. After running this file automatically a SPSS-syntax will be created.

Nutritional data have to be entered into the PC using EPIC-Soft. When exporting the interviews (an interview database) three kind of files are created: 1 *.BAK file, 1 *.XML file, 5 *.CSV-files. All the send *.XML files will be merged and produce data (with an identification number of the participant) ready for analysis.

The CAPI will be programmed with the Blaise® application. The CAPI questionnaires will produce a *.BDB (Blaise database) file containing data magnitude of approximately 1 MB. The CAPI questionnaires will be developed by Sabine Drieskens. The produced file will be imported into the ICT-application and converted to a SAS-file via an ASCI-file.

All the data of the accelerometer, CAPI questionnaires and EPIC-Soft together will be approximately 6 MB per interviewer which has to be uploaded on a server at the central level.

The structure the previous ICT-application of the HIS2008 may be followed for developing the new ICT-application.

The coding of the questionnaires

The data entry of the PAPI and logbook will be done by administrative personnel of the WIV-ISP. This part of the system has to permit the data entry of the responses on the PAPI questionnaire and the logbook. The puncher-administrator will first import the personal information on the respondent, only if the information correspond to an activated respondent. The questionnaires are composed by different modules. Every module corresponds to a subject. The Blaise application uses the rules of questionnaires such as filters, jumps, question types or maps. In case the interviewee is a child, one of the parents (usually who does the cooking) may be a proxy and complete the questionnaire, but interaction with the child is recommended. The respondents are only eligible when they speak French or Flemish.

- Filter: the filter defines which respondents are the target respondents, with other words to whom the question is directed. This may vary from one modules to another. This filter may also occur within a module in defining that one or more questions within the module is directed to one specified group of respondents.
- Jumps: a question may include a jump in a way that the respondent will be directed to another following question further in the questionnaire without having answered the questions in between.
- Types of questions: Open-ended (e.g. how many hours), semi-open-ended (e.g. if yes how many) and closed-ended questions (e.g. yes or no) may have

been used. There are also questions for which several answers may be checked.

A set of rules will be implemented in the system to minimize the error in the introduction of data.

5.3.3 Data analysis

1. Indicator development

Data analysis begins with data cleaning and the construction of new variables called “indicators”. These are defined as “variables that indicate certain conditions of interest” and will be used for the final analysis of the data. In some cases indicators are just copies of existing variables (after cleaning) while in other cases they result from the recoding of several variables. The creation of the indicators is performed in a separate SAS programme for each module of the questionnaires. The SAS programme is called: XX2014.sas (XX for the two letters of identification of each specific module) which can be found in the directory \FCS\FCS2014\Data analysis\modules\XX. All the procedures performed are documented within the SAS programme itself. The source variables, a number of socio-demographic background indicators and the specific indicators for that specific module are saved in a data file called: XX2014.sas7bdat which can be found in the directory \FCS\FCS2014\Data analysis\modules\XX.

2. Analysis plan

Depending on the outcome, results are expressed as a proportion, a distribution, a mean, a median and other percentiles. The results are presented in a final report including tables, graphs and an explanatory text. They are reported for the whole of Belgium. In regard to Brussels the findings will have to be interpreted with care because the margin of error will increase. Further exploration of the data varies from

one module to another and is described in the concept papers of the concerned module. When relevant, extra analyses are performed including also other variables.

All steps in the analysis will be executed by means of command syntaxes which will be saved in program files or macros to ensure reproducibility of the analysis. All program and output files will be saved in the same (sub)directory on the server at the WIV-ISP (\HIS\FCS\FCS2014\Data analysis\). Original data files will never be overwritten but saved under a different name. The .sas program files need to be structured according to a logical framework and include short explanatory comments between syntax commands. Each program needs to include at least following subsections: data input, data management, value labels, statistical analysis and output. They should also start off with the following notes: version of software used, working directory, name program, path and name input data file(s), objectives of program, author of program, date (update) and name of output file(s).

Daily and/or habitual usual intake

The combination of the data from the two EPIC-soft interviews and the FFQ will be done for further analysis. In order to assess the daily and/or habitual usual intake of a series of macro- and micronutrients and food groups, we will use the software R® like it is done by the European instances . This way, we will also be able to make comparison of intake with dietary guidelines.

Food safety data

Descriptive analysis will be used to evaluate the data on food safety: frequencies, means, median distribution, …

To compare the means distribution in different groups (age, gender, region, socio-economic level, …), we will use t-test and ANOVA. If these distribution are asymmetric, the analysis of medians distribution we be performed through Wilcoxon tests and Kruskall-Wallis tests. Variables in category will be analysed with the use of chi-square and V of Cramer.

All these analysis will be done for each modules: knowledge, attitude and behaviour.

Physical activity

The way we will analyse the data on physical activity still has to be decided.

3. Software selection

Except for the analysis of the daily usual intake (which will be done with R® software, analyses will be carried out using the statistical package SAS® version 9.3. Detailed documentation (text books, manuals) on the functionalities of this software package is available at the WIV-ISP.

4. Treatment of missing values

Throughout the database, negative values correspond to missing values and are to be interpreted as following:

-6 = Not interviewed
-5 = No valid information
-4 = Mistake interviewer
-3 = Not applicable
-2 = Does not know
-1 = No response

5. Programming

A number of programs will be developed for the data management and the analyses:

1. the program to construct a cleaned global dataset including all variables and the socio-demographic background indicators; this program includes also the construction of the survey weights;
2. the programs dealing with the analyses of the methodological aspects of the FCS (description of population, participation rate, etc.);
3. the programs dealing with data cleaning, construction of indicators and computation of crude results for the individual modules;
4. the programs to produce adjusted results and more advanced analyses
5. the programs constructing the final databases used for the interactive analyses via the website and the final databases for external users

1. *Program to construct the cleaned global dataset*

The cleaned global FCS2014 SAS® dataset will be constructed on the server of WIV-ISP with the four databases created during the study. These consist of:

4- Accelerometer data
5- Nutritional data (EPIC-Soft)
6- Data from CAPI questionnaire
7- Data from PAPI questionnaires

The program consists of the following steps:

- Data input from the server
- Construction of new variables at individual level (e.g. age groups, deficit; excess in some nutriments)
- Correction of inconsistencies
- Calculation of survey weights

A technical document describing the calculation of the survey weights in the FCS2014 will be presented in annex XX (to be developed).

2. *Programs dealing with analyses related to the methodological aspects of the FCS*

A set of programs deals with methodological aspects of the FCS such as:

- Calculation of time needed to complete all interviews
- Description of people in function of their participation status
- Reasons for non-participation
- Description of sample in function of background characteristics

3. *Programs dealing with data cleaning, construction of indicators and computation of crude results for the individual modules*

These analyses are done by module. For each module the program consists of the same steps:

- Input of relevant variables of FCS2014 database

- Data cleaning (correction of inconsistent data), allocation of missing values, formats
- Calculation of the indicators as described in the concept paper
- Computation of crude results by background characteristics for basic tables (total population)
- Computation of crude results by background characteristics for regional results
- Computation of database to be used as input file for adjusted tables (see next point)

4. Programs to produce adjusted results and more advanced analyses

Macros are developed for the following types of analyses or outputs:

- Tables with adjusted results for percentages and means (presenting crude results, adjusted results + 95% confidence intervals in function of background characteristics) for the final report
- Graphs presenting percentages or means for each variable by age and sex with 95% confidence intervals for the final report
- Models of logistic regression with the dependant variables “Deficit” or “Excess” for some minerals and vitamins in order to identify the “at risk population”
- Multi-level analysis to take account of the SES.

6. Inference methods

The inferences methods that will be used in the FCS2014 is under construction.

7. Internal and external validation

Statistical experts are consulted to ensure the validity of the methods, calculation of weights, etc. The programmes for both the data cleaning and the analyses are created by the FCS researcher responsible for the given module and systematically verified through internal peer review. Also for the macros that are produced internal and external quality checks are performed.

8. Presentation of results

The final report with tables presenting crude and adjusted results for all indicators will be available in PDF-version on the FCS2014 website. Results will be presented for Belgium and for each of the three Belgian regions separately.

Via NUTRIA, an interactive website based tool, it is possible to generate tables with crude and adjusted results in function of background variables that can be selected by the user him/herself (see chapter 12).

5.4 Methodology used to improve the quality control of data management

There will be quality control on five levels:

1. communication,
2. fieldwork, i.e. data collection,
3. data flow
4. data management
5. dissemination.

In addition, an ICT-application, NUTRIS, will used to supervise and look after the quality of the field work.

5.4.1 Recruitment and training of the interviewers

In order to recruit ± 80 dieticians (64 for the study + a minimum of 16 extra candidate-interviewers), we will contact both regional dietetic associations (VBVD and UPDLF), schools and magazines which are all related to nutrition. The candidates who will do the fieldwork for the VCP2014 will be selected according to following important criteria:

- Bachelor degree as a dietician
- Independent worker
- Available in the evening and the week-end

All interviewers active in the VCP 2014 will have to follow three days of collective training. A separate training will be organised for Dutch and French-speaking dieticians (separated in two groups). During this training 3 major themes will be

addressed: (1) training in the use of the two CAPI-applications (EPIC-SOFT and General Questionnaire) (theory + practical use) (2) outlines of the FCS2014 survey (content of the questionnaires, procedures and proceedings in contacting the selected person and execution of the interview, downloading and sending of the collected data; importance of compliance, ….), (3) supplementary tasks in the context of the food investigation-survey (administration of the accelerometers and measurement of the anthropometric measurements). They all will receive an interviewer manual which describe their tasks precisely in regard to the different parts of the survey.

Special attention will go to the communication with the selected persons, because this, besides of the public information campaigns, may have a determining role in the willingness to participate in and the quality of the survey.

How the interviewer interacts with the respondents may determine the quality of assessment and further participation. Some interviewers may drop out throughout the data-collection phase. Efforts will be made to limit this drop out: candidate-interviewers will be informed what is expected of them, which kind of problems they may face during data collection (e.g. when contacting people) and how much they will be paid.

5.4.2 Manual for the interviewer

The general manual of the interviewer comprises six parts: (1) The general execution of the FCS 2014, (2) Detailed protocol for the house visits and telephone interviews, (3) Detailed description of content of questionnaires, (4) Anthropometrical measurements, (5) User manual for the CAPI (Blaise) and (6) Accelerometer and Actilife. For EPIC-Soft a separate manual was created in Flemish by the UGent which was subsequently translated into French. This manual was based on the original manual of EPIC-Soft created by the IARC. The manual of EPIC-Soft contains six annexes.

5.4.3 Manual for the interviewee

- Detailed information on the survey (overview of house visits) in information folder which interviewee receives during first house visit. This information form contains contact information in case of addition questions.
- Manual on the proper use of accelerometer (besides oral explanation of interviewer)
- Every questionnaire contains an explanation at the beginning on how to fill in the questionnaire and an example.

5.5 Evaluation of the interviewers

5.5.1 Control of the interview proceedings

In the perspective of ensuring quality in the FCS2014 a system of monitoring the quality of the field work will be established using NUTRIS. This will allow to monitor day by day the work progress on the field, to identify quickly those interviewers for which the work is not progressing as expected and to monitor the participation rate.

In addition, the way of making contact and performing the interview will be investigated using some random controls. The sample of the individuals who will be controlled is formed from the pool of activated interviewers. This control will take place one time per trimester six weeks after starting the fieldwork. The quality check will take place using a semi-structured interview questionnaire addressing three topics about the contact with the interviewees:

- the way of invitation to participate
- the first contact
- the interaction with the participants or refusers

The work in regard to the quality control includes two steps:

- looking for the telephone number if this number is not already provided by the interviewer
- making contact with 2 persons (the selected person him or herself or guardian) from the list of every interviewer: one participant and one refuser.

The responses will be directly encoded in the database.

5.5.2 Generating monitoring indicators

Several sources of information are required for the evaluation of quality of the fieldwork:

- Progress report (bi-weekly): reporting on the number of realized interviews, the number of refusing persons, the number of persons with a stand-by status and a “in process” status.
- Overview of non-response, non-participation, refusal, non-contactable and de-activated persons (at national, provincial and municipal level).
- Overview of accrual rates for each interviewers
- Overview of accrual plot at national and provincial level (Mean number of realized interview – number of people participating).
- Number of interviewers to be replaced

The information needed for the follow up of the fieldwork will be automatically transferred from the portable computer of the interviewers (they have to fill in on a daily basis some information about the work progress for each of the selected persons) to the central NUTRIS application. Those fieldwork indicators will be calculated automatically, on a daily basis, using the NUTRIS application.
The state of realization of interviews is monitored to finally realize the objective of the 3200 interviews.
A summary table of the investigations realized by group, by region and quarter is available in real time to monitor the evolution of the investigation, participation rates, distribution of days of the week, …
At the beginning of each trimester, to compensate certain interviewers who do not realize their quota, extra individuals will be activated in other groups.

A report of the data about the reception of the questionnaires will be generate in real time. In this way it will be possible to follow the number and the types of the questionnaires received compared with information provided to NUTRIS about the interviews.
A summary table will be created to look for irregularities.
These indicators will be used to:

- manage the pool of interviewers
- verify the performance of the interviewers

- assess the progression and the quality of the field work
- distribution of the days

5.5.3 Management of the interviewers

Basically, 64 experienced and well-trained interviewers will perform the interviews and collect the data from the respondents. The interviewers are engaged to be active during the whole year. It can be foreseen that some interviewers will drop out during the year. Therefore a pool of 80 interviewers is composed, from which interviewers can be activated during the years of the fieldwork.
The following indicators are used to manage the interviewers:

- Turn-over: this is the ratio of the number of interviewers that stopped during the fieldwork and the number of interviewers ever activated.
- The number of groups for which the interviewer need to be replaced.
- The number of groups for which the interviewer is on holidays.
- The number of groups for which the information about the contact with the selected persons is not regularly uploaded on NUTRIS.

5.5.4 Performance of the interviewers

In evaluating the performance of the interviewers, two aspects can be distinguished:

(a) are the persons contacted according to the guidelines,

(b) is the interviewer able to convince the persons to participate in the survey.

The following indicators – that can be constructed from the NUTRIS application will be used to evaluate the performance of an interviewer.

Completed interview procedure:

I_1: The proportion of persons interviewed

Not participating persons:

I_2: The proportion of refusals

I_3: The proportions of non-contactable persons

I_4: The proportion of de-activated persons

Stand-by interviews:

I_5: The proportion of stand-by persons

In process persons:

I_6: the proportion of “in process” interview

For these calculations, the number of activated people that should be contacted by the interviewer will be used as the denominator. From each interviewer, values for these indicators can be calculated. For I_2, I_3 and I_5, extremes in each province can be detected by using tools like deciles, box plot, etc.

In addition, the following indicators will be calculated to evaluate the performance of each interviewer separately:

I_7: number of persons classified as non-contactable, while the procedure was not properly applied.

I_8: Number of persons that are not contacted at the end of the first 14-day interval. This information will also be presented as a proportion: the proportion of the activated persons for a specific period to which were not contacted within 14-days.

I_9: (Binary) Indicators whether or not one third of the quota is reached half way the trimester. So, for each group, 4 interviews need to be done at week 6.

The first time that the guidelines are violated, so when I_7=1 or I_8=1, a letter will be sent to the interviewer to inform him about the violation and to ask him to correct the mistake. In case both indicators I_7 and I_8 equal one, or when one of the indicators is larger than one, the central secretariat will contact the interviewer by phone to find out what is going on.

Halfway the trimester, all the interviewers will when I_9=0 will be contacted by phone to motivate them to speed up the fieldwork so that at the end of the trimester the quota can be reached.

Another indicator can be the proportion of interviews done on Monday (recall day), Tuesday, Wednesday, Thursday, Friday , Saturday and Sunday (number of interviews done on Monday divided by total interviews) multiplied by 100. Every interview has to be done twice and for every interviewer 7 interviews have to be done on each day of the week. Because the interviewer has to repeat every interview twice the total amount has to be 100 ,meaning 14 interviews on each day of the week. Therefore, this indicator should be more or less equal to 14%.

Another indicator can be the proportion of pair interviews done with an interval of 3-6 weeks and done on correct days.

Finally, the percentage of drop-out participants should be monitored (percentage of respondents with 2 interviews). These indicators can be calculated from the “Individual interviews form”.

Any interviewer suspected of interview falsification will have 100% of his/her work verified. In all such cases, these interviews will be re-taken.

5.5.5 Quality of the fieldwork

To evaluate the quality of the fieldwork we will look at the transgressions regarding the contact procedure:

- The number of persons that are not yet contacted at the end of the first 14-day interval, and the proportion with respect to the number of activated persons.
- The number of persons classified as non-contactable, but for which the procedure of contacting was not correctly applied, and the proportion with respect to the total number of non-contactable persons.

5.5.6 Progress of the fieldwork

The performance of the interviewers is reflected in the progress of the fieldwork. Therefore indicators, similar to the ones used to evaluate the performance of the interviewers are used to evaluate the progress of the fieldwork. Every 14-days, the following indicators will be presented, based on all data collected since the start of the survey.

Completed interview:

I_1: The proportion of persons interviewed

Not participating persons:

I_2: The proportions of refusals

I_3: The proportions of non-contactable persons

I_4: The proportions on de-activated persons

Stand-by interviews:

I_5: The proportion of stand-by interviews

In process interviews:

I_6: The proportion of “In process” interviews

The results should be presented bi-weekly in table and graph format. In the table, the ratio “refusals/ (refusals + responders)” and “completed/target” will also be displayed.

An accrual plot, showing the “ideal accrual” and the “actual accrual” is used to decide whether or not the interviewers need to be motivated/contacted to speed up the fieldwork and to make sure that at the end of the trimester the quota is reached. An example is showed in the figure 5.

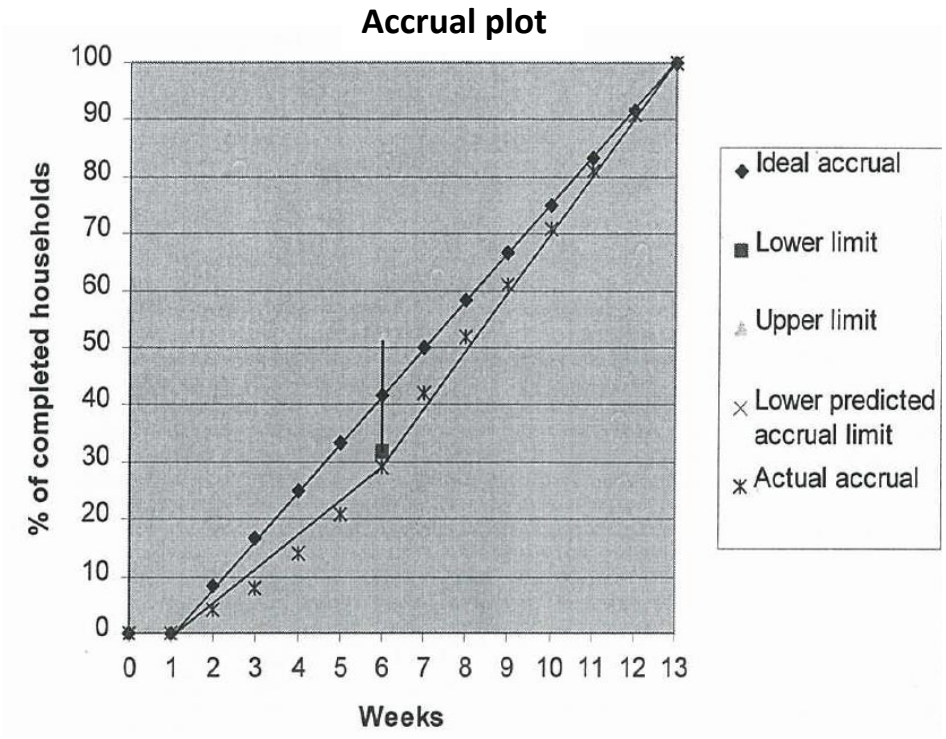


Figure 8. Accrual plot

The above picture is an example of the first trimester of a study. The survey started in fact in the second week of January. Ideally, the accrual plot is equally spread over time. In practice however we expect the accrual to be a bit slower at the start. At the week 6, the ideal and accrual are compared to see if action needs to be taken. In the ideal situation in fact 41.7% of the people should have been interviewed at this point of time. We do however allow a deficit of 10% before taking action. If less than 31.7% of the people are interviewed at week 6, the central secretariat contacts the interviewers. A straight line from the actual accrual at week 6 and the quota to be reached at week 13 can be drawn. To ensure that the quota is reached, we expect

that observed accrual rate is in the triangle formed by the two lines in the accrual plot.

5.5.6.1 Additional functional needs of the software system NUTRIS to guard the quality and safety of the database

1) Horizontal coherence

The researchers at WIV-ISP will regularly carry out horizontal controls of the encoded data coming from the questionnaires. This will allow to verify if the encoded responses from the self-completed questionnaires are consistent and supervise the quality of the encoding work performed by the administrative personnel.

2)Security

Every user (interviewer using a portable computer, supervisor using the NUTRIS application at the central level) will have to login with a name and password . The name will be recognized by the system and correspond to specific profiles and rights on the database.

5.6 Software development: NUTRIS (Nutrition Information System)

5.6.1 Description and planning (project team or subcontracting)

NUTRIS is a centralised software program that is aimed to manage the fieldwork of the food survey. Indeed, it is important to have constant contacts with the interviewer in order to avoid as much as possible waste of time, abandonment of interviewers and above all to have the exact number of respondents wanted at the end of 2014.
In the WIV-ISP, The ICT service in charge of developing and/or updating NUTRIS.

The system has to be operational before September 2013. At that time a pilot study will be done and the system will be implemented and tested.

5.6.2 Validation

NUTRIS was develop and used in 2004 for the first FCS. Its creation was based on similar programs that have already been develop at WIV-ISP for the HIS (2004 and

2008). For the FCS 2014, several adding were implemented and will be validated during the pilot study.

5.6.3 Importation of the sample

After being anonymized by the platform eHealth, each individuals will be given an unique identification number (8 numbers).

The national registry will be in charge of the sampling and will send 4 time a year the trimestral sampling to the secretariat of WIV-ISP. Each time, the data will be imported in the NUTRIS system. These files contains clusters of 4 individual (with the same characteristics). Each cluster will be scrambled as describe in the sampling methodology (see 5.2 p14).

5.6.4 Management of individuals

At the beginning the trimester, the secretariat of WIV-ISP will send invitation letters to the selected individuals.
The address of the individual is printed on a letter via a mail-merge procedure. If the selected individual is less than 18 years old, the letter (adapted) will be send to the reference person (parents/guardian). The letter is written in the language of the region: Flemish and French for the Flemish region and the Walloon region respectively. For Brussels, the invitation letter will be in both languages. All the letters go together with an explanatory flyer/brochure.

In the same time, the secretariat will then assign a zone with 50 interviewees to each interviewer. They will receive by mail his/her own list of individuals so be interviewed. This list contains :

- Address of the interviewer
- Personal code of the interviewer
- Code of the group for which the interviewer is responsible
- Address of individuals to be contacted
- Name and age of the individual
- Personal code of the individual

- Status of the interviews

All the interviewers will also receive by mail a communication form. For each contact or contact attempt, every interviewer has to fill in it with information about:

- ✓ Participant's ID
- ✓ Participant's phone number
- ✓ Date and type of contacts with participant
- ✓ Participant's status (successful interview 1 ; successful interview 2 ; refusal first interview, refusal second interview, pending/suspended, unreachable)
- ✓ Date of the last contact
- ✓ Date of the next contact (interview face to face or by phone)

When the interviewer submit his/her communication form, all the data about participant are automatically updated on NUTRIS and a mail is sent to the FCS team. If an interviewer has 4 negatives status (refusal, suspended, unreachable), he/she needs replacement people.

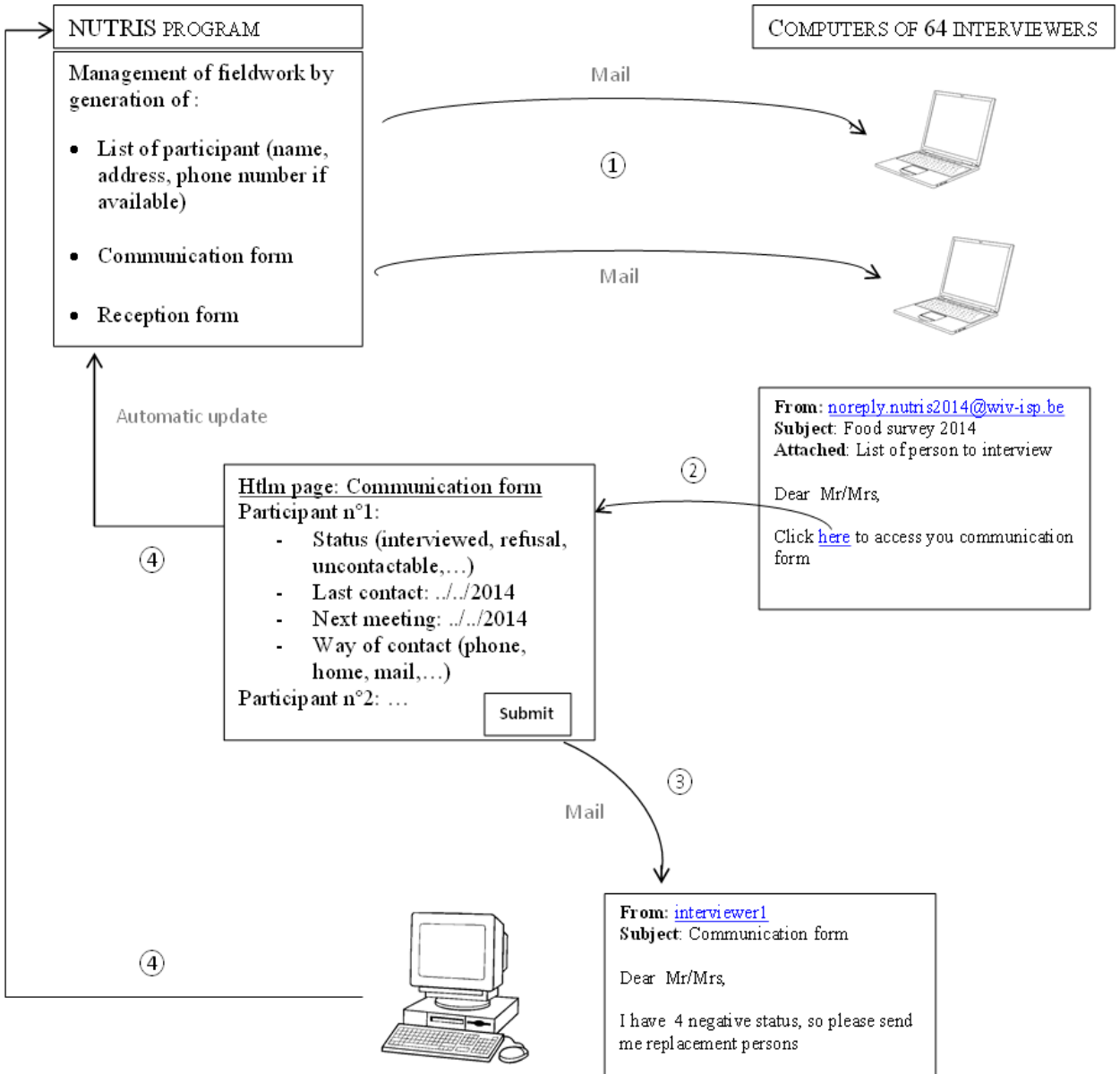
The manager of the fieldwork (member of the FCS team) will then send a new list of participant automatically generated by NUTRIS. Figure 6 below summarize these dataflow.

Figure 9. Dataflow in NUTRIS program

5.6.5 Management of the interviewers

Before the beginning of the survey, the secretariat will make a list with all the interviewers recruited. This list is uploaded in the software NUTRIS and contains:

- First name selected person
- Last name selected person
- Address
- Phone numbers (fix line and cell phone)



- E-mail address
- Bank account number
- Municipality (PSU)

The system will add the individual code of the interviewer.

The secretariat will then assign an work area (group) to the interviewer. If an interviewer quit, this information will be implemented in the system. All the complete interview will then be paid automatically (see below). Another interviewer will be assigned to the group of the previous interviewer.

If a dietician (=interviewer) will be not available for a known period of time (e.g. holiday), this has to be implemented in the system to block the sending of the list of individuals. For example, one week before the start of the vacation, it's possible to stop sending list of new individuals to the dietician. The administration has to be able to visualize the list of availability of the interviewers at every moment.
Another challenge is that one interviewer may work over more than one group of 50 selected persons or more dieticians may cover one group. The system has to be flexible also in that way. The administration may have the possibility to visualize at every moment information on the interviewers about status of the interviewer (active, not available or quit) and his or her commentaries and date of dispatch of these.

5.6.6 Payment of the interviewers

The interviewer will be paid at the end of each trimester and for every successful interview. A list of successful interviews is automatically generated and NUTRIS consecutively writes three exemplars of wage slip: one for the interviewer, one for the project leader and one for the accounting department.
When an interviewer quits this has to be noted on the list and all the interviews which have been successfully done will be paid.

5.6.7 Encoding of the questionnaires

A part of the system allows the encoding of the PAPI questionnaires (FFQ, health questionnaire, food safety questionnaire). A questionnaire can only be encoded if the individual is activated.

5.6.8 Monitoring of the fieldwork.

NUTRIS generates statistics about :

- The status of individuals by:
  - Interviewers (for each interviewer, by trimester)
  - Province
  - Municipality (64 PSUs)

  A special attention will be focus on the non-respondent*.

  *Furthermore, a little description of non-respondent (why refusal, age, sex and description of residence) is made by the filling in of the reception form (paper form).

- The negative status by:
  - Province
  - By group/interviewer
- The number of interviewers who quitted by:
  - Province
  - Trimester
- Number of interviewer that are or vacation
- Number of individual classified as “unreachable” with less than 5 contact attempt.
- Number of activated individuals who were not contacted since 14 days
- Percentage of the distribution of the “recall day” by interviewer.

These statistics are made to track the progress of each investigator in his/her fieldwork. In this way, we can follow the interviewers if they have difficulties to make contact with people, if they don’t do the interviews on time or if they do some mistakes in the management of their interviews.

5.6.9 Communication of the final report to the interviewees

NUTRIS keeps the address of all the participants, which allow the FCS team to send the results of the FCS2014 to the individuals who have participated.

5.6.10 Summary of functionalities and capacity.

Table XII. Functionalities of NUTRIS

ID	Functions

PC	Sending communication forms Sending reception forms Sending list of interviewees Communication of the final report to the person how participated
WIV-ISP server	The server will also include the data from: Sampled population The interviewer list Documents to be sent in personalised way to the interviewees Providing information needed to have the follow-up of the FCS at different levels: global, region, municipality, each interviewer, each interviewee Handling of sample: activation of dieticians and selected persons

Table XIII. Capacities of the software system

Type of database	Units	Volume unit Kbytes	Quantity Per 3 months	Duration of retention (month)	Total volume (Mb per one year)
Management of the interviewees	6400 (50% part rate) letters	150 invit letter 150 list dietic 150 commu form	7500 1215 1215	18 18 18	1125 723 723
Sample data	3200 resp	13000	1	18	52

Interviewers	64	10	400	18	0.5
Questionnaires	9600 CAPI	5	3000		
	3200 PAPI				
Accelerometers	270	1500	60	18	500
Log book	270				
Reception of the Qs					
Evaluation					
Indicators					
Exportation		15000	1	18	60
Reimbursement		150	250	18	150
Data of exploitation		150	250	18	10
Total					

5.7 Website

The official website of the FCS will be developed in three languages: French, Dutch and English. It will contain simplified explanations for the public and more detailed explanation for scientists.

6 SCIENTIFIC REVIEW

6.1 Scientific board of the research project

In context of the VPC2014 a scientific steering committee (SSC) has been established that will assure the scientific and technical follow-up of the study. The SSC consists of a set of members from public health authorities and scientific organizations. If necessary, the SSC can consult extern experts. The SCC will meet every two months and makes decisions by majority vote of the persons present.

6.2 Other mechanism for scientific review

Scientific advice can also be obtained by scientific members from other WIV-ISP units (e.g. from the HIS team). Independent of the SSC, and in the context of quality assurance, the study protocol was also reviewed by two members of the Operational Direction Public Health and Surveillance: Sébastien Fierens (Service Health and Environment) and Nicole Boffin (Service Healthcare services research)

Participation in the annual EFSA-meetings are included in the planning. The project leader (Cuypers Koenraad) is proposed to represent Belgium as a new member in the network/expert group on food consumption and exposure data. He is supposed to present the proceedings of the survey at those meetings and anticipate eventual comments.

7 ORGANIZATION OF THE RESEARCH PROJECT

7.1 Starting and completion date

The project consists of three different phases:

- **The preparation phase** which is scheduled to start on 15.11.2012 and continue until 31.12.2013.
- **The fieldwork phase (data collection)** which is scheduled to start on 02.01.2014 and to continue until 31.12.2014.
- **The analysing and reporting phase** which is scheduled to start on 01.01.2015 and continue until 30.10.2015.

7.2 Timetable

Annex IX provides a timetable with all the phases, activities and milestones of the FCS2014.

7.3 Subcontracting

A collaborative agreement of two years (December 2012-December 2014) between the IARC and the WIV-ISP was concluded. The IARC will provide the EPIC-Soft methodology and contribute to the implementation and preparation of the Belgian country-specific EPIC-Soft versions (a Flemish and French version) for the FCS 2014 project. The IARC will also provide the existing pictures of the EPIC-Soft picture book in electronic form to the WIV-ISP.

A subcontract was also concluded with the University of Ghent (UGent) for a scientific and methodological collaboration for the FCS project. UGent will help with the preparation of a new EPIC-Soft version, the EPIC-Soft training, development of EPIC-Soft manuals, support of the WIV dietician at the start of the fieldwork. UGent also has an advising function and will attend meetings of the Scientific Steering Committee. Ultimately, they will write an end report and final report.

8 RESOURCES

8.1 Team

The WIV-ISP is in charge of the study. The main responsibility is with the Service of Surveys, Lifestyle and Chronic Diseases (SLCD), research group Nutrition and Health. Several people of this unit are involved at different levels (see table XIII).

Table XIV. Team members

First name	Last name	Qualification	Full time equivalent (FTE)	Function

Koenraad	Cuypers	PhD in community medicine, researcher	100	Project leader
Gaëlle	Isaac	Epidemiologist, researcher	100	Team member
Charlotte	Stiévenart	Dietician, researcher	100	Team member
Sarah	Bel	Dietician, researcher	100	Team member
Ledia	Jani	Administrative	100	Team member
Sofie	Van den Abeele	Dietician, researcher	100	Team member
Jean	Tafforeau	MD		Project responsible and Head of Division
Herman	Van Oyen	MD, PhD		Director of Directorate Public Health and Surveillance

In addition, the activity of the team is supported by the research group Health Interview Survey, the ICT Unit and the Financial and P&O units of the WIV-ISP.

8.2 Availability of space, fund and material

8.2.1. Space

The Nutrition team is based in the buildings of the Operational Directorate Public Health and Surveillance of WIV-ISP (Kroonlaan/Avenue de la Couronne 310, 1050 Brussels). Storing space for the survey documents (information sheets, paper questionnaires, photo books, logbooks, informed consents, etc.) and material is available in the office. Storing space for the anthropometric instruments (scales, stadiometers and tapes) is foreseen in an office on the ground floor of the Operational Directorate Public Health and Surveillance building.

8.2.2. Funding

The funding of the survey was negotiated as a collaboration between the WIV-ISP and the Federal Public Service Health, Food Chain Safety and Environment (FOD-SPF). This funding covers a period of three years, distributed over the different posts. The total budget for this period is 2.350.862,88 €.

- 500.000 € per project year funded by the FOD-SPF
- 200.000 € single funding by the EFSA
- 319.749 € funded by the WIV-ISP
- 132.812 € funded by the WIV-ISP PUB-working
- 229.302 € funded by the WIV-ISP

8.2.3. Material

In order to perform the CAPI questionnaires 75 mini-laptops have been purchased to provide each interviewer with a mini-laptop for the fieldwork. For the anthropometric measurements executed by the interviewers 75 portable scales, 75 portable stadiometers and 75 non-stretchable measuring tapes have been purchased. For measurement of physical activity in the participants 375 accelerometers and straps have been purchased.

8.3 Budget plan

A detailed budget plan has been prepared and is available on the WIV-ISP server (X:\HIS\FCS\FCS-2014\Budget\Budgetplan_FCS_aanwijzing_organen_voorslag_KC_ HVO.xls).

9 RISK AND BENEFITS FOR PARTICIPANTS

The ethical conduct of public health surveillance requires an evaluation of both the benefits (information needed to direct public health interventions) and risks (embarrassments or discrimination of people or groups if information about their

behaviour is released inappropriately). We will collect the surveillance data judiciously and manage the data responsible in following strict house rules in regard to data handling and storage and dissemination routines.

The FCS2014 research protocol is discussed – and approved by – the Steering Committee. The research protocol will also be submitted to the Ethical Committee (UGent) and the Privacy Commission for approval to see if the privacy of the respondents and all ethical requirements are met. The sectorial committee of the national register and the sectorial committee of social security and health will be asked to approve the acquirement and use of the data from a representative sample from the national population register.

It is essential to ensure that research participants are not harmed physically or psychologically during the conduct of research. However, the risk of harm to those who take part in an epidemiological investigation like the FCS2014 is limited. The greatest risk to individuals could be caused through the disclosure of personal data. Participants gain no direct personal benefit in participating to the FCS, but they improve their knowledge about nutrition through personal discussions with the dieticians. In recognition of their participation, they should thus be treated well with respect and informed with professional knowledge. Respect for individuals in research entails informing them correctly about the research purpose and subject, obtaining their consent to participate or accepting their right to refuse to participate.

9.1 Information of the participants and informed consent

People that are selected to participate to the FCS receive notification about the survey, its practical organization, the institution in charge, the commissioners of the survey and the contents via a letter and an information leaflet personally addressed to them. It is clearly stipulated that participation is voluntary. An e-mail address, Internet website and telephone number at the WIV-ISP are clearly indicated on the leaflet if selected people need further information or want to withdraw. Potential participants can also ask more about the survey or refuse to participate at the moment the interviewer contacts them to ask their consent and make an appointment. As stated in the leaflet, a summary of results is communicated to all participating people to express our gratitude for having taken part at the survey.

9.2 Respect of confidentiality of the collected data and their management

Measures are taken in the management of the survey to ensure that only the FCS scientific team can identify the participants of the survey. The data will be coded and anonymized before analysis and the key will be kept at a physically divided third trusted party. Interviewers sign a confidentiality clause that is inserted in their contract. Interviewers are forbidden to disclose any information gathered during the interview to a third party. Researchers have an obligation of confidentiality by contract and by status. Besides, only the researchers implied in the FCS team have access to the data (protected network emplacement). Finally, all results are divulged in an aggregated format (tables of statistics, graphs) that impedes recognition of individuals.

9.3 Security measures

Access to documents and databases related to the project is restricted to the FCS team members and the administrative personnel each with their specific functions. The administrative personnel mainly manage the imported data, but cannot make changes or deletions. The latter is only admitted for the Nutrition team.

10 PROPRIETY RIGHTS OF STUDY MATERIAL AND RESULTS

All data gathered by means of the survey is in principal the property of the collaborating parties (the WIV-SPF and the FOD-SPF). The propriety rights of the results and use of data are described in article 10 of the contract between the WIV-ISP and the FOD-SPF. The data are encoded and anonymized at the WIV-ISP. The use of the coded data will be asked for approval by the CPP for statistical treatment. A series of data protection measures have to be implemented to ensure safety of the data.

11 CLIENT SATISFACTION

11.1 Definition of the clients

The project has two types of clients: the FOD-SPF and the *external users* of the data. The WIV-ISP can, under certain conditions provide the FCS dataset to external users, public administrations, universities or other research groups after approval of an application. The WIV-ISP can also perform specific analysis upon request for individuals or institutions, which are also potential clients.

11.2 Contacts with the clients

11.2.1 Commissioners

The Steering Committee is informed on 'the state of the art' of the FCS project at least every 6 months. They also receive a financial report and an activity report once a year. The Steering Committee is systematically consulted to agree on the:

- budget for the project
- content of the FCS questionnaires
- content of the final report, including the indicators' selection.
- the content of the press release concerning the results of the survey
- sharing FCS data with external users that are not linked to a university or a public administration

11.2.2 External users

The HIS data are also made available for use and in depth analyses by external users (see article 11 conditions), i.e. in research projects from academic or ministerial instances. A specific database will be created for external users. In this database, some variables will be removed (e.g. statistical sector, date of birth) or aggregated (e.g. age).

The conditions for external users to obtain the dataset will be described on the FCS 2014 website. The FCS, the context and the conditions under which the data are made available to external users, and practicalities to obtain the data will be described.

A protocol for the utilisation of the VCP data will go more into details about access modalities, aims and limitations of using the FCS data, authors rights, quality control, publications, validity period and prices. An application form will be available on the website.

This document has to be completed and sent back to the WIV-ISP by the external user who wishes to use the FCS data for a given project. Based on this document, a contract is prepared and has to be signed by an authorized person in the institution who made the request, as well as by the director of WIV-ISP*.*

11.3 Treatment of complaints

11.3.1 Commissioners

Complaints expressed by commissioners during the meetings of the Steering Committee will be mentioned in the minutes of the meeting. The follow up of the actions taken in response to a complaint will be reported in the following meetings. A letter has also been sent to the commissioners informing them that any complaint in relation to the FCS project can be directly addressed to the director of the WIV-ISP. When appropriate, a document from the quality assurance called FORM I/03/14/NFwill be completed and followed up.
Recommendations for these procedures are given in the SOP I/03/22F(N) for the WIV_ISP and specifically for the unit of public health and surveillance in SOP 30/006/N (Beheer van niet-conformiteiten, preventieve acties en externe klachten) and SOP 30/006/F (Gestion des non-conformités, actions preventives et plaintes externs).

11.3.2 External users

For external users, complaints can be addressed to the FCS team directly. They can also follow the official procedure under the quality insurance system described above. Those complaints are managed by the operational direction and conserved by the quality insurance officer in close collaboration with the FCS team.

11.2.5 Interviewers

Complaints of the interviewers who perform the fieldwork will be collected in a logbook. The complaints will be managed by the FCS team.

12 COMMUNICATION OF RESULTS AND REPORTS

The final goal of the FCS is not merely to draw a picture of the overall nutritional status of the Belgian population. The FCS is above all designed to serve a wider purpose, that is, to provide scientific information to the decision makers and politicians in order to promote adequate nutritional policies and practices as well as to establish nutritional-oriented regulations. Furthermore, the study is also meant to supply the scientific community with a wide-ranging set of nutritional-related data for an in-depth analysis of particular topics. Finally the FCS results can also be used to make the general population aware about nutritional issues and nutritional determinants. Rules on publications and other communication are described in article 12 of the contract between the WIV-ISP and the FOD-SPF. The results that stem from the analysis of the FCS data are first communicated to the Steering Committee (owners of the data) by means of periodic reports and presentations. Results are then communicated to the public through press conferences and by placing the reports on the FCS website. Participants personally receive a summary of the main results. Finally, results are presented to the scientific community through peer reviewed publications and Conferences.

Regular contact with commissioners of the FOD-SPF are scheduled. Internal and external meetings with collaborators and team members are planned (personal encounters, skype and telephone). This will ensure the most adequate development and execution of the survey.

Participation in the annual EFSA-meetings are included in the planning. The project leader (Cuypers Koenraad) is proposed to represent Belgium as a new member in the network/expert group on food consumption and exposure data.

12.1 Reporting mechanism

The results will be reported for the whole of Belgium, as well as independently for the three regions of the country. The reports will be made available in Dutch and French. To compare the results of subsamples, the region of Wallonia and Brussels will be coupled to enlarge the sample (because the size of the sampling for Brussels is too low for having significant results in the subsample).

In accordance with the SOP 30/002/E a specific template (FORM 30/019/E) will be used to write the study report.

The methodological report includes information on the commissioners, the objectives of the FCS, its contents, the sampling procedures, the fieldwork organization, the participation level and an introduction to the results.

For ecological and financial reasons, printouts of the reports are limited (one copy for each commissioner), but the full electronic report (in a PDF-file) will be made available on the FCS website.

12.2 Publication plan: peer-reviewed publications and others

While the report prepared for the commissioners is basically descriptive, further in depth analysis exploring the associations between variables remains an important issue to look into. The database will be further analysed by the FCS team at the WIV-ISP. The results of the additional analyses will be presented – as an oral presentation or poster – during scientific conferences, symposiums, national and international meetings. They will be also published in scientific journals. An up-to-date list of publications will be found on the website.

12.3 Other forms of communication of results

To meet the diffusion objectives more broadly, the results of the FCS are made available and will be published in different formats (i.e., reports, summaries, folders, press release, power point presentations, interactive database, etc.). Most of these

can be found on the website of the WIV-ISP. The format of the presentation is adapted to the target public:

- *Policy makers and other stake holders*

  Slide presentations will be created to present the results of the survey.

- *Media and the general public*

  For dissemination of the FSC results among the general public a press release, conferences and/or interviews will be created.

- *Website*

All relevant information and results will be made available to the public on the website of the Institute at the following address: in French: http://fcs.wiv-isp.be/fr/ ; in Dutch: http://fcs.wiv-isp.be/nl/
Information displayed on the website will be related to the objectives, methods, year of implementation, persons to contact, level accomplishment, publications, sources of financing, external collaborations and keywords.

Besides a static presentation of the results an interactive and user-friendly data analysis tool will be available for data analysis (NUTRIA).The purpose is to enhance the accessibility of these data for a broad range of the potential users. The application is interactive. Pre-defined procedures accessible through menus make it very user-friendly, as it does not require any preliminary knowledge of the statistical package (the topic "How to use" contains important instructions). The application only covers the information coming from the questionnaires.

- *Participants and interviewers*

A leaflet describing the results in lay terms is sent out to the participant that took part in the survey, together with warm greetings for their participation. The interviewers who worked for the FCS also receive an exemplar of this leaflet.

13 ARCHIVING PROCESS

13.1 Data management

Storing and archiving of all the files will be done as described in the SOP 31/E/007. All documents are stored in a new subdirectory “FCS2014”. This subdirectory can be found in:\\iph.local\FS\Services\33_SLCD\DATA\FCS\FCS2014.

The structure of the storage system of the computer files used for the FCS 2014 will be documented in a SOP “Management on electronic documents”.

13.2 Documents

The original contracts with the FOD-SPF are stored in the appropriate directories. The completed questionnaires are kept in files at the WIV-ISP (Service Surveys, Lifestyle and Chronic Diseases) for at least 5 years (according to the available place), together with the contracts with the interviewers and the contracts with the external users.

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ANNEXES

Annex I: Collaborative agreement between WIV-ISP and IARC

X:\FCS\FCS2014\Administration\IARC\IARC Collaborative Agreement_EPIC-Soft Belgium_signed.pdf

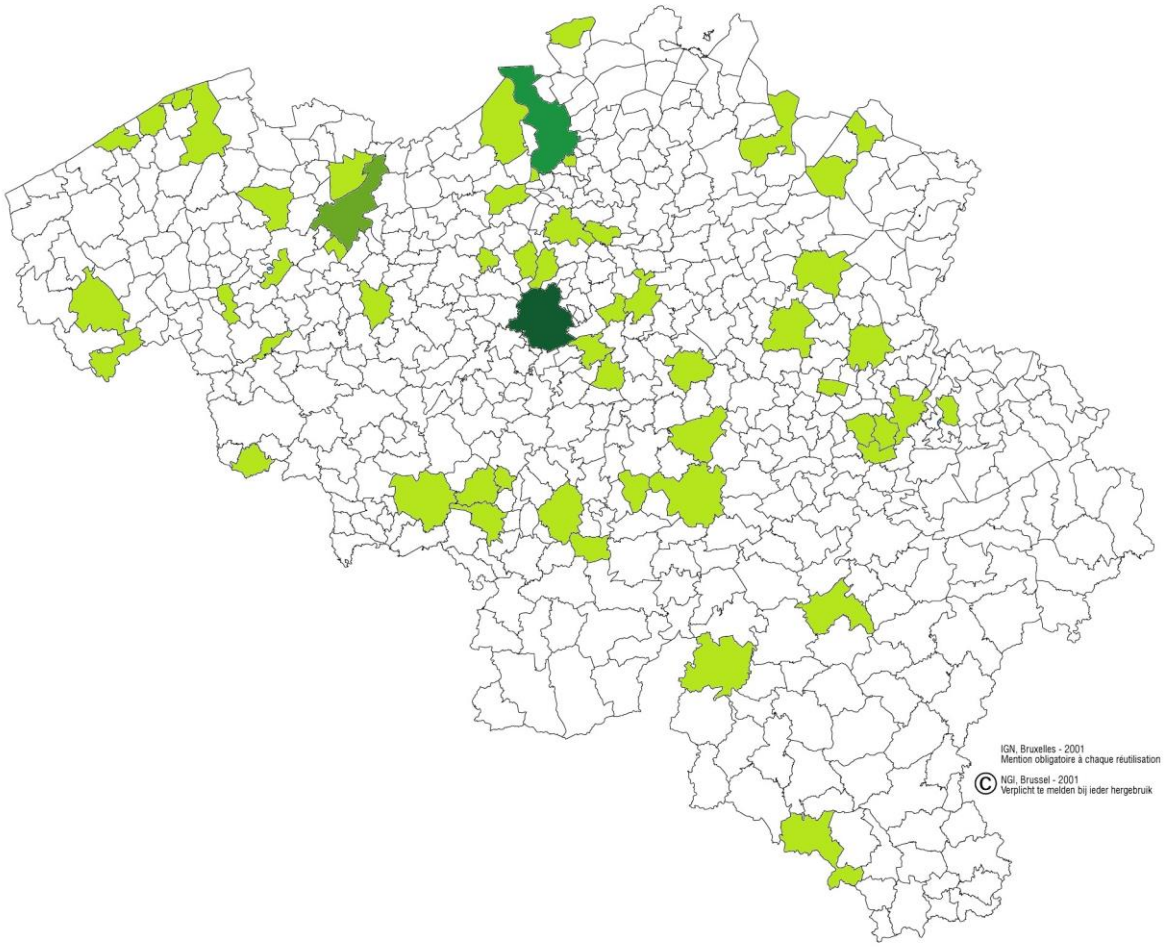
Annexe II: Subcontract agreement between WIV-ISP and UGent

See X:\FCS\FCS2014\Administration\UGent\VCP 2013_UGENT CONTRACT.pdf

Annex III: Agreement between WIV-ISP and FOD-SPF

See X:\FCS\FCS2014\Budget\Contract SPF-FOD 20121210.pdf

Annex IV: Selected municipalities



No groups selected

1 group

2 groups

3 groups

4 or more groups

Annex V: Protocol of a validation study of the EHIS physical activity questionnaire

1. Background

Physical activity has been reported to be positively associated with health indicators, whereas sedentary activities are suggested to be associated with increased risk for all-cause mortality and morbidity (75;76). Both behaviours seem to be independent related to health outcomes in both children (77) and adults (78).

Sedentary behaviour conceptualised as sitting, TV-viewing, sleeping or automobile transportation is distinct from physical inactivity, defined as lack of moderate-to-vigorous physical activity.

Representative data are necessary to assess and monitor physical activity in populations and the use of self- report method is usually the most feasible and economically most interesting way. To assess representative data and to study trends standardized questions are recommended. The standardised questionnaires have to be simple to use but also show high validity and reliability in all layers of the population.

One frequently used questionnaire is the international physical activity questionnaire (IPAQ).

The IPAQ was designed by a multinational working group. The IPAQ-SF was developed in 1997 as a result of various research projects. But, the validity of the questionnaire in regard to the different activity levels has been questioned (79), especially for the low activity level.

Experts of the EHIS who tested the feasibility of the IPAQ in a health interview survey reported the IPAQ not suitable. Following issues were raised:

- The questions are difficult to understand, difficulties to grasp the essence of the modules
- The understanding of vigorous and moderate are to intuitive to answer
- The repeated questioned validity and reliability of the Q
- Difficulty for the respondents to calculate their answers
- The vagueness of some questions
- Ignorance of other PA dimensions, leisure time activity

Classification of level of physical activity: MET or TEE, PAL. 1 MET relate to the metabolic rate Energy expenditure at complete rest.

There are several reasons to bother to measure physical activity better:

- To estimate the true effect size
- To specify which dimension of physical activity is of most importance for a particular health outcome
- To make cross-cultural comparisons
- To monitor temporal trends within populations
- To measure the effect of interventions.

2. Definitions

Criterion validity: a questionnaire is validated against an objective method.

The relationship is frequently reported as a correlation coefficient (Pearson, Spearman).

Absolute validity: The absolute outcome (i.e. EE or time spent in activity) is compared to data from an objective instrument which provides the same outcome measure. The association is usually reported as the degree of agreement (Bland and Altman method).

Concurrent validity: A questionnaire is compared to another self-report instrument (i.e. diary or another questionnaire). Although a high correlation between two subjective instruments suggest validity, the instruments are not of a different type and may be subject to correlated error.

3. Methods

Instruments

- *IPAQ*

The IPAQ-SF applies an assessment approach that measures the dimension of 'total physical activity' in terms of total energy expenditure on a metabolic-equivalent (MET) basis using a generic assessment approach. More

specifically, it measures the number of days and the duration in the last 7 days of a) vigorous-intensity physical activity, b) moderate-intensity physical activity, c) walking and d) sitting. It assigns MET-values to the respective intensity categories of physical activity in order to obtain a total physical-activity indicator. The IPAQ has been validated and employed in numerous studies in both adolescents (IPAQ-A) and adults (80). Answers of the IPAQ will be recoded in a categorical score, classified into three categories: low, less than 3 METs; moderate, 3-6 METs, high activity, equal to > 6 METs.

- *EHIS*

Development of the EHIS-PAQ

The new Instrument (EHIS work group, 2011) is based on the framework of the Global Physical Activity Questionnaire (GPAQ) (1) using a modified version of the current question from the Behaviour Risk Factor Surveillance System (BRFSS) to assess work-related physical activity, the current NHIS-PAQ question to assess muscle-strengthening physical activity, and modified versions of the GPAQ questions to assess transportation physical activity, and leisure-time physical activity. In addition, it is designed to measure compliance with the new WHO physical activity recommendations for the adult population aged 18-64. The resulting outcome indicators of the new instrument cover three public-health-relevant domains of physical activity, which were selected by the EHIS Core Group: (A) work-related physical activity, (B) transportation (commuting) activity, and (C) leisure-time physical activity.

The principle aim of cognitive testing (CT) was to determine how the questions worked with different segments of the survey populations in four different countries and to explore:

- Respondents´ understanding of the questions
- Respondents´ ability to answer the questions
- Issues of sensitivity
- How the questions worked when administered
- Which questions worked better than others, and why

The EHIPAQ applies classification into minutes of low, moderate or high PA level or METs.

- *Accelerometer*

Besides the assessment of physical and sedentary behaviour relying on self-reports with varying validity and reliability, there are now more objective measurements to assess both behaviours available. Accelerometers are considered to be more valid and reliable. In populations survey and recall instruments have to be used cautiously because respondents have difficulties recalling such information and possibility of reporting bias due to social desirability. Accelerometers measure accelerations caused by body movements in three orthogonal planes (vertical, mediolateral and anteroposterior). Accelerometers generate the activity counts and minutes spend above predefined thresholds (22).

Accelerometers are shown to provide accurate information on levels of physical activity, including sedentarism (23). The use of accelerometry in youth warrants for extra attention to the compliance. The accelerometer will measure and calculate the total energy expenditure (TEE) and physical activity level (PAL). PAL is defined as the TEE divided by basal metabolic ratio. The accelerometer will also calculate the MET value each minute which expresses intensity of the intensity of the activity compared to the resting energy expenditure. Basic metabolic rate will be calculated using the FAO/WHO equation (http://www.fao.org/docrep/MEETING/004/M2995E/M2995E00.HTM).

Participants

The number of participants will be determined using power calculation for the sample, given effect size and alpha-level. The adult persons will be randomly sampled from the sample of the food Consumption Survey2014.

Reliability

Test-retest reliability: Repetition of EHIS-PAQ after 4-5 weeks
Parallel-test method: International Physical Activity Questionnaire (IPAQ) long or short (is more valid!) version – parallel assessment

Validity

Concurrent validity: IPAQ parallel assessment

Construct validity: 7-days physical activity recall protocol

Criterion validity: Accelerometer (GT3X plus, ActiGraph) – for one week

Annex VI: Motivation for the assessment of psychological distress in adolescents and adults

Since stress is hypothesized to be involved in the aetiology of obesity, both biological and behavioural, it may be advantageous to assess psychological stress in the participants. Several non-communicable disease share inflammation as a common link.

Dietary strategies clearly influence inflammation and various dietary components via modulating sympathetic activity and pro-inflammatory cytokine production modify health risk. On the other hand studies provide evidence that stress is not only provoking inflammation through the same pathways, but influences also food choices and enhances maladaptive metabolic responses to unhealthy foods (81) and modulating the nutritional status and morphology (82). Thus, it is not only of importance in understanding the food consumption and dietary behaviour to have an indication of the stress-level in the population, but also in evaluating the inferences and the impact the food consumption has on the health of the population (83-86).

Measurement tools

- For scientific purposes measuring a score of depression and anxiety might serve reasonable well and may be a proxy for mental distress, because most states of mental distress are accompanied by anxiety and depression. The SCL-5 showed good psychometric properties (87).

- De Vriendt et al., 2011 used in the HELENA-study the revised 56-item version of the Adolescent Stress Questionnaire (ASQ) of Byrne, Davenport and Mazanov.

- General Health Questionnaire (http://www.gl-assessment.co.uk/products/general-health-questionnaire-0?css=1)

The General Health Questionnaire (GHQ) is a widely used questionnaire to assess general well-being and distress. Several versions of different length are available. In epidemiological
studies a 12-items version is mostly used. GHQ that was developed by the psychiatrist Sir David Goldberg in Manchester, UK (88).

The GHQ-12 is used in the Health Interview Survey, Belgium. The GHQ has been proposed as a good measure of psychological distress whereas the SCL is more for screening anxiety and depression psychopathologies (89).

Annex VII: Motivation for the assessment of pubertal development in adolescents

Since pubertal status is suggested to be important in regard to eating behaviour (90) and fat development, we implemented questions on pubertal development. We used the Pubertal Development Scale to assess self-reported pubertal status. The PDS was originally developed by Petersen et al., 1988 (91) and found to have good reliability and validity Petersen et al., 1988 (91) and Shirtcliff 2009 (92). The PDS is also extensively used in the Young-HUNT (93), (94).

Annex VIII : Motivation for the assessment of eating problems

Definitions of Eating Disorders

- **Anorexia nervosa:**

A syndrome in which the individual maintains a low weight as a result of preoccupation with low body weight, construed either as a fear of fatness or pursuit of thinness. Weight is maintained at least 15 percent below the expected or body mass index (weight/height²) is below 17.5. Weight loss is self-induced by exercise, vomiting or purgation, and avoidance of fattening foods. A widespread endocrine disorder involving the hypothalamo-pituitary-gonadal-axis is present. In female, this is manifested as amenorrhoea and in males by loss of sexual interest and impotence. Other psychosocial features such as mood disorders, obsessive compulsive symptoms and social withdrawal are common.

- **Bulimia nervosa:**

A syndrome characterised by recurrent episodes of binge eating and by compensatory behaviour (vomiting, purging, fasting or exercising) in order to prevent weight gain. Binge eating is accompanied by a subjective feeling of loss of control over eating. This is a normal weight syndrome in which BMI is maintained above 17.5 kg/m².

- **Eating Disorders not Otherwise Specified (EDNOS).**

Eating disorders that closely resemble anorexia nervosa and bulimia nervosa, but are considered atypical, as they do not meet the precise diagnostic criteria for these conditions. Eating disorders include a cognitive, a behavioural and a physiological component. The cognitive component may be disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or denial of the seriousness of the current low body weight. The behavioural component may involve dieting, avoiding fat, binge eating, compensatory behaviours as purging or excessive exercising, while the physiological component are weight problems, menstrual disturbance or other somatic complications.

According to the diagnostic systems ICD-10 or DSM-IV, eating disorders are relatively well-defined disorders fulfilling the diagnostic criteria for anorexia nervosa, bulimia nervosa or atypical eating disorders.

Definition of eating problems

Eating problems, however, are not well defined, but like eating disorders, include cognitive, behavioural and physiological elements, and the severity range from sub-threshold eating disorders to mild eating problems not qualified for an eating disorder diagnoses. Different descriptors as disordered eating, disordered eating habits, disordered eating attitudes, eating disturbances, eating dysfunction, eating disorder symptoms and partial syndromes of eating disorders are terms used to describe problems, and using the same descriptor does not always indicate a common definition of eating problems. This makes comparisons between prevalence and associations reported in different studies difficult.

Screening-instruments to assess eating problems

- **EAT (Eating Attitude Test)**

A large literature has documented the use of EAT, especially the 26-item version as a screening instrument for eating problems in a variety of cultures (95). The EAT has good psychometric properties of reliability and validity, and reasonable sensitivity and specificity for eating disorders, but very low positive predictive value. The Eating Attitude Test (EAT) was first developed by Garner and Garfunkel in the late 1970s as a self-reporting questionnaire, indicative, but not diagnostic, of the symptoms of eating disorders (96;97). The instrument exists in three versions, EAT-40, EAT-26 and EAT-12. The original instrument, the 40-item-version consisted of the following seven factors: 1) food preoccupation, 2) body image for thinness, 3) vomiting and laxative abuse, 4) dieting, 5) slow eating, 6) clandestine eating and 7) perceived social pressure to gain weight. The instrument was abbreviated by the original authors including the 26 items loading on three factors labelled “dieting”, “bulimia and food preoccupation” and “oral control”. The fourteen items extracted did not load on any of these factors.

In a former Norwegian study, Ung i Norge (UIN, Young in Norway)(98), a 12-item version was constructed selecting four items from each of the three factors in EAT-26. EAT-26 applies a 6-point scale, while a 4-point scale was used in EAT-12. In the reduction of number of items from EAT-26 to EAT 12, the three-factor structure is retained. The dieting factor was removed, and the items used consists only the two factors “oral control” (EAT-A) and “bulimia and food preoccupation” (EAT-B). The items selected had high factor loadings on the three factors isolated, and in addition seemed clinically meaningful.

Due to limitation in available space in the questionnaire and in trying to keep the questionnaire as comprehensive as possible seven of the 12 items from EAT-12 are used in the FCS2014 in comparison to Young-HUNT-1. At the time when EAT-12 was constructed (1991), vomiting was a very infrequent behaviour in adolescents and gave little in the analyses. This item from the original factor “bulimia and food preoccupation” was therefore omitted, resulting in a 7-item version (EAT-7) where EAT-A is identical with the 4 items in the “oral control” factor in EAT-12, and EAT-B consists of 3 of the 4 items forming the “bulimia and food-preoccupation”-factor in EAT-12. The psychometric properties of EAT-7 was validated in Young-HUNT-1(99). In addition, a test of the sensitivity and specificity of the EAT-7 sum-score (EAT-S) versus EAT-12 sum score was done, and the contribution of the subscales to the sum score of ETA-12 was evaluated. EAT-26 has a cut-off of 20/21, a score above 20 should therefore correspond to a score of 9.7 or more on EAT-12.

The comparison is not perfect, because use of different scales. However, this should have no impact on the results since we only will study the two factors EAT-A and EAT-B. Using EAT-7, both the sum-score (EAT-S) and the two subscales EAT-A (oral control) and EAT-B (bulimia and food preoccupation) was used in the analyses of prevalence of eating problems.

Eating Attitude Test (EAT) is a test developed as a screening instrument for eating disorders, but the factor oral control in this study have properties resembling a psychological trait rather than a symptom of a disease. A psychological trait is defined as a stable part of the personality, while a symptom is more a state, and will change over time. Oral control may be a “restrictive trait”, protecting against overweight and obesity. This is in accordance with findings using TFEQ (The Three Factor Eating Questionnaire, another questionnaire used to assess eating disorders), and EDE (Eating Disorder Examination, a structured diagnostic interview for eating disorders). TFEQ has a factor called “dietary restraint”, and EDE has a subscale called “restraint scale”. Dietary restraint has been found to be a component in a package of genetically determined physiological, sociocultural and psychological processes that regulate energy balance, and might predispose for anorexia nervosa. The EAT-factor oral control resembles dietary restraint, and high degree of oral control may be a trait like dietary restraint predisposing for underweight and anorexia. The study of Bjornelv et al. (100) indicates that the two factors oral control and food preoccupation might be important mediators in the development of weight problems.

- **Other screening instruments for eating problems**

Eating problems are also assessed using other instruments. Eating Disorder Inventory (EDI) is a reliable and valid 91-item multidimensional self-report instrument, and the whole instrument or subscales as DT (drive for thinness), BD (body dissatisfaction) and B (bulimia) is used. Other instruments as BASS (Body Area Satisfaction Scale), BEDT (Branched Eating Disordered Test), WIC (weight and image concern) and PEC (Problematic eating conduct) have also been used to study the prevalence of eating problems. To assess bulimic symptoms, Bulimic Investigatory Test, Edinburgh (BITE) and the Bulimia Test- Revised (BUILT-R) has been used. Dieting is frequent among adolescents, and is also often used as an indicator of eating problems. In epidemiological studies, dieting and dieting frequency is assessed using different questions, usually questions especially designed for the specific study.

Prevalence

- **Eating disorders**

Eating disorders are relatively uncommon; the reported prevalence for anorexia nervosa is about 0.3%, bulimia nervosa 1.0 %, while atypical eating disorders are found in 2-3 % of young women. The validity of many epidemiological studies of eating disorders is questioned due to different methodological problems concerning both selection of population and identification of cases. A two-stage screening approach is the most widely accepted method, in the first stage the population is screened using a screening questionnaire.

- **Eating problems**

Due to different definitions, the prevalence of eating problems differs between studies, from 1.8 %, to 22.3 % in girls and 1.8- 7.0 % in boys. The lowest prevalence

is found in studies where the definition of eating problems is narrow and the severity is close to clinical eating disorders.

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VALIDITY OF THE EATING ATTITUDE TEST AMONG EXERCISERS

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Annex IX : Timetable and milestones

To be created.